NHS
National Institute for Health and Clinical Excellence

Understanding NICE guidance

Information for people who use NHS services

Treatment of tremor and dystonia (but not that seen in Parkinson's disease) with deep brain stimulation

NICE 'interventional procedure guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.

This leaflet is about when and how deep brain stimulation can be used to treat people with tremor or dystonia (except for that associated with Parkinson's disease) in the NHS in England, Wales, Scotland and Northern Ireland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence). NICE has produced separate guidance on the use of deep brain stimulation in people with Parkinson's disease (see www.nice.org.uk/IPG019).

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 tremor and dystonia 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.

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. 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.

Information about NICE interventional procedure guidance 188
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What has NICE said?

This procedure can be offered routinely as a treatment option for people with tremor or dystonia provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

A team of specialists should work together to ensure the right patients are chosen for this procedure and that patients are cared for appropriately.

Other comments from NICE

Deep brain stimulation can be done in several different ways. It can be used with or after other types of surgery or drug treatments.

The success of the procedure may be affected by the type of rehabilitation the patient has.

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

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

Deep brain stimulation

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

Tremor and dystonia are symptoms of neurological diseases, such as essential tremor and multiple sclerosis.

Tremor is rhythmic repetitive movement that a person cannot control. It mostly affects the arms. In dystonia, muscles that normally work alternately both contract at the same time, causing spasm.

Treatment of tremor with rehabilitation or drugs can be successful if started early. However, it doesn't always help the patient in their everyday life. Surgery can be used if drugs don't work.

Dystonia is harder to treat. Treatment may reduce the symptoms but does not stop the disease that is causing the spasm. Surgery can be used, but it doesn't always help in the long term.

Another treatment option is deep brain stimulation, which uses permanent electrodes planted in the brain. During the procedure, small holes are made in the skull, and one or more electrodes are placed in part of the brain that causes the tremor or dystonia. Wires from the electrode are threaded under the skin of the chest and are connected to a pulse generator placed inside the body. An electrical current sent from the pulse generator helps to control the tremor or dystonia.

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 one review and five studies.

How well does the procedure work?

In one study, tremor improved in patients treated with deep brain stimulation for up to 27 months, but other measures of effectiveness did not improve. However, in another study, daily living activities were improved at 3 months' follow-up in patients with tremor.

In 22 patients with dystonia, deep brain stimulation improved symptoms (measured using two different methods) for at least 12 months.

Three studies on patients with multiple sclerosis found that deep brain stimulation improved tremor. In two studies, however, this improvement didn't necessarily help patients with their daily living activities.

The expert advisers were unsure whether deep brain stimulation works in the long term, as the tremor may stop responding to the electrical stimulation.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks that deep brain stimulation is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

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?

Risks and possible problems

In one study the pulse generator failed in 6 of the 12 patients (50%). In three studies, the stimulating electrode in the brain became displaced in 6–15% of patients and the leads broke or failed in up to 6% of cases. Some of these patients had to have further surgery to repair the problem.

Problems reported were short-term build up of fluid (oedema) in the frontal lobe of the brain, problems in the scalp, skin infection and bruising near the stimulator. None of these caused any long-term problems.

The expert advisers said that the possible problems with the procedure are infection, bleeding (possibly leading to paralysis on one side of the body), failure of the equipment, effects on speech, oedema on the brain and possibly death.

They said that the theoretical risks were stroke, effects on some brain functions (speech, cognitive function [acquiring knowledge]), depression, suicide and risk of injury during any future magnetic resonance imaging.

More information about tremor and dystonia

NHS Direct online (**www.nhsdirect.nhs.uk**) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

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. 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 and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG188

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1106).

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