

MRI Guided Focussed Ultrasound Stage 1 Specialist Service: Outline Proposal

1. Description of service one side of the

MRI-guided focused ultrasound (MRgFUS) is used to create small lesions within the Thalamus (brain tissue) to treat Essential Tremor. MRgFUS has recently gained NICE approval for unilateral treatment of patients with Essential Tremor, the approval comes with a recommendation that the patient should be advised of alternative interventions that offer bilateral treatment, and further that the intervention is delivered under specific local clinical governance oversight. The applicant highlights that approval of the application to treat Essential Tremor will allow the University of Dundee to progress work on the management of Parkinson's disease in a research setting.

2. Provider & Location

NHS Tayside - National Centre for Neuro MRgFUS, Ninewells Hospital, Dundee (in partnership with the University of Dundee). All clinical treatment will be offered under the governance arrangements of NHS Tayside.

3. Assessed Needs

Whilst the number of patients with essential tremor is high (~20 000) only 1:5 will seek treatment and of those only a small proportion will wish to proceed to unilateral MRgFUS. The only equivalent service in UK (St Mary's Hospital London) has a substantial waiting list for MRgFUS. It is suggested that the Scottish centre would be able to deliver 2 treatments / day on the one day / week that MRgFUS would be available for NHS use.

4. Level of evidence to support the proposal

NICE has published interim guidance supporting the technology and its use to provide unilateral treatment – with caveat that all patients be advised of other treatments that offer a bilateral intervention; and that any intervention is done under specific governance arrangements.

5. Level of external support for proposal

The proposer has discussed the intervention with the MSN for neurosurgery and informal feedback suggests the proposal gained support with caveat that the pathway is aligned to the movement disorder clinic in NHS GG&C which in turn is aligned to the DBS surgical service delivered in Glasgow.

There is evidence of strong support from 3rd sector representing patients with Essential Tremor, and from the MSP who chairs their group who has already sponsored a debate in Scottish Parliament.

Application to CSO for funding was declined as NICE have already advised it is a recognised intervention (for Essential Tremor) even though additional research is needed to demonstrate its efficacy in Parkinson's Disease and tremor associated with Multiple Sclerosis.

6. NSD Evaluation of proposal

• Strengths of proposal

The proposal seeks to deliver an evidence based intervention in Scotland to a group of patients who have a condition with limited treatment choice at present. Current medical therapies are limited in benefit and only the most severely affected patients will be eligible for assessment for DBS. Essential Tremor is not a condition that currently benefits from a curative intervention – yet

it is a condition with significant impact on the activities of daily living. The proposed intervention would offer hope for those with Essential Tremor – even if only one side can be treated. The University of Dundee already has in place the Magnetic Resonance Imaging equipment needed to allow targeting of the MRgFUS beam and has significant expertise in its use.

- **Opportunities afforded by proposal**

NHS Scotland would be seen as at the leading edge of use of a new technology that appears to offer an intracranial treatment that until now a traditional surgical or radiotherapy intervention would have been assessed as too high a risk.

Implementation of the service would move a small number of patients from the waiting list for DBS – albeit the full potential for this will not be realised until the evidence base for use in Parkinson's Disease is proven.

The introduction of the MRgFUS device would allow University of Dundee to lead on research into other treatments for movement disorder related including Parkinson's Disease and Multiple Sclerosis.

- **Weaknesses identified with proposal as stands**

The MRgFUS device has not been purchased and whilst an outline business case for running the service has been considered there is a capital challenge to be overcome in acquiring the machine. UoD has committed funds against a reduced cost agreed with the manufacturer (which intends to offer initial funding for the running costs on basis of being able to access data on outcomes). NHS Scotland is being asked to fund 50% of the cost. If application were to proceed consideration would be needed on whether NHS Tayside or another body would fund the initial capital purchase and funding recovered over the first 5 years running as a revenue payback.

The MSN have advised the importance of aligning this programme clinically with the MSN for neurosurgery movement disorder clinic provided by NHS GG&C

Commitment to 4 days usage of the MRgFUS equipment in a programme of research led by University of Dundee.

- **Threats relating to proposal**

Set up cost – the capital ask of 50% of £1.2m – exceeds most current capital plans within the NHS. Political concern if the proposal is not taken forward – a high level of patient / user expectation has been raised in parliamentary debate and ongoing MSP level interest.

7. Issues for Discussion

NPPPRG is asked to review Stage 1 proposal and decide whether there is sufficient basis to proceed to stage 2

**NPPPRG Secretariat
November 2018**