NHS
National Institute for Health and Clinical Excellence

## Understanding NICE guidance

**Information for people who use NHS services**

# Vagus nerve stimulation for treatment-resistant depression

*NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.*

This leaflet is about when and how vagus nerve stimulation can be used in the NHS to treat people with depression for whom other treatments have failed (treatment-resistant depression). It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe vagus nerve stimulation or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

**Information about NICE interventional procedure guidance 330**
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## What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. If a doctor wants to use vagus nerve stimulation for treatment-resistant depression, they should make sure that extra steps are taken to explain the uncertainty about how well it works, and the uncertainty surrounding potential risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure. The procedure should only be used in patients for whom other treatments have failed.

A team of specialist clinicians should decide which patients should be offered this procedure, and should also look after them. The team should include a psychiatrist and a surgeon (usually a neurosurgeon), with other relevant specialists, for example a clinical psychologist and a trained technician.

NICE has encouraged further research into this procedure and may review the procedure if more evidence becomes available.

## Vagus nerve stimulation

*This procedure may not be the only possible treatment for treatment-resistant depression. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.*

The procedure is not described in detail here – please talk to your specialist for a full description.

Depression causes feelings of sadness, hopelessness and lack of interest in life. People with severe depression may be unable to eat or sleep or to take part in social activities. Sometimes they harm themselves, have thoughts about suicide, or may attempt suicide. They may also have hallucinations and delusions.

Treatments for depression include antidepressant medicines, psychological therapies including cognitive behavioural therapy (CBT) or a combination of these. If the depression does not respond to other treatments (known as treatment-resistant depression), electroconvulsive therapy (ECT) may be used.

The aim of this procedure is to improve mood and reduce depression by stimulating the vagus nerve, which carries impulses to the area of the brain involved in mood regulation. The procedure is carried out with the patient under a general or local anaesthetic. The surgeon makes a small cut on the left side of the neck and places an electrical stimulator around the vagus nerve. The wires from the stimulator are passed down through the chest to a device like a pacemaker, which is inserted through a cut in the chest wall. The device is then set up to produce the electrical impulses.

## Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described here. NICE looked at 7 studies on this procedure, but it was not clear whether some patients had been reported on in more than 1 study.

## What does this mean for me?

If your doctor has offered you this procedure, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information, and will give you more information about this.

### You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

## How well does the procedure work?

Depression was scored using the Hamilton Depression Rating Scale. An analysis of 18 studies involving a total of up to 1251 patients who had vagus nerve stimulation reported that the procedure gave a satisfactory response in up to 58% of patients in studies lasting 12 months or more. In a study in which 112 patients had vagus nerve stimulation and 110 patients had a sham (placebo) treatment, patients' depression scores were not significantly different between the 2 groups. In a study of 74 patients with severe depression, patients' depression scores had improved significantly when their progress was checked 1 year after the procedure. The study showed that 55% of patients had a response to vagus nerve stimulation.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that success factors are improved depression scale scores, quality of life and a reduced need for antidepressant medication or support services.

*You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.*

## Risks and possible problems

In the analysis of 18 studies, 1 study reported serious or medically important problems in 10 out of 59 patients receiving vagus nerve stimulation (exact details not reported) and that 2 patients' depression had worsened. In 6 studies in the analysis, 2 patients stopped treatment because of problems (no more detail was given). In the study of 74 patients, 2 patients had committed suicide by 12 months after the procedure. Three studies reported problems after vagus nerve stimulation, such as manic episodes and worsening depression.

In the study of 74 patients, 10% reported shortness of breath, 20% reported pain, 26% reported a cough and 63% reported changes to their voices when their progress was checked after 3 months.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that problems with speech and hoarseness are possible. In theory, other problems could include cardiac arrest, heart rhythm problems, cognitive disturbances, vocal cord paralysis, diarrhoea and inflammation at the site of the procedure.

## More information about depression

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on depression, visit our website at www.nice.org.uk

## About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

*To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance*

*This leaflet is about 'vagus nerve stimulation for treatment-resistant depression'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG330*

*You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2069). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.*

*We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.*

**National Institute for Health and Clinical Excellence**
MidCity Place, 71 High Holborn, London, WC1V 6NA; www.nice.org.uk

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