

Vagus nerve stimulation for refractory epilepsy in children

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg50

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of vagus nerve stimulation for refractory epilepsy in children appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 The procedure should only be undertaken by specialist paediatric epilepsy teams.
- 1.3 Almost all the current evidence on the efficacy of the procedure relates to reducing seizure frequency only. However, the effect on quality of life remains uncertain. Future audit and research should include quality of life measures. Patients, carers and children should be informed about the unpredictability of benefit. Use of NICE's information for the public is recommended.

2 The procedure

2.1 Indications

- 2.1.1 Vagus nerve stimulation is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients who are refractory to anti-epileptic medication. This includes patients whose epileptic disorder is dominated by partial seizures (with or without secondary generalisation) or generalised seizures.

2.2 Outline of the procedure

- 2.2.1 A battery-powered pulse-generating device is implanted under the skin of the upper left chest. A wire is tunnelled under the skin and connected to the left vagus nerve in the neck. The stimulation parameters (pulse width and frequency, current intensity, and on/off cycles) are programmed into the pulse generator via a programming wand. Patients or carers can give additional stimulation or temporarily inhibit stimulation. The battery lasts 8 to 10 years and can be replaced under local anaesthesia. A typical treatment regimen might comprise intermittent stimulation for 30 seconds every 5 minutes throughout the day and night.

2.3 Efficacy

- 2.3.1 In one study of 50 children aged 12 years and younger, 23 (46%) experienced a greater than 50% reduction in seizure frequency. In a study of 28 children aged 12 years and younger, a mean reduction of 62% in seizure frequency was reported at 1 year. There was some evidence to suggest that quality of life improved following the procedure. Comparisons are difficult to make between the studies because of variations in the patient populations, the methods of outcome assessment and the reporting of outcomes. For more details, see the [overview](#).
- 2.3.2 The Specialist Advisors also noted that the procedure seemed to have some benefits in terms of mood and quality of life.

2.4 Safety

- 2.4.1 The most commonly reported complications were hoarseness, sore throat and cough. In a case series of 125 children, 73 children (58%) experienced voice alteration and 48 children (38%) experienced coughing during stimulation. More serious adverse events included infection (requiring device removal) in 3% (3 out of 100) to 6% (1 out of 16) of patients, and breathing irregularities in 19% (3 out of 16) of patients. For more details, see the [overview](#).

2.4.2 The Specialist Advisors believed that this is a safe procedure with no major complications.

3 Further information

3.1 NICE has issued a [guideline on epilepsies in children, young people and adults](#).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).