

Vagus nerve stimulation for refractory epilepsy in children

Understanding NICE guidance –
information for people considering the
procedure, and for the public

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Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0494. A version in Welsh and English is also available, reference number N0495. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0495. The NICE interventional procedures guidance on which this information is based is available from the NICE website (www.nice.org.uk). Copies can also be obtained from the NHS Response Line, reference number N0493.

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About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called vagus nerve stimulation for refractory epilepsy. It is not a complete description of what is involved in the procedure – the patient’s healthcare team should describe it in detail.

NICE has looked at whether vagus nerve stimulation is safe enough and works well enough for it to be used routinely for the treatment of refractory epilepsy in children.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of vagus nerve stimulation and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE’s work on ‘interventional procedures’ (see ‘Further information’ on page 10).

About vagus nerve stimulation

Refractory epilepsy is the medical term for epilepsy that has not improved with the usual epilepsy medicines. Vagus nerve stimulation can be used for children whose epilepsy has not improved with medicines alone.

The vagus nerve (sometimes called the vagal nerve) runs from many parts of the body to the brain. Nerve messages that travel along the vagus nerve are involved in controlling many things in the body such as breathing, digestion and the heartbeat. In the brain, the vagus nerve has a connection with the area thought to be involved in epileptic seizures. With vagus nerve stimulation, a burst of nerve messages is sent through the nerve. Although it's not clear exactly what happens in the brain, the burst of messages can help to stop seizures from happening or make them less severe.

The device used to send the burst of nerve messages is called a pulse generator. It's powered by a battery that lasts for 8 to 10 years. The pulse generator is put under the skin of the left side of the child's chest. A wire is passed up from the device to connect to the vagus nerve in the neck. After it has been put into place and connected up, the pulse generator is set to produce the messages using a computer and a 'programming wand'. For example, it might be

set to send a burst of messages for 30 seconds every 5 minutes. On top of this, the child or their parent or carer can use a special magnet to get an additional burst of nerve messages if they think a seizure is about to happen.

How well it works

What the studies said

One study looked at the effect of having a pulse generator in 50 children aged 12 years and younger. Having the device cut the number of seizures by more than half in 23 of the children. And in another study that looked at the results 1 year on, the 28 children in the study were having fewer than half the seizures they were having before, on average. There were also signs of improvements in the general wellbeing of some of the children who had a pulse generator.

What the experts said

The experts said that vagus nerve stimulation seemed to improve children's wellbeing and mood.

Risks and possible problems

What the studies said

In the studies NICE looked at, the most common problems were a hoarse voice, a sore throat and a cough while the pulse generator was sending messages. In one of the studies, just over half of the children found that their voice changed when the pulse generator was sending its burst of messages. And nearly four out of ten children said that they coughed when the pulse generator was activated.

Serious problems were not common, but they included:

- infection that meant that the pulse generator had to be removed (this affected 3 to 6 children in 100)
- breathing irregularities (these affected 19 children in 100).

What the experts said

The experts thought that the procedure was safe and that there were no common serious problems.

What has NICE decided?

NICE has considered the evidence on vagus nerve stimulation in children with refractory epilepsy. It has recommended that when doctors use it for children with refractory epilepsy they should be sure that:

- the child or their parent or carer understands what is involved and agrees (consents) to the treatment
- it's explained to the child or their parent or carer that vagus nerve stimulation doesn't work for everyone so there is no guarantee of an improvement
- the results of the procedure are monitored.

The procedure should only be carried out by a medical team that specialises in treating children with epilepsy.

NICE has also recommended that from now on doctors and researchers should aim to assess the effect of vagus nerve stimulation on children's lives in general and not just on the number of seizures they have.

What the decision means for you

Your doctor may have offered you or your child vagus nerve stimulation. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS.

Nonetheless you should understand the benefits and risks of vagus nerve stimulation before you agree to it. Your doctor should discuss the benefits and risks with you and explain that it's not possible to predict how well vagus nerve stimulation will work for a particular child. Some of the benefits and risks of vagus nerve stimulation may be described above.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you or your child receives. You may want to discuss this guidance with the doctors and nurses looking after you.

You can visit the NICE website (www.nice.org.uk) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on vagus nerve stimulation for refractory epilepsy in children is on the NICE website (www.nice.org.uk/IPG050guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0493. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you want more information on epilepsy, a good starting point is NHS Direct (telephone 0845 4647) or NHS Direct Online (www.nhsdirect.nhs.uk).

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