

Citizen Participation and Public Petitions Committee

3rd Meeting, 2021 (Session 6), Wednesday 8
September 2021

PE1723: Essential tremor treatment in Scotland

Note by the Clerk

PE1723: Lodged 4 July 2019

Petitioner Mary Ramsay

Petition summary Calling on the Scottish Parliament to urge the Scottish Government to raise awareness of essential tremor and to support the introduction and use of a focus ultrasound scanner for treating people in Scotland who have this condition.

Webpage <https://petitions.parliament.scot/petitions/PE1723>

Introduction

1. The Session 5 Public Petitions Committee (PPC) last considered this petition at its meeting on [10 March 2021](#). At that meeting, the Committee agreed to continue this petition and include it in its legacy paper for its Session 6 successor committee, along with a suggestion to seek an update from the Cabinet Secretary for Health and Sport on the Scottish Government's plans to make an application to the National Specialist Services Committee for a MRgFUS service.
2. A summary of past consideration of the petition and suggested areas for future investigation is provided for the Committee's consideration.

Background

3. According to the [National Institute for Health and Care Excellence \(NICE\)](#)—

'Essential tremor is the most common cause of disabling tremor and is distinct from Parkinson's disease. It typically affects the arms and hands, although it may also involve the head, jaw, tongue and legs. The cause is not known but many patients have a family history of the condition. At first, the tremor may not be present all the time. However, it gradually worsens. Purposeful movement, stress, tiredness, hunger, heightened emotions or extremes in temperature make it worse.'

4. Drug treatment is the first line therapy for Essential Tremor (ET); however, this is a condition which does not respond to drug treatment in many patients. 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.
5. Deep Brain stimulation (DBS) is the surgical procedure that is currently commissioned for patients with ET. Electrodes are inserted into a specific area of the brain that is responsible for modifying movements. In ET, the area of the brain targeted to improve tremor is the ventral. 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.
6. Magnetic Resonance-guided focused ultrasound (MRgFUS) is the treatment the petitioner is hoping will be provided in Scotland. This is a relatively new treatment for ET, with a trial begun in 2016. MRgFUS uses an MRI to guide powerful focused ultrasound to a very small point in the body. At that point, the ultrasound causes molecules to vibrate extremely quickly, creating an intense local heat. That heat can destroy tissue. MR-guided focused ultrasound allows a very specific focal point to be targeted, ensuring that only this targeted tissue is affected.
7. This non-invasive procedure is used to treat a number of conditions, such as fibroids in the womb. But it has proved much more difficult to find a way to use this technology in the brain'. The procedure has been the subject of a trial at the Imperial College Healthcare NHS Trust since 2016 following a grant of £1 million to purchase the equipment. On 6 June 2019, the Trust put out a [press release](#) about the study, where patients received treatment to both sides of the brain, although [NICE has approved it as a treatment](#) on one side only since 2018. The full results of the study will be published later this year and the Trust is working with NHS England to make the treatment available on the NHS. The company [INSIGHTEC®](#) produced the technology and equipment for the procedure. The company [cites a number of treatment centres and approvals for the technology](#) (including EU CE mark) for Essential Tremor.

Scottish Government submissions

8. In its initial submission of [3 December 2019](#), the Scottish Government notes it is committed to making sure all people living with neurological conditions in Scotland are able to access the best possible care and support, and benefit

from healthcare services that are safe, effective and put people at the centre of their care.

9. It advises that it worked with the neurological community to develop Scotland's first ever National Action Plan on Neurological Conditions. The submission states:

“The vision is that everyone with a neurological condition will be able to access the care and support they need to live well, on their own terms. These aims include improving the co-ordination of services and ensuring high standards of person-centred care”.
10. [The Neurological Care and Support in Scotland: A Framework for Action 2020 – 2025](#) was published on 18 December 2019. The Scottish Government noted it aims to fulfil its vision by working nationally, regionally and locally with relevant organisations.
11. In June 2018 the National Institute for Health and Care Excellence (NICE) published guidelines on the use of unilateral MRI-guided focussed ultrasound thalamotomy for treatment-resistant essential tremor. This concludes that while clinical evidence does not raise safety concerns, current evidence of efficacy is limited. Therefore, evidence of patient benefit is too limited for the NHS to currently adopt MRI guided ultrasound technology for treatment of essential tremor.
12. The Scottish Government notes that the National Specialist Services Committee (NSSC) met on 4 December 2018 to consider a stage one application for specialist treatment of patients with ET using MRgFUS. The committee was unable to endorse the application for funding as a nationally designated service. It was highlighted that NICE guidance is ‘permissive’ and whilst there is some evidence for use of MRgFUS in essential tremor, there is a clear statement that research is needed into its application for Parkinson’s Disease and MS tremor.
13. NSSC was clear that should the evidence base be further developed and MRgFUS be recognised as a safe and effective intervention for treatment of tremor the committee would be willing to consider a re-application in future
14. In its submission of [25 February 2020](#), the Scottish Government advised that NHS England was developing a national clinical commissioning policy for MRgFUS for essential tremor. However, no decision had been taken (including on eligibility and reimbursement) and the treatment is not routinely available until a further evidence base is gathered through the work of the Imperial College Healthcare NHS Trust London.
15. The submission notes NHS Scotland National Services Division are continuing to engage with both clinicians in Dundee and with commissioning colleagues in England to assess how this treatment might be made available to Scottish patients should it be proven effective with the required evidence base.

16. On [16 December 2020](#) the PPC took evidence from Professor Dipankar Nandi, Consultant Neurosurgeon & Head of Department, Charing Cross Hospital & St Mary's Hospital, and Professor, Imperial College London.
17. Professor Nandi advised only one hospital in England currently carries out MRgFUS. However he noted that the “treatment has been around in the world for six or seven years and the number of centres keeps growing. When we started four years ago, we were the eighth centre in Europe. Now there are about a dozen. Worldwide, there are about 30 to 35 centres, so it is not very common. Unfortunately, we are only one in the United Kingdom, so far”.
18. Professor Nandi confirmed NHS England agreed a clinical commissioning policy to provide the procedure for up to 150 patients a year and is recommending that it is funded as an in-year service development in November 2020.
19. The PPC raised the issue of NICE guidelines with Professor Nandi who advised that, although the clinical evidence did not raise safety concerns, current evidence of benefits was limited, so evidence of patient benefit was too limited for the NHS. Professor Nandi stated:

“We will never have the numbers to establish the case at the outset, but it is a moving field. As I suggested, the provenance and the scientific literature proofs are all there for the actual procedure—the act of making a precise lesion deep in the brain, in that part of the thalamus. The literature runs into hundreds of thousands of cases over the decades. Focused ultrasound has only made that a whole lot safer to do, because it does not involve incisions or putting anything inside the brain”.
20. When asked whether further evidence is required on the safety and efficacy of the treatment, Professor Nandi advised:

“I can confidently and comfortably state that that ship has sailed. The treatment got Food and Drug Administration approval five years ago, and it has Council of Europe approval. Clinically, in terms of the safety profile, it is a lot safer than the current gold standard of treatment, which is deep brain stimulation.”
21. Following that session, the PPC wrote to the Cabinet Secretary for Health and Sport asking for confirmation of whether the Scottish Government’s decision on funding MRgFUS would be reviewed following NHS England’s decision to fund the procedure.
22. The then Cabinet Secretary’s submission of [11 February 2021](#) confirms that NHS Scotland National Services Division are continuing to engage with clinicians in Dundee and commissioning colleagues in England to assess how this treatment might be made available to Scottish patients. However, in light of Covid-19, new applications through National Specialist Services Committee (NSSC) are paused.

23. The submission noted that when the original application for designation for a MRgFUS service was put to NSSC, it advised there was a lack of evidence on the proven effectiveness of the treatment and further research was required in order to approve the application for stage 2.
24. The then Cabinet Secretary stated:
- “I appreciate further evidence has emerged since this time and forms part of NHS England’s national clinical position. However it was noted at that point that providing a small service is not wholly dependent on National Designation through the National Specialist Services Committee”.
25. The submission advises that clinicians in Dundee have charitable funding in place to begin initially treating one patient on a trial basis for 6 months. The then Cabinet Secretary highlighted that this will, along with the evidence from the NHS England clinical position “contribute to further advancing the evidence base on MRgFUS effectiveness for treating essential tremor and all of this will be looked at as part of a fresh application to NSSC when it is possible”.

University of Dundee fundraising

26. The University of Dundee undertook a fundraising campaign to acquire MRgFUS equipment and pay for its installation. The University, in its submission of [14 October 2019](#), advised that if it was successful in achieving this goal it would expect initially to be able to provide Scottish patients with access to treatments as part of clinical research trials.
27. The University of Dundee noted:
- “Going forward, as the evidence for the efficacy of this treatment grows we would expect a significant demand for MRgFUS as part of routine clinical NHS practice. We would therefore welcome any support from the Scottish Government in the view of the anticipated costs we expect will be necessary to meet the needs of these patients”.
28. In its submission of [18 December 2020](#) the University advised that it has achieved its fundraising target for acquiring the MRgFUS equipment. It is hopeful the system will be ready to treat the first patients in Scotland in 2021. The exact timeframe for this is subject to necessary installation, training and clinical governance approvals.
29. The submission also highlights NHS England published a comprehensive review of MRgFUS for treatment of Essential Tremor in November 2020 which resulted in the approval of this treatment as part of routine NHS care in England from April 2021.
30. The University of Dundee stated:
- “We would welcome, as would patients in Scotland with Essential Tremor, clarification from NHS Scotland as to whether or not they will adopt the same policy in order to allow equity of access. Equally, in the event that they do not

wish to align their position to that of NHS England, the reasons for this need to be justified, as it is likely that this will lead to delays in accessing this treatment for Scottish patients”.

NICE submission

31. The NICE submission of [14 October 2020](#) advises it is not for it to take a view on what actions the Scottish Parliament or Government should take in relation to awareness and treatment of this condition as that is a matter for them.
32. The submission states NICE interventional procedures guidance (IPG617) on unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor says: The evidence on the safety of unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor raises no major safety concerns. However, current evidence on its efficacy is limited in quantity. Therefore, this procedure should not be used unless there are special arrangements for clinical governance, consent, and audit or research.
33. The independent interventional procedures advisory committee (IPAC) IPAC advises NICE on the formulation of guidance on the safety and efficacy of interventional procedures. The submission notes IPAC identified that “further research, which could include randomised controlled trials, should address patient selection, report on functional improvement and quality of life, and provide long-term follow-up data.”
34. NICE highlights that the guidance represents its views but is not mandatory and notes decisions to fund procedures are made at a local NHS level and usually on a case-by-case basis.
35. While NICE’s interventional procedures guidance (IPG) applies in Scotland, any introduction would be a local decision and should be in line with NICE recommendations on special arrangements.

Petitioner submissions

36. The petitioner advised her tremors, and the lack of understanding surrounding them, has impacted on her entire life. People with essential tremor deserve better, and there is a better option.
37. In her submission of [8 April 2020](#) the petitioner raises concerns that the longer a decision is delayed to fund MRgFUS in Scotland the harder it becomes for fundraisers, as the cost of the equipment and initial setting up continues to increase. The petitioner advises “I believe the extra funding needed now is an added £100,000 which, in the current climate, is very hard to achieve. And that figure will be increasing day by day.”
38. The petitioner does not believe there is a need for further research and evidence into the effectiveness of MRgFUS before the Scottish Government backs it, noting this treatment for Essential Tremor is currently available on Medicare in the USA, the NHS in Japan, and in other countries around Europe.

39. The submission advises NHS England recently published its draft commissioning policy on the use of transcranial MRgFUS for the treatment of medication refractory Essential Tremor. They carried out public consultation in the form of an online survey on its draft commissioning policy, prior to making a final commissioning policy this summer. The consultation period provided an opportunity for individuals and groups to show their support for ensuring patients can access MRgFUS on the NHS.
40. NHS England currently offer this treatment in one hospital, St Mary's in London, however NHS England has a proposal to commission the treatment from a second provider. The petitioner notes there is a campaign for it to consider three or four centres to make the treatment reasonably accessible across the whole of England.
41. The petitioner believes "while England is proceeding a pace with providing this treatment, unfortunately Scotland is falling behind as the costs for bringing it to Scotland are increasing."

Action

42. The Committee is invited to consider what action it wishes to take.

Clerk to the Committee

Annexe

The following submissions are circulated in connection with consideration of the petition at this meeting-

- [PE1723/L: NHS Tayside submission of 18 December 2020 \(9KB pdf\)](#)
- [PE1723/M: Cabinet Secretary for Health and Sport submission of 11 February 2021 \(91KB pdf\)](#)

The Scottish Parliament launched a new website at the end of Session 5.

All written submissions received on the petition before May 2021 can be viewed on the petition on the [archive webpage](#). Any written submissions received on the petition after May 2021 can be viewed on its [new webpage](#).