

# Statement on Neurosurgery for Mental Disorder (NMD), also known as Psychiatric Neurosurgery

Position statement CERT 05/17

Approved by the Royal College of Psychiatrists, Committee on ECT and Related Treatments: February 2017

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#### INTRODUCTION

The overwhelming majority of patients affected by psychiatric disorders can experience significant benefit from the broad range of available pharmacological, psychological and other interventions. However, there are patients who fail to experience significant, or sustained, benefit despite the optimised delivery of such therapies. The evidence base to support the use of almost all interventions in such clinical circumstances is effectively non-existent, with the notable exception of neurosurgical therapies.

There is increasing interest and activity worldwide in the evaluation of the efficacy and safety of neurosurgical therapies for a range of psychiatric disorders<sup>1</sup>. The Royal College of Psychiatrists considers most of this activity to represent *research* and not to represent *'established care'*. The College view on such research is consistent with the principles espoused in other position statements - PS01/2011 *Research Priorities for Psychiatry*<sup>2</sup> and PS02/2011 *Ethics of Psychiatric Research*<sup>3</sup>.

The College position is that, for carefully selected patients, with difficulties in specific symptom domains – specifically those with Depressive Disorders and Obsessive Compulsive Disorders – neurosurgical therapies may reasonably be considered. In each individual case, consideration of the appropriateness of offering any form of NMD must balance the risks and benefits of surgery with the risks and benefits of continuing with 'treatment as usual' and should also acknowledge patient preference. Further caveats are described below.

COLLEGE POSITION ON NEUROSURGERY FOR MENTAL DISORDER (ALL INTERVENTIONS)

The Royal College of Psychiatrists considers that the delivery of safe and effective neurosurgical interventions represents an important element of the ethical and optimised management of patients with chronic, otherwise treatment refractory mental disorder – specifically mood disorders (Major Depression and Bipolar Disorder) and Obsessive Compulsive Disorder (OCD). The evidence base

to support this College position is derived from an accumulated literature comprising open case series evaluations, some of prolonged duration and high quality <sup>1, 4-7</sup>. There is limited randomised, controlled evidence, but this is available for some lesion surgical approaches<sup>8</sup> and for Deep Brain Stimulation (DBS) for OCD<sup>9</sup>. The College position on the clinical place for NMD and the requirement for strong clinical governance and safeguarding is consistent with that recently described in detail by the Psychiatric Neurosurgery Committee of the World Society for Stereotactic and Functional Neurosurgery (WSSFN)<sup>1</sup>.

The College wishes to emphasise that contemporary stereotactic neurosurgical procedures –whether stereotactic lesioning, or deep brain stimulation – bear no resemblance to those of lobotomy and leucotomy.

# CORE PRINCIPLES FOR ETHICAL, SAFE AND EFFECTIVE NMD

- 1. NMD procedures must only ever be performed with a specific therapeutic intention, i.e., for symptom relief and restoration of function.
- NMD provision (lesion procedures AND invasive stimulation methods) should be subject to ethical and clinical governance oversight by an independent body. Special attention must be paid to the processes of patient advocacy, the assessment of capacity and the nature of informed consent.
- 3. NMD should only be provided by neurosurgeons familiar in functional stereotactic surgery within specialist centres, and the clinical programme should be led by experienced psychiatrists with relevant expertise in the target disorders.
- 4. All patients who are considered as candidates for NMD must be informed that neurosurgery is only one component of a more comprehensive psychiatric management plan that will also include attention to wider aspects of psychological, social and occupational functioning.
- 5. Relevant Mental Health Legislation (there are regional variations within the UK) must be adhered to.
- 6. Candidates for all forms of NMD (including lesion procedures and invasive stimulation methods) must be robustly evaluated by clinicians with specific expertise in the management of the target disorder and confirmed to meet consensus criteria with respect to the severity and refractoriness of the presenting condition.

- 7. Patient selection procedures and any discussions about possible NMD should be conducted by experienced multidisciplinary teams with close working between as a minimum stereotactic and functional neurosurgeons, psychiatrists, mental health nurses and expert psychological therapists. Where Deep Brain Stimulation (DBS) is the surgical method proposed, this must also involve neurologists and specialist nurses familiar with the management of DBS systems and their programming.
- 8. Comprehensive pre and post-operative evaluation with specific attention to disorder-specific symptom outcomes, cognition, social and interpersonal functioning & health-related quality of life measures must take place, with an identified mechanism for reporting the immediate and longer term outcomes within a robust clinical governance structure.
- 9. Post-operative care plans should be developed collaboratively; should cover a period of at least 12-months; and should include the full participation of locality mental health services. Surgery should not take place unless a detailed, collaborative, patient-centred post-operative care plan has been agreed.

## COLLEGE POSITION ON INDIVIDUAL NMD TREATMENTS

## ABLATIVE NEUROSURGERY FOR MENTAL DISORDER

Ablative neurosurgery (the creation of small targeted lesions by focal applications of radiofrequency induced heat, by radiation or by ultrasound) is the form of NMD with the strongest evidence base and longest reported follow-up<sup>4-8</sup>. In particular, this relates to the two procedures most commonly offered as treatments for patients with otherwise refractory and disabling Depression and OCD – Anterior Cingulotomy and Anterior Capsulotomy. Both procedures have been considered as representing acceptable, safe and effective established clinical practice in the UK for many years, including following review by independent, multidisciplinary, expert groups.

The Royal College of Psychiatrists considers that the delivery of safe and effective ablative NMD – subject to the general caveats above - represents an important element of the ethical and optimised management of patients with chronic, otherwise treatment refractory Depression and OCD.

There is currently no compelling evidence to support ablative NMD for any other psychiatric indication.

#### DEEP BRAIN STIMULATION FOR MENTAL DISORDER.

Deep Brain Stimulation (DBS) is a surgical approach whereby deep structures of the brain can be directly stimulated electrically using permanently implanted electrodes and an externally programmed, implantable pulse generator. This technology is an established method for the optimised management of some patients with movement disorders such as Parkinson's Disease, essential tremor and dystonia.

Over the past 16 years, there have been numerous open case series reporting generally encouraging results for the use of DBS targeting different deep brain structures in patients with a variety of psychiatric disorders, see for example<sup>9</sup>.

Recent pivotal blinded controlled comparisons of active DBS with sham stimulation have failed to demonstrate efficacy for the two most commonly performed DBS surgeries for refractory Depression<sup>10,11</sup>. There has been no such blinded, sham controlled study reported for the treatment of OCD using DBS, although several high-quality case series have included robust elements of blinded comparison with lengthy follow-up <sup>9, 12</sup>.

The College considers that *all* DBS procedures for *all* psychiatric indications should continue to be viewed as investigational and therefore should not be performed unless as part of an ethically approved research protocol.

## VAGUS NERVE STIMULATION FOR MENTAL DISORDER

Vagus Nerve stimulation (VNS) is a surgical approach whereby the cervical (neck) portion of the left vagus nerve can be directly stimulated electrically using an electrode implanted around the vagus nerve in the neck and an externally programmed, implantable pulse generator. VNS is an established method for the optimised management of some patients with refractory epilepsy. Its mechanism of action is completely unknown.

Over the past 14 years, there have been several open case series reporting encouraging results for the use of VNS in patients with chronic and refractory Depression. However, the literature is generally of low quality and a pivotal blinded controlled comparison of active VNS with sham stimulation failed to demonstrate efficacy<sup>13</sup>.

The College considers that VNS for *all* psychiatric indications, including Depression, should continue to be viewed as investigational and therefore should not be performed unless as part of an ethically approved research protocol.

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