

Deep brain stimulation for difficult-to-treat epilepsy

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

This document is about when and how deep brain stimulation can be used in the NHS to treat people with difficult-to-treat epilepsy. 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 document is written to help people who have been offered this procedure (or in the case of children, their parents or carers) to decide whether to agree (consent) to it or not. It does not describe difficult-to-treat epilepsy or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The document 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 page 7.

What has NICE said?

There is not much good evidence about how well deep brain stimulation for difficult-to-treat epilepsy works. Current evidence on the safety of the procedure shows that there are serious but well-known risks. If a doctor wants to use deep brain stimulation for difficult-to-treat epilepsy, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the potential risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient (or their parents or carers) should be given this document 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.

A specialist healthcare team with expertise in the management of difficult-to-treat epilepsy should decide which patients might benefit from the procedure, carry it out and monitor patients after the procedure. The team should include a neurologist, a neurophysiologist, a neuroradiologist and a neurosurgeon who specialises in the treatment of movement disorders.

NICE also recommends that more research is carried out to see how effective deep brain stimulation is at reducing the number of seizures in patients and improving their quality of life.

Other comments from NICE

NICE recognised that difficult-to-treat epilepsy can cause serious disability and distress, and that affected patients can die suddenly. NICE said that any treatment that helps patients to have fewer seizures, a lower risk of dying, reduces the amount of medication they need or otherwise improves their quality of life would be a welcome option.

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

Deep brain stimulation

The medical name for this procedure is ‘deep brain stimulation for refractory epilepsy’.

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

Epilepsy is a long-term condition in which the brain’s normal electrical activity becomes overactive and abnormal, causing seizures. Difficult-to-treat (refractory) epilepsy is epilepsy that is inadequately controlled by medication. Patients experience frequent seizures and are at risk of status epilepticus and also sudden death in epilepsy (SUDEP). Status epilepticus is a condition in which a seizure lasts for 30 minutes or more, or there are several seizures over 30 minutes or more, and the patient does not regain consciousness in between them.

Deep brain stimulation can be used for some patients with difficult-to-treat epilepsy for whom surgical resection is unsuitable. It involves electrical stimulation of particular areas of the brain, which may reduce or stop the abnormal electrical activity associated with a seizure.

Deep brain stimulation is done under a general or local anaesthetic. A thin wire is inserted through the skull into the brain. Leads tunnelled under the skin of the scalp and neck connect the wire to an electrical pulse generator implanted under the skin of the chest. The pulse generator is usually permanently switched on.

What does this mean for me?

If your doctor has offered you (or your child) deep brain stimulation for difficult-to-treat epilepsy, he or she should tell you that NICE has decided that the benefits are uncertain and there are serious but well-known risks. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure 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 document, and have the opportunity to discuss it with your doctor before making your decision.

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 procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

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

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 9 studies on this procedure.

How well does the procedure work?

In a study of 109 patients who had devices implanted, 54 patients treated with deep brain stimulation (pulse generator switched on) had a 29% greater decrease in the number of seizures in 3 months than the 55 patients who did not have deep brain stimulation (they had the procedure, but the pulse generator was switched off). Afterwards, all 109 patients received deep brain stimulation, and 2 years after the procedure the number of seizures had fallen by 56%.

The study also found that after patients had received deep brain stimulation their quality of life was much higher at both 13 months (102 patients) and 25 months (98 patients) after the procedure.

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 the aim of the procedure is to reduce the number of seizures patients have and the amount of medication they need to take, and to improve their quality of life.

Risks and possible problems

In a study of 17 patients, 1 patient had bleeding in the brain during the procedure and had to have open surgery. The patient had weakness on one side of their body and reduced mental ability 1 week after the bleeding.

In the study of 109 patients, 5 patients had bleeding that had not shown any symptoms. The bleeding was noticed when the patients had routine brain scans.

The study of 109 patients reported that 14 patients had infections where the wire was inserted or where the leads or pulse generator were implanted. All patients were treated with antibiotics, and 9 patients also had the generator, wires or leads removed.

In the same study, 8 patients of the 54 treated with deep brain stimulation had depression, compared with 1 patient of the 55 who were not treated with deep brain stimulation. 4 of the 8 patients recovered in an average of 76 days.

In the same study, 7 of the 54 patients treated with deep brain stimulation had memory problems, compared with 1 of the 55 patients who were not treated with deep brain stimulation. None of these problems were thought to be serious and all patients had recovered within between 12 and 476 days.

The same study of 109 patients reported that 5 patients died during the follow-up period (which was an average of 3 years after the procedure). 1 patient died before the wires were implanted, and this was thought to be because of SUDEP. 2 more patients died from SUDEP, 1 during the part of the study where all 109 patients received deep brain stimulation and the other after the procedure. 1 patient drowned, and 1 patient committed suicide after the procedure. These deaths were not thought to have anything to do with the device.

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 the possible problems were stroke, brain damage and breakage or movement of the leads used in the device.

More information about difficult-to-treat epilepsy

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 epilepsy, 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 document is about ‘deep brain stimulation for refractory epilepsy’. This document and the full guidance aimed at healthcare professionals are available at <http://guidance.nice.org.uk/IPG416>

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.

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ISBN 978-1-84936-774-5

Jan 12

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