NHS
National Institute for Health and Clinical Excellence

Understanding NICE guidance

Information for people who use NHS services

Treating chronic pain syndromes (except headache) using deep brain stimulation

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 deep brain stimulation can be used in the NHS to treat people with chronic pain syndromes (except headache). 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 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 chronic pain syndromes 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 382
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What has NICE said?

Current evidence on the safety of deep brain stimulation for chronic pain syndromes (excluding headache) shows that there are serious but well-known risks. There is evidence that the procedure works in some patients in whom other forms of pain control do not work. Therefore this procedure can be offered routinely as a treatment option for these patients 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.

Patients should be informed that the procedure may not control their symptoms and told in full about the possible risks associated with this procedure, including the small risk of death.

It should only be used in patients with who have chronic pain syndromes (excluding headache) that other treatments have failed to control. Patients should be selected by a team specialising in pain management.

Other comments from NICE

It was difficult for NICE to make a decision because the studies available were for different groups of patients and used different methods. Also, many were published some years ago and techniques for deep brain stimulation have since developed. There was not enough evidence to decide how well it worked for particular patient groups.

NICE noted that patient feedback was very positive. Some patients said that even partial relief of their pain had greatly improved their quality of life.

Deep brain stimulation for chronic pain syndromes (except headache)

This procedure may not be the only possible treatment for chronic pain syndromes. 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.

Chronic pain syndromes are often poorly understood. Pain can occur anywhere in the body, is long lasting and can have a significant impact on quality of life. The causes of chronic pain syndromes vary and can be complex. A variety of physical, psychological and/or drug treatments can be used depending on the cause and precise symptoms. Stimulation of an area of the brain called the motor cortex, or nerves in the spine or elsewhere in the body (peripheral nerves) have also been used to treat chronic pain syndromes that do not respond to other treatments.

This procedure involves stimulating precise areas of the brain using electrodes. Small holes are drilled into the skull and permanent electrodes are inserted into carefully selected targets deep in the brain using computer guidance. This is usually done with the patient under a local anaesthetic and/or sedation, but sometimes a general anaesthetic is used. A test stimulation is used to check for any problems. Wires from the electrodes are

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

threaded under the skin and connected to a device called a 'pulse generator', placed into the chest, which controls the electrical stimulation.

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.

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

How well does the procedure work?

A study of 43 patients with pain following stroke reported pain reduction of more than 60% in 3 patients out of 12 (25%) who had deep brain stimulation and 15 out of 31 (48%) who had motor cortex stimulation.

A study of 112 patients with a type of nerve damage pain called deafferentation pain reported that 42 out of 89 were pain-free and 28 out of 89 were 'improved' at up to 6 years. The procedure did not help 19 patients.

In a further study, 50 out of 65 patients with a type of nerve pain called peripheral pain were able to control their pain using 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 that key success factors are a reduction in frequency and severity of pain, improvement in physical and mental ability, and quality of life, and reduction in need for medication.

Risks and possible problems

In 1 study of 141 patients with either deafferentation pain or another type of nerve pain called nociceptive pain, 5 patients had a brain haemorrhage (bleed) (2 recovered, 2 had damage to the brain leading to considerable disability and 1 died).

In a study of 122 patients, 2 deaths were reported; 1 caused by brain haemorrhage and swelling, and 1 caused by a heart attack occurring 9 weeks after a brain haemorrhage due to the procedure.

In the study of 141 patients, 17 had infections. Treatment was not described for 3 patients, but was successful in 14 patients, although 11 needed to have their electrodes removed. The study of 122 patients reported infections in 6 patients, successfully treated with antibiotics, although 2 patients needed the stimulation system removed.

The stimulation system had problems of deterioration in 10 patients in the study of 141 patients; 5 patients had it removed and 5 had a new one inserted. Movement of the electrodes happened only with early versions of the system.

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 possible problems include the development of new pain if the wires move, mood changes, temporary side effects of stimulation such as speech problems, and fits. In theory, other problems might include a type of stroke called a cerebral infarction.

More information about chronic pain syndromes

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 pain, 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 'Deep brain stimulation for refractory chronic pain syndromes (excluding headache)'. This leaflet and the full guidance aimed at healthcare professionals are available at **www.nice.org.uk/guidance/IPG382**

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2474). 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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