National Institute for Health and Clinical Excellence

20/3 – Uterine artery embolisation for fibroids

Consultation Comments table

IPAC date: Thursday 9th September 2010

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Specialist Adviser NHS Professional	**1**	aim is to deprive the fibroids of blood so that they die (necrosis). They do shrink but that is a secondary effect. the aim is to releive symptoms.	Thank you for your comment. The lay procedure description in the overview will be changed.
2	Consultee 2 Royal College of Obstetricians and Gynaecologists Specialist Society	**1**	The Royal College of Obstetricians and Gynaecologists supports the provisional recommendations. Â They are in line with the recommendations of the RCOG/RCR Joint Working Party Report "Clinical recommendations on the use of uterine artery embolisation in the management of fibroids.	Thank you for your comment.
3	Consultee 3 Royal College of Radiologists (RCR) Specialist Society	**1**	The Royal College of Radiologists (RCR) welcomes this further literature review of Uterine Artery Embolization (UAE) for symptomatic fibroids and hopes that positive guidance will lead to greater equity of service so that women are not presented with a single option of organ removal surgery as they now.	Thank you for your comment.
4	Consultee 6 Bupa Healthcare Organisation	**1**	Bupa agrees	Thank you for your comment.

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5	Consultee 4 Patient FEmISA UFE patient group	**1.1**	This is the 3rd time I have filled this in. Â It is deleted each time. Â FEmISA has sent a separate report as there is insufficient room to show all the evidence 1.1 It is also effective in the long-term 10 years- FEmISA members results are included in HOPEFUL.	The Committee did not consider that there was enough evidence to include 'long-term' in section 1.1 of the guidance.
6	Consultee 4 Patient FEmISA UFE patient group	**1.2**	1.2 Patients need to be fully informed about all the treatment options for fibroids, not just the complications of UFE.	The lay version of the guidance will state that there may be other treatment options available and that the healthcare team should discuss these with the patient.
7	Consultee 5 NHS Professional	**1.2**	1.2 Success rates are very high (80-90%) being typical and therefore the statement as written is too negative/conservative. I would suggest the following. During the consent process .....symptom relief may not be achieved in a small minority of women, that symptoms may return etc.	Thank you for your comment. Section 1.2 of the guidance will be changed.
8	Consultee 4 Patient FEmISA UFE patient group	**1.3**	1.3 It is patient choice having been fully informed, not patient selection by doctors. Â It should be ensured that an interventional radiolgist is included in the team to se all women with fibroids. Â FEmISA helps approx. 1 woman/week gain accesss to UFE beacuse her gynaecolgist has not informed her of UFe or an alternative to hysterectomy	Section 1.3 of the guidance states that an interventional radiologist should be included in the multidisciplinary team.
9	Consultee 4 Patient FEmISA UFE patient group	**1.4**	1.4 FEmISA fully supports this and further resaerch into long-term effects - see report	Thank you for your comment.

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10	Consultee 7 Patient	**2.1**	I had an embolisation for uterine fibroids in 2001 because I had severe back pain due to the fibroid pushing my pelvic bones apart. Â Although the fibroid has never completely disappeared the symptoms have been entirely relieved. Â From a matter of months after the operation I was able to run and do exercise which I had not been able to do for some time. Â This has improved my general health massively. I mention this as you suggest that the main reason for having the procedure is for increasing fertility - I think improving general health must be equally important in the long run for the general health of the female population.	Thank you for your comment
11	Consultee 1 Specialist Adviser NHS Professional	**2.1**	current treatment is also UAE	Thank you for your comment. The subject of the IP guidance is not normally listed in section 2.1.3, which instead lists other common treatments.
12	Consultee 4 Patient FEmISA UFE patient group	**2.1**	2.1.1Pedunculated fibroids develop outside the walls of the uterus and until recently pedunculated subserosal fibroids on thin stalk could not be treated by uterine artery/fibroid embolisation [UFE], but now they can. Â However, this is not included in the review. 2.1.2 and bulk symptoms from large fibroid masses can cause sciatica, pressure on surrounding organs e.g. kidney enlargement etc uterine artery embolisation can also treat post-partum and post abortion haemorrhage very effectively allowing the younger woman to remain fertile	Thank you for your comment. The guidance does not specify the type of fibroid that may be treated using the procedure. This review is solely assessing UAE for fibroids. Other indications are not included.
13	Consultee 6 Bupa Healthcare Organisation	**2.1**	No comments, thank you	Thank you for your comment.

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14	Consultee 4 Patient FEmISA UFE patient group	**2.2**	An extremely important fact missing from this section is that UFE normally only requires a 1-night hospital stay compared with 5-10 days with hysterectomy or myomectomy. Also, women can return to work/normal life considerably quicker with UFE, normally 2-3 weeks compared with ~3 months with hysterectomy. Â Women also require much less convalescence at home and care from members of their family with UFE compared with these 2 surgical treatments. The other important advantages of UFE are that – • a woman remains fertile • does not appear to suffer early menopause associated with hysterectomy and often requiring HRT • a woman can become pregnant after UFE • can return to work and normal life in 2-3 weeks versus 3 months with hysterectomy • a woman's family do not normally need to take time off work to look after her compared with hysterectomy were women are told 'not even to lift a kettle' and not to drive for over a month after this surgery • UFE can be used to successfully treat women whose fibroids have re-grown after myomectomy • Requires normally only a 1-night hospital stay compared with 5-10 with hysterectomy or myomectomy • Can also be used to successfully treat post-partum haemorrhage – maintaining fertility • There is no scar after UFE and unlike surgical treatments no damage to surrounding muscle, which subsequently needs to heal and restricts normal life significantly • UFE can be successfully combined with myomectomy o before myomectomy to reduce bleeding, which can be significant o immediately after embolisation for a pedunculated subserosal fibroid on a thin stalk o after fibroid re-growth from an earlier myomectomy o myomectomy after fibroid re-growth from an earlier embolisation	Thank you for your comment. Section 2.2 of the guidance will be changed. Duration of hospital stay is included in the overview.

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15	Consultee 6 Bupa Healthcare Organisation	**2.2**	No comment	Thank you for your comment.
16	Consultee 10 Boston Scientific Manufacturer	**2.2**	NICE Clinical Guidelines on Heavy Menstrual Bleeding published in 2007 indicate that When surgery for fibroid-related HMB is felt necessary then UAE, myomectomy and hysterectomy must all be considered, discussed and documented. It could be added in 2.2.1 here.	Thank you for your comment. Please see response to comment number 11.
17	Consultee 1 Specialist Adviser NHS Professional	**2.2.1**	2.2.1 and preserve the uterus	Thank you for your comment. Section 2.2.1 of the guidance will be changed.
18	Consultee 8 NHS Professional	**2.2.2**	2.2.2 The aim of UAE is to cause fibroid infarction Â not shrinkage. There may be symptomatic improvement with no demonstrable shrinkage and there is no evidence that improvement of symptoms (menorrhagia or pressure) correlates with shrinkage.	Thank you for your comment. Section 2.2.2 of the guidance will be changed.
19	Consultee 9 Biocompatibles Manufacturer	**2.2.3**	2.2.3, Â Various embolisation agents can be used for this procedure. Â • The committee should consider article Uterine Artery Embolisation for Leiomyomas: Percentage of Infarction Predicts Clinical Outcome (Kronke et al Radiology 225 (3) 834-841 2010). Â This paper reported significantly better symptom control and fewer re-interventions in patients that achieved 90% infarction rates than patients with lower infarction rates. Â This section of the guidance document should state the aim to achieve 90% infarction on imaging to achieve maximum clinical benefit.	Thank you for your comment. This paper was identified in the post-consultation literature search and will be added to appendix A of the overview.
20	Consultee 6 Bupa Healthcare Organisation	**2.3**	2.3.8 - It is important to see evidence on duration of the benefit.	Thank you for your comment. Section 2.3.8 of the guidance is the opinion of the Specialist Advisers and will not be changed.
21	Consultee 7 Patient	**2.3**	I have had no adverse symptoms since having the procedure - only positive outcomes.	Thank you for your comment.

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22	Consultee 3 Specialist Society Professional Body	**2.3**	We are a little surprised that greater emphasis has not been placed Â on cost effectiveness and would suggest a careful analysis of appropriate studies like the referenced HTA funded study which gives a good overview of the cost effectiveness of UAE (O Wu, A Briggs, S Dutton, A Hirst, M Maresh, A Nicholson, K McPherson Uterine artery embolisation or hysterectomy for the treatment of symptomatic uterine fibroids: a cost-utility analysis of the HOPEFUL study BJOG 2007 114:1352-1362.) We hope also that NICE will give due credit to the efforts of UK Interventional Radiologists who funded the UK registry and in the absence of any outside help produced a very worthwhile study (O'Grady EA, Moss JG, Belli AM, et al. (2009) UK uterine artery embolisation for fibroids registry 2003–2008. The British Society of Interventional Radiology).	Thank you for your comment. Cost-effectiveness is not part of the remit of the IP Programme. Data from the UK Interventional Radiologist registry report (O'Grady EA, Moss JG, Belli AM, et al. (2009) were used to develop this guidance and the report is included in the overview. The Health Services Research Unit (HSRU), University of Aberdeen, and the School of Health and Related Research (ScHARR), University of Sheffield, provided support to data collection and compilation and statistical analysis.

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23	Consultee 9 Biocompatibles Manufacturer	**2.3**	• 3y followup after UFE is reported in the literature. Â Walker et al (BJOG 113464-468, 2006) reported 5-7y follow-up on 172 patients: 88% patients satisfied/very satisfied and 85% reporting better QoL following UFE. • Retention of fertility following UFE is documented in the literature (unlike following hysterectomy). Data is limited due to the older average age of patients undergoing UFE and their desire/not to become pregnant. Homer's systematic literature review & meta-analysis identified 227 completed pregnancies after UAE (Fertil Steril 2010 Jun94(1):324-30). Rates of preterm delivery, IUGR and malpresentation were similar in age matched patients with fibroids. Only risk of miscarriage appeared to be increased following UAE. Pron (Obstet Gynecal 2005 105(1):67-76) documented 21 pregnancies following UAE, most resulted in term deliveries and appropriately grown newborns. • Recovery time following a procedure is a significant outcome. Â REST study showed significantly shorter hospital stay in the UAE group (median 1d) vs surgery group (median 5d) Â and significantly shorter time to return to work (median 21d UAE vs 53d surgery) These points should be in the guidance document	Thank you for your comment. Walker et al (2006) is listed in appendix A. Section 2.3.7 of the guidance reports pregnancy after UAE. Homer et al (2010) was identified in the post-consultation literature search and will be added to table 2 of the overview. The trial reported by Pron et al was included in the ReBIP systematic review. Length of hospital stay is reported in the overview.

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24	Consultee 4 Patient FEmISA UFE patient group	**2.3**	There have been over 1007 paper published on UFE, 611 since the last review, but NICE have only reviewed 18 papers covering 36 others. Â Please see FEmISAs responce document - sections on Pregnancy & fertility, Long-term outcomes and effectiveness for a full repose only part of the section on effectiveness is copied here-39 recent significant papers , only 5 of which have been reviewed by NICE. The advances in UFE treatment do not appear to be reflected in the NICE review, probably because so few papers were reviewed. Â In particular pedunculated subserosal fibroids on a wide stalk can be safely embolised and on a narrow stalk can be embolised and then immediately removed by myomectomy. Â This also reduces blood loss in myomectomy, which can be significant. Â Women previously having been treated with myomectomy can be successfully re-treated with UFE after fibroid re-growth and vice versa. Of particular significance are 2 papers studying re-embolisation after an initial failure. Â The success rates are high and this should be considered as a standard follow-up before hysterectomy. Â There are also papers advocating a bilateral versus unilateral Â approach to reduce radiatio [end of comment]	Thank you for your comment. The overview is a brief document, including an assessment of the most relevant studies found by literature searches. The remaining eligible studies that are not included in the evidence summary table are listed in appendix A. The aim of appendix A is to give a broader overall picture of the procedure and to reinforce the fact that the studies included in table 2 are the most reliable and valid amongst a larger literature. Out of 37 papers cited by the consultee for effectiveness and advances, 5 were included in table 2 and 5 were included in appendix A. A further four were identified in the post-consultation literature search. Two studies were not previously identified but neither met the inclusion criteria for table 2 or appendix A (1 was a small case series and the other focused on evaluation of a specific catheter). All of the remaining papers had already been reviewed and none of them met the criteria to be included in table 2. Three papers did meet the criteria for appendix A and will be added to the overview.
25	Consultee 1 Specialist Adviser NHS Professional	**2.4**	rsik of emergency hysterectomy and myomectomy is very very low from the US and UK registries and well below 1% The first sentence 2.4.1 is very misleading and suggests Â a 1 in 21 risk of death ! There have been 2 deaths reported worldwide and another 2 which we are aware of. You quote a risk of emergency hysterectomy of 1% in hysterectomy treated patients ! Is this in women who have a second uterus ?	Thank you for your comment. Section 2.4.1 of the guidance will be re-ordered.

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26	Consultee 5 NHS Professional	**2.4**	2 Deaths in the UK, 2 in Mainland Europe and 3 in the USA out of over 140,000 would suggest a UFE mortality of around 1 in 20,000 rather than the 1 in 21 suggested by your first sentence. This is alarmist and completely exaggerates the danger. Mortalities for Hysterectomy are usually quoted at between 1 in 1000 and 1 in 5000, suggesting that UFE is between 4 and 20 times safer than Hysterectomy. How can you have emergency hysterectomy or myomectomy after hysterectomy this makes no sense. Your second sentence suggesting UFE is 3x more likely to cause serious infection is not an accurate reporting of the HOPEFUL study findings where the complication rate after UFE was 17.6% and after hysterectomy 26.1% After Hysterectomy PE, major organ damage, transfusion and other major complications were much more common. The safety record of UFE is at least comparable and in most published studies you quote in your IP 20/3 document better than Hysterectomy. How then can this section suggest it is more dangerous? Section 2.4.1 will need re-writing in a more objective and evidence based fashion.	Thank you for your comment. Please see response to comment 25.

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27	Consultee 10 Boston Scientific Manufacturer	**2.4**	Boston Scientific is concerned about the way safety outcomes are presented in this draft guidance. Whereas the Efficacy section describes results for UAE in comparison to hysterectomy and myomectomy, the Safety section only selects the most serious adverse events reported on UAE, without giving any information on the safety profile of hysterectomy or myomectomy. Adverse events related to UAE should be presented in a more balanced way, putting it in perspective with the number of procedures performed and comparing it with major adverse events following a hysterectomy or a myomectomy. We believe that the wording and the language of this section could be misleading for a reader not familiar with the procedure, and could discourage patients or referring physicians to consider UAE as an option.	Thank you for your comment. Please see response to comment 25.
28	Consultee 3 Specialist Society Professional Body	**2.4**	We would also point out that many of the re-interventions referred to in many papers are in fact planned myomectomies for very large vascular intramural fibroids or more commonly large subserosal fibroids preceded by UAE to avoid bleeding complications. In addition many hysterectomies (but not all) are done post UAE because of apparent treatment failure when in fact appropriate time has not been allowed for it to work Â (up to 12 months) or repeat UAE could be offered.	Thank you for your comment. Section 2.2 of the guidance will be changed.

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29	Consultee 4 Patient FEmISA UFE patient group	**2.4**	The comments in the consultantion document about the safety of UFE are potentially alarming to patients and public and do not accurately refelect the data from the NICE review Â and certainly not the larger review shown here. Eleven papers on safety are shown in appendix 4, only 1 of which has been reviewed by NICE. Â However these papers should be read alongside those on Long-term Outcomes and Effectivness as most studies look at safety and effectivness together. The largest UK study is the Fibroids Registry published by BSIR. The summary of their findings on safety is copied here from 1,500 patients Safety • 2% of patients suffered a pre discharge adverse event but in only 1% of patients did this result in delayed discharge • 94% of patients were discharged within 48 hours • There were no deaths within 30 days. • 14% of patients reported a post discharge adverse event, the majority occurring within the first 12 months • One death was recorded 17 months post UAE from a uterine sarcoma. Â The small risk of sarcomatous change is well known one of the drawbacks to UAE, in common with other uterine conserving treatments, is that the uterus is not removed.	Thank you for your comment. Please see response to comment 25. Of the 11 papers on safety cited by the consultee, 2 are included in the main summary table and 3 are included in appendix A. One paper was identified in the updated literature search but will not be added to the overview as it was a small study focusing on histopathology of surgical specimens. Of the remaining 5 papers, 1 was not previously identified – this was a small study (n = 20) focusing on optimisation of radiation dose and will not be included in the main summary table or the appendix.

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30	Consultee 4 Patient FEmISA UFE patient group	**2.4 cont**	• Only 2.7% Â of patients were known to have a subsequent hysterectomy • 70% of patients received prophylactic antibiotics there were significantly more infective complications post discharge for patients who did NOT receive antibiotic prophylaxis Comapre this with hysterectomy figures below The VALUE study is probably the most definitive study on hysterectomy, as it is an audit of results, from all hospitals Â - Maresh MJA et al - The VALUE national hysterectomy study: description of the patients and their surgery - British J Obstet & Gynae March 2002 Vol 109 302-312 N37, 298 •Hysterectomy for fibroids - 6,571 + total hysterectomy - 87% sub-total hyst -3.9% vaginal - 6.9% laproscopic - 2.2% Length of hospital stay -overall 5 days (range 1-205) Abdominal - 5 days Vaginal - 4 days Laproscopic - 3 days Deaths - 14 - 6 weeks post-op (0.38/1,000) PE - 3, MI/Cardiac arrest/coronary atheroma - 4, multiple organ failure/sepsis - 2, bronchopneumonia - 1, unknown - 1, brain heamorrhage - 1, MS - 1, hyponatraemia - 1 Fibroids - 2 (0.30/1,000) 1 - unknown, 1- cardiac arrest Operative complications Total - 3.5% (1 in 30 women) Abdominal - 3.57% Vaginal - 3.07% Laproscopic- 6.07% Resp/heart - 0.35% Visceral - 0.73% - mainly bladder Major haemorrhage - 2.27% Return to theatre - 0.76% Post-operative complications Total - 9% (1 in 10 women) Only 10% of ovaries removed had specific pathology - 30% may have had ovaries removed prophtlactically The mortality rate for UFE is not known as the numbers of procedures are not known, but it is very rare. The complication cited in the NICE document are so unusual that each serious adverse event tends to have a paper published about it.	

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31	Consultee 9 Biocompatibles Manufacturer	**2.4**	• The safety section is presented very negatively. Â Data from many studies show UFE to be safe. The provisional recommendations state “there is no major safety concerns”. Â Safety data from the HOPEFUL trial show: Â fewer complications experienced by women following UAE (17.6%) vs hysterectomy (26.1%) fewer severe/major complications per patient following UAE (3.9%) vs hysterectomy (11.4%) lower incidence of infections in the UAE group (5.9%) vs hysterectomy group (13.5%). • The single case of septic shock and multiple organ failure in 1 out of 21 patients is not representative of the incidence of death following UFE. Â In 2009 it was reported that only 5 deaths worldwide are documented in the literature, that are associated with the UFE procedure itself (Hamoda CVIR 32, 1080, 2009). • In the NICE Guidance on Heavy Menstrual Bleeding (CG44, Revised 2007 pp12,), Table 5.1 shows complications for UAE, myomectomy and Hysterectomy, A comparison such as this is missing from the safety section of the guidance. • In hysterectomy, death has been observed in 37 out of 172,344 procedures for fibroids (J Am Coll Surg 2009, 208(4), 599).	Thank you for your comment. Please see response to comment 25. The IP programme does not compare the efficacy and safety of interventions against comparator interventions.
32	Consultee 6 Bupa Healthcare Organisation	**2.4**	No comment	Thank you for your comment.
33	Consultee 9 Biocompatibles Manufacturer	**general**	Biocompatibles manufacturers an embolisation agent used in uterine artery embolisations	Thank you for your comment.

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34	Consultee 4 Patient FEmISA UFE patient group	**general**	FEmISA is a wholly independent, voluntary patient group set up to support women with fibroids and to ensure they have access to this treatment. Â Despite the earlier NICE Interventional Procedures Review and NICE Guidelines on Heavy Menstrual Bleeding many women are not told about UFE as a treatment option by their gynaecologists and GPs and are not given a choice.	Thank you for your comment.
35	Consultee 4 Patient FEmISA UFE patient group	**general**	**1,007 published papers listed on uterine artery embolisation with 611 new papers since the last review.** See Appendix 7 (*page 62*) for a complete listing of these abstracts, the most recent first. NICE has reviewed only 18 papers, although state that these cover 36 papers. FEmISA has reviewed all 611 papers and these show important advances in UFE missed by the NICE review. It is also important to read the full summaries	Thank you for your comment. The overview was based on a systematic review of 36 papers and an additional 5863 patients from 2 registries, 3 RCTs, 1 non-randomised comparative study, 3 case series and 3 case reports. A further 51 studies were included in appendix A of the overview.
36	Consultee 4 Patient FEmISA UFE patient group	**general**	**1. Pregnancy and Fertility– abstracts of important papers Appendix 1 (Page 16)** There are a number of papers that consider fertility rates after UFE and compare these with myomectomy. Originally UFE was not recommended for women wishing to become pregnant, so results from earlier papers may not have been a fair reflection on fertility after embolisation. Ref 8. 12 of the most recent significant studies papers are shown in appendix 1, only 2 of which is included in the NICE review of literature. Early papers are highlighted in purple in appendix 7. Success from UFE is better than myomectomy in the latest paper, but results vary from paper to paper. Blood loss can be reduced significantly by pre-treating with UFE before myomectomy.	Thank you for your comment. Of the 12 papers on pregnancy and fertility cited by the consultee, 2 were included in the main summary table and 2 were included in appendix A of the overview. Five studies were identified in the post-consultation literature search; of these 3 will be included in appendix A, 1 will be included in table 2 and 1 will not be added to the overview because it was a general review of myomectomy. None of the remaining 3 studies met the criteria for inclusion in table 2 or appendix A of the overview.

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37	Consultee 4 Patient FEmISA UFE patient group	**general**	**2. Long-Term Outcomes– abstracts Appendix 2 (Page 20)** Many FEmISA members had UFE treatment over 9 years ago. There was little data on the long-term side effects such as effect on age of menopause etc. This is still the case. Most longer-term studies have follow-up at 5 years, but particularly for younger women having UFE more long-term data is needed. FEmISA asks that the Fibroid Registry is funded to enable it to continue to collect data for up to 25 year follow up.	Thank you for your comment. Of the 10 papers on long-term outcomes cited by the consultee, 2 were included in the main summary table and 3 were included in appendix A of the overview. One paper was identified in the post-consultation literature search and will be added to appendix A of the overview. Of the remaining 4 papers, 3 did not meet the criteria for inclusion in table 2 or appendix A of the overview. One paper was identified in the post consultation literature search and will be added to table 2 of the overview.
38	Consultee 4 Patient FEmISA UFE patient group	**general**	**3. Effectiveness and Advances in UFE– abstracts Appendix 3 (page 29)** 39 recent significant papers can be found in appendix 3, only 5 of which have been reviewed by NICE. The advances in UFE treatment do not appear to be reflected in the NICE review, probably because so few papers were reviewed. In particular pedunculated subserosal fibroids on a wide stalk can be safely embolised and on a narrow stalk can be embolised and then immediately removed by myomectomy. This also reduces blood loss in myomectomy, which can be significant. Women previously having been treated with myomectomy can be successfully re-treated with UFE after fibroid re-growth and vice versa. Of particular significance are **2 papers studying re-embolisation after an initial failure. The success rates are high and this should be considered as a standard follow-up before hysterectomy**. There are also papers advocating a bilateral versus unilateral approach to reduce radiation dose. This does however, mean two femoral artery punctures instead of one. A question arose about **sexual dysfunction** at the NICE Interventional Procedures Review meeting. There are 2 papers showing that UFE does not adversely affect sexual function, as well as an earlier one by Watkins not cited here.	Thank you for your comment. Please see response to comment 24.

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39	Consultee 4 Patient FEmISA UFE patient group	**general**	**4. Safety – abstracts Appendix 4 (page 50)** The comments in the consultation document about the safety of UFE are potentially alarming to patients and public and do not accurately reflect the data from the NICE review and certainly not the larger review shown here. Eleven papers on safety are shown in appendix 4, only 1 of which has been reviewed by NICE. However these papers should be read alongside those on Long-term Outcomes and Effectiveness as most studies look at safety and effectiveness together. The largest UK study is the Fibroids Registry published by BSIR. The summary of their findings on safety is copied here from 1,500 patients **Safety** 2% of patients suffered a pre discharge adverse event but in only 1% of patients did this result in delayed discharge 94% of patients were discharged within 48 hours There were no deaths within 30 days. 14% of patients reported a post discharge adverse event, the majority occurring within the first 12 months One death was recorded 17 months post UAE from a uterine sarcoma. The small risk of sarcomatous change is well known; one of the drawbacks to UAE in common with other uterine conserving treatments, is that the uterus is not removed. Only 2.7% of patients were known to have have a subsequent hysterectomy	Thank you for your comment. Section 1.1 of the guidance states that “There are no major safety concerns” in relation to the procedure. Please see response to comment 29.

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			70% of patients received prophylactic antibiotics; there were significantly more infective complications post discharge for patients who did NOT receive antibiotic prophylaxis	

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