# National Institute for Health and Clinical Excellence

## 343 – Magnetic resonance (MR) image-guided transcutaneous focused ultrasound ablation for uterine fibroids

## Comments table

## IPAC date: Thursday 15th March 2007

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| Individual Respondent - Patient | **1** | 1 | My personal experience was that the safety and efficacy was beyond question especially compared to the other treatments available on the NHS namely hysterectomy and UAE. In a risk evaluation, I considered this treatment a far safer option given that it was a minimally invasive technique, on an out patient basis, returning home the same day. My strong belief is that it should be available on the NHS to all women who face this issue, as a viable alternative and that they should be given all the facts against risk / efficacy of all treatments for fibroids that are available. The patient can then decide on what course of action they wish to take. | Noted, thank you. |
| Individual Respondent - Patient | **1** | 2 | clear written information and very careful verbal explanations were given to me at all appointments. I do not believe the procedure to have serious safety issues. | Noted, thank you. |
| Individual Respondent - Patient | **1** | 3 | I am a patient who experienced a successful intervention. I was made fully aware of the risks to my own safety and the potential outcomes efficacy before engaging in treatment. My health has improved significantly. Knowing the risks and engaging in the treatment meant I think I have avoided what would have certainly needed to be a full hysterectomy in 2006 due to symptomatic heavy bleeding, anemia, pain and emotional distress as a result of a 10CM fibroid. My life and health have improved significantly. | Noted, thank you. |

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| Individual Respondent - Patient | **1** | 4 | I volunteered to be a research subject for MRI-guided focused ultrasound treatment. Although the procedure was still very new, it was preferable to the alernatives - major invasive surgery such as a hysterectomy or myomectomy. Given the risks involved in such surgery, plus the long recuperation period, the "special arrangements for consent" for the MRI treatment appear to be excessive. I had the procedure as an oupatient and was back at work the next day, suffering very minimal and short term side effects (abdominal cramps similar to period pain for about 8-12 hours). | Noted, thank you. |
| Individual Respondent - Patient | **1** | 5 | I would not agree that in most cases fibroids are asymptomatic. I was acutely aware of my small fibroid that grew bigger and bigger over the course of 6 years prior to treatment. Most women I talk to with fibroids say the same.<br><br>In the Section 2 notes, I believe it is irresponsible not to describe the size (mine was as large as a cantaloupe), and different placements of some fibroids. Not all are constrained to the walls of the uterus. You make no indication that fibroids can be inside the uterine cavity, or outside, but still attached to the uterus. A tremendous number of blood vessels support fibroids -- the larger the fibroid, the more numerous the blood vessels. This adversely impacts a woman"s health. Because of the size of my fibroid prior to treatment, I believe a myomectomy would most certainly lead to full hysterectomy -- there were simply too many blood vessels involved with a fibroid of my size for removal without serious risk to my health (ie bleeding to death). Again, b/c of the size, embolisation I was told that embolization would have been difficult and unadvisable. | The Committee added: “In many cases they are asymptomatic” to Section 2.1.2<br><br>The size and placement of fibroids is mentioned in the section on treatment alternatives in Section 2.1.3. |

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| Individual Respondent - Patient | **1** | 6 | It is still a non surgical procedure.I had much more information on this procedure than I did on the alternatives which involved surgery and were initilally offered to me in a very cavilear way.The assumption was that I didn"t mind having a hysterectomy as quote""You have had your children"".I haven"t and didnt want this done.If anything I was given more time re this procedure than the surgical option and if anything you should look how women are treated having a hysterectomy.Having had the procedure which I can confirm is very uncomfortable but I had a nurse with me and a team onlooking as it was done.I felt at no time that they were putting me at risk.I could not fault the initial procedure to check to see if I was suitable | Noted, thank you. |
| Individual Respondent - Patient | **1** | 7 | agree - but also to ensure provision is made for aftercare and a procedure to be put in place for the following up of patients who have been affected by the treatment | Thank you for your comment. Detailed recommendations on aftercare arrangements are beyond the remit of the Programme. However, Sections 1.2 and 1.3 encourage follow-up of patients. |
| Individual Respondent - Patient | **1** | 8 | I strongly disagree with your provisional recommendations. I had the procedure at the end of February 2004 and cannot recommend it highly enough. This procedure literally changed my life. I had and still have no issues with safety or efficacy. Given the risks inherent in hysterectomy and other treatments, for example uterine artery embolisation, I cannot think but that this procedure should be the first and preferred option wherever possible. It is safe, non-invasive, has a short recovery period, does not lead to depression and loss of self esteem, does not trigger early menopause with its myriad health problems, can be carried out without the patient staying in hospital and is highly effective. Problems, such as they are, associated with this procedure are insignificant, particularly in comparison with hysterectomy where problems are legion and should not be underestimated. | Noted, thank you. |

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| Individual Respondent - Patient | **1** | 9 | Compared to all the other treatment options for fibroids (e.g. embolisation, hysterectomy, myomectomy), I felt that focused ultrasound was the least invasive procedure available. Approximately, 75 % of my 11 cm diameter fibroid was ablated and shrunk to 9 cm over a 5 month period. This was a 45% reduction in volume. I experienced slight discomfort (occasional burning sensation) during the procedure, but this discomfort was quite minor compared to the pre-treatment fibroid symptomatic complications. My extremely heavy bleeding returned to pre-fibroid levels by my first menstrual cycle. I felt that that the procedure was very safe as the treatment was being monitored in real-time with an MRI. | Noted, thank you. |
| Specialist Adviser | **1** | 10 | I believe that the draft guidance is superficial and has not assessed all the available information so that the assessment is incomplete and that the draft guidance is not consistent with other guidances issued by IPAC. I believe that if this draft guidance is not thoroughly reassessed taking into account these other factors, that the final result will be regarded as highly unsatisfactory by the vast majority of patients and would further damage the reputation of regulatory bodies of this type. | The Committee reviewed all relevant studies published in peer-reviewed journals, in line with NICE's normal methods. An updated literature search was conducted between consultation and publication of the final guidance, and the results of this were presented to the Committee. |
| Individual Respondent – Patient | **1** | 11 | Like any procedure, it takes specialist knowledge and skills to perform and it is my believe that this procedure is no exception.<br><br>The statistics that I was given before I decided on being treated was encouraging enough for me to have confidence that there was a very high possibility of an improvment in my condition. | Noted, thank you. |

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| Individual Respondent - Patient | **1** | 12 | I was advised that safety mechanisms had been put in place to ensure there were no further incidents of nerve damage which had happened in 1 case during trials in America. I was aware that the treatment may not be a long term solution, but was advised that other treatment options including myomectomy would still be available if FUS failed (however it seems that this may not be the case for me). Given my age & personal circumstances was hopeful treatment would achieve sufficient reduction in size/relief in symptoms until menopause. Clinical outcomes of all patients should be reviewed. Been advised I am only person to have suffered long term/permanent damage as result of | Sections 1.2 and 1.3 encourage follow-up of patients. |
| Individual Respondent - Patient | **1** | 13 | As a patient who has successfully undergone treatment during one of these trials, I am surprised at the provisional recommendation that the safety and efficacy do not appear adequate. The alternative surgical treatments (myomectomy and hysterectomy) both involve a far greater safety risk in terms of having to undergo surgical procedure under general anaesthetic; given the short time that embolisation has been available, the long-term effect of it is not known. I believe that case studies of myomectomy have shown that in many cases new fibroids quickly grow to replace those removed. MRI-guided focussed ultrasound therefore appears to offer women a lower-risk alternative than any of the alternative procedures. | Noted, thank you. |
| Individual Respondent - Patient | **2.1** | 14 | I had the treatment because my fibroids were causing heavy & prolonged menstrual bleeding (leading to anaemia)and severe menstrual cramps lasting 5 days | This is covered in the indications Section 2.1.2 “In most cases they are asymptomatic, but fibroids can cause symptoms such as abnormal bleeding, a feeling of pelvic pressure, or pain;” |

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| Individual Respondent - Patient | **2.1** | 15 | You go the the doctors with fibroids(not knowing what the problem is) as you are having problems.In my case I was having difficulty attending work due to very heavy periods.I could not sleep when I was having my period unless I slept on towels and having to get up constantly in the night due to increased presuure on my bladder.This condition is very diffcult to live with.The options are hsterectomy unless like me you very lucky to see a Consultant who knew of this research and even then you don"t know if you are suitable.They took alot of time to see if I was.Size of the fibroid/position etc | This is covered in the indications Section 2.1.2 “In most cases they are asymptomatic, but fibroids can cause symptoms such as abnormal bleeding, a feeling of pelvic pressure, or pain;”.<br>The size and placement of fibroids is mentioned in the section on treatment alternatives Section 2.1.3: “Depending on size, number and location, symptomatic fibroids can be removed surgically by hysterectomy or myomectomy” |
| Individual Respondent - Patient | **2.1** | 16 | My symptoms were not very severe, but due to the fact that I travel a lot, I did not want to worry in case heavy bleeding occurs, also I was getting up 4-5 times during the night to go to the loo. | Noted, thank you. |
| Individual Respondent - Patient | **2.1** | 17 | Given the massive size of my fibroid and the fact that I wanted to get pregnant, I thought that focused ultrasound presented the least risk. The risk that I could lose my uterus during a myomectomy was too high in my opinion. Embolisation would expose the ovaries to radiation for an extended period and the radiologist that I consulted would not treat women who still desired to get pregnant using this procedure. | Noted, thank you. |
| Specialist Adviser | **2.1** | 18 | Current CE marking of this application does not yet allow it to be used for the routine treatment of patients who are actively attempting to get pregnant outside of ethically approved trials. Therefore to make significant comments on its role in fertility is very premature and inappropriate. | Noted, thank you. |

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| Individual Respondent - Patient | **2.1** | 19 | The procedure was explained to me as well as any possible symptoms following the treatment. The staff in attendance were thorough, clearly explaining each step of the treatment and were in attendance at all times throughout. With regard safety, the possibility of skin burns were again explained, but the area susceptible was carefully protected to prevent such an occurrence. As my 6 month follow-up period is not yet up, it is difficult to confirm a reduction in size of the largest fibroid, but there has been a significant reduction in the symptoms - reduced bleeding; number of days; pain; and loss of working days or generally not being able to go to far from home for fear of embarrassing accidents. Your overview states uterine fibroids are common, occurring in one third of all women, and are asymptomatic, which suggests woman should just put up with them; however, hysterectomies are all too readily suggested to women with fibroids with no mention of other available treatments. After many years of pain and discomfort and evidence of them increasing in size, I felt this procedure offered the next best alternative to a hysterectomy which I was running out of reasons for not having. I think this procedure should become more widely available in order to get more data for better evaluation; also the 6 month follow-up period should be reduced. | The Committee changed section 2.1.2 to: “In many cases they are asymptomatic”. |
| Individual Respondent - Patient | **2.1** | 20 | 2.1.2 I was one of those patients who had severe syptoms of the condition such as pelvic pressure/pain, severe pains during intercourse, heavy periods etc. I somehow fell pregnant natually though my baby was delivered at 29 weeks and although the medical team could be not be 100% sure that it was due to my fibroids, they were most confident that I contributed to my early delivery.<br>2.1.3. Apart from the symptoms, I also expressed an interest of having more children as such I refused the option of having them removed invasively for fear of leaving my womb with scars and therefore affecting my furture firtility. This was a major factor in the team considering me for the search at Phase 3 [successfully pregnancy/birth after the treatment]. | Noted, thank you. |

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| Individual Respondent - Patient | **2.1** | 21 | 2.1.3 Alternatives to major surgery (in particular hysterectomy) for this common benign condition need to be available to women, but should be researched, developed and carried out carefully with patient safety being paramount. | Noted, thank you. |
| Individual Respondent - Patient | **2.2** | 22 | correct | Noted, thank you. |
| Individual Respondent - Patient | **2.2** | 23 | This is correct. The notes neglect to mention that a nurse was by my side (as with all patients, I presume) at all times during my procedure. I had a ""panic"" button in my hand throughout the treatment which allowed me to stop treatment the moment I felt uncomfortable. I felt that I was at no risk and was in full control of the procedure. | This respondent gives more detail of the procedure than is normally included in the guidance document |
| Individual Respondent - Patient | **2.2** | 24 | Yes this part of the procedure is uncomfortable but I knew exactly what was occurring and had a nurse and panic button with me.This option for me was stil 100% better than surgery | Noted, thank you. |
| Individual Respondent - Patient | **2.2** | 25 | The procedure was explained in great detail, everyone was very helpful and kind, after I was scanned again, I felt much better when the doctor told me that I will need only about 17 ""blasts"" because zoladex reduced the size of my fibroids (albeit temporarly) quite a lot! The procedure itself was absolutely fine, I never used the panic button at all! | Noted, thank you. |
| Individual Respondent - Patient | **2.3** | 26 | My bleeding duration has decreased from 7 - 3 days. More significantly, the intensity of bleeding has reduced. I no longer have huge blood clots and ""rushes"" of blood which interfered with my ability to work. I have not yet had my one year MRI measure, but an ultrasound measure has shown size reduction. For me, however, the most significant measure is that my fibroid has not continued to grow. At 44 now (43 at the time of treatment) I have a number of years left until menopause -- and fully expect my fibroid to have continued to grow at a rate of about 2 cm per year. I would have HAD to have a hysterectomy. I DO NOT WANT to lose my uterus -- regardless of whether I am able to become pregnant or not. I am grateful for the opportunity to have taken part in cutting edge research and felt my care was exemplary throughout. | Noted, thank you. |

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| Individual Respondent - Patient | **2.3** | 27 | The procedure has significantly improved my menstrual conditions even though the fibroid has not been eradicated. | Noted, thank you. |
| Individual Respondent - Patient | **2.3** | 28 | I have had this proceedure in july 2006, within 2 months my bleeding was reduced from 4 days changing sanitary tampon and towel every 1.25 hours to one day of changing each 2.5 hours and 2 days of changing every 5 -6 hours! my bleeding has remained like this. the volume of the fibroids is hard to gauge, until i return for my yearly scan. i believe they are less painful and solid since the treatment when pressure is applied | Noted, thank you. |
| Individual Respondent - Patient | **2.3** | 29 | The treatment greatly alleviated my symptoms. Prior to the procedure, my menstrual bleeding was heavy and problematic. I had to plan activities around my menstrual cycle due to the risk of "flooding" and the consequent embarrassment. The bleeding would last up to 12 days, with the first 5 to 6 days the heaviest. In addition, I had severe menstrual pain, lasting for 5 days, for which I was taking co-codamol and ibuprofen together. The pain would wake me during the night (I would have to get up to take more painkillers) and leave me feeling tired, irritable and nauseous. In the months following the treatment, my menstrual pain became less and less severe. I managed to cut down on the painkillers and only needed to take them for a maximum of 2 days. My menstrual bleeding also became much lighter and now lasts for a much shorter time. I was able to return to my more active lifestyle, including cycling, which I had previously had to give up because of the heavy bleeding. On the basis of my experience, I would recommend MRI-guided ultrasound for the treatment of fibroids and hope that it will become more widely available | Noted, thank you. |
| Individual Respondent - Patient | **2.3** | 30 | At 4 months following treatment my symptoms have reduced substantially. 1) menstrual bleeding has reduced from 17 days to 7 days 2) pain suffered has reduced from severe to an almost normal level of pain expected during a period 3) blood loss has reduced dramatically (no longer anaemic after each period) | Noted, thank you. |

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| Individual Respondent - Patient | **2.3** | 31 | Following treatment I did not suffer any adverse side effects. I felt able to resume everyday activities immediately. I was only in hospital for a morning. | Noted, thank you. |
| Individual Respondent - Patient | **2.3** | 32 | In my case the procedure has been effective in reducing not necessarily the actual volume of the fibroid but the symptoms, esp. painful bleeding that no hormonal intervention had been able to reduce, plus the constant feeling of fatiguing heaviness and pressure in my lower abdomen. Since I have - as many women - more than one fibroid, I would greatly appreciate the chance to have the other symptomatic fibroid ablated by this procedure. | Symptom severity was the major efficacy outcome assessed in the studies reviewed (not fibroid size). |
| Individual Respondent - Patient | **2.3** | 33 | My procedure resulted in a reduction in fibroid mass, eliminating severe back pain that had been caused by the fibroid. Although I later went on to have a hysterectomy as my fibroid was very large, I believe that if I had been offered this treatment when the fibroid was diagnosed in 2001, this major surgery could have been avoided as I would have been able to treat the fibroid when it was much smaller. | Noted, thank you. |
| Individual Respondent - Patient | **2.3** | 34 | I would say that my treatment was very successful.My fibriod was reduced.I know this as they showed me the scans each time and I have not had to return for any further treatment since having this done | Noted, thank you. |
| Individual Respondent - Patient | **2.3** | 35 | After the procedure, I had no burns, pain or discomfort, | Noted, thank you. |

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| Individual Respondent - Patient | **2.3** | 36 | Symptoms: I had extremely heavy periods losing over 1 pint of blood every four weeks, tampon changes every 45 mins, periods lasting around one week. It had reached the point where leaving the house was barely possible one week in 4 and I wondered if I would have to give up my job. Socially embarrassing bleeding makes a prisoner of you. Hb was down to 7. This procedure returned my periods to normal - 4 days of moderate bleeding and no worries at all about leaks. So I am no longer anaemic and live a normal life again; 2. Fibroid size: significantly reduced. I have gone back down a dress size with no pressure symptoms; 3. This procedure was 100% successful for me. | Noted, thank you. |
| Individual Respondent - Patient | **2.3** | 37 | Focused ultrasound was able to decrease the volume of my single 11 cm diameter fibroid by about 45% over s 5 month period. My heavy menstrual bleeding was reduced to pre-fibroid levels by the first cycle. I also felt extremely energetic after having the procedure. | Noted, thank you. |
| Specialist Adviser | **2.3** | 38 | I believe that if the same criteria that have been used to draw up this report were to be applied to hysterectomy, myomectomy or fibroid embolisation, none of them would ever be approved. I also am aware of several other procedures that have had a much more favourable response from IPAC in the same field, which have much greater complication rates than MRgFUS of fibroids and yet were placed in the context of other alternative treatments and received a much more favourable response. Procedures must be viewed in context. There is much more available information re efficacy which has not been taken into account by the review committee which is dissappointing. | The Committee reviewed all studies published in peer-reviewed journals, in line with NICE's normal practice. An updated literature search was conducted between consultation and publication of the final guidance, and the results were presented to the Committee The Committee considers the evidence on each procedure in the context of its risks and benefits. This includes comparison of a procedure's efficacy with that of established procedures when they are used to treat the same condition. This applies also to safety: the frequency and gravity of complications of any established procedure are used as a benchmark against which the complications associated with a new procedure are judged. |

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| Individual Respondent - Patient | **2.3** | 39 | 2.3.2 In my case beeding day has decreased from 5-6 to 3-4 days with less pain and also the number of days interval between cycles has increased from 21 days to 28 days. | Noted, thank you. |
| Individual Respondent - Patient | **2.3** | 40 | 2.3.4 I underwent GnRH analogue pre-treatment which apparently only reduced the fibroid from approx 12cm to approx 9cm. Although this was limited reduction it did afford me temporary relief from my bulk related symptoms. Had my treatment been successful and the fibroid ablated enough to retain this reduction, rather than the fibroid essentially being missed and serious nerve damage being caused, the treatment could have been a success in reliving my fibroid symptoms until I reached menopause, thus negating the need for major surgery | Noted, thank you. |
| Individual Respondent - Patient | **2.3** | 41 | Only a hysterectomy can offer a total guarantee that a woman will be free of symptoms of fibroids in the long term. For women who do not wish to undertake that procedure, the efficacy levels of MRI-guided focussed ultrasound appear to be comparable with those of myomectomy. | Noted, thank you. |
| Individual Respondent - Patient | **2.4** | 42 | I had no after effects from the treatment that were at all negative. | Noted, thank you. |
| Individual Respondent - Patient | **2.4** | 43 | My fibroids had been symptomatic for some time. But having experienced the severly detrimental physical and psychological effects of uterine surgery in two cases in my family, I had decided against such surgical intervention and was looking for a safer, less invasive way with no longer-term after-effects. With the focussed ultrasound ablation procedure I finally found a way to achieve this. In my case, this procedure turned out extremely safe - I was able to travel home by bus from London to Canterbury two hours after the intervention. Apart from some pain the two following days (far less than any period pain I had experienced beforehand) I experienced no after-effects. I did not even have to take time off work, and I was able resume sexual activity (important for psychlogical state after intervention) a few days afterwards. | Noted, thank you. |

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| Individual Respondent - Patient | **2.4** | 44 | I can only comment on my experience: I did not suffer any side effects apart from abdominal cramps similar to period pain immediately following the treatment. The pain lasted less than 12 hours - and was worth it considering the alleviation of my menstrual pain as a result of the treatment | Noted, thank you. |
| Individual Respondent - Patient | **2.4** | 45 | at the time of the treatment, the pain was similar to severe period pain, but the burning sensations were reduced to nothing when i pushed my abdomen out into the gel to ensure no air pockets and i had no burns. the aching body afterwards lasted about 3 days, but may have been due to tensing during proceedure! my only option other than this treatment is a hysterectomy, i am 36 years old, have 2 children and may consider more in the future. having a hyst. now would be a major trauma to me, both physically - problems of early menopause etc; and mentally - lack of sex drive, no longer feminine etc. this is a ray of hope in what is for us sufferers a very black hole where people constantly tell us that a hyster is fine and why do we want our most female parts! unless you"ve suffered you have no idea about the nightmare fibroids cause to many women. | Noted, thank you. |
| Individual Respondent - Patient | **2.4** | 46 | I have no adverse reactions. No burning, no pain in my sciatic nerve, and no backache. I was tired after the procedure but that had more to do with not eating breakfast than anything else. I was in charge of my safety and felt entirely safe. Again -- please note I walked home! 2-3 miles following a procedure that took more than 3 hours. | Noted, thank you. |
| Individual Respondent - Patient | **2.4** | 47 | I had none of the complications listed above. I had a slight ache in the abdominal region for a few days after the treatment.<br><br>When compared to the risks involved in the other treatments, this is nothing. In my opinion, this highly effective treatment is superb. When you look at the risks and safety issues of hysterectomy and UAE, the issues listed in your safety section pale into insignificance | Section 2.4.1 lists adverse events that were recorded in the literature. Section 2.4.2 lists potential complications provided by Specialist Advisors.<br><br>Noted, thank you. |

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| Individual Respondent - Patient | **2.4** | 48 | I did have a problem and did have pain in my nerve but this was monitored after the event and did not cause me a problem either then or now.A small price to pay for a non surgical new procedure .I would still have this done again.This procedure was for me fantastic .Although painful at the time the fact that I didn''t have to have surgery and wasn''t off work for months and that I could reamin with all my bits was amazing.I would recommend this procedure and the team that took me through this were great.Very caring ,taking time to explain all the difficulties.This should be an option for some women.I was so pleased to have been part of the research and the fact that my outcome was succuessful was down to the careful monitoring and care of the research team.Your findings are some what brief(parts of the process is missing and I noticed that they do not really focus on any aspect of how the outcomes have made any of the women feel afterwards or during.This reasearch feels like it has been done by an auditor just focusing on data.This procedure was an option that I could never have had a chance to have say 5 years ago.You need to focus more on the human aspect of this! | Noted, thank you. |
| Individual Respondent - Patient | **2.4** | 49 | I was a patient who had minor stomach burns & loss of use of right leg following treatment,was sent home immediately after treatment with no painkillers, no medication for burns and no transport offered, discharged at check up as treatment didn''t work - no further contact made,saw a neurologist & eventually recieved physio months later - | Noted, thank you. |
| Individual Respondent - Patient | **2.4** | 50 | At no time at all I felt unsafe or not sure what was going on. Everyone was fantastic! | Noted, thank you. |
| Individual Respondent - Patient | **2.4** | 51 | I considered the potential side effects of the treatment tiny in comparison to the only alternative treatment offered, a hysterectomy in my case which carries far greater risks physically and mentally to the patient. I was able to return to work the following day with no side effects atall. | Noted, thank you. |

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| Individual Respondent - Patient | **2.4** | 52 | I had a minor skin burn which healed quickly. I simply cannot imagine concern about burns might prevent a recommendation for this treatment - how utterly insignificant a small temporary burn is. Mild diarrhoea is, as you say, mild and who does not feel tired after sedation? A bit of backache is nothing. These are trivial matters, especially compared with hyterectomy - no problems with lifting kettles with this! Do not forget that a research volunteer is asked to look out for and detail complaints. A hysterectomy patient is not and feels she must get on with it. | Noted, thank you. |
| Specialist Adviser | **2.4** | 53 | The safety concerns, which have been raised are, I believe, grossly exaggerated and as one of the two most experienced practitioners in this field in the world, I am very confident that the procedure as it is practised now and as it has developed over the last 5 years is very effective and safe. One of the particular areas, I believe, that has not been adequately taken into account in the draft guidance, is the placing of this procedure in the context of other alternative procedures available for the treatment of fibroids. MRgFUS is a completely non-invasive procedure, which is done as an outpatient and should directly be compared to other procedures that are used to treat fibroids such as hysterectomy, myomectomy or uterine artery embolisation, all of which are much more invasive and have substantially greater complication rates in all areas | Noted, thank you. |
| Individual Respondent - Patient | **2.4** | 54 | 2.4.1 During the treatment at times I felt the temperature was too high and so used the buzzer to inform the treating team which they always responded by pausing a little and adjusting the temperature, this was in line with the information which I had been given before I was taken into the treatment room. I did not suffer any physical burns as a result of the treatment. | Noted, thank you. |

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| Individual Respondent - Patient | **2.4** | 55 | 2.4.1 I was advised that safety measures were now in place to ensure there could be no further incidents of nerve damage,& that skin burns had only occurred in areas where there was existing scar tissue or body hair 2.4.2 Because the hospital made the decision to continue with my treatment despite the problems they had with thermal mapping, & the pain I was experiencing, & indeed carried out excessive manual adjustments to the equipment against manufacturers recommendations, I suffered severe nerve damage from which I have not fully recovered & which has devastated my life and the life of my partner. I understand reports were submitted to MHRA and received from Insight. I repeatedly requested copies of these full reports but never received them. The hospital has advised me that modifications have now been made to the software to restrict the amount of manual adjustment that can be carried out so that this cannot happen again. However given that I was advised prior to treatment that safety mechanisms were already in place to avoid nerve damage & that the whole procedure was subject to real time monitoring so as to avoid damage to adjoining organs, tissues etc, I am not sure whether the treatment requires further research or greater care needs to be taken during individual treatment to avoid anyone else being damaged physically & psychologically by the treatment. | Noted, thank you. |
| Individual Respondent - Patient | **2.4** | 56 | While it is important to consider safety, the problems of skin burns experienced by a minority of women constitute, in my view, a far smaller risk to the woman than that of any invasive surgical procedure, such as hysterectomy or myomectomy. | Noted, thank you. |

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| Individual Respondent - Patient | **2.5** | 57 | I believe that to look at the ultrasound procedure as a treatment for sub-fertility is too simplistic - I understand it as a means of preserving and possibly enhancing the short-term chances for pregnancy, unlike some surgical and other treatments: I was not able to conceive, no cause was diagnosed except that the fibroids might be contributory. Yet, as stated before I delayed the treatment of my fibroids for a couple of years, because I felt that the potential outcome of the existing more interventionist procedures on offer did not outweigh the safety concerns I had. Unfortunately, the ultrasound ablation procedure came too late for me to be able to pursue any reasonable fertility treatment. I wish I had had the chance to have this procedure earlier in life! | Noted, thank you. |
| Individual Respondent - Patient | **2.5** | 58 | I am really happy with the results of the treatment. Nearly 4 years after the treatment, it appears that I have some new fibroids growing. However, had I undergone invasive surgery such as a myomectomy, I feel that it is very likely that this would still be the case (having been informed by my gyneacologist that fibroids can grow back within 2 years of the operation). Despite this, my syptoms are still much milder than they were before the MRI treatment. I had hoped to have the treatment again in the future (if necessary) and am very concerned that instead, only invasive procedures may be available. I feel that the treatment I had has been of great benefit to me and is a viable alternative to major surgery. The side effects oulined on this form appear mild in relation to those of surgery (such as pain, risk of infection, risk of complications requiring further surgery, having a general anaesthetic) or uterine embolisation. The fact that the MRI treatment can be carried out on an outpatient basis (rather than requiring up to 3 months recuperation)should also be taken into consideration. | Noted, thank you. |
| Individual Respondent - Patient | **2.5** | 59 | Prior to treatment, an HSG and MRI showed that my fibroid blocked one of my fallopian tubes, reducing my potential for pregnancy by 50%. My fibroid has reduced in size and density -- and I would imagine it is no longer blocking that tube. I am not trying to become pregnant at the moment but may choose to try in the next year"s time. Prior to treatment I was reluctant to try for pregnancy because of the size of my fibroid. | Noted, thank you. |

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| Individual Respondent - Patient | **2.5** | 60 | I presume the trials did not look at this aspect. That is no reason to be cautious about recommending this procedure. | Noted, thank you. |
| Individual Respondent - Patient. | **General** | 61 | I underwent a treatment with intra muscular injections to decrease the size of my many uterine fibroids knowing the eventual discomfort of the treatment.<br>The result of the treatment was positive in my case, few hot flushes, minor headaches which could have occurred from my anemic state that lead me to being tired unlike me usually.<br>I went through the procedure with very slight feeling of pain over the treated area. I had a line on my arm with administrated sedative from time to time and assisted by a professional nurse next to me and assisted by the professional team outside.<br>I did not feel any physical pain to interrupt the procedure, it went by smoothly and safely.<br>I felt relieved and slowly gained back my shape and strength from all these years where I had to live with these uncomfortable fibroids. | Noted, thank you. |

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| Individual Respondent - Patient | **General** | 62 | For several years I suffered from heavy menstrual bleeding and incontinence. These conditions led to the quality of my life being extremely miserable. Several fibroids were discovered, one of which was the size of a 26 week foetus. I was informed that the only course of action was to have a hysterectomy.<br>After treatment lasting approximately three hours, I was able to leave the hospital unaided and return home. I have nothing but praise for the treatment I received, as I am now able to live a normal life.<br>If there are any females on the panel I would ask them the following question. If you had fibroids that were making your life a misery, which would you prefer. 1/ Three hours of discomfort followed by two days taking it easy. 2/ Several weeks of apprehension before an operation, then having several internal organs removed followed by several weeks of being physically useless, and probably a bout of depression. | Noted, thank you. |

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| Individual Respondent - Patient | **General** | 63 | I cannot recommend this procedure highly enough – it has completely changed my life for the better. Having undergone an unsuccessful uterine artery embolisation in 2005 I only wish that MRgFUS – a quick, non-invasive out-pateitns procedure – had been available to me then.<br>During the preceding months I was bleeding 24 hours a day. Due to frequent excessive bleeds I became severely anaemic 3 times, requiring hospitalization on one occasion, and my life was completely debilitated: the unpredictability and heaviness of the bleeds forced me to be housebound for days on end; I was taking drugs every 6 hours day and night; I was unable to undertake any sporting or strenuous activities; and I had frequent extremely painful stomach cramps.<br>Whilst I found the MRgFUS treatment uncomfortable, I was given intravenous pain relief which helped immediately. I experienced no adverse side-effects from the treatment at all and have now had three weeks without any bleeding – the first time in over 6 months.<br>It is difficult to convey just how much the successful treatment of my fibroids has made a difference to my life: physically, psychologically, emotionally. Had it not been for MRgFUS I would have had to undergo a hysterectomy, and I can only hope that a positive NICE evaluation of MRgFUS will enable other women to similarly avoid such major surgery. | Noted, thank you. |

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| Specialist Adviser | **General** | 64 | I would like to comment on the recently published draft guidance for the use of MR Guided Focused Ultrasound for the treatment of uterine fibroids. I was one of the expert opinions sought concerning this guidance and I filled in a form in some detail relatively rapidly about my knowledge of this procedure.<br><br>The draft guidance that has been produced is extremely disappointing in the context of my submission. I do not believe that my comments and expert opinion in this area have been properly reflected in the draft guidance and indeed, it is very hard for me to recognise my comments and expert opinion in the published conclusions at all. I also feel that the advisory committee has not researched this area fully enough and has not taken into account the total sum of information that it could have had available to it, but instead has carried out a relatively superficial assessment. The safety concerns, which have been raised are, I believe, grossly exaggerated and as one of the two most experienced practitioners in this field in the world, I am very confident that the procedure as it is practised now and as it has developed over the last 5 years is very effective and safe. One of the particular areas, I believe, that has not been adequately taken into account in the draft guidance, is the placing of this procedure in the context of other alternative procedures available for the treatment of fibroids. MRgFUS is a completely non-invasive procedure, which is done as an outpatient and should directly be compared to other procedures that are used to treat fibroids such as hysterectomy, myomectomy or uterine artery embolisation, all of which are much more invasive and have substantially greater complication rates in all areas. Indeed, I believe that if the same criteria that have been used to draw up this report were to be applied to these three procedures I have mentioned above, none of them would ever be approved. I also am aware of several other procedures that have had a much more favourable response from IPAC in the same field, which have much greater complication rates than MRgFUS of fibroids and yet were placed in the context of other alternative treatments and received a much more favourable response.<br>In summary therefore, I believe that the draft guidance is superficial and has not assessed all the available information so that the assessment is incomplete and that the draft guidance is not consistent with other guidances issued by IPAC. I believe that if this draft guidance is not thoroughly reassessed taking into account these other factors, that the final result will be regarded as highly unsatisfactory by the vast majority of patients and would further damage the reputation of regulatory bodies of this type. | Specialist Advisers' advice is considered in detail by the Committee in making its recommendations, however, the format of NICE's IP guidance is such that Specialist Advisers' comments are summarized in the guidance document. The Committee considers the evidence on each procedure in the context of its risks and benefits. This includes comparison of a procedure's efficacy with that of established procedures when they are used to treat the same condition. This applies also to safety: the frequency and gravity of complications of any established procedure are used as a benchmark against which the complications associated with a new procedure are judged. |

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| Individual Respondent - Patient. | **General** | 65 | At all times I was assured that focus ultrasound was an extremely safe proceedure. X recommended that I have hormone treatment to reduce the size of the fibriod prior to the focus ultra sound treatment. I was initially prescribed three injections of Zoladex, two of which failed. Two more were prescribed and successful. This vastly reduced the size of the fibroid which no longer pressed against the bladder.<br>When I was going through this proceedure I alerted the ultrasound team that I was experiencing direct sharp pain to the coccyx and I was told that I should endure as much pain as I possibly could before pressing the stop button as the more I could endure, the more the fibroid would be zapped, as it were. I took this on board and put up with excruciating sharp pain in the coccyx.<br>There was very little noticeable reduction in the size of the fibroid especially after the mentrual cycle returned. I have since had embolization treatment, which had little effect but frankly was nowhere near as painful as the ultrasound treatment. And finally a myomectomy carried out by a Y.<br>When I saw the consultant some weeks after the proceedure I explained that when carrying any weight (ie shopping) I had terrible pain in my lower back, specifically in the coccyx. She was disinterested and said she had never heard of this from other patients. The mere fact that from her perspective the fibroid had reduced, even though it was completely unnoticable to me, was of more interest to her. For a good two years I was unable to lift any heavy weight without acute pain in the coccyx and aching afterwards for a few days. Occassionally a mere turning of position could induce the pain as though trapping a nerve. I am a medium framed, strong woman who was made feeble by this proceedure. I can only associate the pain I now have (less so with time) from this proceedure as it was my coccyx that was being concentrated on during the focused ultrasound treatment.<br>Based on my experience, I believe this treatment should continue to be viewed as experimental and overseen/monitered as such. At the time of my treatment, I was a relatively early patient in the history of this treatment and yet no interest in following up injury to my coccyx was shown, nor measurement of fibriod reduction after a year. In my opinion, insufficient interest or knowledge about my symptoms post-proceedure was exhibited, and further study would be justified. | Noted, thank you. |
| Insurer | **General** | 66 | Agree that it is not safe and efficacious. No other comments | Noted, thank you. |

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| Manufacturer | **General** | 67 | **SECTION I: IP343**<br>IP343 does not include all the evidence available at the time the report was written [searches listed in the report were carried out on 6 September 2006]<br>The evidence omitted in IP343 is relevant to key issues of concern to the Specialist Advisers and on which the provisional guidance appears to be based, namely:<br>• the safety profile of MRgFUS<br>• the duration of effect of MRgFUS<br><br>Even on the basis of the evidence used, the Assessment report:<br>• is unreasonably critical of both the safety profile of MRgFUS and its duration of effect<br>• does not sufficiently relate these to the benefits of MRgFUS<br>• does not take account of the limitations of conducting a clinical trial in this field<br>• does not place the technology and its evidence base in the context of other relevant technologies and their evidence base.<br><br>(IP343) contains some apparent errors and inconsistencies<br><br>We have also made some drafting suggestions in respect of the summary outline of the procedure (para 2.2.1 of IP343), but these are not germane to the key recommendation about the technology in para 1.1 of IP343 (see "InSightec IP343 comments Annex 1 – drafting suggestions.doc". | See responses below |

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<tr><td>Manufacturer</td><td>General</td><td>68</td><td>SECTION II: additional evidence available<br>In addition to evidence available at the time IP343 was written (referred to above), further evidence is now available which reinforces the case for the safety and duration of effect of MRgFUS. We believe that if IPAC takes account of this evidence, it will wish to re-examine the criticisms made in IP343 in respect of both of these considerations.<br><br>This additional evidence includes that relating to three studies whose methodology has been agreed with the US Food and Drug Administration [FDA] and is being reported semi-annually to the FDA. A summary of the June 2006 report was freely available on InSightec's website (www.InSightec.com) at the time IP343 was written (see above) but a further report (December 2006) is now available. These reports present on-going results for three prospective cohort studies:<br><br>• the pivotal study (UF002)<br>• a continued access study (UF005)<br>• a cohort study of African-American women (UF014).<br><br>The numbers of patients involved and the length of follow up [to the December 2006 report] are summarised in Table 1 below. Note that studies are ongoing and not all patient visits have been completed.<br><br><u>Table 1</u><br>Numbers of patients enrolled by group and at follow up time points to 36 months<br><table><tr><th>Study protocol</th><th># treated</th><th># at 3 months</th><th># at 6 months</th><th># at 12 months</th><th># at 24 months</th><th># at 36 months</th></tr><tr><td>UF002</td><td>109</td><td>102</td><td>109</td><td>59</td><td>42</td><td>27</td></tr><tr><td>UF005</td><td>160</td><td>149</td><td>147</td><td>108</td><td>68</td><td>11</td></tr><tr><td>UF014</td><td>73</td><td>63</td><td>63</td><td>21</td><td>-</td><td>-</td></tr></table><br>Note that in the case of UF002, 4 of 6 follow up is attributable to protocol changes required by the FDA after patients had been recruited: initially, patients were asked to participate in a study involving a follow up of six months. In the case of UF005 and UF014, follow up figures reflect the time which has elapsed since recruitment.</td><td>• the pivotal study (UF002)<br>Data from this study are reported in the main table of the overview - Stewart & Hindley<br><br>• a continued access study (UF005)<br>Data from this study are included in a manuscript that has been submitted to Radiology - confirmed as "in press" with a possible publication date of April 2007.<br>- 160 patients with follow-up to 12 months<br><br>• a cohort study of African-American women (UF014).<br>Data available in FDA report on InSightec website</td></tr>
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| Manufacturer | **General** | 69 | IPAC should note that the FDA took the unusual step of issuing a 'Talk Paper' on MRgFUS when it approved the technology. These Talk Papers are intended to alert the public to a technology which the FDA considers is of particular importance. In the Talk Paper the FDA stated that they had "expedited the technology because it offers significant advantages over existing treatment options".<br><br>The Assessment Report has raised concerns about safety. We set out in detail in the main body of this document why we believe that the Assessment Report has neither used all the data available nor interpreted the data in a balanced way. IPAC should bear in mind that the MRgFUS technology involves a substantial capital outlay, and that this will mean that MRgFUS is confined to specialist centres: there is no prospect in the medium-term that a typical DGH, or a dilettante consultant, will have access to the technology. Those administering MRgFUS will therefore be experienced in the technique. | Noted, thank you. |

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| Manufacturer | **General** | 70 | **Section III: context of the guidance**<br>We consider that the evidence base available for MRgFUS is comparable in quality and quantity to the evidence base for other technologies for which IPAC has issued guidance equivalent to the guidance which we believe is appropriate for MRgFUS, namely that this procedure, though not free of AEs, is safe enough for routine use and that its benefits outweigh any AEs. We have summarised the evidence base used by IPAC to give guidance on technologies relating to UAE for uterine fibroids, various endometrial ablation techniques, and two focused ultrasound techniques (for the treatment of atrial fibrillation and of prostate cancer).<br><br>IPAC should also note that the Chief Medical Officer highlighted in his Annual Report for 2005 the need to reduce the number of hysterectomies performed in England, many of which are performed for uterine fibroids. Less invasive alternative treatments for uterine fibroids which have shown that they are both safe and efficacious will help to contribute to this public health goal. All the alternative methods have advantages and risks: the balance between this is not unequivocal, and we believe that the evidence to support the use of MRgFUS is sufficient, and sufficiently strong, to warrant making it available as one of the options which patients and their doctors can choose. IPAC should note that despite the difficulties in securing reimbursement for MRgFUS as a new technology, to date over 250 women have been treated at St Mary's Hospital in Paddington (and over 2500 worldwide). | The Committee considers the evidence on each procedure in the context of its risks and benefits. This includes comparison of a procedure's efficacy with that of established procedures when they are used to treat the same condition. This applies also to safety: the frequency and gravity of complications of any established procedure are used as a benchmark against which the complications associated with a new procedure are judged.<br><br>Noted, thank you. |