National Institute for Health and Clinical Excellence

343/2 – Magnetic resonance image-guided transcutaneous focused ultrasound for uterine fibroids

Consultation Comments table

IPAC date: Thursday 8 September 2011

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 British Society of Interventional Radiology	**1**	The document presents a summary of the limited trial data currently available (several more US studies including an FDA funded project looking at fertility are in the pipeline).	Thank you for your comment.
2	Consultee 2 Private Consultant Australia	**1**	The new proposed guidance on MRgFUS more accurately reflects current evidence and clinical practice. Thank you for considering and taking into account the comments submitted. However, I am still concerned about the wording of the first sentence (1.1) and the continued emphasis on potential adverse events. It creates a wrong impression which may deter many women from seeking this safe and efficacious treatment. I would therefore urge you to move the first sentence in section 1.1 to another place in that paragraph.	Thank you for your comment. Section 1.1 of the guidance will be changed.

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3	Consultee 2 Private Consultant Australia	**1**	In my experience, and in discussions with colleagues around the world, there are many mitigation techniques for reducing the likelihood of adverse events and therefore the number and severity have greatly decreased, a point that the revised guidance recognizes (2.4.2, 2.5.2).	Thank you for your comment.
4	Consultee 2 Private Consultant Australia	**1**	I have treated more than 115 patients since mid 2009 and have experienced no cases of burns or adverse events requiring hospitalization. A recent paper of 130 patients treated at the Mayo Clinic from 2005-2009 also reports no burns. All adverse events, with the exception of one case of deep vein thrombosis were minor and resolved with the use of over the counter pain medication. This has been my experience as well.	Thank you for your comment. The paper cited by the consultee is included in table 2 of the overview (Gorny KR et al., 2011).
5	Consultee 2 Private Consultant Australia	**1**	Furthermore every surgical treatment is associated with well recognized potential complications, however, NICE guidance does not necessarily lead off its guidance with this statement. The main alternative treatment modalities for uterine fibroids (hysterectomy, myomectomy and UAE) have significant adverse events, at a rate which is similar to that of MRgFUS and possibly higher (ie postembolization syndrome in patients undergoing UAE or post operative infection rates after hysterectomy, etc).	Thank you for your comment. It is beyond the remit of the programme to compare the safety profile of different comparative procedures.

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6	Consultee 3 Manufacturer	**1.1**	We would like, therefore, to suggest the following amendments to the wording of the guidance: 1. That the wording of paragraph 1.1 be altered to: "The evidence of efficacy in the short term is adequate, although further treatment may be required and the effect on subsequent pregnancy uncertain. Current evidence on the safety of magnetic resonance image (MRI)-guided transcutaneous focused ultrasound for uterine fibroids shows that there are well -recognised potential complications, although these appear to have reduced over time as the procedure has been refined and can be minimised by following the manufacturer's instructions carefully. The procedure may be used with normal arrangements for clinical governance and audit."	Thank you for your comment. Section 1.1 of the guidance will be changed. Section 2.5.2 of the guidance states that 'The Committee noted that there is continuing evolution and development of the techniques used in this procedure.'
7	Consultee 3 Manufacturer	**1.3**	That the wording of paragraph 1.3 be altered to: "Patient selection should be carried out by a multidisciplinary team, including a gynaecologist and an appropriate imaging Specialist. The procedure should only be performed by a doctor who has been trained to carry it out."	Thank you for your comment. A new section 1.4 will be added to the guidance referring to training of the operator.
8	Consultee 1 British Society of Interventional Radiology	**2.4**	The document labours the skin burn issue a bit.	Thank you for your comment.

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9	Consultee 3 Manufacturer	**2.4.2**	That the wording of paragraph 2.4.2 be altered to: "The case series of 287 patients reported skin burns in 7% (10/144) of patients treated in 2003–5 compared with 1% (2/143) of patients treated in 2005–6 (p = 0.04). A full-thickness burn in the lower abdomen (treated by elliptical excision of the burned area an d direct closure) has been described in a case report."	Thank you for your comment. Section 2.4.2 of the guidance will be changed.
10	Consultee 3 Manufacturer	**2.4.4**	That the wording of paragraph 2.4.4 be altered to: "Bowel perforation following treatment by the procedure was reported in a patient (submitted as an adverse event report to the US Food and Drug Administration [FDA] Manufacturer and User Facility Device Experience [MAUDE] database) which contains details of more than 5000 MRgFUS procedures. Surgical management was required, confirming perforation in 3 bowel sites."	Thank you for your comment. The total number of patients included in this database is uncertain: a statement to reflect this will be added to section 2.4.4 of the guidance.
11	Consultee 1 British Society of Interventional Radiology	**2.5**	The document does not address the economic issues, i.e. that in comparison to other fibriod treatments, including UAE, MRI guided ablation is expensive. Here in the Midlands we have had to shelve our private MRgFUS service for reasons of economic viability. The only active programme in the UK at the moment is at St. Marys in London.	Thank you for your comment. Cost-effectiveness is not within the remit of the IP programme.

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12	Consultee 4 Patient Group (Focused Ultrasound Surgery Foundation)	**General**	The Focused Ultrasound Surgery Foundation (FUSF) is an independent global non-profit organization dedicated to accelerating the development and adoption of patient treatments using this technology. We are primarily funded through philanthropic donations by individuals who support our scientific collaboration, translational and clinical research, education, and patient outreach initiatives.	Thank you for your comment.
13	Consultee 4 Patient Group (Focused Ultrasound Surgery Foundation)	**General**	The Foundation is pleased that you have revised the provisional recommendations on MRgFUS, eliminating the proposed additional barriers to access for women seeing longer-term relief, such as younger women. As several of the patient comments to your previous draft demonstrate, many women want to ability to make an educated choice based on their medical condition and desire for future fertility.	Thank you for your comment.
14	Consultee 4 Patient Group (Focused Ultrasound Surgery Foundation)	**General**	We agree that women should be informed about the potential risks and benefits of this treatment approach, but feel that your recommendations over-emphasize complications without acknowledging that women who undergo MRgFUS experience significantly fewer adverse events compared to those who undergo surgery or UAE. We believe that section 1.1 should lead with a sentence about efficacy, with any further mention of safety in context with other treatments.	Thank you for your comment. Section 1.1 of the guidance will be changed. The Interventional Procedures programme does not assess the efficacy and safety of comparator interventions.

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15	Consultee 4 Patient Group (Focused Ultrasound Surgery Foundation)	**General**	The body of evidence in support of the safety and efficacy of MRgFUS continues to grow. As part of our mission of scientific exchange, the Foundation hosts a biannual International Symposium on MRgFUS. We held a half-day session at our October 2010 Symposium that featured new research regarding more than 1,000 patients treated with MRgFUS in Germany, Korea, Netherlands, Spain, Russia, India and the US. These studies demonstrated an enhanced safety and efficacy profile.	Thank you for your comment.
16	Consultee 4 Patient Group (Focused Ultrasound Surgery Foundation)	**General**	Attached are abstracts from two studies presented at this conference: The study by Dr. Kurashvili treated 611 patients with a very low rate of complications (.8% or 5 cases out of 645 procedures). The MRgFUS treatment resulted in volume reduction, symptomatic improvement, increase in QOL and long-term durability of 2.5-3 years. The durability of symptom improvement correlated with the non-perfused volume of the fibroids.	Thank you for your comment. The consultee refers to a non peer-reviewed study. The NICE Interventional Procedures Programme Methods Guide highlights that the efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee.
17	Consultee 4 Patient Group (Focused Ultrasound Surgery Foundation)	**General**	• Dr. Matzko presented a study with 41 women that resulted in no major complications and significant improvement of symptoms after three months. We hope that you will take these studies into consideration in summarizing the body of evidence surrounding the treatment.	Thank you for your comment. The consultee refers to a non peer-reviewed study. The NICE Interventional Procedures Programme Methods Guide highlights that the efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee.

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18	Consultee 4 Patient Group (Focused Ultrasound Surgery Foundation)	**General**	We appreciate your ongoing search for more information and testimonials about MRgFUS in treating uterine fibroids and we look forward to your revised recommendations.	Thank you for your comment.
19	Consultee 5 Private Consultant Germany	**General**	I have treated over 400 patients since 2008 with MRgFUS and have found the treatment to be safe and efficacious. I had no serious adverse events and only four minor skin burns in patients with "high energy treatments" in fibroids with an elevated blood flow. Most of the patients are very happy with the treatment and we encourage NICE to make this more available to women. Our institution managed to get reimbursement of two major public health insurance groups in Germany, that is a major step forward to avoid unnecessary operating procedures and reduce the number of hysterectomys with all its problems in the short term and long term follow up.	Thank you for your comment.
20	Consultee 5 Private Consultant Germany	**General**	As such we would ask you to reduce the emphasis placed on complications, which may have the effect of turning women away from the technology. http://www.uterusmyome.de/en/index.php	Thank you for your comment. Section 1.1 of the guidance will be changed.

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21	Consultee 3 Manufacturer	**General**	Thank you for the opportunity to comment on the revised proposed guidance for MRgFUS in the treatment of uterine fibroids. In our view, the current proposed guidance represents a much better reflection of the evidence currently available for this procedure. However, we still consider that the wording of the document places more emphasis on the adverse events actually or potentially associated with the procedure than the evidence warrants.	Thank you for your comment. Section 1.1 of the guidance will be changed.
22	Consultee 6 Private Professional Korea	**General**	Thank you for contacting me regarding comments to the revised proposed guidance for MRgFUS in the treatment of uterine fibroids. I appreciate that you have taken into account the fact that the technology has evolved and that the current state of practice is much improved over that reflected in the early published papers, which tend to lag advances in practice by several years.	Thank you for your comment.
23	Consultee 6 Private Professional Korea	**General**	However, I am still concerned by the emphasis on adverse events in the revised guidance and in particular in the first sentence (1.1). I have found the treatment to be effective and safe with speedy recovery and few adverse events. Women are interested in this treatment because it enables them to preserve their fertility and they get back to normal life quickly.	Thank you for your comment. Section 1.1 of the guidance will be changed.

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24	Consultee 6 Private Professional Korea	**General**	Out of 523 treatments performed since 2006, there were a total of seven (1.3%) occurrences of skin burns (6 first degree and one second degree). With the implementation of improved techniques, I have experienced no skin burns since mid 2009 (153 treatments performed since the last occurrence of burn). The occurrence of burns dropped significantly from 2.5% at the end of 2007 (4/159) to 1.2% during 2008 (2/157) and further dropped to 0.5% from the beginning of 2009 to date (1/203) which is a 5-fold improvement in the treatment's safety. This also reflects recent experience around the world, as described in the most recent congress on MRgFUS, held by the Focused Ultrasound Foundation in Washington DC, in the fall of 2010 (www.fusfoundation.org).	Thank you for your comment. Section 1.1 of the guidance will be changed.
25	Consultee 6 Private Professional Korea	**General**	NICE guidance which begins with the issue of potential complications, rather than efficacy, may deter potential patients unnecessarily despite NICE guidance that the procedure can be used under normal circumstances. Although I entirely support patients and their physicians having full information about adverse effects before making a decision as to which treatment is most appropriate, moving this sentence from its present 'pole' position would result in more balanced guidance.	Thank you for your comment. Section 1.1 of the guidance will be changed.

and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."