

HEAVY MENSTRUAL BLEEDING GUIDELINE – CONSULTATION ON DRAFT SCOPE 20 Sept – 15 Oct 2004

Commentator	Section	Comment	Response WCH
Action and Support Group for Medical Victims of Richard Neale		This organisation was approached but did not respond.	
Addenbrooke's NHS Trust		This organisation was approached but did not respond.	
Airedale General Hospital		This organisation was approached but did not respond.	
Anglesey Local Health Board		This organisation was approached but did not respond.	
Association for Continence Advice (ACA)		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)	General	ABPI welcomes this guideline which is long overdue. We believe the scope is fine and we have no specific comments.	Thank you for your help. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
AstraZeneca UK Ltd		AstraZeneca have no comments to make on the draft scope for the above clinical guideline.	Thank you for your help. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
Barts and The London NHS Trust	1	The title should be management of menorrhagia (when is hysterectomy indicated in an otherwise normal uterus?)	Thank you. There is a consensus amongst stakeholder groups that the guideline should be extended to cover not just hysterectomy but the pathway for diagnosis and management of heavy menstrual bleeding (menorrhagia). This change to the scope allows the alternatives to hysterectomy to be evaluated and the choices available clearly set out for women. These changes have been undertaken in the revised scope. Please see the revised scope for details of changes.

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Barts and The London NHS Trust	1	Managements of Fibroids are better considered separately.	This was carefully considered but the decision was made to include fibroids, where menorrhagia is the main presenting symptom. Fibroids are a very common cause of menorrhagia, hysterectomy is the most common treatment and they often present undiagnosed in women considered to have dysfunctional uterine bleeding.
Barts and The London NHS Trust	3	In the diagnosis section, the blood tests (FBC and Ferritin) should be mentioned.	Blood tests will be included when consideration is given to diagnosis. There is a consensus amongst stakeholders that the diagnosis section needs to be expanded. This has been undertaken in the revised scope. However, it is not possible to provide an in-depth description of all diagnostic and treatments examined in the scoping document. Please see section 3 of revised scope for details.
Barts and The London NHS Trust	3g	Managements of fibroids also include transcervical resection and Laparoscopic myolysis.	Thank you. Fibroids, where menorrhagia is the main presenting symptom, are covered. However, transcervical resection and laparoscopic myolysis for fibroids will not be covered, unless menorrhagia is the main presenting symptom, and therefore will not be explicitly mentioned in the scope. Please see sections 3 and 4.3 for details.
Barts and The London NHS Trust	3g	The discussion on conservation of the ovaries or their removal should also be included.	This issue is already outlined in the scope (section 4.3.c), but will be given greater emphasis in the revised document (see section 4.3.h).
Barts and The London NHS Trust		Abdominal versus vaginal hysterectomy should be discussed, as prolapse may be one of the added complaints.	Thank you. The different types of hysterectomy will be examined, and this has been made explicit in the revised scope. Since the guideline has been extended to cover heavy menstrual bleeding, prolapse will not be considered as a separate entity. Please see sections 3 and 4.3 for details.
Bedfordshire & Hertfordshire NHS Strategic Health Authority		This organisation was approached but did not respond.	
Biocompatibles UK Ltd		This organisation was approached but did not respond.	
Biosphere Medical Europe		This organisation was approached but did not respond.	

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Birmingham Heartlands & Solihull NHS Trust		This organisation was approached but did not respond.	
Boston Scientific Limited		This organisation was approached but did not respond.	
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 of Interventional Radiology	3g	This paragraph is discussing uterine artery embolization but this is not mentioned by name.	Thank you. The text has been revised, and UAE has been explicitly mentioned. Please see section 3g of the scope for details. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
British Society of Interventional Radiology	3h	Long term problems of hysterectomy should also be included as these are significant and known in such an established procedure.	Thank you. There is a consensus amongst stakeholders that the scope needs to explicitly state short- and long-term outcomes and complications will be investigated for each treatment comparison.
British Society of Interventional Radiology	4e	Shouldn't myomectomy be included here?	Thank you. Myomectomy has been added to those treatments covered by the review. Please see sections 3 and 4.3 for details.
British Society of Interventional Radiology	6	There is no reference to NICE Interventional Procedures Guidance for uterine artery embolization, nor to the systematic review performed by the Review Body and which I gather is on the NICE website.	Thank you. These references will be added. Please see section 6 for details.
British Society of Interventional Radiology	General	For most of the treatment options, gynaecologists will be the most appropriate specialists to comment on the techniques and procedures, but for uterine artery embolization, an interventional radiological opinion should be sought. If other specialists perform any of these other techniques, then they should also be represented.	We agree. We intend to include a radiologist on our Guideline Development Group (GDG).
Buckinghamshire Hospitals NHS Trust		This organisation was approached but did not respond.	
Campaign Against Hysterectomy (CAH)	3a	The figure 47,000 hysterectomies cannot be correct. Hospital episode statistics are very hard to follow and the statistics gleaned from obscure. The following is fact 1,500	Thank you. We have checked our figures and have revised them (please see section 3a). However, we can only use available figures, such as hospital

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		gynaecologists in England Wales + 3,642 other grades (1997 NHS Executive Quality framework document) + 5,142 doctors all doing hysterectomies. If only 47,000 hysterectomies performed then each doctor and consultant would only do 9 hysterectomies per year. As it is almost impossible to find a woman over the age of 40 who has not had a hysterectomy this statistic just has to be a lie.	episode statistics, and cannot use estimates. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
Campaign Against Hysterectomy (CAH)	3a	The Director of the Kings Fund who collaborated with me on an article in 1995, said that 1 out of every 3 hysterectomies are done privately. I do not therefore believe that the statistics are in any way correct. When I researched the subject for my book, I discovered a figure in the region of 100,000 per year for the UK which has never been challenged as incorrect. The Case Against Hysterectomy Pandora 1996.	Thank you. Please see above comment on published figures.
Campaign Against Hysterectomy (CAH)	3b	It is ridiculous to say that cause is unknown. It is well known that a sub acute level of hypothyroidism causes heavy menstrual bleeding, but this is not what the people who control endocrinology and gynaecology want to believe so 'cause unknown'. Is much easier to state. HMB is very common so is sub acute hypothyroidism. The RCOG has been registered since 1929. So why have they never done any research which would help women with this problem? Could it be that they could not care less? Could it be that they make so much money from private hysterectomies, that to make changes would reduce their incomes?	Hypothyroidism is indeed a cause of HMB and thyroid function is likely to be assessed in those who have other symptoms of this condition and in those unresponsive to medical treatments.
Campaign Against Hysterectomy (CAH)	3b	Fibroids are indeed very common, but they are not the reason that so many women have hysterectomies. That is because no other treatment is offered to them. There is a deliberate practice by gynaecologists of denying women access to alternative treatments.	Thank you. This statement relates to service provision and professional standards, which are outside the remit of the guideline. All appropriate treatments for HMB will be considered. It is hoped that the guideline recommendations will be followed by all relevant health professional groups.
Campaign Against Hysterectomy (CAH)	3c	Other drugs offered are zoladex and danazol and prostop which are powerful GNRH inhibitors and the cause of nausea and a number of harmful side effects.	Thank you. These treatments have been added to those covered by the guideline. The benefits and harms of each treatment will be examined and reported on. Please see sections 3 and 4.3 for details.

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Campaign Against Hysterectomy (CAH)	3d	No. Hysterectomy is the first treatment offered in most cases.	Thank you. We would be interested to see published data relating to this point.
Campaign Against Hysterectomy (CAH)	3e	Ultrasound and hot water ablation techniques are much safer but rarely offered to patients.	Thank you. These treatments have been added to those covered by the guideline. Please see sections 3 and 4.3 for details.
Campaign Against Hysterectomy (CAH)	3g	Sub-serosal fibroids rarely cause HMB and are not usually painful. The problem occurs only when they become large and press on surrounding organs. Only about 1000 myomectomies are performed each year in England. Gynaecologists do not have the skills required to do myomectomies nowadays. Doctors training for gynaecology are only taught hysterectomy in their training, so not surprisingly they do not know anything else.	Thank you. Medical education and training recommendations will be made where felt necessary.
Campaign Against Hysterectomy (CAH)	3h	The procedures are already available to reduce the hysterectomy rate. Gynaecologists do NOT want to change their practice to these minimally invasive procedures, because they do not earn so much in private medicine. For this reason hysterectomy rates will continue to be the highest performed in Europe. The government should be addressing this now but they are not. Almost all of the minimally invasive treatments are cheaper to perform than hysterectomy, but they will not be taken up by gynaecologists unless they are forced to. Hysterectomy and also surgical myomectomy take a very long time to recover from, damaging women's jobs, relationships and career potentials. The psychological and emotional effects are just not taken into consideration. Removing womb and ovaries is CASTRATION. Removing the womb causes INFERTILITY.	Thank you. Examination of cultural/political issues, such as those mentioned here, are outside the remit of the guideline. The aim of the guideline is to objectively assess available evidence and make recommendations on treatment based on this evidence. It is hoped these will be followed by relevant health professional groups.
Campaign Against Hysterectomy (CAH)	3i	I blame the RCOG for the parlous state of gynaecology and obstetrics. They endorse the bad practice of gynaecologists. The book John Studd RCOG wrote every woman over the age of 40 should have her womb and ovaries removed and take HRT. It is thinking like this that costs the NHS dear by performing unnecessary operations. The 1998 menorrhagia task force established that most of the women having hysterectomies did not have menorrhagia defined as a blood loss in excess of 80 ml of blood per menstruation.	Thank you. Not all gynaecologists share Prof Studd's views. Menorrhagia is also not the only reason why women opt for hysterectomy.

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Campaign Against Hysterectomy (CAH)	Question	The guideline was supposed to include the removal of healthy ovaries. Why is there no mention of this?	The issue of the removal of healthy ovaries is mentioned in section 4.3.c, but this will be made more explicit in the revised document. Please see section 4.3.g
Campaign Against Hysterectomy (CAH)	Question	Why stop at fibroids? Endometriosis also causes HMB but is not included in the study.	Thank you. This is an important point. The reason for limiting the study to HMB with or without fibroids, is due to the high prevalence of HMB with fibroids.
Campaign Against Hysterectomy (CAH)	Question	Why do 60% of women having hysterectomies also lose one or both ovaries?	Is this proposed as a clinical question for the guideline to address? As was mentioned earlier, the issue of healthy ovary removal has been made more explicit in the scope.
Campaign Against Hysterectomy (CAH)	Question	Why are you not looking at the younger and younger age of hysterectomy patients?	Is this proposed as a clinical question for the guideline to address? The population covers women between menarche and the menopause.
Campaign Against Hysterectomy (CAH)	Question	Why are you not looking at unnecessary hysterectomies resulting from poor obstetric care?	Obstetric reasons are an uncommon cause for hysterectomy. This guideline will consider only those where HMB is the reason.
Campaign Against Hysterectomy (CAH)	Comment	I am disappointed with this scope as you led me to believe that it would be wider. Unless you seriously look at the problem of unnecessary removal of the ovaries and the health consequences of womb removal then this is totally useless forum and a waste of time.	We are sorry if you feel that the draft scope was too limited, and we hope that you find the revised scope more appropriate – where the issue of removal of ovaries is made more explicit.
Campaign Against Hysterectomy (CAH) 2	General	X and I, plus many other stakeholders with whom we have discussed this, do feel very strongly the scope should : either not be so very limited, or, that if it is, it should be called menorrhagia and its control, and a second study considering all or at least most of the other reasons for the other 50% of hysterectomies, and this time include the other 40% of women currently ignored as they are over 45.	Thank you. There is a consensus amongst stakeholder groups that the guideline should be extended to cover hysterectomy and the diagnosis and management of heavy menstrual bleeding (menorrhagia). These changes have been undertaken in the revised scope. Women over the age of 45 who have not yet reached the menopause will also be included. Please see sections 1 and 1.1 of the revised scope for details of changes.
Campaign Against Hysterectomy (CAH) 2	General	A study on menorrhagia would be immensely valuable, especially the dissemination of information about the numerous treatments available to both GPs and the women themselves. This alone would help prevent a great deal of inessential and damaging surgery.	Thank you. This is now the subject of the guideline. The reason for extending the guideline to cover HMB is because it was felt a more clinically useful guideline would be produced, that set out choices for women. Please see sections 1 and 1.1 of the revised scope for details of changes.

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Campaign Against Hysterectomy (CAH) 2	General	It is very important that post-operative effects are also considered, both physical: incontinence, prolapse of bladder and bowel; higher rates of cancers, and the emotional side: loss of fertility; hormonal changes; damaged self-image as a feminine woman, loss of libido which, according to Relate, can lead to marriage breakdown.	Thank you. There is a consensus amongst stakeholders that the scope needs to explicitly state short- and long-term outcomes and complications will be investigated for each treatment comparison. This change has been made in the revised scope. Please see section 4.3 for details.
Campaign Against Hysterectomy (CAH) 2	General	This work cannot be entitled 'Hysterectomies' as it deals with only half of the hysterectomies performed and only on those under 45 years. 40% of the operations are carried out on women over 45, and indeed several decades older, too often with no better diagnosis than that this is the only way to avoid cancer of the womb, and no problems ever mentioned. No biopsies are made as these are irrelevant; it is already known the womb is healthy.	Thank you. The title of the guideline has been changed to 'Heavy menstrual bleeding: investigation and treatment'. Please see sections 1 and 1.1 of the revised scope for details of changes.
Campaign Against Hysterectomy (CAH)2	General	If the scope of this is too large for one study, then there should be two, one entitled 'Menorrhagia and its control' and the other of the other 50% of operations and include older women. Otherwise this will be presented to women as the definitive answer for all hysterectomies and UK's exceptional and unacceptably high level of hysterectomies never truly considered.	We agree. The current guideline has been extended to cover the clinical pathway for HMB. Please see sections 1 and 1.1 of the revised scope for details of changes. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1 December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
Change People		This organisation was approached but did not respond.	
Chartered Society of Physiotherapy		This organisation was approached but did not respond.	
CIS'ters		This organisation was approached but did not respond.	
Denbighshire Local Health Board		This organisation was approached but did not respond.	
Department of Health		Thank you for the opportunity to comment on the above Scope. The Department of Health has no comments.	Thank you for your help. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
Dudley Group of Hospitals NHS Trust		This organisation was approached but did not respond.	

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Endometriosis SHE Trust (UK)	General	Need to develop a 'pathway' of training/care for GPs/Practice Nurses to recognise need for referral of patients to gynaecologists.	Thank you. The remit of the guideline has been change so it better reflects the treatment pathway, and this will include referral criteria. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
Endometriosis SHE Trust (UK)	General	Need to develop 'pathway' of diagnostic tests and investigations to obtain the correct diagnosis.	Thank you. There is a consensus amongst stakeholders that the diagnosis section needs to be expanded. This has been done. Please see section 3 of the revised scope for details.
Endometriosis SHE Trust (UK)	General	Once diagnosis has been made, patients should receive the appropriate care for their specific problem – unexplained menorrhagia, fibroids, adenomyosis, endometriosis etc.	We agree. The guideline has been amended to cover HMB, with or without fibroids, so that it better reflects the clinical pathway.
Endometriosis SHE Trust (UK)	General	Each of these diseases should have appropriate management protocols and areas of expertise for specific problems.	Within this guideline the treatment of HMB will dominate and treatment of fibroids will be examined where menorrhagia is the main presenting symptom. .
Endometriosis SHE Trust (UK)	General	It needs to be noted at some point that contrary to the advice of some Gynaecologists, hysterectomy may NOT be a total cure for endometriosis.	Thank you. Due to the revision of the scope, endometriosis will not be considered separately. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1 December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
Endometriosis SHE Trust (UK)	General	Need long term follow up of patients to look at outcomes and effectiveness of treatments undertaken.	Thank you. There is a consensus amongst stakeholders that the scope needs to explicitly state short- and long-term outcomes and complications will be investigated for each treatment comparison. This change has been made in the revised scope. Please see section 4.3 for details.
Faculty of Family Planning and Reproductive Health Care		This organisation was approached but did not respond.	

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FEmISA	3h	The long term side effects and complications of hysterectomy are not mentioned – including time off work [2-3 months], urinary incontinence, vaginal prolapse, sexual dysfunction, time to feeling completely well and more importantly early or instantaneous menopause requiring HRT. Hysterectomy is used inappropriately as a treatment c.f. prostatectomy in men - mainly used only to treat cancer, even though benign prostatic hyperplasia is common in men it is not treated by prostatectomy. There are approximately 50 deaths from hysterectomy every year in England [NCEPOD].	Thank you. There is a consensus amongst stakeholders that the scope needs to explicitly state short- and long-term outcomes and complications will be investigated for each treatment comparison using the best available data. This change has been made in the revised scope. Please see section 4.3 for details. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
FEmISA	4.1	The population should be broadened to all women of all ages who are currently treated by hysterectomy for non-cancerous conditions. "Reproductive age" could be construed as pre-menopausal, or women in their 30's, since reproduction in the 40's is more difficult. There is a distinct attitude amongst some gynaecologists that women's reproductive organs aren't necessary once they have had their families. Women of any age offered hysterectomy should be included.	Thank you. There is consensus amongst the stakeholder groups that the study population needs to be clarified. The revised guideline is being restricted to women of reproductive age with heavy menstrual bleeding, with or without fibroids.
FEmISA	4.1.1a	Menorrhagia, fibroids and all other non-cancerous conditions currently treated by hysterectomy should be included, since the treatments offered for these are not acceptable to many women and women are often bullied into hysterectomy without being told of alternatives.	Thank you. This is an important point. The change in the scope of the guideline means that hysterectomy is no longer the focus. And the reason for limiting the study to HMB, with or without fibroids, is due to the high prevalence of HMB with fibroids. All treatment options will be reviewed.
FEmISA	4.1.2a	Adenomyosis can be effectively treated by uterine artery embolisation and it should be included.	Thank you. The text has been revised, and UAE has been explicitly mentioned. Please see section 3g of scope for details.
FEmISA	4.1.2b	Other diseases such as prolapse should be included. These can be caused by hysterectomy and can be treated in much less invasive ways.	Thank you. The extension of the scope means that the guideline will concentrate on appropriate investigations and treatments for HMB rather than just hysterectomy. This means that prolapse will not be covered by the guideline.
FEmISA	4.3b	The Royal College of Radiologists should be included in the diagnostic guidelines. The usual diagnosis [if there is a proper diagnosis] is by ultrasound. In many cases this is not sufficient. E.g. it does not show the size, position or	We agree. We intend to invite a radiologist onto the development group.

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		number of fibroids and does not give enough information for a gynaecologist to know whether the cervix should be removed. This is unacceptable to many women. Many women have hysterectomies without a proper diagnosis of the cause of their disease.	
FEmISA	4.3c	The removal of healthy ovaries should be reviewed in detail, since there seems to be very little evidence that it has any benefit and causes women a great deal of harm.	The issue of the removal of healthy ovaries is mentioned in section 4.3.c, but this will be made more explicit in the revised document. Please see section 4.3.g.
FEmISA	4.3d	It should also consider the skills, experience, training and outcomes of other clinicians treating women for gynaecological conditions currently treated by hysterectomy.	The main aim of the guideline is to identifying effective treatments for HMB. However, medical education and training recommendations will be made where felt necessary.
FEmISA	4.3e	Very important – as well as surgery interventional radiology treatments should be included – uterine artery embolisation is mentioned, but also myolysis and focused ultrasound.	Thank you. This treatment has been added to those covered by the guideline. Please see sections 3 and 4.3 for details.
FEmISA	4.3e	Myomectomy should also be included.	Thank you. This treatment has been added to those covered by the guideline. Please see sections 3 and 4.3 for details.
FEmISA	4.3f	As mentioned previously the scope should be broadened to include other [non-cancerous] conditions leading to hysterectomy.	Thank you. This is an important point. The change in the scope of the guideline means that hysterectomy is no longer the focus. And the reason for limiting the study to HMB with or without fibroids, is due to the high prevalence of HMB with fibroids.
FEmISA	4.3f	There should be long-term follow-up.	Thank you. There is a consensus amongst stakeholders that the scope needs to explicitly state short- and long-term outcomes and complications will be investigated for each treatment comparison. This change has been made in the revised scope. Please see section 4.3 for details.
FEmISA	4.3g	Myomectomy should be included.	Thank you. This treatment has been added to those covered by the guideline. Please see sections 3 and 4.3 for details.
FEmISA	4.3h	Pharmaceutical products are often used outside those licensed and normal protocols should be considered rather than this rigid rather inflexible approach.	Where appropriate data are available, use outside the licensed indications can be considered.
FEmISA	6	It is notable that no mention is made of uterine artery embolisation or myolysis both of which have been through NICE Interventional Procedures Reviews recently. These	Thank you. These treatments have been added to those covered by the guideline. Please see sections 3 and 4.3 for details.

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		should be included.	
FEmISA	General	Other clinicians treating gynaecological conditions should be included particularly interventional radiologists – BSIR .	We agree. We intend to invite a radiologist onto the development group
FEmISA	General	Informing patients of treatment options. FEmISA has been contacted by a very large number of women who do not want hysterectomy, but are offered no alternative even though these are available. The guidelines should look at patient information at primary care and secondary & tertiary care level. It will probably be necessary to run educational programmes to update GPs in particular and some Gynaecologists.	We agree that information provision is central to good practice. Patient education and information provision will be examined by the guideline. This issue has been made explicit in section 4.3.
FEmISA	General	Informing patients of possible complications and side effects. The initial results from research carried out by FEmISA shows that patients are very well informed about the possible complications and side effects of newer treatments such as UAE, but not of older surgical treatments like hysterectomy. This is unacceptable and does not allow patients to make an informed choice. This needs to be included.	We agree that information provision is central to good practice. Please see our previous comment.
Fibroid Network Charity	General	Fibroid Network Charity is a UK National Charity. The Founding Director provides help line support, information on where to get fibroid treatments, workshops & seminars on fibroids and available treatments to the NHS, charities and Women's support groups. We have received over 250,000 enquiries from women in the last 4 years. This scope affects over 10 million women in the UK therefore it is a major public health issue which should be fully investigated. Our main feedback is that women want womb repair not womb removal.	Thank you. The evidence for undertaking hysterectomy will be examined and reported on as will other treatments for fibroids. Please see section 4.3.g. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.

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Fibroid Network Charity	General	The guideline should reflect the fact that modern women are delaying childbirth. The average age of childbirth is now 29. The average age of menopause is 51 and is sometimes higher in ethnic minorities, therefore defining "childbearing" age is problematic. Also the use of synthetic female hormones often extends the fertile period of women. A third of girls are reaching puberty at 9. From NHS statistics hysterectomies are being performed between the ages 15-19 years. There are as many hysterectomies performed under 35 as over 35, therefore it is important not to restrict the guideline to only women of childbearing age as it would exclude 50% of women affected by hysterectomy. Older women's health should be valued and extensive physically traumatic, major surgery should only be used where absolutely necessary, when no other options are possible.	Hysterectomy is done rarely on pre-pubertal girls unless there is malignant disease. It is also an unusual treatment for HMB on HRT in post-menopausal women. The indications in these instances are outside the scope of the review.
Fibroid Network Charity	General	Women make up to 50% of the UK workforce, therefore they desire treatments which are less invasive and have shorter recovery times.	Thank you. Cost effectiveness of each treatment will be reviewed where data are available. Although health economics will be included in the guideline, the societal level economic impact of treatment may be outside the scope of the guideline.
Fibroid Network Charity	General	50% of NHS treatments for fibroids each year are hysterectomy. Fibroid removal (myomectomy) makes up only less than 5% of fibroid treatments, despite the fact that most women given hysterectomy are in their childbearing years. Embolisation is less than 1%.	Thank you. The scope of the guideline is to analyse the available evidence on treatment, and make recommendations on treatment used based upon this. If the evidence suggests that current patterns of practice are flawed then the recommendations made should impact on these treatment patterns.
Fibroid Network Charity	General	In our survey of 1,700 women, 95% of women who contacted us wanted an alternative to hysterectomy.	Thank you. These are important points.
Fibroid Network Charity	General	The main issues for women contacting us are:	
Fibroid Network Charity	General	Lack of Patient Choice – leading to lack of informed choice	We agree that information provision is central to good practice. Patient education and information provision will be examined by the guideline. This issue has been made explicit in section 4.3.
Fibroid Network Charity	General	Doctors not giving information on alternatives to hysterectomy.	We agree that information provision is central to good practice. Please see our previous comment.

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Fibroid Network Charity	General	Lack of Written Information on what fibroids are, available treatments & risks & benefits of procedures.	We agree that information provision is central to good practice. Please see our previous comment.
Fibroid Network Charity	General	Lack of referrals to support groups & counselling for loss of fertility as a result of womb removal & for depression and hormone disruption as a result of endocrine organ removal.	We agree that information provision is central to good practice. Please see our previous comment.
Fibroid Network Charity	General	Removal of additional organs i.e. ovaries & cervix etc.	The issue of the removal of healthy ovaries is mentioned in section 4.3.c, but this will be made more explicit in the revised document. Please see section 4.3.g.
Fibroid Network Charity	General	Doctors telling women that fibroids could become cancerous without giving statistics or carrying out diagnostic tests, leading to unnecessary emotional distress & encouraging reluctant consent to hysterectomy.	We agree that information provision is central to good practice. Please see our previous comment.
Fibroid Network Charity	General	Women being sterilised by hysterectomy during their childbearing years.	This is an important issue, and could certainly be developed into a specific clinical question to be addressed by the guideline. Within the scope a paragraph has been added about the implications of treatment.
Fibroid Network Charity	General	Women face age discrimination in treatment by hysterectomy, the current scope would continue this position.	Thank you. This statement may be true, but needs to be substantiated. We are unclear as to exactly what is meant by this statement.
Fibroid Network Charity	General	Women, especially ethnic minorities are often afraid to go to their Doctor for treatment they are afraid he will "take their womb out", because this practice is so common in the gynae community. This leads to women waiting until their pain , heavy bleeding, or incontinence (from large fibroids pressing on their bladder) becomes so acute that they made need emergency treatment which may involve hysterectomy.	Thank you. This statement may be true, but needs to be substantiated.
Fibroid Network Charity	General	Lack of early diagnosis leads to women suffering with symptoms for many years before finally receiving treatment.	Thank you. There is a consensus amongst stakeholders that the diagnosis section needs to be expanded. This has been done. Please see section 3 of revised scope for details.
Fibroid Network Charity	General	Hysterectomy is often offered as a first not a last resort.	Thank you. This statement may be true, but needs to be substantiated. It also relates to a service provision issue, which is outside the remit of this guideline.

Commentator	Section	Comment	Response WCH
Fibroid Network Charity	General	At least 85% of women are fertile in their childbearing years, even with fibroids (which is in line with the general population), therefore it is important to preserve their wombs, where required. Many women are first diagnosed during pregnancy. It doesn't affect your ability to produce eggs.	This is an important issue, and could certainly be developed into a specific clinical question to be addressed by the guideline. Within the scope a paragraph has been added about the implications of treatment.
Fibroid Network Charity	1	Heavy Bleeding & fibroids are not the only indications for hysterectomy. These conditions usually co-exist with other problems. Endometriosis, womb cancer, chronic pelvic pain, adenomyosis, pelvic inflammatory disease, prolapse, abdominal enlargement from large fibroids often lead to hysterectomy. Excluding these other conditions would lead to these women not having a choice of alternatives to hysterectomy. It would maintain the status quo of Doctors failing to advise on available treatments for these disorders.	Thank you. This is an important point. The change in the scope of the guideline means that hysterectomy is no longer the focus. And the reason for limiting the study to HMB with or without fibroids, is due to the high prevalence of HMB with fibroids. However, it will not be possible to consider all conditions that lead to hysterectomy. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1 December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
Fibroid Network Charity	1	Other countries have prepared hysterectomy guidelines including the other conditions. In addition management of fibroid guidelines have been prepared, we attach 2 SOGC examples as to the scope of these guidelines.	Thank you. We certainly will examine these, but the reason for NICE guidelines is to examine treatment within the context of the UK.
Fibroid Network Charity	1	It can't be a overall guideline for hysterectomy if it only covers 2 out of a approx 8 main conditions that lead to hysterectomy. Denying the other women access to Patient Choice.	Thank you. This is an important point. The focus of the guideline has been changed from hysterectomy to HMB. It would be impractical to produce a guideline on all the causes of HMB, so the guideline will focus on HMB with or without fibroids, as HMB is often the main symptom with fibroids and treatment pathways are very similar.
Fibroid Network Charity	2	The referral by the Dept of Health & Wales assembly does not tell NICE to restrict the guideline to women of childbearing age. It asks to prepare guidelines for hysterectomy & alternative treatments for menorrhagia and <u>OTHER CONDITIONS</u> .	Thank you. The reason that an age restriction is outlined for the population is that by definition HMB occurs in women of reproductive age, and as the emphasis of the guideline is now on HMB it is appropriate that this restriction is outlined. Please see sections 1 and 1.1 of the revised scope for details of changes.

Commentator	Section	Comment	Response WCH
Fibroid Network Charity	2	It is cost effective to overview the other diseases, as it would be more expensive financially & in consultation time in order to prepare individual guidelines for each other condition.	Thank you. The reason that an age restriction is outline for the population is that by definition HMB occurs in women of reproductive age, and as the emphasis of the guideline is now on HMB it is appropriate that this restriction is outlined. Please see section 1 and 1.1 of the revised scope for details of changes.
Fibroid Network Charity	2	There are many stakeholders registered who can assist with the preparation of a general guideline & necessary research.	Thank you. As part of the NICE guideline development process a representative group of stakeholders is always invited to help with the guideline development. And it is this Guideline Development Group that decides what questions are asked and which recommendations are made.
Fibroid Network Charity	3a, b, c	Women are not getting good management of heavy bleeding at GP level. Information should be available at GP's surgeries.	We agree that information provision is central to good practice. Patient education and information provision will be examined by the guideline. This issue has been made explicit in section 4.3.
Fibroid Network Charity	3a, b, c	There is a need to define heavy bleeding. Some women feel severe bleeding for 4 days is heavy; others may experience 2 weeks of non-severe bleeding, some may experience flooding (severe haemorrhagic bleeding) leading to anaemia & blood transfusions in some cases, others may have negative associations with their periods (possibly due to earlier child abuse) so they may have negative feelings generally about their menstrual cycle. Will it be defined in this guideline?	Please see previous comment on diagnosis. This issue is fundamental to the guideline and will be covered.
Fibroid Network Charity	3a, b, c	MRI scans are useful in diagnosing menstrual disorders and are the only way of distinguishing between fibroids & adenomyosis without surgery.	Although MRI is useful for determining the cause of HMB, it is a very expensive investigation and not freely available in most regions. Its use will be considered in the section on diagnosis.
Fibroid Network Charity	3a, b, c	Ultrasound is helpful in identifying large masses in the womb.	The uses of ultrasound will be considered in the diagnosis section of the guideline.
Fibroid Network Charity	3a, b, c	It is important to advise on diagnostic tests for cancer, to distinguish between benign and cancerous causes of menstrual bleeding.	HMB as a presenting symptom for cancer will be considered in the diagnosis section of the guideline.
Fibroid Network Charity	General	Consent to hysterectomy is a difficult decision. Providing written information would provide women with impartial information on hysterectomy and alternative treatments. They should be advised on the risks and benefits of each procedure. The choice of treatment should lie with the	We agree that information provision is central to good practice. Please see our previous response for details.

Commentator	Section	Comment	Response WCH
		woman.	
Fibroid Network Charity	3d	Other HMB treatments; myolysis of fibroids, embolisation, hydrothermal and other forms of ablation, focused ultrasound. Myomectomy is effective in over 60% of cases in reducing heavy bleeding & preserving fertility. Embolisation and endometrial ablation is approx 80% effective in reducing heavy bleeding. Also lifestyle: Diet & exercise research should be examined (There has been large studies in this area worldwide).	Thank you. These treatments have been added to those covered by the guideline. Please see sections 3 and 4.3 for details.
Fibroid Network Charity	3e	Hydrotherm ablation is quite successful at reducing uterine perforation compared to other ablation techniques.	Thank you. The effectiveness of this treatment will be assessed within the guideline.
Fibroid Network Charity	3h	The rate of hysterectomies hasn't changed because most women are not made aware of alternatives. In addition older Doctors who are confident in their skills at hysterectomy and not in myomectomy, tend to recommend mainly the treatment they can do , rather than refer women for other treatments elsewhere. The General Medical Council in its good conduct guidelines is trying to discourage this practice amongst Doctors.	Thank you. A fundamental concern of the guideline is to evaluate appropriate treatments for HMB. The guideline will make appropriate recommendations on medical education.
Fibroid Network Charity	3h	Less than 5% of Hysterectomies are performed for cancer/life-threatening illnesses. In addition, HRT use has become a controversial issue, but is an issue for women facing hysterectomy, as often young women have to cope with premature surgical menopause as a result of this procedure and they need to stay on it for longer. This increases their risk of breast cancer, cardiovascular disease & blood clots, replacing life threatening illnesses for treating essentially benign non-life threatening illnesses.	Thank you. The long-term outcomes of surgery, such as HRT use, are very important, and will be examined within the guideline. Please see sections 3 and 4 for more detail.
Fibroid Network Charity	3h	In addition hysterectomy has a small but significant higher risk of death than other alternatives including Embolisation. Serious complication rates are higher in hysterectomy than other alternatives.	Thank you for this information. As was outlined above, adverse outcomes will be examined for each treatment option where data are available.

Commentator	Section	Comment	Response WCH
Fibroid Network Charity	3h	Complication and Death rates for hysterectomy may be currently under diagnosed because this may occur in the 6 weeks after the woman returns home from her in-patient stay. The woman may then return to hospital to the emergency, casualty depart for heavy bleeding, pain adhesions, bowel or bladder injury & be referred to the relevant specialist department i.e. urology etc and see a different Doctor, so the problems do not show in the hysterectomy statistics. Proper monitoring should be advised in this guideline. Also women should be told what to expect after the operation and what symptoms they must report back to their hospital.	Thank you. We shall consider this when examining medium- to long-term outcomes of the procedures. The guideline will make audit recommendations. However, the nature of these depends on the results of review process with consideration of data from studies designed to address this point where these are available.
Fibroid Network Charity	4.1	Please see comments on 2 above. We ask that this guideline does not age discriminate on women facing hysterectomy.	Thank you. There is consensus amongst the stakeholder groups that the study population needs to be clarified. The revised guideline is being restricted to post-puberty and pre-menopausal as it is, by definition, this group that will have heavy menstrual bleeding. Vaginal bleeding in women outside this group is not treated as HMB. Of course there may be a grey area, but that can be clarified by investigations.
Fibroid Network Charity	4.1a	Please see my earlier comments above re childbearing an age of menopause.	Please see previous response.
Fibroid Network Charity	4.1a	At least 95% of GP's surgeries & hospitals do not have information provided to women on fibroids therefore restricting the scope of the guideline to these two groups would resign other women to hysterectomy without any info on alternatives, which would maintain the current high levels of hysterectomy.	See above comment on information provision. However NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1 December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
Fibroid Network Charity	4.1a	Many women have to have alternative treatments privately for these and the other conditions due to gynaecologists reluctance to offer alternatives. This is unfair to women, who often don't have health insurance cover as they have a pre-existing illness, which is usually excluded by insurance companies. This is especially unfair as these alternatives are available on the NHS.	Thank you. The decision of individuals to purchase private health insurance is not within the remit of this guideline. NICE guidelines are aimed at NHS professionals with the objective of considering the treatments and making appropriate recommendations based on the best available evidence, and may influence the National Service Framework. Issues relating to cost effectiveness are considered; however, it is outside the scope of the guideline to make resource allocation decisions or

Commentator	Section	Comment	Response WCH
			comment on private healthcare.
Fibroid Network Charity	4.1a	CASE STUDY_I spoke at a women's health group, a Muslim woman, on income support, told me that her NHS consultant told her that he could perform a hysterectomy on the NHS. He said he could perform a myomectomy, but only if she did it with him privately. If the woman was suitable for myomectomy then it should have been given on the NHS. This lady , for whom, fertility was culturally & emotionally important, has, had to delay any treatment whilst her relatives helped her save up for a private myomectomy. This is one of similar stories I have heard in the last 4 years. Women are generally reluctant to complain about these issues as they are embarrassed about talking publicly about their sexual organs, and the consequent loss of fertility, or complications from treatment including incontinence, which has led to the current situation re: unnecessary hysterectomies. They often trust & rely on Doctors to give them the best advice. It is rare to find books on fibroids in shops & libraries and not many women access the Internet for health information.	Thank you for this information.
Fibroid Network Charity	4.1b	See above comments re other conditions & polyps & neoplasia.	Thank you. This is an important point. The scope of the guideline has been extended in response to stakeholder comments to cover HMB and hysterectomy, and therefore other conditions will not be addressed in this guideline.
Fibroid Network Charity	4.1b	Large fibroids are often not diagnosed until menopause &/or may start to cause problems in menopause or following HRT use, these situations would be outside the current scope.	Thank you. HMB whilst on HRT is outside the remit of the guideline.

Commentator	Section	Comment	Response WCH
Fibroid Network Charity	4.1b	There is no logical reason to exclude post-menopausal women from the guideline, preventing them from access to alternatives to hysterectomy and information on risks & benefits. This would exclude over 3 million women from information about safe less-invasive treatments. From NHS statistics up to half of hysterectomies are in the post-menopausal category. Information is not readily available from other sources.	Post menopausal women are excluded since this population do not present with HMB, which is the subject of the guideline. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1 December 2004 suggestions can be made via the NICE website (www.nice.org.uk).
Fibroid Network Charity	4.1b	The community health centres have been closed down in local areas, and there are no other easily accessible sources of information.	Thank you. Although service provision is outside the remit of the guideline, means of providing information to patients will be carefully considered.
Fibroid Network Charity	4.1.2a	See above comments re: other conditions which should be covered.	See previous responses.
Fibroid Network Charity	4.1.2a	<u>Case Study</u> I am 34. I had large fibroids without heavy bleeding. The main pedunculated fibroid was 20cm high, 35cm in diameter plus additional fibroids. It made me appear as if I had a full term pregnancy. It caused occasional lower back pain, tiredness, some bladder pressure leading to frequent urination. These sort of symptoms can also affect quality of life. The main removed fibroid, weighed 5 kilos (11 pounds). Most NHS Dr's would deal with large, multiple fibroids by hysterectomy, which is often a shorter theatre procedure. I had my fibroids removed by abdominal myomectomy in July 2004. I was out shopping within 7 days of the operation. Post-op I went from a size 14/16 to a clothes size 10 solely because of the size of my fibroids. My womb and ovaries were preserved for fertility. I had no complications. Restricting the guideline would have excluded me from alternative treatment information. I had to go privately for my treatment to get a fibroid & fertility specialist to remove my fibroids.	Thank you for this information.

Commentator	Section	Comment	Response WCH
Fibroid Network Charity	4.1.1.1b	Fibroids are often only discovered in an advanced stage, as most women are unaware of what fibroids are until they are diagnosed. Some women just think they are just putting on weight, rather than realising their enlarging abdomens are due to fibroids. If they are more aware of the condition, they may be able to be treated earlier with less invasive surgeries, before heavy bleeding starts to affect their life. <u>Case Study</u> by the time I was diagnosed at 25, I had 4 fibroids, the largest being 10cm. At that time the general approach of Doctors was to perform hysterectomies on anything over 16 week size. Now skilled Doctors are able to treat larger fibroids.	We agree that information provision is central to good practice. Patient education and information provision will be examined by the guideline. This issue has been made explicit in section 4.3.
Fibroid Network Charity	4.1.1.1b	Intra-uterine devices can sometimes perforate the womb-lining, leading to heavy bleeding, so they should be discussed.	Thank you. The use of the progestogen-secreting intrauterine system will be considered in the guideline. Please see section 3 for details.
Fibroid Network Charity	4.1.1.1b	The mirena coil (inter-uterine device) has been used to control heavy bleeding in women with fibroids, therefore it should be investigated.	Thank you. This treatment will be considered.
Fibroid Network Charity	4.1.1.1b	There are alternatives to hysterectomy for prolapse, so they should be included. It is also relevant to the discussion of how much should be removed of the womb & surrounding structures during a hysterectomy.	Thank you. As the scope of the guideline has been extended to cover HMB. It is not within the remit of the guideline to examine hysterectomy for prolapse.
Fibroid Network Charity	4.2a	The guideline should ensure women get written information from their GP's & hospitals, reducing the fear & misunderstanding, when told they have a "tumour" without proper explanation of the frequency of the problem & small risk of cancer, without further tests. Often there is an average 6 week wait for an ultrasound or months for an MRI scan whilst no other info given. Often fibroids are briefly explained in an average 5 min consultation at the Dr's office. It is perhaps not possible to go through all the info verbally in that time.	We agree that information provision is central to good practice. Patient education and information provision will be examined by the guideline. This issue has been made explicit in section 4.3.
Fibroid Network Charity	4.2a	This may also help to reduce cancelled hysterectomy operations through lack of informed choice & consent.	Thank you.
Fibroid Network Charity	4.2a	Often Dr's tell women to have a hysterectomy because it could be cancerous without doing further tests, & only find out after the op that it's not, putting the woman through an unnecessary procedure, when alternatives existed.	Thank you. Issues relating to the exclusion of malignancy will be considered in the guideline.

Commentator	Section	Comment	Response WCH
Fibroid Network Charity	4.2a	Women do want information on self-help i.e. if diet or exercise can reduce their symptoms, there is some research to support this.	This is an important issue. Self-management/patient education has been added to the guideline scope. Please see sections 3 and 4 for details.
Fibroid Network Charity	4.3c	Removing healthy ovaries is unnecessary, as not all ovaries fail if the womb is removed. This would reduce the need for HRT in women who don't wish to use it. It would help to contribute to the endocrine system, reducing sudden female hormone disruption which may occur when the womb & ovaries are removed.	Thank you for this information. This issue is addressed within the scope, and a specific clinical question will be developed within the guideline to answer this question. See section 3.1 for details.
Fibroid Network Charity	4.3c	Women are increasingly delaying childbirth & using new technologies to preserve eggs from ovarian tissue. This guideline should be looking to the future in order to allow women to preserve what they can of their healthy reproductive organs.	This issue is outside the remit of the guideline.
Fibroid Network Charity	4.3c	Ovarian cancer is very rare & therefore not a justification for removing healthy ovaries in women who did not wish for them to be removed. Women should be informed of the risks, statistics & benefits of keeping them before the hysterectomy. Also increased risk of cervical & ovarian cancer following long term use of HRT should be examined for risk.	Thank you. Please see the previous comments on patient information and removal of ovaries.
Fibroid Network Charity	4.3h	It should advise Doctors to keep up to date on successful new fibroid treatments. <u>Case Study</u> Some Dr's had heard Goserelin, Zoladex could shrink fibroids and alleviate heavy bleeding and were using it as a cure for fibroids for over 10 months. Zoladex is used to reduce oestrogen levels in the womb therefore reducing the blood supply to the womb & reducing fibroid size by up to 40% making hysterectomies & myomectomies easier to perform & inducing a temporary menopausal state. Long-term studies showed that if you used it as a stand-alone treatment for fibroids, after you stop giving the drug, if you hadn't surgically removed the fibroids, then they often grew back larger than before, often necessitating hysterectomy. In addition some women who were close to menopause went permanently into menopause. And the early preparations sometimes induced osteoporosis. If the Drs had kept up to date with the research these complications could have been avoided.	Thank you. These treatments will be considered by the guideline. Please see section 3 for details.

Commentator	Section	Comment	Response WCH
Fibroid Network Charity	6	Related NICE guidelines should also include, Sterilisation.	Thank you. Related guidance will be considered.
Fibroid Network Charity	5	It is appalling that you must receive support/counselling if necessary for abortion, which is the loss of one child, but not for the total loss of your fertility with hysterectomy.	Thank you. Issues of fertility will be considered as part of the treatment options.
Fibroid Network Charity	5	Also The Uterine Artery Embolisation & Fertility guideline. And Focused Ultrasound for fibroids when it becomes available.	Thank you. Related guidance will be considered.
Fibroid Network Charity	Appendix	There should be specific structured training programmes for Doctors with a special interest in this area.	Detailed assessment of professional training and competences is outside the remit of the guideline, but general comment about required competences for specific treatments can be made.
Fibroid Network Charity	Appendix	Local services should ensure that hysterectomies performed are monitored for:	The guideline shall consider audit criteria based on best available evidence. However, local service issues are beyond the remit of the guideline.
Fibroid Network Charity	Appendix	Users views of service & quality.	See previous comment on audit.
Fibroid Network Charity	Appendix	Local reasons for high levels of hysterectomies.	See previous comment on audit.
Fibroid Network Charity	Appendix	Investigation into consistent geographical variation.	See previous comment on audit.
Fibroid Network Charity	Appendix	Preserving patient anonymity to allow for women to praise or complain about the service received in independent surveys.	See previous comment on audit.
Fibroid Network Charity	Appendix	Drs should fully participate in audits of patients & operations.	We agree.
Fibroid Network Charity	Appendix	The NHS should provide lists to Doctors of where to send patients for alternatives to hysterectomy.	Thank you for your comment. This is an interesting point.
Fibroid Network Charity	Appendix	Hysterectomy & fibroids figures are poorly recorded in NHS statistics.	Thank you for your comment.
Fibroid Network Charity	Appendix	Primary diagnosis is problematic. Some fibroids are recorded as the primary diagnosis, however they may also come under menorrhagia, as the heavy bleeding was diagnosed first, i.e., a woman may have an emergency hysterectomy for heavy bleeding and during the surgery fibroids are found.	Please see section on diagnosis and referral of HMB. Also, coding issues will not be covered in the guideline.
Fibroid Network Charity	Appendix	Some fibroid treatments are combined in the NHS codes with endometriosis & other procedures without a breakdown of figures.	Coding issues will not be covered in the guideline.

Commentator	Section	Comment	Response WCH
Fibroid Network Charity	Appendix	Individual treatments i.e. laparoscopic myomectomy or other types of endoscopic procedures are lumped together as i.e. endoscopic procedures on the uterus.	Coding issues will not be covered in the guideline.
Fibroid Network Charity	Appendix	Embolisations are being under recorded.	Coding issues will not be covered in the guideline.
Fibroid Network Charity	Appendix	Complication rates of all procedures are poorly recorded.	Coding issues will not be covered in the guideline.
Fibroid Network Charity	Appendix	Operations categorised by Ethnic minorities are poorly recorded with up to 30% no definition recorded.	Coding issues will not be covered in the guideline.
Fibroid Network Charity	Appendix	Women's choice of private treatment rather than NHS should be surveyed to access whether it is for convenience, or for necessity, as cannot get alternatives to hysterectomy on the NHS.	Unfortunately, due to limited resources, service delivery issues are outside the scope of the guideline, though future service patterns may be influenced by the results of a guideline.
Fibroid Network Charity	Appendix	Monitoring of whether Doctors are giving information on hysterectomy & alternatives to hysterectomy.	Audit recommendations will be made on the basis of the best available evidence.
Fibroid Network Charity	Appendix	The above requires independent surveys of patient views.	Audit recommendations will be made on the basis of the best available evidence.
Fibroid Network Charity	Appendix	The GMC states that the duties of a Doctor include "Recognising the limits of your professional competence, keeping their professional knowledge and skills up to date & working with colleagues in the ways that best serve the patients interests". Some Doctors are helpful but from the 1,000's of feedback we've received many are stuck in the past, wanting to use Victorian womb removal for modern treatable diseases.	Thank you. The aim of the guidelines is to encourage all health professionals to follow best practice.
Fibroid Network Charity	Appendix	There are Human Rights Issues in removing wombs in fertile women without informed choice of alternatives, which infringes their Right to Found a Family through misinformed consent.	Thank you for your comments. The guideline shall fall within the confines of Human Rights legislation; however, issues of informed consent will not be considered.
Fibroid Network Charity	Appendix	There are Doctors contact us who, would like to refer women for alternative treatments, as the NHS does not have lists of where to obtain alternative fibroid specialist treatment.	Thank you for your comment.
Fibroid Network Charity	Appendix	Our charity has lists of centres and we are creating a Directory, as a response to Drs & patients requests. We have no outside funding at present. Women therefore must rely on the Health Service for information; therefore we are grateful that this guideline will help patients if Doctors adhere to it.	Thank you for your comments and contribution.

Commentator	Section	Comment	Response WCH
Gloucestershire Hospitals NHS Trust	1	Suggest 'Hysterectomy for menorrhagia and <i>fibroids</i> '. ' <i>...other conditions</i> ' is vague, and 4.1.2 says other co-morbidities will not be covered by the guideline.	Thank you. There is a consensus amongst stakeholder groups that the title of the guideline needs to be changed. The guideline will cover hysterectomy, the diagnosis and management of heavy menstrual bleeding (menorrhagia) with or without fibroids. These changes have been undertaken in the revised scope. Please see section 1 and 1.1 of the revised scope for details of changes. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
Gloucestershire Hospitals NHS Trust	1.1	Short title is dangerous! There are too many other reasons for hysterectomy which come outside this guideline.	The short title has been changed in line with the more general changes outlined above.
Gloucestershire Hospitals NHS Trust	General	Will the guideline address <i>irregular</i> bleeding? If not, then should specify.	Thank you. The guideline will not address irregular bleeding, and this has been made clear in the revised scope. Please see section 4.1 for details.
Gloucestershire Hospitals NHS Trust	3e	Specify number of patients requiring hysterectomy <i>at some time</i> after ablation. Many have increased pain, or bleeding some years after ablation, with partial obliteration of the endometrial cavity. The number requiring hysterectomy is considerably higher than 0.2-0.6 per cent. See RCOG Mistletoe study.	Thank you for this information. Both the short and long term outcomes of treatment will be considered where data are available.
Gloucestershire Hospitals NHS Trust	3f	Not all second generation techniques can be performed under local anaesthetic. Careful selection of both patients and technology is necessary.	Thank you for this point, with which we agree.
Gloucestershire Hospitals NHS Trust	3g	Presumably this refers to embolisation, not hysterectomy or myomectomy.	Thank you. This issue has been clarified in the revised scope.
Gloucestershire Hospitals NHS Trust	4.1.2	Adenomyosis may not be the best example, as it is often diagnosed retrospectively after hysterectomy. Endometriosis may be more appropriate.	Thank you. We have changed the example. See section 4.1.2.
Gloucestershire Hospitals NHS Trust	4.3f	Incomprehensible.	This paragraph has been removed.
Gloucestershire Hospitals NHS Trust	General	1) What are pros and cons of subtotal vs total?	Thank you. This question will be noted and will be considered in the guideline.
Gloucestershire Hospitals NHS Trust	General	2) Is there a size of uterus/fibroid at which hysterectomy may be recommended, if asymptomatic?	Thank you. The treatment of asymptomatic fibroids will not be considered.
Good Hope NHS Trust		This organisation was approached but did not respond.	

Commentator	Section	Comment	Response WCH
Gorlin Syndrome Group		The Gorlin Syndrome Group will not be contributing to this particular guideline.	Thank you. Please note that major changes have been made to the emphasis of the scope in response to stakeholder comments.
Greater Peterborough Primary Care Partnership-North PCT		This organisation was approached but did not respond.	
Haemophilia Society, The		This organisation was approached but did not respond.	
Healthcare Commission		This organisation was approached but did not respond.	
Hospital Infection Society		This organisation was approached but did not respond.	
Independent Healthcare Association		This organisation was approached but did not respond.	
Johnson & Johnson Medical	3a-i	The contents of this section are descriptive and do not make explicit the reason that a guideline is needed.	Thank you. We have edited the justification section to make a more convincing argument for the need for a guideline. Please see section 3. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
Johnson & Johnson Medical	3d	The number of endometrial ablations is probably under reported. It is difficult to measure this using NHS reporting systems. Many rollerball and TCRE procedures are subsumed within OPCS Q17. In addition, there are no specific OPCS codes to cover second generation procedures and these are therefore coded under generic headings at the discretion of the surgeon.	Thank you. We have to use the best published data. However, coding issues are not within the remit of the guideline.
Johnson & Johnson Medical	3f	No complication rates are given for second generation techniques whereas these are given for hysterectomy and non-surgical or first generation techniques. Given the way this paragraph is worded the report may give a false impression that second generation techniques are more risky than older alternatives.	Thank you. Rates of adverse events will be examined for all treatments that are included.

Commentator	Section	Comment	Response WCH
Johnson & Johnson Medical	3h	This paragraph suggests complete cessation of menstruation is the key clinical outcome in treating HMB. As recognised in the recent technology appraisal (no. 78) the primary purpose of the management of heavy menstrual bleeding should be to reduce bleeding to within acceptable ranges, complete cessation being just one point on this continuum, and as such amenorrhea may not be the preferred outcome for the patient.	Thank you. We do state in the document that the aim of treatment is the reduction of bleeding and improvement in quality of life.
Johnson & Johnson Medical	4.2a	The document does not mention "location of care" under settings. It was stated in the consultation meeting that it was not intended to include "location of care" in the scope. However, if indications for alternative treatments are to be covered along with evidence on cost-effectiveness, it will be necessary to distinguish between settings. For example, endometrial ablation carried out in outpatients provides much faster recovery and at a lower unit cost of treatment. Treatment under local anaesthetic in outpatients is less risky. Two RCT's are underway comparing outpatient ablation to conventional settings and data from these studies will be available during the consultation period. Furthermore, in order to comprehensively cover care in the primary care setting, it will be necessary to take into account that the safety features of second generation techniques make it possible for endometrial ablation to be carried out in primary care along with diagnostic hysteroscopy. There are examples of this happening already.	Thank you. We will make the distinction between outpatient and inpatient care and published data considered where these are available.
Johnson & Johnson Medical	4.1.2	The wording should not exclude consideration of the wider effect and complications of treatments for heavy menstrual bleeding.	Thank you. There is a consensus amongst stakeholders that the scope needs to explicitly state short- and long-term outcomes and complications will be investigated for each treatment comparison.
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.	

Commentator	Section	Comment	Response WCH
Luton and Dunstable Hospital NHS Trust	General	Consider including "retention of normal cervix (subs-total hysterectomy)" in scope.	Thank you. This has been added. See section 4 for details. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
Luton and Dunstable Hospital NHS Trust	General	As indicated at the meeting, whilst addressing fibroids and heavy periods only will allow a simpler approach, if you fail to consider other indications for hysterectomy you will be failing to fulfil the brief from DoH and the Welsh Assembly Government.	Thank you. The scope of the guideline has been extended to cover HMB, with or without fibroids.. However, the guideline will not be addressing all indications for hysterectomy.
Luton and Dunstable Hospital NHS Trust		I assume my colleague has pointed out that rates for hysterectomy and all procedure for heavy periods have actually fallen over the last few years.	Thank you. This has been noted. However, HMB still remains an important issue that needs to be addressed since non-surgical treatments are available. Recent figures for the numbers of procedures carried out will be considered.
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	General	The clinical need is not specifically stated although a number of statements are made within that section of the scope. Taken together these statements imply that there are 'too many hysterectomies' and that up to 50% involve the removal of a normal uterus. Existing treatment options are listed including drug therapy. The clinical need section does not explicitly state what the need is. Is it	Thank you. We have edited the justification section to make a more convincing argument for the need for a guideline. Please see section 3. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
Microsulis Medical Limited	General	1) To ensure that hysterectomies for menorrhagia are reduced where feasible?	Treatments for menorrhagia/HMB will be considered in the guidelines.
Microsulis Medical Limited	General	2) To efficaciously and effectively treat menorrhagia?	Treatments for menorrhagia/HMB will be considered in the guidelines.
Microsulis Medical Limited	General	The clinical need section also references the 2 RCOG guidelines, one of which relates to the initial investigation of menorrhagia. Initial investigation does not necessarily happen at the 'clinical' level but at the General Practitioner level.	Thank you. The scope does state that management will be examined on all levels. See section 4.2.

Commentator	Section	Comment	Response WCH
Microsulis Medical Limited	General	If the clinical need is 1) above then the clinical guideline would only relate to the secondary care treatment of menorrhagia. If the clinical need is 2) then it would also need to consider the primary care of menorrhagia.	Thank you. The scope of the guidelines covers management of HMB in both primary and secondary care. Previous guidelines published on the subject will be considered.
Microsulis Medical Limited	1.1	The short title suggests that the clinical guideline is about hysterectomy which is not accurate based on the guideline title. The short title should relate to the title of the guideline but that can only be clearly enunciated if the clinical need is stated unambiguously.	Thank you. The short title has been changed to 'Heavy menstrual bleeding' in response to the changes in the scope.
Microsulis Medical Limited	2a	If there are differences in the evidence levels for each treatment then the guideline should qualify recommendations accordingly.	Thank you. NICE guidelines use a standardised hierarchy for reporting the quality of evidence used to make any recommendations.
Microsulis Medical Limited	3c	The clinical evidence for majority of second/third generation treatments not only reports outcomes on reduced menstrual bleeding (subjective outcome) but also on complete cessation of menstrual bleeding (objective outcome) thus amenorrhoea should not be ignored.	Thank you. There is a consensus amongst stakeholders that the scope needs to explicitly state short- and long-term outcomes, in relation to both quantity of bleeding and quality of life and also, complications will be investigated for each treatment comparison.
Microsulis Medical Limited	3d	The statement that 'surgical treatment is usually offered to patients who do not respond to drug treatment follows existing RCOG guidelines but these guidelines did not encompass second/third generation EA. Additionally it does not correspond with the HTA on TBEA and MEA.	Thank you. This section has been removed, as the whole section has been edited to improve the justification for the guideline rather than providing a description of the treatments. Previous publications, such as this HTA, will be considered.
Microsulis Medical Limited	3d	This point was raised in an appeal against the FAD of the HTA on TBEA and MEA. As a result, the original wording of Ground 1a " ... TBEA and MEA are recommended as treatment options for ... [HMB] in cases where it has been decided (by the woman and the clinician responsible for her treatment) that surgical intervention is the appropriate next step in management of the condition." Was changed to "Fluid-filled thermal balloon endometrial ablation and microwave endometrial ablation are recommended as treatment options for women with heavy menstrual bleeding in cases where it has been decided (by the woman and the clinician responsible for her treatment) that surgical intervention is appropriate for the management of the condition."	Thank you. This paragraph has been removed. However, section 4 outlines the various EA options that will be examined.
Microsulis Medical Limited	3i	The RCOG guidelines did not cover second or third generation EA.	Thank you. These guidelines will cover all current treatment.

Commentator	Section	Comment	Response WCH
Microsulis Medical Limited	6	NICE Technology Appraisal Guidance No. 78. : This guidance was issued in 2004 but reports written to inform it (PenTAG) were conducted many months before. As such, additional clinical papers on MEA have been published since then or are about to be published. References are given at the end of this table.	Thank you. This guideline will be based on all currently available evidence.
Microsulis Medical Limited	6	NICE Interventional Procedures Guidance No. 7 and NICE Interventional procedures Guidance No.6. There are differences in consistency of content and fact between these Guidance documents e.g.	Thank you. The application of each treatment will be outlined based on standard recommendations for use.
Microsulis Medical Limited	6	1) Section 2.2.1 in the TBEA guidance document No. 6 states that 'It can often be carried out using local anaesthesia on a day-case basis.' The MEA guidance document No. 7 does not say the same for MEA yet MEA has clinical evidence to support this through an RCT published in BJOG. The reference is supplied at the end of this table.	Thank you. This review will independently review available evidence. It must also be pointed out that this review group has no influence over previous publications, and any concerns with previous publications must be directed to the relevant individuals.
Microsulis Medical Limited	6	2) Section 2.3.2 in TBEA guidance document No 6 states "Rates of amenorrhoea varied from 30% to 60%". This is erroneous and misleading on several fronts. The statement combines data for two separate devices (Thermachoice and Cavaterm). The 60% figure comes from case series on Cavaterm for a very small population (n=50) and data of this sort is not of robust quality, as defined by quality guidelines for evidence based medicine. From RCT clinical evidence available and used in NICE Technology Appraisal Guidance No. 78, amenorrhoea rate for one TBEA product (Thermachoice) was 13-15% and amenorrhoea rate for other TBEA product (Cavaterm) was 29-30% from RCT evidence (excluding Cavaterm case series mentioned above). The statement that amenorrhoea rate for TBEA is 30%-60% is misleading. RCT clinical evidence on MEA and used in NICE Technology Appraisal Guidance No.78, shows MEA has amenorrhoea rate of 40-47%. Yet no mention of this parallel statistic in the MEA IP guidance. Additionally, further RCT published recently in JAAGL which demonstrates 50-60 % amenorrhoea rate for MEA. Reference given at the end of table.	Thank you for this information. The published evidence relating to these treatment modalities will be considered.

Commentator	Section	Comment	Response WCH
Microsulis Medical Limited	6	3) Section 2.4.2 of the MEA IP guidance document advises that one expert noted that there was no long term data on MEA. It is believed that a paper on long term data on MEA has been accepted for publication by BJOG.	Thank you for this information.
Microsulis Medical Limited	6	4) There is no mention in the MEA guidance document that MEA can treat a much greater range of patients than can TBEA. This serious limitation on the use of TBEA is highly material information for the NHS generally and clinicians particularly, when deciding which treatment to use/recommend to patients. Without it, it is difficult to see how the guidance documents can give an accurate, proper and informative assessment of efficiency. MEA can treat significant numbers of women (up to 60%) who would be excluded from TBEA treatment due to uterine irregularities or abnormalities.	Thank you for this information. These issues will be considered by the GDG.
Microsulis Medical Limited	6	References to additional publications unavailable for NICE Technology Appraisal Guidance No.78: Wallage, S., et al. "A Randomised Trial Comparing Local Versus General Anaesthesia for Microwave Endometrial Ablation," British Journal of Obstetrics and Gynaecology. September 2003, Vol. 110, pp. 799-807/ Cooper, JM, et al. "Microwave Endometrial Ablation vs. Rollerball Endometrial Ablation for Menorrhagia: A Multicenter Randomized Trial," Journal of the American Association of Gynecologic Laparoscopists. August 2004, Vol. 11, No.3 pp. 394-403/ Cooper, K G., et al. "A Randomised Comparison of Microwave Endometrial Ablation with Transcervical Resection of the Endometrium; five year follow up" (BJOG)	Thank you. These will be reviewed, where relevant.
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.	

Commentator	Section	Comment	Response WCH
National Endometriosis Society	General	We feel it is clear that this guideline is directed towards only heavy periods and apart from fibroids does not really address any other benign gynaecological condition such as endometriosis. We are disappointed in this and would ask you to consider inclusion of endometriosis or (preferably) for NICE to consider establishing a guideline specifically directed towards the management of pain associated with endometriosis.	<p>Thank you. There is a consensus amongst stakeholder groups that the of the guideline should be extended to cover the diagnosis and management of heavy menstrual bleeding (menorrhagia) and hysterectomy. These changes have been undertaken in the revised scope. Please see sections 1 and 1.1 of the revised scope for details of changes.</p> <p>NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1 December 2004 suggestions can be made via the NICE website (www.nice.org.uk). Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.</p>
National Osteoporosis Society	General	The National Osteoporosis Society (NOS) would urge the guideline development group to acknowledge the long term consequences of hysterectomy for the bone health of women.	<p>Thank you. The long-term effects of treatment will be considered by the GDG.</p> <p>Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.</p>
National Osteoporosis Society	General	In particular we would highlight that following premenopausal bilateral oophorectomy women are at an increased risk of osteoporosis due to oestrogen deficiency ¹ . (1. Aitken JM et al. Osteoporosis after oophorectomy for non-malignant disease in premenopausal women. BMJ 1973; ii, 325-328.)	Thank you. Data will be systematically assessed.
National Osteoporosis Society	General	There is also some suggestion that 25-30% of women will experience premature ovarian failure following hysterectomy, despite conservation of one or both of their ovaries, and also left at an increased risk of osteoporosis ² . (2. Beavis et al. Ovarian function after hysterectomy with conservation of the ovaries in pre-menopausal women. Br J Obstet Gynaec 1969; 76, 969-978.)	Thank you. Data will be systematically assessed.
National Osteoporosis Society	General	It is important that the fracture risk of these women, particularly those who are under 45 years of age, is assessed and if necessary that treatment is provided.	Thank you. The effects of treatment on risk factors will be considered where appropriate.

Commentator	Section	Comment	Response WCH
National Osteoporosis Society	General	We would ask NICE to ensure that the guideline addresses this important long term consequence and at the very least cross refers to the osteoporosis guideline.	Please see previous comment on long-term outcomes.
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.	
NHS Information Authority (PHSMI Programme)		This organisation was approached but did not respond.	
NHS Modernisation Agency, The		This organisation was approached but did not respond.	
NHS Quality Improvement Scotland		This organisation was approached but did not respond.	
North Tees and Hartlepool NHS Trust		This organisation was approached but did not respond.	
Nuffield Dept of Obstetrics and Gynaecology	General	Our group has four papers submitted, currently under review, on a comparison, from self completed questionnaire at five years post surgery, between TCRE, hysterectomy and hysterectomy with prophylactic bilateral oophorectomy for DUB alone (or HMB without known cause). These data come from an unselected national sample of 24,000 women treated surgically for DUB in 1993-5. Covering: 1. General health, cancer incidence and readmissions; 2. Urinary problems; 3. Psychosexual health; 4. Readmissions. These may be relevant to your processes - but I imagine you would be reluctant to consider non peer reviewed material. Similarly the collaborators and Journals may have views about prior dissemination. Some guidance would be helpful however.	<p>Thank you. NICE's current policy is that only published data can be included in a guideline, but this is currently under review. We will certainly examine the papers you mention when they are published.</p> <p>Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.</p>
Nuffield Dept of Obstetrics and Gynaecology	General	We have looked at the NICE SCOPE for Hysterectomy and clearly much of this is relevant. As you will know we are undertaking now a retrospective cohort study of embolisation for fibroids compared with hysterectomy - around 2000 women. This is well in progress.	Please see previous comment about the use of unpublished data.
Nuffield Dept of Obstetrics and Gynaecology	General	Your paragraph (g) appears to have omitted a description of the Uterine Arterial Embolisation procedure to introduce the detailed description of what happens, in the second sentence. It sounds like a description of myomectomy with this omission. Also at the end you should add an IPG for	Thank you. This paragraph has been removed. However, explicit reference is now made to UAE within the scope.

Commentator	Section	Comment	Response WCH
		UAE.	
Oxford Radcliffe Hospitals NHS Trust		This organisation was approached but did not respond.	
Princess Alexandra Hospital NHS Trust		This organisation was approached but did not respond.	
Queen Mary's NHS Trust		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 Wales		This organisation was approached but did not respond.	
Royal College of Nursing (RCN)	1	Should include '& medical treatments' for menorrhagia.	<p>Thank you. There is a consensus amongst stakeholder groups that guideline be extended to diagnosis and management of heavy menstrual bleeding (menorrhagia) and hysterectomy. These changes have been undertaken in the revised scope. Please see sections 1 and 1.1 of the revised scope for details of changes.</p> <p>Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.</p>
Royal College of Nursing (RCN)	1For menorrhagia and other conditions. It may be more correct to state 'and associated conditions' rather than 'other conditions' as scope is clear many other conditions will not be covered.	Thank you. This change has been made.
Royal College of Nursing (RCN)	General	HMB should be assessed on patient history and lifestyle disruption – not any type of measurement tool.	Thank you. It is true that treatment is largely based on perceived levels of bleeding and impact on quality of life, rather than any formal measurement tool.
Royal College of Nursing (RCN)	General	It may be useful to include the 'watch and wait' scenario.	Thank you. The concept of watchful waiting can certainly be developed into a clinical question, and has been added to the scope as a potential management option.
Royal College of Nursing (RCN)	General	Should it include guidance on retention of cervix with Total Abdominal Hysterectomy?	The different types of hysterectomy will be considered in the guideline.

Commentator	Section	Comment	Response WCH
Royal College of Nursing (RCN)	General	Although there may be a need for guidance in the presence of other clinical factors e.g. pelvic pain etc we believe to include other conditions would make the document too large and difficult to apply.	We agree. We are limiting the guideline to diagnosis and treatment of HMB. We will not pursue treatment for conditions where HMB is not the main focus of treatment, for example, endometriosis.
Royal College of Nursing (RCN)	3c	Also long acting progestogens.	Thank you. This treatment has been added to the scope. Please see sections 3 and 4 for details.
Royal College of Nursing (RCN)	3f	<i>Third row...</i> but are not suitable for all women, particularly those with fibroids and cancer. (We consider there should be an addition such as the above)	Thank you. As you highlight, the causes of HMB vary, however this guideline will concentrate on HMB. Fibroids will be considered only where menorrhagia is the main presenting symptom.
Royal College of Nursing (RCN)	3g	<i>....In this procedure.....second sentence: We presume the procedure described refers to uterine artery embolisation of fibroids. This is not stated and is not clear.</i>	Thank you. The treatments being examined are now explicitly listed in sections 3 and 4.
Royal College of Nursing (RCN)	4.1a, b	Possibly the same groups of women as if you have uterine fibroids you are likely to have HMB.	Fibroids are to be considered where HMB is the primary presenting symptom.
Royal College of Nursing (RCN)	General	The guideline should contain advice on the type and appropriateness of information to be given to women to inform choice.	Thank you. Recommendations on patient information can be made where evidence exists; if no evidence exists then good practice points can be made.
Royal College of Obstetricians & Gynaecologists	General	The RCOG is pleased to see the guideline scope being confined to heavy menstrual bleeding and fibroids. The title of the guideline needs to be redefined to reflect content.	Thank you. There is a consensus amongst stakeholder groups that the guideline be extended to cover the diagnosis and management of heavy menstrual bleeding (menorrhagia) and hysterectomy. These changes have been undertaken in the revised scope. Please see sections 1 and 1.1 of the revised scope for details of changes. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
Royal College of Obstetricians & Gynaecologists	General	Whilst there may be some temptation to include conditions such as endometriosis, this must be resisted as alternative treatments for endometriosis differ from the other conditions under discussion. We would strongly support a separate guideline on the management and treatment of endometriosis.	We agree. We are limiting the guideline to diagnosis and treatment of HMB. We will not pursue treatment for conditions where HMB is not the main focus of treatment.
Royal College of Obstetricians & Gynaecologists	General	Clinical questions: What are the pros and cons of subtotal versus total hysterectomy?	Thank you. This will be considered by the GDG.

Commentator	Section	Comment	Response WCH
Royal College of Obstetricians & Gynaecologists	General	Clinical question: Is there a size of uterus/fibroid at which hysterectomy may be recommended, if asymptomatic?	The treatment of asymptomatic fibroids will not be considered by the GDG.
Royal College of Obstetricians & Gynaecologists	General	Can we state the obvious that issues related to patient choice are very important.	We agree. A clinical question may also be developed on the issue of patient information.
Royal College of Obstetricians & Gynaecologists	3a	More recent data should be used, if available. The 2000-2001 data may not include data about second generation endometrial ablation devices.	Thank you. The most up to date information will be considered.
Royal College of Obstetricians & Gynaecologists	3b	This section should be split into two - one on heavy menstrual bleeding and the second on fibroids.	Thank you. As has been mentioned earlier, the scope of the guideline has been extended to HMB. Fibroids will be considered, only where menorrhagia is the main presenting symptom.
Royal College of Obstetricians & Gynaecologists	3c	Treatment of heavy menstrual bleeding with non-surgical options - should the use of injection Depo Provera 150 mg IM at 3 monthly intervals be also included? This is an effective way of controlling menstrual symptoms in a selected group of women.	Thank you. Non-surgical options will be considered including hormonal methods. Please see sections 3 and 4 for details.
Royal College of Obstetricians & Gynaecologists	3e	The scope quotes a rate of perforation for endometrial resection as 12/1000 but does not point out that this is simple perforation with dilators as at a D&C. The rate of active perforation is about 1/1000.	Thank you. These figures have been removed, but your point is noted.
Royal College of Obstetricians & Gynaecologists	3e	Complications of first generation endometrial ablation should also include bowel injury requiring further surgery.	Thank you. There is a consensus amongst stakeholders that the scope needs to explicitly state short- and long-term outcomes and complications will be investigated for each treatment comparison.
Royal College of Obstetricians & Gynaecologists	3e	The number of patients requiring hysterectomy at some time after ablation should also be specified. Many have increased pain, or bleeding some years after ablation, with partial obliteration of the endometrial cavity. Evidence on the number requiring hysterectomy should be available from the <i>Mistletoe study</i> - it may be higher than the quoted rate of about 2-6 per 1000 procedures.	Thank you. These figures have been removed, but your point is noted. Subsequent treatment will certainly be examined where data is available.
Royal College of Obstetricians & Gynaecologists	3f	This section describes two second generation endometrial ablation techniques, i.e. fluid filled thermal balloon ablation versus microwave ablation. Both have adverse events reported. These complications should be identified clearly with each method of ablation.	Thank you. These figures have been removed, but your point is noted. The long-term outcome of treatment will certainly be examined where data is available.

Commentator	Section	Comment	Response WCH
Royal College of Obstetricians & Gynaecologists	3f	Not all second generation techniques can be performed under local anaesthetic. Careful selection of both patients and technology is necessary.	Thank you. These figures have been removed, but your point is noted.
Royal College of Obstetricians & Gynaecologists	3g	It appears that this section is missing a procedure called <i>uterine artery embolisation</i> - it has been described but not named.	Thank you. This procedure has been added. See section 4.3 for details.
Royal College of Obstetricians & Gynaecologists	3g	We are not aware of any studies of endometrial embolisation of over five years? Do we know the number of patients needing hysterectomy following this technique?	The long term effects of treatment modalities will be considered by the GDG, including the need for further treatment.
Royal College of Obstetricians & Gynaecologists	3h	It would be important to differentiate clearly between subtotal abdominal hysterectomy and total abdominal hysterectomy as there are fewer complications associated with the former procedure, especially related to bladder injury. Is there any evidence to support the impression that the number of subtotal hysterectomies has significantly gone up because of ease of the procedure?	Thank you. We will certainly examine the various types of hysterectomy, and this is now outlined in the scope. Please see section 4 for details.
Royal College of Obstetricians & Gynaecologists	4.1	There should be some distinction between women who have already completed their family who now suffer from heavy menstrual bleeding and those who are desirous of future pregnancy.	We agree. This is a very important issue, and management options have to be explicit about the impact on future fertility.
Royal College of Obstetricians & Gynaecologists	4.1.2	Adenomyosis may not be the best example, as it is often diagnosed retrospectively after hysterectomy. Endometriosis may be more appropriate.	Thank you. We have made this change. Please see sections 3 and 4 for details.
Royal College of Obstetricians & Gynaecologists	4.3d	The work on competencies should be carried out separately as it may well be beyond the expertise of the guideline development group members.	Thank you. We will certainly highlight the general levels of competence required, but, as you state, specific education recommendations are more an issue for the relevant professional organisation.
Royal College of Obstetricians & Gynaecologists	4.3f	This paragraph needs to be clarified.	Thank you. This paragraph has been removed, and others added that hopefully clarify the scope of the guideline better.
Royal College of Obstetricians & Gynaecologists	4.3g	In considering different techniques, it would be important to consider cost and resource implications, in particular in relation to laparoscopically assisted vaginal hysterectomy where there may be misconceptions.	Thank you. All NICE guidelines include a health economics evaluation. We will make this more explicit in the document.
Royal College of Pathologists	3a	The identification of a normal uterus depends on the rigour of the histological examination. The effectiveness of fixation and preservation of the endometrium may also prevent an assessment of subtle or more obvious abnormalities of the endometrium. Exhaustive slicing of the myometrium may identify fibroids or areas of	Thank you. It is an interesting point. It has also contributed to the inclusion of fibroids in this guideline. There is a consensus amongst stakeholders that the diagnosis section needs to be expanded. This has been done. Please see section 3 of the revised scope for details.

Commentator	Section	Comment	Response WCH
		adenomyosis that are not apparent if single midline samples are taken. Consequently different surgeons and pathologists will have varying rates of hysterectomy for "normal" uteri.	Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
Royal College of Pathologists	3g	This section seems to refer to treatment by embolisation, but a defining sentence appears to have been omitted.	Thank you. This paragraph has been deleted, but all the treatments covered in the guidelines have now been made explicit. Please see sections 3 and 4 for details.
Royal College of Pathologists	4	The guideline would ideally advise on minimum standards of pathological examination of excised specimens. This should contribute to standardisation and provide useful comparator data.	Thank you. We recognise that this issue is important but it is beyond the remit of this guideline.
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		This organisation was approached but did not respond.	
Scottish Intercollegiate Guidelines Network (SIGN)	General	I think the scope is appropriate. However, both the short and long guideline titles are misleading (particularly the short one) – I think this should be replaced with something like ' <i>diagnosis, management and treatment of heavy menstrual bleeding.</i> '	Thank you. There is a consensus amongst stakeholder groups that the guideline be extended to cover the diagnosis and management of heavy menstrual bleeding (menorrhagia) and hysterectomy. These changes have been undertaken in the revised scope. Please see sections 1 and 1.1 of the revised scope for details of changes. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
Scottish Intercollegiate Guidelines Network (SIGN)		I am pleased to see that uterine artery embolisation is included.	Thank you.
Sheffield Teaching Hospitals NHS Trust		This organisation was approached but did not respond.	

Commentator	Section	Comment	Response WCH
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.	
The Hysterectomy Association		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 Royal Society of Medicine	General	There is no mention of the possibility of a malignant lesion being present, reference is made to pre-malignant conditions by which I assume the author is referring to endometrial hyperplasia and atypia. This in itself may need breaking down into the degree of atypia and complexity but it must not be forgotten that endometrial cancer does occur in a significant number of patients under the age of 50, ie pre-menopausally. It also occurs in women in their 30's with particular high risk factors, such as obesity and polycystic ovaries. Exclusion therefore of a malignancy is of paramount importance. At the same time severe or heavy menstrual bleeding as it is called here can occur in relation to a cervical cancer and therefore appropriate examination and investigation is always required.	Exclusion of malignancy will be included in the diagnosis section of the guideline. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.
The Royal Society of Medicine	General	It is far too limited to regard menorrhagia & fibroids as only indications when trying to put together guidelines on hysterectomy for benign disease. We virtually never do hysterectomy for menorrhagia because there are many other techniques that are very successful for this indication & the only ones that we perform hysterectomy on nowadays in our department, are patients who fail to benefit & they usually have adenomyosis. We still however have to do hysterectomies for patients with severe endometriosis who have failed all other possible therapeutic avenues & approaches & this is the leading indication in our hospital for hysterectomy. It would seem quite wrong to not include indications for pelvic pain because if you ignore these then your guidelines are going to be very incomplete indeed. I also agree that although you might not be including malignancy itself you probably are going to have to include various endometrial hyperplasias & atypias which are within the provenance of	Thank you. There is a consensus amongst stakeholder groups that the guideline be extended to cover the diagnosis and management of heavy menstrual bleeding (menorrhagia) and hysterectomy. These changes have been undertaken in the revised scope. Please see sections 1 and 1.1 of the revised scope for details of changes. The scope is compiled in such a way that it is feasible to achieve recommendations within the time scale of the guideline.

Commentator	Section	Comment	Response WCH
		a normal gynaecological surgeon but would not necessarily require the skills of a gynaecological oncologist.	
The Royal Society of Medicine	3g	As far as fibroids and embolisation is concerned, (page 3, paragraph G), this is a technique for which there are no long term results yet available with regard to the effect this procedure has on not only heavy menstrual bleeding, but also the ability of the endometrium to sustain a pregnancy in younger women wishing to retain infertility who are troubled by large uterine fibroids. There is evidence to show that the over all size of the uterus may be decreased in time but not as dramatically as anticipated.	Thank you. Both short and long term data for the effect of treatment options on HMB will be considered where available.
The Royal Society of Medicine	3g	This technique is now being used in patients with large fibroids and massively enlarged uteri prior to myomectomy. I suspect the technique will be utilised further in an attempt to avoid hysterectomy, especially in the light of the recent report on the morbidity of hysterectomy indicating that this is highest in patients undergoing the procedure for fibroids. ***** will have a much better idea of the role of embolisation as he has been working in Guildford with one of the pioneers of this technique in this country.	Thank you. The data relating to UAE will be considered by the GDG.

Commentator	Section	Comment	Response WCH
The Royal Society of Medicine	4.3e	There is scant reference given to the use of the progestogen containing intra-uterine coil. This is by far the simplest method for controlling menorrhagia or dysfunctional uterine bleeding from all points of view, including inconvenience, cost, risk of morbidity. It is the least invasive and appears to be just as successful success rate. Hysterectomy for a relatively normal sized uterus and no other significant pathology is to be avoided.	Thank you. We now explicitly outline the treatments that will be examined in the guideline. Please see sections 3 and 4 for details.
The Royal Society of Medicine	Appendix	There should be an additional comment on page 8 in the final recommendations regarding the guidelines on technique and operative procedures which should take in to account the size of the uterus, previous surgery, any bladder symptoms or pathology, prolapse, as well as the individual skills of the surgeon and any other co-morbid factors, of which there are increasingly more of significant complexity. Fully informed patient consent needs to be emphasised especially with the increasing trend to use new techniques in association with a shorter hospital stay. This is not always appropriate, although they do need to be taken into account, encouraged and considered.	Thank you. These are important points. The indications for the different routes of hysterectomy will be considered together with the long term outcome where data are available. Also, patient information and education will be included.
The Royal Society of Medicine (2)		I was a little disappointed to find that there were more non medical people than medical people and there seemed to be a large number of people from industry and various pressure groups but very little input from people who have great importance in this particular subject. Namely there was no one to represent the radiologists from the Royal College of Radiologists and I would suggest that you approach ***** who is the interventional radiologist at ***** because he is not only one of the pioneers of embolisation in this country and I believe we were the first to start this procedure in the United Kingdom after I had seen a poster about it at a conference in Paris and drew the attention to ***** to the potential of this operation. We were not the first to publish on this technique because we waited to have a larger series but some of the initial people who published have for various reasons stopped doing it, certainly on the National Health Service. However, ***** has the largest series in Europe and I think would give you the best advice about the indications, contra indications and his results.	<p>Thank you. The stakeholder meeting was open to any organisation that registered an interest; and groups cannot be excluded simply for being non-medical.</p> <p>We agree that radiologists are an important group, and we intend to invite a radiologist representative.</p>

Commentator	Section	Comment	Response WCH
		He also has some very good fact sheets which would be of interest to your committee."	
The Royal West Sussex Trust		This organisation was approached but did not respond.	
University College London Hospitals NHS Trust		This organisation was approached but did not respond.	
University Hospital Birmingham NHS Trust		This organisation was approached but did not respond.	
Welsh Assembly Government (formerly National Assembly for Wales)		Thank you for giving the Welsh Assembly Government the opportunity to comment on the scope. We are content with the document as drafted and have no further comments to make at this stage.	Thank you for your help. Please note that major changes have been made to the emphasis of the scope in response to stakeholder comments.
Wirral Hospital NHS Trust		This organisation was approached but did not respond.	
Women's Health	1	The current guideline title of the draft scope is far too broad in its remit as it potentially covers an enormous range of conditions.	Thank you. There is a consensus amongst stakeholder groups that the guideline be extended to cover the diagnosis and management of heavy menstrual bleeding (menorrhagia) and hysterectomy. These changes have been undertaken in the revised scope. Please see sections 1 and 1.1 of the revised scope for details of changes. Please note that there have been major changes made to the scope in response to stakeholder comments. Please see revised scope for details.

Commentator	Section	Comment	Response WCH
Women's Health	1	The narrow remit presented in the draft scope excludes other gynaecological conditions that have an enormous impact on individual women.	<p>Thank you. It is only possible to cover relatively small areas of healthcare, usually relating to one particular condition, in any one guideline. This is because of the limited time and resources available to develop the guideline.</p> <p>However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1 December 2004 suggestions can be made via the NICE website (www.nice.org.uk).</p>
Women's Health	1	We are reluctant to agree that the scope should be limited in this way, but can appreciate that it needs to be manageable both in terms of content and time.	Thank you.
Women's Health	1	If the current guideline on hysterectomy is to cover menorrhagia (unexplained by other pathologies) and fibroids (as a cause of menorrhagia), we would very much like to see a commitment from NICE to produce further guidelines in future. Without being exhaustive, some examples of other conditions that may lead to hysterectomy are: endometriosis, adenomyosis, fibroids that do not cause heavy bleeding, uterine prolapse, chronic pelvic pain, endometrial hyperplasia and gynaecological cancers.	<p>Thank you. We agree that concentrating on a single condition means that other areas are omitted. However, NICE welcomes suggestions for future topics from stakeholders, healthcare professionals and the public, and would encourage you to put your views forward. From 1 December 2004 suggestions can be made via the NICE website (www.nice.org.uk).</p>
Women's Health	1	We feel that the guideline title should specify what 'other conditions' are to be covered.	We agree. The guideline needs to have a clear target population. Therefore, we have up-dated sections 1 and 4.11 to reflect the fact that HMB only is being examined.
Women's Health	1.1	We feel that the current short title is misleading. Titles such as 'Hysterectomy and the alternatives' seem not altogether satisfactory either. Maybe the short title needs reconsideration?	Thank you. Please see above comment about the change in the scope of the guideline.
Women's Health	3	As an Independent organisation specialising in gynaecological and sexual health, Women's Health receives thousands of enquiries from individual women every year about a broad range of health issues. Many women approach us via our Helpline, website and written enquiry service wanting impartial information about hysterectomy, its alternatives, heavy bleeding and fibroids	Thank you. This is an important issue. Education and information provision will be examined as part of the guideline.

Commentator	Section	Comment	Response WCH
		amongst others.	
Women's Health	3	Our experience over the last two decades as a provider of health information, has enabled us to become extremely knowledgeable about these issues, and has led to us giving voice to women's concerns and needs. It is this part of our work that has led us to participate in NICE's Referral Guidelines for Menorrhagia (printed May 2000) and more recently to contribute as patient/carers advocates to the Technology Appraisal for Fluid-filled Thermal Balloon and Microwave Endometrial Ablation Techniques for Heavy Menstrual Bleeding.	Thank you.
Women's Health	3	As well as its prevalence, heavy menstrual bleeding has a significant negative impact on women's quality of life, as discussed in Women's Health's submission to NICE in October 2002.	Thank you. We have edited this section, and it now states that HMB has a major impact on quality of life.
Women's Health	3	In terms of clinical need, we would like to see a Guideline that recognises and allows for women's individual needs and concerns. For instance, we regularly receive calls on our Helpline from women for whom retaining their womb is their primary objective. Some women may view hysterectomy as an appropriate option for them as it <i>guarantees</i> the cessation of periods. For other women, it may be <i>reducing</i> the blood loss that is of prime importance to them, and complete lack of periods may <i>not</i> be what they desire. Women who wish to retain their fertility have yet another range of needs. The treatment pathway should not be seen in a purely linear way – some women may strongly object to using drug or hormone treatments, but may find an ablative technique acceptable. Women's Health are also contacted by a broad range of women, including women with specific needs which may relate to their ethnicity, disability, learning disability or sexuality. A helpful Guideline would reflect the complexity of these issues and help clinicians and women, through a process of collaborative consultation, to reach decisions about the most appropriate treatment.	Thank you. Individualisation of treatment is a very important point. The effect of treatment on quality of life is now included in the scope. Information and options for the women will be an important component.

Commentator	Section	Comment	Response WCH
Women's Health	3c	In our experience, women are still prescribed norethisterone by GPs. If this is now considered to be an ineffective treatment for heavy menstrual bleeding, could the guideline reflect this.	Thank you. The guideline will consider all established treatments for HMB.
Women's Health	3d	It is our experience that women are not always made aware of surgical options. Women commonly report that they are offered drug treatments for heavy bleeding for many years. Sometimes a series of different preparations are used in the hope that a treatment will eventually work.	Both medical and surgical treatments will be considered, as well as patient information.
Women's Health	3d	We therefore feel it is important that women are given information about <i>all</i> possible treatment options so that they can make an informed choice.	We agree. Please see our earlier comment about patient education and information provision.
Women's Health	3d	We note that this section states that endometrial ablation techniques are less invasive and require fewer resources than hysterectomy but do not guarantee complete cessation of menstruation. We would say again, that drawing upon the broad range of experience we have, for many women complete cessation of periods is not what they necessarily desire.	Thank you. We agree that the aim of treatment is not the complete cessation of menstrual bleeding. This section has been edited to reflect these comments. Please see section 3 for details.
Women's Health	3e	We welcome the recent guidelines from NICE on the second-generation endometrial ablation techniques. We hope that training and resources will enable these to speedily replace the first-generation procedures, which appear to have more potential complications and require greater skill from the operator.	Thank you.
Women's Health	3f	We recognise that the second-generation endometrial ablation techniques are not suitable for all women. We would like the guideline to clearly state in which cases these techniques would be appropriate.	We agree. Any recommendations made by the guideline will include which patient group the treatment is suitable for.
Women's Health	3g	It is not clearly stated that this paragraph refers to uterine artery embolisation.	Thank you. UAE is now explicitly outlined. Please see section 3 for details.
Women's Health	3g	Myomectomy is mentioned in the draft scope, but without any further explanation; as a treatment option for women with fibroids who wish to retain their fertility, perhaps this should be considered alongside uterine artery embolisation.	Thank you. Unfortunately, it is not possible to provide in-depth discussion on the use of treatments in the scope. However, a more in-depth explanation will be provided in the full guideline.
Women's Health	3g	Should the piloted MRI-guided laser ablation technique for uterine fibroids be included?	Thank you. Please see earlier comment on revised scope of guideline. All treatment options will be considered where data are available.

Commentator	Section	Comment	Response WCH
Women's Health	3h	Women contacting our Helpline report a range of long-term effects of hysterectomy which may be officially unrecorded or go unrecognised. These include urinary incontinence to a greater or lesser degree and prolapse of other pelvic organs or of the vaginal vault, for example. Many women report that hysterectomy improves their quality of life; however a significant number have concerns about the long-term negative impact they feel the procedure has on their lives and general well-being.	Thank you. The change in the scope of guideline means that hysterectomy is no longer the main focus. However, all outcomes, both long and short, will be examined.
Women's Health	3h	Given the range of treatment options available, and the fact that women in our experience tend to prefer less invasive options, we are surprised that the scope states that hysterectomies are expected to remain at their current level <i>or increase</i> .	This statement was based on other publications. The most recent figures will be obtained to inform the guideline.
Women's Health	3l	In addition to the RCOG guidelines, please note that NICE has produced Referral Practice Guidelines for menorrhagia, published in May 2000.	Thank you. Other relevant guidelines will be considered.
Women's Health	4.1.1b	Should state women of reproductive age with uterine fibroids <i>and menorrhagia</i> (and excluding women with uterine fibroids who do not experience menorrhagia).	Thank you. The change in the scope of guideline means that these changes will be incorporated.
Women's Health	4.1.2b	It should be clearly stated and transparent that this draft scope <i>excludes</i> several categories of women for whom hysterectomy may be offered at some stage in their treatment. This would include women of post-menopausal age, as well as women whose conditions primarily present with <i>pain</i> rather than heavy menstrual bleeding.	Thank you. There is consensus amongst the stakeholder groups that the study population needs to be clarified. The revised guideline is being restricted to women of reproductive age where heavy menstrual bleeding is the main complaint. Please see section.
Women's Health	4.2	We agree that all these healthcare settings should be included.	Thank you.
Women's Health	4.3a	We would like to see the guideline reflect the need, at all levels, for accessible written information; to include information in as many formats as possible, e.g. visual, tapes, large print, other languages. This should be in addition to clear verbal information, to facilitate women to be fully informed before they give their consent for any treatment or surgical procedure.	Thank you. These are important points. Any recommendations made will consider on which patient group it should be undertaken. Also, a clinical question on patient information and education will be outlined.

Commentator	Section	Comment	Response WCH
Women's Health	4.3b	We would ask for non-medical management to be part of the continuing assessment of women who have heavy menstrual bleeding. The concept of 'watchful waiting' may be useful to women in both primary and secondary health care settings. We would however, urge that this is led by the needs of the woman. In our experience (as reflected in our submission to NICE in October 2002) women may struggle on for lengthy periods of time with distressing and uncomfortable symptoms <i>before</i> presenting to their GP. We recognise that for these women, early specialist intervention or treatment is absolutely essential for their emotional and physical well-being.	Thank you. The concept of watchful waiting can certainly be developed into a clinical question, and has been added to the scope as a potential management option. The benefits and harms of all treatments will be systematically assessed and reported on.
Women's Health	4.3c	'Healthy ovaries' requires definition. We can see no reason why healthy ovaries should be routinely removed. Even women of menopausal or post-menopausal age who contact our Helpline express the desire to retain their ovaries wherever possible. The removal of healthy ovaries has serious implications for younger women.	Thank you. One of the questions to be addressed in the guidelines will be on the removal for ovaries. Please see section 4.3 for details.
Women's Health	4.3c	We would also like the guideline to look at options for hysterectomy for women who wish to retain their cervix, where appropriate.	The change in emphasis of the guideline means that hysterectomy is no longer the main focus. However, the different types of hysterectomy will be examined in relation to HMB.
Women's Health	4.3d	We would very much like the guideline to look at the competencies of surgeons as this is of paramount importance to the overall well-being of women. If the 'postcode lottery' is an issue, perhaps there is a need for regional 'centres of excellence' where women can be referred to when appropriate.	Thank you. The guideline will certainly outline appropriate competence levels and audit criteria are defined as part of the guideline process. However, it is not within the scope of the guideline to consider the assessment of performance of specific units or individuals.
Women's Health	4.3e	We assume this is not an exhaustive list. We would like to see myomectomy included. It is our experience that women also use a range of complementary and self-help measures. Where possible we would like to see the guideline embrace this so as to give women greater choice.	Thank you. Myomectomy will be included and other treatments where appropriate data are available.
Women's Health	4.3f	We would like to see post-operative care included.	Thank you. There is a consensus amongst stakeholders that the scope needs to explicitly state short- and long-term outcomes and complications will be investigated for each treatment comparison. Rehabilitation will not be examined in detail.

HMB guideline – comments received from stakeholders with the developer's response

Commentator	Section	Comment	Response WCH
Women's Health Concern		This organisation was approached but did not respond.	