National Institute for Health and Care Excellence

IP1536 – Unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor

Consultation comments table

There was a second round of consultation following a change in the main recommendations. The first consultation ran from 26/10/2017 to 23/11/2017 (IPAC date: 14 December 2017). The second consultation ran from 22/02/2018 to 22/03/2018 (IPAC date: 12/04/2018)

CONSULTATION 1

Due to the large number of comments received, the comments have been organised into the following categories:

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New Com. no.	Old/ Original Com. No.	Consultee name and organization	Sec. no.	Comments	Response Please respond to all comments
1 - Comments from patients, carers and patient organisations					
1	1	Consultee 1 Patient	**General**	Dear Sirs The following personal statement is in response to NICE's call for submissions relating to the treatment of my essential tremor (ET) - On 26 October 2017, NICE (National Institute for Health and Care Excellence) published draft interventional procedures guidance [IPG] on MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor [GID-IPG10053] I am a participant in the above trial and had the MRI-guided ultrasound treatment on 13th July 2017 and was advised of the NICE consultation by the Neurology team at Charing Cross Hospital and have made the attached submission for consideration by NICE. Best regards [redacted] **The following personal statement is in response to NICE's call for submissions relating to the treatment of my essential tremor (ET) - On 26 October 2017,**	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.

				NICE (National Institute for Health and Care Excellence) published draft interventional procedures guidance [IPG] on MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor [GID-IPG10053] **Background:** [redacted] – Age [redacted] (dob: [redacted]) First aware of ET affecting hands about the age of 14years, although earlier memories of criticism at school for 'poor handwriting'. Lived in west London since 1972 First referred to consultant relating to ET circa 1985 – Movement Clinic at Hammersmith Hosp /Charing Cross Hosp. Discharged September 2008 – condition was considered stable and not worsening. I had been prescribed with slow-release Propranalol (initially 80mg and later 160mg/Diem) and taken daily through to December 2014. Re-referred by GP to [redacted] Hosp Neurology Dept. in November 2014 – First appointment December 3rd 2014 Dr. [redacted]. My ET had become an increasing problem and generally affecting my lifestyle. For example it was difficult to use screwdrivers and other tools. Writing was virtually impossible and keyboards skills were poor. My Propranalol medication was increased to 240mg/diem in December 2014 and to 320mg in May 2015. From November 2015 Primidone as added to the daily medication – starting at 125mg/diem for the first month and increasing to 250mg three times a day. The Primidone caused adverse reactions for the first week	

				after which it was generally tolerated but causing increased tiredness as the dosage increased. At the meeting with Dr. [redacted] in July 2016, she discussed the trials with MR guided-ultrasound under Dr. [redacted] at [redacted] Hosp. and agreed to write to him regarding me being a possible subject for the trial. In February 2017 it was decided to replace Primidone with Alprazolam with a run-down period for the Primidone. The Alprazolam daily dosage was initially 0.25mg/diem and scheduled to increase to 0.5mg three times a day. Dr. [redacted] wrote a second letter to Dr. [redacted] on 27th February 2017 recommending me for the trials with MR guided-ultrasound. Overall the on-going Propranalol plus the Primidone/Alprazolam dosages brought no significant improvement with the ET symptoms. **Personal experience as patient during trials with MR guided-ultrasound thalamotomy treatment** I was sent information about the trials by Dr. [redacted] in September 2016 which covered details of the medical staff involved, the scope of the trials, the treatment involved, details of the known risks to patients and the patient's rights in the event of adverse results from the treatment. My first meeting with Dr. [redacted] was 2nd June 2017 to confirm I was suitable for the trails and included a standard neurological examination. The letter arranging this appointment includes a second copy of the patient's trial information and timetable for the treatment and	

				follow-up visits for the year after the treatment. The visit included a CT scan. A following meeting was arranged for 30th June 2017 - the Baseline visit – which included an MRI scan, the signing of the consent document and the completion of the Quality of Life in Essential Tremor Questionnaire. The treatment took place at [redacted] Hosp. during the morning of 13th July 2017; thereafter transfer was arranged to [redacted] Hosp. for an overnight stay and the first follow-up visit on 14th July 2017 with Dr. [redacted]. Subsequent follow visits have taken place: 7 days follow-up 21st July 2017 1 month follow-up 4th August 2017 3 months follow-up 6th October 2017 The following visits are scheduled for 2018 and 2019 6 months follow-up 12th January 2018 12 months follow-up To be scheduled 18 months follow-up 21st February 2019 **Conclusion** Immediately after the treatment the right hand had greatly reduced ET; probably as near to normal as one could expect. The left hand still has ET (as was expected). Some getting used to the 'new' situation is still required. For example over the years I have increasingly relied on the left hand, with its tremors, more than I realised and after the treatment and to a lesser extent now I still automatically attempt to use the left hand too much. It is very beneficial having one good hand now, although using a keyboard is somewhat slow.	

				The other major improvement to the quality of life has been the reduction in both the variety and the dosage of the daily medication. The daily dosage of Propranalol was reduced to 240mg from the October 2017 follow-up visit and will be further reduced to 160mg from the beginning of December. The Alprazolam was phased-out after weekly dosage reductions by the end of October. The daily Propranalol will continue indefinitely until a similar MR guided-ultrasound thalamotomy treatment can be applied to left-side in due course. In September I was discharged by Dr. [redacted] as a patient and now my consultant is solely Dr. [redacted]. Finally, I am available for an interview with NICE if this could be helpful. [redacted] 2017-11-15	
2	2	Consultee 2 Carer	**1**	Dear Sir/ Madam , I believe that at the moment NHS patients cannot be offered the above treatment without being enrolled into a formal research study which NICE currently recommends. As we are in the period of consultation until November 23rd 2017 I would like to share my experiences with you which have led me to strongly believe that this treatment is life changing for the thousands of people in the UK that live with Tremors and also how reassured I am that the ultra sound treatment is the only option now for a solution for a number of these people.	Thank you for your comment. The Committee very much welcomes hearing from carers of patients who have the condition which this procedure intended to treat. The committee considered your experience and views in their deliberations. The consultee disagrees with main recommendation.

				My father has had a tremor for almost fifteen years. During this time he has seen a number of doctors, consultants and neurologists at various hospitals across the UK.He has had access to some detailed scans followed by trying various drugs to either reduce or stop his tremors. All of these haven't worked and over time his tremors have got worse. In fact using a computer or writing a letter to contribute to this consultation will be impossible unless he has the help of a friend. He lives alone in the country. This has had an impact on his ability to perform basic everyday tasks safely, which in turn means he is often in a situation were he can harm himself. A simple task like making a drink, taking a meal out off a hot oven or climbing the stairs becomes a hazardous situation where he, like many others with a tremor endlessly hurt themselves. There is also an emotional and social side to having a tremor which also has an impact on my father. He is unable to write his grandchildren a birthday card. He shakes too much. A small thing to those that are able, but when you can't is very upsetting. On a social side, he, like others has to really think about where they can go out with friends. Where is easy to access?, Are the paths flat? Can I have a plastic cup instead of a glass incase my tremor means I knock another drink over? Can they fill my cup half full incase I knock it over my friends? These are a very small selection of examples. There are many.	The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				I'm fairly sure the impact of a tremor stops many attempting to go out at all once they become too unsteady. Over the course for the years my father and our family have looked into various remedies that may help the tremor, reduce it or make everyday living a little safer. We also are aware this treatment is already being used in the USA with brilliant results. We are confident that focused Ultra sound treatment is now the only safe option and together with our doctor can make an informed decision that it is the last option to significantly transform my fathers (and many many others) lives for the better, not only by reducing / stopping the tremor but avoiding the unforeseen trips to hospital in the future if they still have one. I would be very grateful to be informed of a decision once the consultation period has closed. I'm also very happy to contribute to any further in this matter. I look forward to hearing from you. Kind regards, [redacted]	
3	3	Consultee 3 Carer	**1**	Dear Sir/ Madam ,	Thank you for your comment.

				I believe that at the moment NHS patients cannot be offered the above treatment without being enrolled into a formal research study which NICE currently recommends. As we are in the period of consultation until November 23rd 2017 I strongly believe that this treatment is life changing for thousands of people living with debilitating tremors which effects every aspect of daily life. My father has had a tremor for almost fifteen years, which has got progressively worse despite seeing doctors, consultants and neurologists over the years. None of the drugs have reduced the severity or stopped the tremor and has instead got worse. Unfortunately this is exacerbated by stress recently with the news that it is unlikely that his last hope has been taken away meaning an improvement in his quality of life is greatly reduced as every aspect of his emotional and social wellbeing is effected. We understand that the treatment is being used in the USA with very favourable results, therefore it is a devastating blow to my father and other people suffering this way in the UK. I would be very grateful to be informed of a decision once consultation period has been reached & I look forward to hearing from you.	The Committee very much welcomes hearing from carers of patients who have the condition which this procedure intended to treat. The committee considered your experience and views in their deliberations The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				Kind regards [redacted]	
4	4	Consultee 4 Carer	**1**	Dear Sir / Madam I am aware that we are in a consultation period regarding MRI guided focused ultrasound to treat essential tremor. I understand that NICE currently recommends this treatment for research purposes and is not currently available to NHS patients. I would like my support to be noted for patients with essential tremor to have the above treatment available without further research. I believe this is already the case for people in America with life changing results. I have my own experiences with helping a close friend who has had a tremor for a number of years. He like many others has exhausted all options available. Scans, prescriptions and endless appointments with various different hospitals. I have seen the impact his essential Tremor has had on both his physical and social well being. He struggles with the most basic everyday tasks safely and I do worry about him being alone in his house. When he tries to leave his house his tremor causes him to be unsteady which has intern caused	Thank you for your comment. The Committee very much welcomes hearing from carers of patients who have the condition which this procedure intended to treat. The committee considered your experience and views in their deliberations. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				other injuries. As his tremor further develops he will be in capable of living by himself and will need further care. The focused ultrasound treatment would instantly change all this. His tremor would be greatly reduced or disappear. He would be able to come off his prescription drugs. He would gain so much more independence which would be of great benefit to his physical and mental health. I would welcome your feedback once this consultation period has finished on the 23rd of November 2017. Kind regards [redacted]	
5	5	Consultee 5 Patient	**General**	Dear Sirs I took part in the trial, under Dr [redacted], Mr [redacted], and Professor [redacted], and I had the procedure on 9th November 2017. I cannot stress too much how good it feels to be able to do simple everyday tasks with my right hand, such as filling a cup or glass, especially with a hot drink without scalding myself. I could only manage a quarter full at best, before. After the procedure I was offered a sandwich, and I just sat looking at it because it was not shaking it apart, much to everyone's amusement.	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations.

				The tremor started before I was ten years old, it made school work very difficult, and I retired from work early because of it. I was becoming somewhat of a recluse because socialising was an embarrassment. My attitude to life since the procedure is a lot more positive, and I am so very pleased that I have had it done. This procedure allows people like myself to be operated on without the significant risks associated with deep brain stimulation. Yours faithfully [redacted] Patient no. [redacted] for the procedure	
6	6	Consultee 6 Patient	**General**	I have been under the medical supervision of Professor [redacted], Consultant Neurologist at [redacted] Hospital, [redacted], for the last 8 years. During this time he has tried a variety of drugs to treat my essential tremor (ET) but without success. Having been made aware of MRI guided focused ultrasound I studied all available information and was ultimately referred to [redacted] Hospital in London where I was advised that I am an ideal candidate for this treatment. My reasons for wishing to undertake this treatment are as follows: The only alternative treatment, since medication has proved ineffective, would be Deep Brain Stimulation	Thank you for your comment. The Committee very much welcomes hearing from patients who have the condition which this procedure intended to treat. The committee considered your experience and views in their deliberations

				which I would not consider as the outcome cannot be guaranteed and risks are considerable. The results from US FDA have been very positive and the procedure has been approved there. I cannot therefore see any reason why this demonstrably successful procedure should not be accepted in the UK. Most importantly, my everyday life is so affected my tremor that I am unable to prepare all but ready meals for fear of scalding myself. I cannot write so that many everyday activities are impossible, my social activities are severely restricted as I cannot eat or drink in a controlled way. Domestic chores are challenging and gardening impossible. As I live on my own all the above are a heightened anxiety and I am constantly aware of my vulnerability. I have already indicated to Mr [redacted] at [redacted] that I would be prepared to participate in any trials of the procedure.	
7	7	Consultee 7 Patient	**1**	I am a 74 year old (dob [redacted]) woman who has been diagnosed with essential tremor for a number of years which affects both my hands. This affects me in the following ways Communication - unable to write legibly, text, email or use the phone. (please note I am dictating this to my husband)	Thank you for your comment. The Committee very much welcomes hearing from patients who have the condition which this procedure intended to treat. The committee considered your experience and views in their deliberations. The committee considered the comments received during the first

				Eating and Drinking - limited to choice of food due to difficulties in using cutlery, sometimes having to be fed. Can only drink from a sealed vessel using a straw. Personal grooming - I am now unable to put on make-up, style my hair or wear certain clothing i.e. buttoned items. Lifestyle - dangerous when preparing and serving food. For the last 12 years I have been employed as a secondary school exam invigilator and have always worked with another person, now due to education cutbacks we are required to work alone, and as I am unable to write on documents/whiteboards, my employment is at risk due to my tremor. Leisure - was an avid quilter, cross-stitcher and card maker, but am now unable to do this. Social mobilization and interaction - loss of confidence with being in a social gathering, especially if food or drink are involved. This tremor as you can see is frustrating, disabling and isolating, MgFUS would give me back my life, without the necessity of multiple hospital visits and intrusive treatment. The US and Canada have been using MgFUS for some years now and I feel that the UK is missing a trick in using a cost effective and safer treatment for its patients, who should be given a choice.	round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				From my own research I believe that MgFUS does the same procedure as DBS and it is safer and effective without two invasive surgeries and a general anesthesia etc. Over the years I have been prescribed different types of medication with little long term benefits. I have been a patient of my local District General Hospital and my Consultant did not recommend DBS as he felt it was too invasive. This inspired me to do my own research, this is how I discovered MgFUS as well as contacting other medical professionals for help and advice, as I want the last years of my life to be of quality and remain a useful member of society and less of a burden to others and the NHS. I feel this research has enhanced my ability to make an informed choice. I try to remain positive and active by using the gym and swimming several times a week. In conclusion I feel very strongly that MgFUS would give patients like me the ability to take back control of the quality of their life with a tried and tested procedure that involves less risk and positive results. MRS [redacted]	
8	8	Consultee 8 Patient	**1**	Dear Sirs, My name is [redacted] and I was part of the essential tremor study at [redacted] Hospital in 2016.	Thank you for your comment. The Committee very much welcomes hearing from patients

				I would like to share my story with you and describe how ultrasound MRI treatment cured my tremor and changed my life so that it can reach out to other patients who may be suffering like I was. My tremor began over 6 years ago and at first I thought nothing of it. However, soon it got worse and started affecting my daily life which was limiting me in carrying out simple Tasks like eating and drinking. I was under a number of specialists at [redacted] Hospital and after extensive tests they diagnosed it as 'Tremor' but could not find the root cause. Over the next few years I was put on various drugs to reduce the Tremor. However, these did nothing but cause severe side effects. My tremor was worsening and it got to a point where I was embarrassed to go out because I was worried I would drop a cup of tea or maybe not be able to pick my fork up during dinner. It felt like my life was closing in on me and that I had no way out. My family could see how depressed I was feeling but they were helpless themselves. It was in early 2016 where I went back to see my consultant and explained how I felt. He then talked to	who have undergone this procedure and considered your experience and views in their deliberations. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				me about the ultrasound MRI treatment. He explained to me that it was a study and that it is something that would be a trial. After careful thought and research on DBS I decided to give it a go. I was so fed up of having to limit my life and was sick of taking those awful drugs which were causing terrible side effects. Focused ultrasound, thalamotomy, is much less invasive than the old type of surgery they did under General anaesthetic. If both DBS and focused ultrasound are safe and effective, both should be offered for clinical treatment. I understand the US FDA has approved this procedure saying it is safe and effective. Why will it not be allowed here in the UK? I realize we can always study things further, but thalamotomy is well known and focused ultrasound does it in a very safe and incisionless way and I would like access to this treatment. Together with my doctors I can make an informed choice of treatments available to me.	

				I need more options for my essential tremor than ineffective medications or very invasive surgery. Hence I feel it should be approved. If my essential tremor affects my ability to perform daily activities, then I will not be able to work and may require a caregiver. This non invasive ultrasound treatment had changed my life. I felt no paint during the treatment and my children were with me during the entire process. I was awake during the process and the Doctors and nurses were with me through every step of the process. At no point did I feel scared or alone. I am now completely tremor free. The best thing about it is that as the treatment goes on the tremor gets less and less instantly. I firmly believe this treatment is fantastic and life changing. I hope that NICE can approve this in the UK because just think how many patients lives you would be changing. The risks associated with this procedure are extremely low and when compared to the invasive method it almost seems like there are no risks.	

				I hope my story has an impact on your decision and that you approve this form of treatment. The Doctors involved in this surgery are just fantastic and act in the most professional manner. They are dedicated to this form of treatment. If I can be of any further assistance, I am happy for you to contact me. Yours faithfully, Mr [redacted]	
9	9	Consultee 9 Patient	**1**	We realize FUS may not be suitable for everyone, but, that is the same for all and every procedure. However, it is important to be able to have it as an option on the NHS for every E.T. sufferer to consider, especially for children! It is more cost effective than a life of medications and medications to counteract side-effects of medications etc... and will allow a growing number of young sufferers the chance to live as normal, productive and independent a life as possible. This condition is rife amongst our young, adult and elderly with very little offered in the hope of a way forward, F.U.S. is groundbreaking for us, please do not dismiss it. Let's give the youngsters some hope that a new treatment maybe available to them in the future. Living in hope	Thank you for your comment. Cost-effectiveness is not part of the remit of the IP Programme. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for

				[redacted]	clinical governance, consent and audit or research.
10	10	Consultee 10 Patient	**1**	Dear sir, I am a long-term sufferer of essential tremor with no medication that brings any relief without drastic side effects. The long awaited news that NICE had not yet granted the application for use of FUS as treatment for Essential Tremor was very disappointing. This treatment holds a lifeline for the many thousands of fellow sufferers of this debilitating condition. ET affects my whole life and day to day living, from drinking a cup of tea to socialising. My hope was for some normality with this treatment being available for my dominant right hand. All the younger sufferers also need this treatment to be available as their tremors become more debilitating. I hope the NICE committee will reconsider and allow this application and give hope to the sufferers of Essential Tremor. Yours [redacted]	Thank you for your comment. The Committee very much welcomes hearing from patients who have the condition which this procedure intended to treat. The committee considered your experience and views in their deliberations. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
11	11	Consultee 11	**1**	To Whom it may concern,	Thank you for your comment.

		Patient		I will start by declaring that I have a vested interest in the subject as someone who has experienced this condition since the age of 15 (though only diagnosed a couple of years ago in Oxford where I now live) and who is now almost 60. I am therefore contacting you to declare my opinion on the availability of this procedure on the NHS. Personally my tremor has not even progressed to the stage where I have to take drugs all the time let alone consider more drastic interventions however I have, through the National Tremor Foundation met many other people with the condition. I take Propranolol when needed for work or social situations where explaining the condition is not appropriate. I believe that a lot of work needs to be done to raise awareness of the condition so that people do not feel the crippling embarrassment and consequent isolation the condition may lead to along with the development of drug and other treatments. The availability of MRI-guided focused ultrasound treatment as part of the package of treatments is supremely important. Given the relatively long hospital stay and risk of infection which DBS involves I must confess to being surprised to hear that there is a possibility that this ultrasound option may not be available on the NHS. I sincerely hope that even if it is not felt that this is advisable at the present time that NICE will be returning to the decision-making process in the not too distant future.	The Committee very much welcomes hearing from patients who have the condition which this this procedure intended to treat. The committee considered your experience and views in their deliberations. The IP programme does not assess the efficacy and safety of comparator interventions. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				Yours Faithfully [redacted] [redacted] [redacted] [redacted] [redacted]	
12	12	Consultee 12 Patient	**1**	Comment on [GID-IPG10053] MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor In development As a patient who has suffered from Essential Tremor (ET) since the age of about 12 years I am concerned that the above procedure has not been approved for use in the NHS. I have personal experience of the way that this condition (ET) worsens with age and in my case it has now become severely disabling and has drastic effects on my social life. I know that many other sufferers experience similar or worse effects. The available medication tends to have a diminishing effect over time - again I have personal experience of this. There is no permanent cure for this progressive condition.	Thank you for your comment. The Committee very much welcomes hearing from patients who have the condition which this procedure intended to treat. The committee considered your experience and views in their deliberations. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside

				Focused ultrasound thalamotomy appears to offer a valid alternative treatment for severe cases of ET and I believe the available trial results indicate that it should be introduced within the NHS and made available to all, subject to constant monitoring of outcomes. I therefore strongly recommend that this treatment be provided on the NHS. Regards [redacted]	the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
13	13	Consultee 13 Patient	**1**	I have Essential Tremor, diagnosed 1974 with mild hand tremor in right hand. Over the following years it has progressed to both hands, head, legs, lips and jaw. The severity has also increased over that time and affects my daily life. Running an ET support group, I meet people with the disorder whose tremors are so severe they have no quality of life and withdraw from society and current medications do not help them. They tell me Guided focused ultrasound surgery would be a blessing. As well as adults I also meet children with ET who along with daily tasks also have difficulty at school because their teachers have never heard of this disorder. Those children are our future. As ET is a progressive disorder just knowing Focused Ultrasound surgery would be available to them in their future years could give them hope they will have a better quality of life.	Thank you for your comment. The Committee very much welcomes hearing from patients who have the condition which this procedure intended to treat. The committee considered your experience and views in their deliberations. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				Please reconsider your guidelines for approval or at least extend the deadline to collect more information/data. Thank you for taking the time to read this request. Kind Regards, [redacted]	
14	17	Consultee 15 Patient	**1**	I wish to comment on the Draft NICE Interventional Procedures Guidance currently available for consultation, believing that, as someone who has received this treatment, my views are important for you to consider and for the benefit of thousands of others in the UK affected by this condition. I received treatment from Dr. [redacted] and his team at [redacted] hospital, [redacted] for my essential tremor on June 22nd this year. I was very satisfied with the outcome, my left hand is now tremor-free and it has led to massive improvements in many of the activities of daily living:- eating, drinking, handwriting, use of touchscreens, keyboard, computer mouse etc. with obvious 'knock-on' benefits to physical and social well-being. I completed and returned a questionnaire to NICE making these points several months ago. I understand that my treatment was part of a UK clinical trial and that this was part of a wider trial involving other countries; I assume that the outcome of this trial	Thank you for your comment. The committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				would be a bank of evidence of sufficient quality and quantity to demonstrate the efficacy of the treatment. Following this trial, should it not be possible to fund MRGFUS in the same way as DBS is? Particularly as DBS is a lengthier invasive treatment, also requiring more aftercare. In contrast, my FUS treatment lasted just a few hours and, although I stayed overnight as a precautionary measure and for check-ups the following day as part of the trial, I felt well enough to leave hospital and have suffered few side-effects (noted in my questionnaire response). Furthermore, my treatment was aimed at only one side of the brain and so eliminated the tremor only in my left hand; if, in future, I wish to have my right hand treated by FUS, do I have to wait to be enrolled in a formal research study first? Should this really be necessary? I consider, and I hope, that the submissions you receive will mean that the current restriction on access to MRGFUS will be removed for the benefit of those who are struggling with this long-term condition and see little hope of permanently removing it. [redacted]	
15	43	Consultee 19 Patient	**1**	I understand that NICE are not minded to fund focused ultrasound for the treatment of Essential Tremor. I was one of those lucky enough to be treated at St. [redacted] hospital and given the improvement in my	Thank you for your comment. The process of funding specific medical treatments in the NHS falls outside the remit of NICE.

				condition I am dismayed that this will not be available to others, particularly young people. I have suffered from ET since childhood and I am now 72 years old. Quite frankly it has blighted my life and since the condition runs in my family I was keen to take part in the trial as much for my family as for me. I did not suffer any side effects but my tremor has improved. I have been unable to write legibly for years, to eat or drink without accident, or to prepare food easily. Now I can look forward to writing my Xmas cards, cooking etc. and most importantly to have a social life. I was too embarrassed to go out much.. This treatment has given hope where for some there was despair. I suppose I can take comfort from the fact that the trials will continue and hope that FUS will eventually be approved by NICE. Economically it would give young people, in particular, a chance to fulfil their potential, earn a living, contribute to a pension, and be less of a burden regarding welfare. [redacted]	Cost effectiveness is not part of the remit of the IP programme. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
16	44	Consultee 20 Other	**1**	I am writing in connection with MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor. [GID-IPG10053]. I understand that NICE has not granted permission for this treatment to be currently available to patients via the NHS.	Thank you for your comment. The Committee very much welcomes hearing from patients who have the condition which this procedure intended to treat. The committee considered your

				While I understand concerns about safety and the lack of evidence of long term benefits of treatment, I would urge you to reconsider. There is no specific treatment for those suffering with Essential Tremor. The drugs that are used are not intended for tremor, for the most part they are either intended for patients with epilepsy or anxiety. For many the treatment does not relieve the tremor and for those where it does, anecdotally the treatment does not seem to provide relief on a continuing basis. Of the interventions that are available such as Deep Brain Stimulation, there is always a risk of infection due to the surgery and the need for continuous monitoring with repeat visits to centres for adjustments to the treatment. It is my understanding that MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor provides instant relief to the side that has been treated, it is non-invasive and can be done as an outpatient reducing costs of hospital beds. As Essential Tremor is the most common movement disorder, there is a very large unmet need and this would appear to be one of the few methods that does provide relief. Regards,	experience and views in their deliberations The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				[redacted]	
17	47	Consultee 23 Patient organisation National tremor Foundation	**General**	**Response to NICE** **MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor: Interventional procedure consultation** **For the attention of: The Interventional Procedures Advisory Committee** **From: The Trustees of the National Tremor Foundation, Long Term Condition Centre, Gubbins Lane, Romford, RM3 OAR** We would like to emphasize the enthusiasm that people suffering from essential tremor have for non-invasive day case surgical treatment of essential tremor with MRI-guided focused ultrasound thalamotomy compared to the conventional invasive techniques of deep brain stimulation and radiofrequency thalamotomy. The reasons for this are self evident given the much easier treatment pathway for the patient and significantly reduced mortality and morbidity associated with MRgFUS compared to invasive stereotactic surgery. At the National Tremor Foundation annual meeting last year the pros and cons of MRI-guided focused ultrasound thalamotomy were discussed.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				The availability of the technique on the NHS will be greeted with relief by people afflicted by essential tremor and their relatives. We hope that following the comments submitted to you in a separate letter by Dr [redacted], one of our trustees, who is vastly experienced in the medical and surgical management of tremor, NICE will approve MRI-guided focused ultrasound thalamotomy so that it can be made available to treat patients with essential tremor without any further delay. Yours faithfully [redacted] On behalf of: [redacted] (Chairman of the board of trustees) Professor [redacted] (Board of trustees) Dr [redacted] (Board of trustees) Mr [redacted] (Board of trustees) Ms [redacted] (Board of trustees)	
18	48	Consultee 24 Patient	**1**	Sirs	Thank you for your comment. The Committee very much welcomes hearing from patients

				Re: NICE draft comments on MR guided high intensity focused ultrasound (HIFU) in essential tremor and other neurological syndromes It was extremely disappointing to learn the potential outcomes of a NICE review of the new technology HIFU for functional neurological ablation therapy. I fear that the UK will become a backwater instead of leading the charge to determine the benefits (& also the possible side-effects) of HIFU. The introduction of HIFU appears to offer an opportunity to dramatically decrease the huge numbers of patients suffering e.g. essential tremor who could now be cured with HIFU rather than managed with inadequate medicines, drastically reducing symptoms, side-effects, delivering a much cheaper service with a seemingly far less toxic side-effect profile and reducing in patient bed-stays by as many as x3-4 fold. I have personally endured the last 12 years with symptomatic Parkinsons disease (PD), as did my father before me, observing my own progressively worsening overall health such that I am recently arrived at the situation where I have had to take partial retirement. I have reached a stage in which attempts to get some control of my symptoms mean having to take more than 10 medications daily in an apparently regular manner but frequently having to change to an irregular sequence that itself has had to be altered on a daily basis (i.e. I have to guess which drug is best taken, when, and how). I also suffer the toxicities from each	who have the condition which this procedure intended to treat. The committee considered your experience and views in their deliberations. The recommendation for further research is not limited to randomised controlled trials. The consultee's comments encompass clinical indications covered by 2 pieces of guidance: IP1536 Unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor and IP1692 Unilateral MRI-guided focused ultrasound thalamotomy for moderate-to-severe tremor in Parkinson's disease. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee

				individual drug (alone & in combination with any number of the alternatives) using differing delivery techniques (oral, transcutaneous and sub-cutaneous) in order to impact a very complex, unpredictable and constantly changing group of symptoms. And my own service to the community (& that of colleagues in similar straits) is already compromised by the need to decrease my workload and in so doing taking premature retirement, despite that the loss of the skills I have gained over >30 years of experience in teaching and caring will also be lost to the community . I struggle greatly with these complex medication regimens – it is not easy to e.g. accurately titrate doses of injectable medicines whilst shaking , or falling etc. It is hard to imagine just how much harder it must be for those now well over 70 years of age with important co-morbidities and living alone to manage? It does not seem possible. And now I find that my PD has progressed to reach the stage where surgery (deep brain stimulation – DBS) is the final meaningful therapeutic option. And whilst having great respect for the fine skills & motivation of operating teams who apply this technique, it is as well to recall from the literature that DBS is open surgery, relatively recent, fairly primitive, and carries further risks e.g. infection rates are high & potentially calamitous (in a world of increasing bacterial resistance to antibiotics), bleeding, strokes, fits etc all occur frequently. And yet the development of HIFU in the UK is to be slowed down by limiting its use only within the context of randomised clinical trials. Thus many will suffer for longer periods whilst clinicians	decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				recruit enough patients to engage in studies which achieve statistically significant differences e.g. between HIFU & open surgery, & consequently could become difficult, maybe even impossible to accrue. Although HIFU will surely shortly begin to replace open surgery by non-invasive, low morbidity, greater accuracy and so on, making clinical trials important, sham groups will increasingly need to be subjected to similar procedures for indefinable benefits and over potentially long periods of time when definitive therapy could markedly improve procedure enhanced outcomes befitting a 21st century health service. In the meantime however, patients will suffer unnecessarily from the delays. Better news is that the first UK RCT on which NICE is reporting has successfully recruited the small numbers required but the time being taken to get this far was substantial and appears not to have been considered sufficiently seriously. Analyses will increase duration of study and so there are lessons encouraging clinical trials but these should be rapidly accelerated into clinical practice if HIFU is to be introduced (but with safety very much also in mind). Many studies are simply repeats of procedures already performed usually in another country, especially China, Europe and in particular especially, the USA, where the FDA has actually now approved its use for essential tremor. This would also appear to give hope to the essential tremor patient. What then is the PD patient supposed to do?	

				All this argues for more rather than less rapid introduction of hardware and clinical trial planning, which need to be put into place with speed to address the positive and encouraging data from studies being reported elsewhere. Today if my PD is disabling and medication doesn't work I have usually only one choice, namely deep brain stimulation (DBS). This involves unilateral (or bilateral) invasive brain surgery, general anesthesia (plus many hours of surgery whilst awake, recovery time, real surgical risks of very serious kinds, and lifelong follow up, limiting where I can live. Focused ultrasound offers procedures e.g. thalamotomy, that PD patients had taken on for PD patients for their own illness and was being performed years before DBS but does so in a safer and much less invasive way. If both DBS and focused ultrasound are safe and effective, both should be offered for clinical treatment with clear indications for whichever group of patients one or the other each is best indicated. I understand the US FDA has approved this HIFU procedure declaring it is safe and effective already. Why will it be delayed / not offered here? I fully appreciate that it is always possible, indeed imperative, to study new technology and in greater depth, before confidently declaring from objective evidence that it is an improvement in terms of benefits, safety and toxicities, Evidence accumulates that e.g. thalamotomy for PD is well known and focused ultrasound achieves it very safely and non-invasively. I	

				am still relatively young and would like access to this treatment. With the help of my doctors, I can then make an informed choice of treatments that improve upon the increasingly ineffective medications or very invasive surgery available presently. And should the difficulties affecting my performance of daily living activities improve, I may well be able to work again and for longer and without the need for a caregiver, giving added benefit to the community. I do hope it will prove possible for assessments of HIFU technology to be rapidly performed, spent broadly countrywide and with minimal delay. Yours sincerely [redacted] Patient with PD now > 12 years	
19	49	Consultee 25 Patient	**1**	Hello As an ET sufferer, I was disappointed to learn that the focused ultrasound treatment has not been approved for delivery on the NHS and will continue to trails only. Thanks [redacted]	Thank you for your comment. The Committee very much welcomes hearing from patients who have the condition which this procedure intended to treat. The committee considered your experience and views in their deliberations.

					The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
2- Comments from professional organisations					
20	14	Consultee 14 Professional Organisations British Society for Stereotactic and Functional Neurosurgery	**1**	"Functional neurosurgery is a very specialized field with only a fraction of UK Consultant Neurosurgeons regularly involved in the delivery of such service. We perform Deep Brain Stimulation (DBS) - which is currently the commonest neurosurgical procedure for treatment-resistant ET and some of us also perform stereotactic Radiofrequency thalamotomy (RF). Occasionally, we perform Stereotactic Radiotherapy thalamotomy (Gammaknife-SRS). MGFUS needs to be evaluated and assessed against these procedures of which DBS is by far the most commonly performed in the NHS in the UK. We shall take each procedure in turn:	Thank you for your comment. There was no study comparing MRI-guided focused ultrasound thalamotomy to DBS or to radiofrequency (RF) thalamotomy in the original literature search done for this procedure. This underpinned the recommendations for use in the context of research. In the update literature search undertaken during the first round of consultation, one study retrospectively comparing MRI-

				DBS: this involves the insertion of electrodes deep into the brain substance to allow neuromodulation through the chronic delivery of electric current generated by a battery pacemaker. Although the procedure is invasive, given its largely reversible, non-destructive and adjustable nature, together with the ability to perform bilateral procedures at the same setting, has made the procedure the intervention of choice for ET patients needing surgery. Some patients eg those not fit for general anaesthetic or those with recurrent infections, may however not be candidates for DBS. Furthermore, there are many patients who prefer a less invasive therapy. MGFUS: there is no skin incision, no opening of the skull, no penetration of the brain. There is no implant to get infected. There is a small risk of possible micro-hemorrhage at the site of the thalamotomy (less than 0.1 %) which may lead to neurological deficits. Furthermore, MGFUS does not need General Anaesthetic. It can be a day-case procedure (and indeed is so in several centres internationally). Serious medical co-morbidities, which currently preclude DBS treatment in many patients who are severely incapacitated by ET, is not a barrier to MGFUS. We would like to highlight that MGFUS is a staged progressive lesioning procedure that is performed with the patient being assessed in real-time by a neurologist and by continuous real-time MRI scanning (the patient is within the MRI-scanner throughout the procedure). The	guided focused ultrasound thalamotomy against RF and DBS was retrieved (Chang 2017). This study has been added to the overview. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				neurologist checks for the presence of any adverse effects while the MGFUS has delivered sub-lesional energy (hence the effects are reversible and transient). It is only when this is confirmed, a permanent lesion is created. (please continue to comment 2)"	
21	15	Consultee 14 Professional Organisations British Society for Stereotactic and Functional Neurosurgery	**1**	"RF thalamotomy: this involves the insertion of a unilateral probe deep into the brain substance. No permanent implant is put in. Instead, a current is passed while the patient is assessed for adverse effects (and clinical response). When a satisfactory response is seen, a permanent lesion is formed. There is a definite risk of intracranial haemorrhage with consequent severe neurological deficit when the probe is inserted. This risk is routinely quoted as about 1-2%. Thus the procedure is almost identical to MGFUS. The only (and with regard to patient safety extremely critical) difference is that MGFUS does not involve insertion of an intracranial probe and hence the risk of causing a haemorrhagic stroke is miniscule. Given that both procedures (RF and MGFUS) do EXACTLY the same anatomical operation â€“ thalamotomy- it is difficult to understand why the latter technique, despite being less invasive, is being given a less favoured opinion by the NICE committee compared to the former. This brings us to the comments on efficacy of MGFUS thalamotomy in ET. Stereotactic thalamotomy for tremor is a treatment which has been regularly performed worldwide for over 60 years. It started decades before the advent of CT or MRI scans.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				There are published series of thalamotomy for tremor that total over 10000s of patients across 300 neurosurgical centres in over 50 countries. Thalamotomy for ET is a currently approved (and practiced) treatment for ET in the NHS in the UK. MGFUS is simply a safer means of doing the same operation.	
22	16	Consultee 14 Professional Organisations British Society for Stereotactic and Functional Neurosurgery	**1.2**	With regard to patient selection, we would like to reiterate that this is the absolute key factor that determines the degree of success in all Functional Neurosurgical procedures. This applies to DBS, RF and to MGFUS. Which is why all these procedures are managed in a truly multi-disciplinary MDT setting which starts with several clinical assessments well before the actual procedure. The role of the Specialist Movement Disorder Neurologist is vital and no centre should perform (and indeed does not) any DBS, RF or MGFUS outside this MDT setting. Gamma-knife SRS: the critical point to make here is that there is no scope for real-time assessment of either adverse effects or clinical response as the effects of radiation do not manifest till weeks (and months) after treatment. In conclusion, we hope the above points justify a rethink by the NICE committee on MGFUS for ET.	Thank you for your comment. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
23	27	Consultee 17	**General**	**MRI-guided focussed ultrasound (MGFUS) thalamotomy for Essential Tremor (ET)**	Thank you for your comment.

		Specialist Adviser (on behalf of the UK-DBS Network)		We, the national UK-DBS Network, represent specialist Movement Disorder neurologists and neurosurgeons in the UK. Every Deep Brain Stimulation (DBS) centre in the UK is represented by the UK-DBS network. We form the local MDTs that care for patients with complex movement disorders. We manage patients pre- and post-operatively. We select and perform stereotactic brain surgeries for the alleviation of symptoms that may arise from a wide variety of movement disorders. We were pleased to be offered the opportunity to comment on the NICE Interventional Procedure Consultation Document on MGFUS in ET published in October 2017. From this, the two principal recommendations are presently: 1.1 Current evidence on the safety and efficacy of MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. 1.2 Further research, which could include randomised controlled trials, should address patient selection and report on long-term follow-up.	
24	28	Consultee 17 Specialist Adviser (on behalf of the UK-DBS Network)	**1**	We wish to add further comment: As we are the principal clinicians who manage such patients in the UK, and who offer the whole range of pharmacological and stereotactic neurosurgical procedures that are available in the NHS, we feel our	Thank you for your comment. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a

				specialist opinion would be important to the process of arriving at a clinically and scientifically rational and justifiable decision with regard to the further application of MGFUS for ET in the NHS. This is a very specialized field with only a fraction of Consultant Neurologists and Neurosurgeons who are regularly involved in the delivery of such care. We perform Deep Brain Stimulation (DBS) - which is currently the commonest neurosurgical procedure for treatment-resistant ET and some of us also perform stereotactic Radiofrequency thalamotomy (RF). Very occasionally, we perform Stereotactic Radiotherapy thalamotomy (Gamma-knife-SRS). MGFUS needs to be evaluated and assessed against these procedures. We offer our view on each procedure in turn: DBS: this involves the insertion of unilateral or bilateral thin electrodes into the brain substance. There is a risk of intracranial hemorrhage with consequent neurological deficit (including paralysis, dysarthria - cannot speak, severe ataxia - cannot walk). This risk is routinely quoted as about 1% to 3% (Refs 10, 11, 12, 13). Furthermore, and perhaps more importantly, there is implanted hardware (brain electrodes, subcutaneous extension wires and the battery) which entails a risk of infection - ranging from 5% to 15% in most published series (Refs 13, 14, 15). MGFUS: there is no skin incision, no opening of the skull or brain linings, and no penetration of the brain. There is	consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				no implant so fully avoiding the risk of hardware infection. There is a risk of micro-hemorrhage at the site of the thalamotomy (less than 1%). The risk of this resulting in significant neurological deficit is less than 0.5% (Refs 1, 2, 3, 4 and 5). Possible side effects include paresthesiae, gait problems, dysarthria, and transient dyskinesia. Furthermore, MGFUS thalamotomy does not need general anaesthetic. It is a day-case procedure. Serious medical co-morbidities, which preclude general anaesthesia for other treatments in patients who are severely incapacitated by ET, are less of a barrier to MGFUS. MGFUS is a staged lesioning procedure that is performed with the patient being assessed in real-time by a neurologist and by continuous real-time MRI scanning (the patient is within the MRI-scanner throughout the procedure). The neurologist checks for the presence of any adverse effects while the neurosurgeon performs MGFUS, initially delivering tests of sub-lesional energy (hence the test effects are reversible and transient). It is only when good a outcome without side-effects is confirmed, that a permanent lesion is created, using higher energy, again under direct clinical and MRI supervision. The procedures takes 2-3 hours and requires dedicated MRI scanner time in addition to neurosurgical and neurological clinical time. It is only performed unilaterally. Bilateral procedures are not performed. The most similar procedure to MGFUS thalamotomy currently is RF thalamotomy: this involves the insertion of a (unilateral) electrical probe into the brain substance to	

				the intended target which is the same anatomical structure that is targeted by MGFUS. A current is passed while the patient is assessed for adverse effects (and clinical response). When a satisfactory response is seen, a permanent lesion is electrically formed. The electrode is then removed. No permanent implant is used. There is a risk of intracranial haemorrhage with consequent neurological deficit (includes paralysis, dysarthria, ataxia). This risk is routinely quoted as about 3% (Refs 8, 17). The only (**and with regard to patient safety)** significant difference is that MGFUS does not involve insertion of an intracranial probe and hence the risk of causing a hemorrhagic stroke is less (Refs 1, 2, 4, 6 and 8). The patient selection, MDT involvement, and clinical commitments are similar, but with MGFUS, a MRI scanner is required while with RF thalamotomy, an operating theatre is required. Another procedure for performing thalamotomy is Gamma-knife SRS: with this there is no scope for real-time assessment of either adverse effects or clinical response as the effects of radiation do not manifest till weeks or months after treatment (Ref 16).	
25	29	Consultee 17 Specialist Adviser (on behalf of the UK-DBS Network)	**1**	We would like to highlight the potential consequences of the current NICE recommendation on MGFUS, as they stand. It implies that it is recommended to expose eligible patients with ET to a greater risk of adverse events through more invasive procedures to achieve similar symptom control (Refs 6, 7).	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside

					the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
26	30	Consultee 17 Specialist Adviser (on behalf of the UK-DBS Network)	**1.2**	With regard to patient selection, we would like to reiterate that this is the key factor that determines the degree of success in all Functional Neurosurgical procedures. The role of the Specialist staff is vital in selection of the most suitable procedure for an individual patient. As experienced Consultant Neurologists and Neurosurgeons, we will continue to do this such that patients who would likely benefit from thalamotomy can have this therapy in the most appropriate manner for that individual, and we believe that this should include MGFUS in patients in whom an MDT decision is such that MGFUS is the best treatment option for that particular patient.	Thank you for your comment. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
27	31	Consultee 17 Specialist Adviser (on behalf of the UK-DBS Network)	**1**	In conclusion, we request NICE to consider our comments for its final recommendations about MGFUS for ET. We would suggest that MGFUS should be made available to patients under careful guidelines of clinical governance. These should include: a) treatment-resistant ET b) carefully selected patients through an established Movement Disorders neurological and neurosurgical MDT c) have a choice between MGFUS and RF thalamotomy	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its

				d) MGFUS is performed in established Clinical Neurosciences Centres that also perform DBS as the clinical expertise needed for both procedures is similar We are happy to be contacted for any further clarification. We recognize that this is an area of very specialist medical and scientific expertise. To aid the NICE Committee further, we are also able to make available one of our Consultant members (with the relevant experience) to meet the Committee, answer questions and make a brief presentation.	recommendations from research only to special arrangements for clinical governance, consent and audit or research.
28	32	Consultee 17 Specialist Adviser (on behalf of the UK-DBS Network)	**References**	**References:** 1. Elias W J, Lipsman N, Ondo W G et al. (2016) A Randomized Trial of Focused Ultrasound Thalamotomy for Essential Tremor. New England Journal of Medicine 375(8), 730-9 2. Gallay Marc N, Moser David, Rossi Franziska et al. (2016) Incisionless transcranial MR-guided focused ultrasound in essential tremor: cerebellothalamic tractotomy. Journal of Therapeutic Ultrasound 4, 5 3. Elias W J, Huss D, Voss T et al. (2013) A pilot study of focused ultrasound thalamotomy for essential tremor. New England Journal of Medicine 369(7), 640-8 4. Chang W S, Jung H H, Kweon E J et al. (2015) Unilateral magnetic resonance guided focused ultrasound thalamotomy for essential tremor: practices	Thank you for your comment. Papers 1 to 5 are included in the main extraction table (table 2) of the overview. Papers 6 and 7 were retrieved by our update literature search and have been added to table 2. Papers 8 to 17 are about radiofrequency thalamotomy, deep brain stimulation or Gamma-knife. Therefore they won't be included in the overview.

				and clinicoradiological outcomes. Journal of Neurology, and Neurosurgery & Psychiatry 86(3), 257-64 5. Lipsman N, Schwartz M L, Huang Y et al. (2013) MR-guided focused ultrasound thalamotomy for essential tremor: a proof-of-concept study. Lancet Neurology 12(5), 462-8 6. Kim M, Jung NY, Park CK, Chang WS, Jung HH, Chang JW. Stereotact Funct Neurosurg. 2017;95(4):279-286. doi: 10.1159/000478866. Comparative Evaluation of Magnetic Resonance-Guided Focused Ultrasound Surgery for Essential Tremor. 7. Zaaroor M, Sinai A, Goldsher D, Eran A, Nassar M, Schlesinger I. J Neurosurg. 2017 Feb 24:1-9. doi: 10.3171/2016.10.JNS16758. [Epub ahead of print]. Magnetic resonance-guided focused ultrasound thalamotomy for tremor: a report of 30 Parkinson's disease and essential tremor cases. 8. Terao T, Takahashi H, Yokochi F, Taniguchi M, Okiyama R, Hamada I. J Neurosurg. 2003 Jun;98(6):1241-6. Haemorrhagic complication of stereotactic surgery in patients with movement disorders. 9. Oh MY[1], Abosch A, Kim SH, Lang AE, Lozano AM. Neurosurgery. 2002 Jun;50(6):1268-74; discussion 1274-6. Long-term hardware-related complications of deep brain stimulation.	

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				Related Infections: Analysis of Rates, Timing, and Seasonality. 15. Tolleson C, Stroh J, Ehrenfeld J, Neimat J, Konrad P, Phibbs F. Stereotact Funct Neurosurg. 2014;92(4):227-33. The factors involved in deep brain stimulation infection: a large case series. 16. Kooshkabadi A, Lunsford LD, Tonetti D, Flickinger JC, Kondziolka D. J Neurosurg. 2013 Apr;118(4):713-8. Gamma Knife thalamotomy for tremor in the magnetic resonance imaging era. 17. Schuurman PR, Bosch DA, Merkus MP, Speelman JD. Mov Disord. 2008 Jun 15;23(8):1146-53. Long-term follow-up of thalamic stimulation versus thalamotomy for tremor suppression. **Professor [redacted] Consultant Neurosurgeon** **Dr [redacted] Consultant Neurologist** **Dr [redacted] Consultant Neurologist** **Professor [redacted] Consultant Neurologist**	

3- Comments from NHS Professionals and Specialist advisers					
29	18	Consultee 16 NHS Professional Reader and Honorary Consultant in clinical neurology.	**2.3**	Response to NICE MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor: Interventional procedure consultation Dear Interventional Procedures Advisory Committee Thank you for producing the MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor: Interventional procedure consultation document to which I would like to respond. I would like to thank the committee for their contribution to this assessment and for allowing an opportunity to respond. I have run the national tremor clinic at Charing Cross Hospital for over 20 years and during that time have had over 15,000 consultations with patients with tremor. I have also been the in theatre neurologist for radiofrequency thalamotomy for 20 years, deep brain stimulation for 15 years and MRI-guided focused ultrasound (MRgFUS) for one year. I am a member of the International Movement Disorder Society Task force on Tremor and a founding trustee to the National Tremor Foundation (a UK registered charity for people with tremor). I would like to make the following points: 1. The medical treatment of essential tremor is limited to the first line drugs: Propranolol and Primidone and second line drugs: Topiramate, Gabapentin and benzodiazepines (Clonazepam and Alprazolam). All these medications have poor benefit to adverse effect profiles for patients with essential tremor. Once tremor is moderate to severe in	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

				severity (grades 5-10 out of 10) on the Bain and Finley (1993), spiral rating scale there is little prospect of significant functional improvement in patients with any of these medicines.	
30	19	Consultee 16 NHS Professional Reader and Honorary Consultant in clinical neurology.	**3.1**	2. It surprises me that the Interventional Procedures Advisory Committee consider the evidence for MRgFUS thalamotomy for essential tremor to be poor, given the randomized control study by Elias WJ (2016) involved MRgFUS v sham thalamotomy and showed clear benefit in terms of reduced tremor, tremor-related disability and quality of life. In my view this study is of high quality. Furthermore, the minimal effect of sham surgery on the 20 patients' tremor, disability and quality of life in this study (Elias WJ 2016) should give the committee confidence that any beneficial placebo effect was small. This information is useful in interpreting the results of the other published case series (Elias WJ 2013, Lipsman N 2013, Chang WS 2015 and Gallay 2016) that involved a total of 51 patients.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
31	20	Consultee 16 NHS Professional Reader and Honorary Consultant in clinical neurology.	**2.1**	3. Medically refractory moderate to severe essential tremor disrupts hand function and produces significant disability and social handicap (reclusiveness). Consequently, these patients seek further treatment for their tremor. However, in my clinical experience, about 50% of these patients do not wish to consider radiofrequency thalamotomy or deep brain stimulation (DBS) because of the approximately 1:10,000 risk of death and 2-3% risk of intracranial haemorrhage inherent in these procedures but are interested in	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee

				considering MRgFUS thalamotomy. Particularly as DBS is associated with numerous problems including: a. Inpatient admission b. Infection or pain around the implanted device c. Hardware failure d. Further surgeries for impulse generator replacement because of battery expiration. e. Complications to MRI protocols and general surgery and dental procedures (bipolar and not monopolar diathermy) because of the implants. f. Considerable medical and nursing time spent checking and reprogramming the stimulators g. Increased travelling time for patients to be reviewed in specialist DBS centres. h. Susceptibility to external electromagnetic fields.	decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
32	21	Consultee 16 NHS Professional Reader and Honorary Consultant in clinical neurology.	**General**	4. One of the potentially major advantages of MRgFUS-surgical treatment of tremor is that the surgeon can move the cursor in 3D-space within the brain in order to target the area(s) that produce optimal tremor control. At each new location a transient lesion can be made and the patient assessed for improved tremor and possible adverse effects before making a lesion permanent. In this regard a thalamotomy is not usually a single lesion but a series of lesions within the circuitry generating tremor. With MRgFUS there is no restriction to the directions of movement. This is different to both radiofrequency thalamotomy and DBS where movement is confined to the electrode path, unless the electrode is removed and reinserted which increases the risk of intra-cranial haemorrhage.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

33	22	Consultee 16 NHS Professional Reader and Honorary Consultant in clinical neurology.	**1**	5. It would appear to me that the short term efficacy of MRgFUS-thalamotomy is clearly established by current publications. Further research is not required to re-establish this fact. However, I agree with the committee that longer term data is highly desirable. This could easily be collected by routine audit of the 1, 5 and ideally 10 year follow-up data, which could be collected in a registry to inform future practice.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
34	23	Consultee 16 NHS Professional Reader and Honorary Consultant in clinical neurology.	**General**	6. At [redacted] NHS Trust, where to date we have treated 14 patients with essential tremor with MRgFUS-thalamotomy, I have asked all of them after surgery to compare their intra-operative experience with that of having a filling at the dentist. Thirteen of 14 patients considered MRgFUS to be preferable. In every case our treated patients could have gone home a few hours after MRgFUS but were kept overnight as an assessment was required, as part of our current trial protocol, the following day.	Thank you for your comment and for sharing your experience of performing this procedure as well as the patients' experience.
35	24	Consultee 16 NHS Professional Reader and Honorary Consultant in clinical neurology.	**General**	7. Although, published data concerns patients with unilateral MRgFUS-thalamotomy I am aware of patients treated in [redacted], Switzerland by Professor [redacted], who have had bilateral MRgFUS surgery for essential tremor. In my view the place of simultaneous or staged bilateral MRgFUS-thalamotomy remains in the	Thank you for your comment on bilateral MRI-guided focused ultrasound thalamotomy.

				research domain and this issue would make a good research project.	
36	25	Consultee 16 NHS Professional Reader and Honorary Consultant in clinical neurology.	**1**	8. Finally, radiofrequency thalamotomy is available to NHS patients but MRgFUS-thalamotomy is not, despite achieving the same objectives without the serious risks involved with the former (see above). Consequently, I recommend to the committee that NICE suggests that MRgFUS-thalamotomy for essential tremor is made available to NHS patients with the proviso that a registry is compiled with 1, 3, 5 and ideally 10 year data to confirm its longevity of benefit. In this regard it would seem that the current proposal in the draft consultation document would put NHS patients with essential tremor at unnecessary risk from radiofrequency thalamotomy as MRgFUS thalamotomy would not be permitted. I would like to thank the committee for their kind consideration of my views. Yours faithfully Dr [redacted] [redacted]	Thank you for your comment. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
4- Comments from company					
37	33	Consultee 18 Company Insightec	**1**	Dear Sir/Madam	Thank you for your comment. The consultee refers to a non peer-reviewed report. The NICE

				Please find attached our formal response to the consultation and a copy of the technical report by Costello referred to in our response document. **ONLY THE EXECUTIVE SUMMARY WAS INCLUDED BECAUSE THE DOCUMENT CONTAINS MORE THAN 10 PAGES** Executive summary We submit that the wording of the proposed guidance on MR-guided focused ultrasound (MRgFUS) thalamotomy for treatment-resistant essential tremor (ET) is flawed and should be revised. We submit that the recommendation that this procedure be performed only in a research setting is not justified considering the quantity and quality of evidence of safety and efficacy available to the committee. The guidance, as drafted, would deny a non-invasive surgical option for the treatment of medication-resistant ET patients, for whom DBS may be unsuitable. The committee does not appear to have taken proper account of the opinion of three of the four specialist advisers that MRgFUS ablation is a variant of an established procedure. We submit that IPAC has not assessed the procedure in the context of current and past standards of care for treating ET. We base this on the following key points that are outlined in more detail in our response:	IP Methods Guide highlights that efficacy outcomes from non peer-reviewed studies or conference abstracts are not normally presented to the Committee, unless they contain important safety data. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.

38	34	Consultee 18 Company Insightec	**3.1**	• MRgFUS treatment is a novel way of performing a thalamotomy. The draft guidance has ignored the literature on thalamotomy in ET, which confirms the long-term effectiveness of the procedure in treating tremor. The long-term outcomes and adverse events of thalamotomy are well understood, as is its place in the treatment of ET.	Thank you for your comment. This guidance is on MRI-guided focused ultrasound thalamotomy and not on radiofrequency thalamotomy. Therefore only the literature relevant to this procedure has been included in the overview.
39	35	Consultee 18 Company Insightec	**General**	MRgFUS represents a more precise and controlled means of performing thalamotomy.	Thank you for your comment. Please refer to comment 38.
40	36	Consultee 18 Company Insightec	**3.1**	• The committee has overlooked three relevant published studies, and has failed to take account of the existing literature on both DBS and thalamotomy. We submit that the available evidence fully justifies guidance permitting these patients to be able to opt for a non-invasive alternative to DBS.	Thank you for your comment and for sending us references of relevant studies. The existing literature on both DBS and thalamotomy falls outside the scope of the guidance. The Huss (2015) reference was retrieved by our original literature search but as a conference abstract only. Therefore it was not originally included in the overview. The full paper has been included in Table 2.

					The Kim (2017) and Zaaroor (2017) papers were published after the overview was prepared. They have been retrieved by our update literature search and have been included in Table 2.
41	37	Consultee 18 Company Insightec	**1**	• MRgFUS has been more rigorously evaluated in its pivotal clinical trial (an RCT with sham control) than other surgical treatment for ET.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
42	38	Consultee 18 Company Insightec	**1**	• Other technologies that might considered to be broadly similar have been the subject of 'special arrangements' or 'normal arrangements' recommendations by IPAC on the basis of an equivalent quantity and quality of evidence.	Thank you for your comment. NICE provides guidance on individual interventional procedures, and not on specific physical principles that apply to individual devices.

					The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
43	39	Consultee 18 Company Insightec	**2.3**	• Compared with DBS, the current alternative available to patients with medication-resistant ET, MRgFUS thalamotomy results in tremor reduction of a similar magnitude and a more favourable adverse event profile (i.e. no serious surgical complications, persistent mild adverse events in minority of patients).	Thank you for your comment. The IP programme does not assess the efficacy and safety of comparator interventions. There was no study comparing MRI-guided focused ultrasound thalamotomy to DBS or to radiofrequency (RF) thalamotomy in the original literature search done for this procedure. This underpinned the recommendations for use in the context of research in the first place. In the update literature search undertaken during the first round of consultation, one study

					retrospectively comparing MRI-guided focused ultrasound thalamotomy against RF or DBS was retrieved (Chang 2017). It has been added to the overview. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for clinical governance, consent and audit or research.
44	40	Consultee 18 Company Insightec	**3.1**	• Two-year data from the RCT have become available. The manuscript has been submitted for publication and acceptance is expected shortly. We submit that it would be perverse for guidance to be published prior to publication of these data, which confirm the longer-term effectiveness of the procedure, consistent with the experience of thalamotomy performed by other means.	Thank you for your comment. The 2-year follow-up of the Elias (2016) study was reviewed by and presented to the committee in part 2 during the IPAC 1 meeting as it was sent to the IP team as academic-in-confidence information.

					Papers that have been accepted for publication can only be included in the overview when the publication date is before the guidance is published. The Chang (2017) paper was published before the second round of consultation and has been included in Table 2.
45	41	Consultee 18 Company Insightec	**1**	As a highly specialised treatment offered to a small number of patients evaluated by an MDT in a tertiary centre, the treatment will be subject to ongoing detailed scrutiny by both commissioners and providers.	Thank you for your comment.
46	42	Consultee 18 Company Insightec	**1**	• We submit that the evidence available to the committee fully justifies a 'special arrangements' recommendation.	Thank you for your comment. The consultee disagrees with main recommendation. The committee considered the comments received during the first round of consultation alongside the new evidence available. As a consequence, the committee decided to change its recommendations from research only to special arrangements for

					clinical governance, consent and audit or research.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, 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."

CONSULTATION 2

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Company INSIGHTEC	**General**	InSightec welcomes the 'special arrangements' recommendation in the redrafted IPG and the references to all the currently available evidence now included in the overview.	Thank you for your comment. The consultee agrees with main recommendations.
2	Consultee 1 Company INSIGHTEC	**1.2**	The second bullet point in §1.2 currently reads: 'Ensure that patients and their carers understand that this procedure can only treat tremor on 1 side of the body, and that the impact of this on the functional ability and quality of life of patients with bilateral disease is uncertain. Explain all alternative treatment options to patients, including those that can treat tremor on both sides of the body. Provide patients with clear written information…' We agree with the committee that patients should be fully informed before consenting to a procedure. However, to the best of our knowledge, it is unusual for IP guidance to direct treating clinicians as to the detail of seeking informed consent, which we submit should be left to them. In addition, we submit that there is an implication that because this	Thank you for your comment. The second bullet point in section 1.2 has been changed to: ''Ensure that patients and their carers understand that this procedure is only done to treat tremor on 1 side of the body, and that the effect of this on the functional ability and quality of life of patients with bilateral disease is uncertain. Patients should be informed about alternative treatments, including those that can be done bilaterally. Provide patients with clear written information to support shared decision-making. In addition, the use of NICE's information for the public is recommended.''

			treatment is (like other methods of thalamotomy to date) not performed bilaterally, it is only suitable for treating unilateral disease. We propose the following wording: 'Ensure that patients and their carers understand that this procedure is only performed unilaterally at present, although studies have been proposed for performing the procedure bilaterally. Ensure that the patient understand that the effect of any unilateral treatment for essential tremor is principally on the contralateral side of the body, but that even though essential tremor is typically a bilateral disease, the majority of treatments currently offered are unilateral.' If the committee considers it important to provide additional detail on seeking informed consent, then we would propose the alternative wording 'Ensure that patients and their carers understand that this procedure can only be done on 1 side of the brain, and that the impact of this on the functional ability and quality of life of patients with bilateral disease is uncertain. Explain all alternative unilateral and bilateral treatment options to patients. Provide patients with clear written information…'.	

			In support of this proposed change in wording, we draw the committee's attention to the following: 1. Research studies are planned on the safety and efficacy of bilateral tcMRgFUS thalamotomy. Bilateral conventional thalamotomy is no longer performed because the disadvantages were considered to outweigh the advantages. However, this may reflect the imprecision of target lesion ablation, to which we have drawn the committee's attention in our consultation comments in November 2017. We recognise that the guidance relates to unilateral procedures and anticipate that the committee would wish to review the procedure were it to be proposed for bilateral ablation. However, it is not true that the procedure can only treat tremor on one side, only that guidance (and clinical opinion) do not currently mandate its use bilaterally. 2. We submit that the wording '…this procedure can only treat tremor on 1 side of the body' is misleading and argue that the evidence is that unilateral treatment can effectively treat ET in many cases, even though it is a bilateral disease. We draw the committee's attention to the study by Huss et al. (1) (included in Table 2 of	

			the overview) that found no difference in the degree of improvement in upper extremity tremor score, disability, or overall quality of life between bilateral DBS and either unilateral DBS or unilateral tcMRgFUS. Unilateral treatment improves quality of life sufficiently to allow many patients to manage activities of daily living and continue with their occupation. A study by Peng-Chen et al (2) showed that unilateral thalamic DBS in ET demonstrated long-term ipsilateral effect: the authors concluded that unilateral thalamic DBS in ET demonstrates significant long-term benefits for ipsilateral arm tremors and can be offered to higher risk and to select patients. Ondo et al (3) found that unilateral thalamic DBS is a safe and effective treatment for ET. Nazzaro et al (4) evaluated unilateral DBS of the VIM nucleus for ET and concluded that it significantly reduced tremor and improved activities of daily living score for up to 12 years after surgery, as measured by the Fahn-Tolosa-Marin Tremor Rating Scale. Ondo et al compared unilateral and bilateral DBS: the authors state that unilateral DBS is accepted as an effective treatment for ET but that few data were available comparing this with bilateral treatment. They concluded that bilateral DBS should be considered when unilateral	

			DBS does not offer satisfactory benefit especially in patients with ET [our emphasis]. 3. With respect to the words '…the impact of this on the functional ability and quality of life of patients with bilateral disease is uncertain…', while we believe that this is true, we submit that there is an implication that this is uniquely true of this procedure. We submit, that the wording should be deleted or, if it remains, should be amended to make it clear that this is as true of other unilateral procedures performed for ET as it is of tcMRgFUS, for example 'this impact of this, and any other unilateral treatment, on the functional ability and quality of life of patients with bilateral disease is uncertain…' 4. In framing the wording §1.2 of the guidance, we submit that the committee should take note of the fact that, as discussed in Part I of the IPAC meeting on 14 December (see also Harrison's Principles of Internal Medicine), ET is typically a bilateral disease. Despite this, and contrary to the implication of the current wording of §1.2, the significant majority of treatments (largely DBS) are unilateral and not bilateral. For example, a 2013 literature review of DBS for ET (5) listed 16 studies assessing the effectiveness of this procedure in the	

			treatment of ET (4, 6-20), reporting results in a total patient population of 471 subjects. In this population, 390/471 (82.8%) had unilateral DBS and 81/471 (17.2%) bilateral DBS. These data support the points above that it is appropriate to use unilateral procedures despite ET being a bilateral disease.	
3	Consultee 1 Company INSIGHTEC	**2.5**	§2.5: We suggest, for reasons discussed in some detail in relation to the wording of §1.2, that the wording 'However, unlike deep brain stimulation, it can only be done on 1 side', while true, is misleading in its implications and is not within the remit of IP guidance. The committee has been very clear in the past that IP guidance does not compare one procedure with another, and in our view, this wording clearly compares tcMRgFUS to DBS. In any case, performing tcMRgFUS (or unilateral DBS) does not preclude performing DBS on the contralateral side at a later date, if required, such that the current wording does not fully explain the full options available to patients and should either be deleted or revised to reflect this accurately.	Thank you for your comment. Section 2.5 has been changed as follows: *'' The potential benefits of unilateral MRI-guided focused ultrasound thalamotomy are that it: is less invasive than the other existing procedures; results in a faster recovery time; and allows for testing of the effects of sub-lethal doses before ablation. However, it is only done on 1 side.''*
4	Consultee 1 Company INSIGHTEC	**3.6**	§3.6: 'This procedure is an alternative to more invasive methods of lesioning the thalamus and the lesion produced should be considered permanent'. The lesion produced by tcMRgFUS thalamotomy is always permanent, and as such, we suggest that the wording is changed to the following: 'This	Thank you for your comment. Section 3.6 of the guidance has been changed as follows: '' This procedure is an alternative to more invasive methods used

			procedure is an alternative to more invasive methods of lesioning the thalamus and the lesion produced is permanent'.	to lesion the thalamus. The lesion produced is permanent.''
5	Consultee 1 Company INSIGHTEC	**References**	1. Huss DS, Dallapiazza RF, Shah BB, Harrison MB, Diamond J, Elias WJ. Functional assessment and quality of life in essential tremor with bilateral or unilateral DBS and focused ultrasound thalamotomy. Movement disorders : official journal of the Movement Disorder Society. 2015;30(14):1937-43. 2. Peng-Chen Z, Morishita T, Vaillancourt D, Favilla C, Foote KD, Okun MS, et al. Unilateral thalamic deep brain stimulation in essential tremor demonstrates long-term ipsilateral effects. Parkinsonism & related disorders. 2013;19(12):1113-7. 3. Ondo W, Jankovic J, Schwartz K, Almaguer M, Simpson RK. Unilateral thalamic deep brain stimulation for refractory essential tremor and Parkinson's disease tremor. Neurology. 1998;51(4):1063-9. 4. Nazzaro JM, Pahwa R, Lyons KE. Long-term benefits in quality of life after unilateral thalamic deep brain stimulation for essential tremor. Journal of Neurosurgery. 2012;117(1):156-61. 5. Chopra A, Klassen BT, Stead M. Current clinical application of deep-brain stimulation for essential tremor.	Thank you for your comment and for providing this list of references. The Huss (2015) paper is included in Table 2 of the overview. The other papers are all about deep brain stimulation.

			Neuropsychiatric disease and treatment. 2013;9:1859-65. 6. Carpenter MA, Pahwa R, Miyawaki KL, Wilkinson SB, Searl JP, Koller WC. Reduction in voice tremor under thalamic stimulation. Neurology. 1998;50(3):796-8. 7. Lyons KE, Pahwa R, Busenbark KL, Troster AI, Wilkinson S, Koller WC. Improvements in daily functioning after deep brain stimulation of the thalamus for intractable tremor. Movement Disorders. 1998;13(4):690-2. 8. Koller WC, Lyons KE, Wilkinson SB, Pahwa R. Efficacy of unilateral deep brain stimulation of the VIM nucleus of the thalamus for essential head tremor. Movement disorders : official journal of the Movement Disorder Society. 1999;14(5):847-50. 9. Obwegeser AA, Uitti RJ, Turk MF, Strongosky AJ, Wharen RE. Thalamic stimulation for the treatment of midline tremors in essential tremor patients. Neurology. 2000;54(12):2342-4. 10. Koller WC, Lyons KE, Wilkinson SB, Troster AI, Pahwa R. Long-term safety and efficacy of unilateral deep brain stimulation of the thalamus in essential tremor. Movement Disorders. 2001;16(3):464-8. 11. Hariz GM, Lindberg M, Bergenheim AT. Impact of thalamic deep brain stimulation on disability and health-related quality of life in	

			patients with essential tremor. J Neurol Neurosurg Psychiatry. 2002;72(1):47-52. 12. Sydow O, Thobois S, Alesch F, Speelman JD. Multicentre European study of thalamic stimulation in essential tremor: a six year follow up. Journal of Neurology, Neurosurgery & Psychiatry. 2003;74(10):1387-91. 13. Rehncrona S, Johnels B, Widner H, Tornqvist AL, Hariz M, Sydow O. Long-term efficacy of thalamic deep brain stimulation for tremor: double-blind assessments. Movement Disorders. 2003;18(2):163-70. 14. Putzke JD, Uitti RJ, Obwegeser AA, Wszolek ZK, Wharen RE. Bilateral thalamic deep brain stimulation: midline tremor control. Journal of Neurology, Neurosurgery & Psychiatry. 2005;76(5):684-90. 15. Lee JY, Kondziolka D. Thalamic deep brain stimulation for management of essential tremor. Journal of Neurosurgery. 2005;103(3):400-3. 16. Pahwa R, Lyons KE, Wilkinson SB, Simpson RK, Jr., Ondo WG, Tarsy D, et al. Long-term evaluation of deep brain stimulation of the thalamus. J Neurosurg. 2006;104(4):506-12. 17. Blomstedt P, Hariz GM, Hariz MI, Koskinen LO. Thalamic deep brain stimulation in the treatment of essential tremor: a long-	

			term follow-up. British journal of neurosurgery. 2007;21(5):504-9. 18. Pilitsis JG, Metman LV, Toleikis JR, Hughes LE, Sani SB, Bakay RA. Factors involved in long-term efficacy of deep brain stimulation of the thalamus for essential tremor. Journal of Neurosurgery. 2008;109(4):640-6. 19. Zhang K, Bhatia S, Oh MY, Cohen D, Angle C, Whiting D. Long-term results of thalamic deep brain stimulation for essential tremor. J Neurosurg. 2010;112(6):1271-6. 20. de Oliveira TH, Ginsberg MR, Cooper S, Nowacki A, Rezai A, Deogaonkar M, et al. Long-term effects of deep brain stimulation for essential tremor with subjective and objective quantification via mailed-in questionnaires. Stereotact Funct Neurosurg. 2012;90(6):394-400.	
6	Consultee 2 Patient	**General**	I am commenting as an Essential Tremor (ET) sufferer. As an ET sufferer aged 28 years, results from trials of this treatment provide hope for the future. ET, even when mild, has a significant impact on everyday life and quality of life in general. Since this treatment appears to be effective in reducing the worst effects of ET on the hands, it will have a big impact in raising	Thank you for your comment. The committee very much welcomes hearing from patients who have the condition that this procedure intended to treat. The committee considered your experience and views in their deliberations.

			the quality of life of ET patients, and will have an economic benefit by reducing the disabling effects of the disorder and keeping patients in work and off benefits for longer. Given the prevalence of ET (an estimated 1 million sufferers in the UK) and the treatment's application to other, more severe movement disorders, it seems prudent to make focused ultrasound available as a treatment option for neurologists and medical specialists as quickly as possible. Thanks.	

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