# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional procedures consultation document

# Implanted vagus nerve stimulation for treatment-resistant depression

Depression is treatment resistant when symptoms have not improved after at least 2 standard treatments. In this procedure, a small electrical stimulator is put under the skin of the chest (through a small cut) and its wires are passed under the skin to the left side of the neck. The wires are connected to the vagus nerve, which carries electrical signals to the brain. The aim is to improve mood by sending signals to the brain through the vagus nerve.

This is a review of NICE's interventional procedures guidance on vagus nerve stimulation for treatment-resistant depression.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

**This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.**

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 20 February 2020

Target date for publication of guidance: May 2020

# 1 Draft recommendations

1.1 Evidence on the safety of implanted vagus nerve stimulation for treatment-resistant depression raises no major safety concerns, but there are frequent, well-recognised side effects. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to do implanted vagus nerve stimulation for treatment-resistant depression should:

- Inform the clinical governance leads in their NHS trusts.
- Give patients clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.

1.3 NICE encourages further research into implanted vagus nerve stimulation for treatment-resistant depression, in the form of randomised controlled trials with a placebo or sham stimulation

arm. Studies should report details of patient selection. Outcomes should include validated depression rating scales, patient-reported quality of life, time to onset of effect and duration of effect, and any changes in concurrent treatments.

# 2 The condition, current treatments and procedure

## *The condition*

2.1 Depression is characterised by low mood, loss of interest and enjoyment in life, and a range of associated emotional, cognitive, physical and behavioural symptoms. Depression is treatment-resistant when symptoms have not improved after at least 2 standard treatments.

## *Current treatments*

2.2 The diagnosis and management of depression is described in the NICE clinical guideline for depression in adults and the NICE guideline for depression in children and young people. Standard treatment for depression includes antidepressants or psychological therapies (including cognitive behavioural therapies) or a combination of both. When 2 or more conventional treatments do not work, neurostimulation (for example, electroconvulsive therapy, transcranial magnetic stimulation, or transcranial direct current stimulation) may be considered.

## *The procedure*

2.3 The aim of implanted vagus nerve stimulation for treatment-resistant depression is to reduce symptoms and improve mood by periodic stimulation of the vagus nerve.

2.4 The procedure is done using general or local anaesthesia. An incision is made on the left side of the neck and the left vagus

nerve is identified. A stimulator electrode is put around the nerve and the leads of the electrode are guided under the skin to the left chest wall. They are attached to a pulse generator unit, which is implanted into a subcutaneous pocket. The stimulator settings can be adjusted or turned off using an external (wireless) programming device.

# 3 Committee considerations

## *The evidence*

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 9 sources, which was discussed by the committee. The evidence included 2 systematic reviews and/or meta-analyses, 2 randomised controlled trials (1 of which resulted in 2 publications), 2 non-randomised comparative studies, 2 case series and 1 single case report. It is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: depressive symptoms, quality of life, and reduction in other treatments and hospital admissions.

3.3 The professional experts and the committee considered the key safety outcomes to be: device failure, infection, and worsening of mood symptoms including risk of suicidality.

3.4 One commentary from a patient who has had this procedure was discussed by the committee.

## *Committee comments*

3.5 The committee noted that there was a high incidence of side effects associated with the procedure including voice change, cough and dyspnoea.

3.6 The committee was informed that there may be a better response to this intervention in patients whose symptoms have responded to electroconvulsive therapy.

3.7 The committee noted that studies on this procedure show a placebo effect.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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