

Consultation Report

Topic details

Title of policy or policy statement:	Transcranial magnetic resonance guided focused ultrasound thalamotomy for treatment of medication-refractory essential tremor (adults)
Programme of Care:	Trauma
Clinical Reference Group:	Neurosurgery
URN:	1904

1. Summary

This report summarises the feedback we received from public consultation during the development of this policy proposition, and how this feedback has been considered. Public consultation was open for 30 days on the NHS England website, and generated 36 responses from clinicians, patients, patient advocacy groups, relatives of patients, members of parliament and patient research ambassadors. Most respondents were in support of the policy proposition and the impact assessment. Some issues were raised, including inclusion/exclusion criteria and numbers of centres providing the proposed treatment which are further discussed in section 5.

2. Background

Essential tremor (ET) is the most common movement disorder. It causes parts of the body to move in an uncontrolled and repetitive manner, most commonly affecting the arms and hands. The cause of ET is not known, although approximately 50% of people affected have a family history of the condition. ET can have a profound impact on people by impacting on their quality of life, social life and employment.

Drug treatment is the first line therapy for ET. Drug treatment will stop working for between a quarter and half of patients and this is known as medication-refractory ET. Surgical intervention in ET is offered to patients whose symptoms are significant and severe and have not responded to medication. Deep brain stimulation (DBS) is a surgical procedure that is currently available for patients with ET. Electrodes are inserted into a specific area of the brain that is responsible for modifying movements. DBS is effective at improving people's symptoms, but the benefits of DBS tend to diminish over time. This is an invasive procedure and the main risks are bleeding within the skull, stroke and infection. Surgical thalamotomy is another procedure that is available for patients with ET. This involves the surgical destruction of the specific area of the brain responsible for modifying movements. Although surgical thalamotomy is still performed today, it is used less than DBS.

This policy proposition considers whether transcranial magnetic resonance guided focused ultrasound (TcMRgFUS) thalamotomy should be made available for patients with medication-refractory essential tremor that are not suitable for DBS. This procedure uses focused ultrasound waves generated externally to the body that are directed to, and alter the function of, the area of the brain responsible for modifying movements to improve tremor. This is done under magnetic resonance imaging (MRI) guidance. This is a non-invasive procedure that does not require the introduction or maintenance of hardware into the brain, avoiding the maintenance of

the inserted hardware (i.e. battery replacement) and minimising the risk of bleeding within the skull, stroke and infection. This can be done as a day-case procedure.

This policy proposition has been written for the proposed treatment to be made routinely commissioned and has been subject to stakeholder testing and public consultation in line with standard methods.

3. Publication of consultation

The policy was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 12th March to the 12th April 2020. Consultation comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the policy might be recommended.

Respondents were asked the following questions:

- Do you support the proposal for TcMRgFUS to be available for medication-refractory essential tremor through routine commissioning based on the evidence review and within the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered in the evidence review?
- The impact assessment has been completed to identify the impact of moving from current pathways of care to the one(s) proposed in the draft policy proposition taking into account the anticipated patient numbers, treatment, cost of the treatment and capacity within providers, do you think that the impact assessment fairly reflects the likely patient numbers, treatment, cost of treatment and the capacity within providers? If not, what do you think is inaccurate?
- The patient pathway describes the patient's journey through the health system to receive current treatment for this condition. Do you think that the policy proposition accurately describes the current patient pathway that patients experience? If not, what is different?
- Please provide any comments that you may have about the potential positive and negative impacts on equality and health inequalities which might arise as a result of the proposed policy that have been described?
- Are there any changes or additions you think need to be made to this document, and why?

4. Results of consultation

There were thirty-six respondents to the public consultation. The breakdown of respondents to the consultation are depicted in [Figure 1](#).

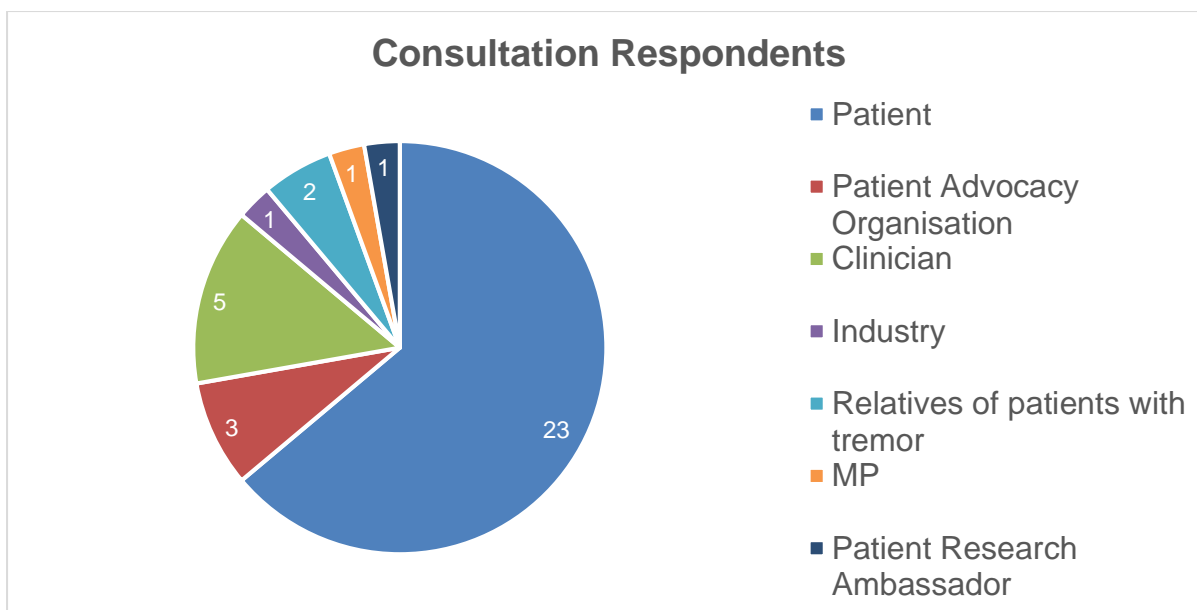


Figure 1: consultation respondents by type.

5. How have consultation responses been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Trauma Programme of Care (PoC). The following themes were raised during engagement:

Keys themes in feedback	NHS England response
Relevant evidence	
None provided	Noted
Impact assessment	
More than 2 centres would widen access.	A large capital investment is required to set up more centres. The proposal is considered to be financially viable at this time and would help to treat the numbers expected as set out in the policy.
More than 150 patients may require this treatment in the future.	If more than 150 patients are eligible for the treatment in the future, the policy will be re-considered at a prioritisation round with a new impact assessment to consider increasing this.
Current patient pathway	
Make clearer that TcMRgFUS is only available to treat unilateral tremor.	TcMRgFUS can be used to treat tremor on one side, regardless of whether the person has unilateral or bilateral tremor. Clarification made within the patient pathway section.
Potential impact on equality and health inequalities	
The proposition would impact positively on availability of treatment of essential tremor.	Noted

Travelling is difficult for people with essential tremor, more than 2 centres across the country would reduce the requirement for travel and improve access.	It is noted that patients with severe, medication-refractory essential tremor can find it difficult or impossible to travel long distances. The proposal for two centres is considered financially viable at this time and would be able to treat the expected numbers as set out in the policy.
This treatment should be available to all patients with essential tremor, not just those that meet the criteria.	The inclusion criteria have been implemented based on currently available evidence and consensus with specialist clinicians on the policy working group.
Changes/addition to policy	
None required	Noted
In regard to the paragraph describing deep brain stimulation. It should be reiterated that DBS is a well-established, clinically effective intervention for medication-refractory ET.	Noted. Amendments made.

6. Has anything been changed in the policy as a result of the consultation?

Minor amendments and clarifications have been made to the policy proposition as a result of consultation. Minor amendments and clarifications were made in response to stakeholder testing.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

The remaining concerns all surround the difficulty that people with severe essential tremor can have travelling long distances. There are concerns that 2 providers of TcMRgFUS across the country would mean that some people that were eligible for this treatment would not be able to get it due to inability to travel.