

Deep brain stimulation for refractory epilepsy in adults

Interventional procedures guidance

Published: 12 August 2020

www.nice.org.uk/guidance/ipg678

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.

This guidance replaces IPG416.

1 Recommendations

- 1.1 Evidence on the safety and efficacy of deep brain stimulation for refractory epilepsy in adults differs according to the site of stimulation:
- For anterior thalamic targets the evidence is limited in quantity and quality, therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE website.
 - For targets other than the anterior thalamus the evidence is inadequate in quantity and quality, therefore this procedure should only be used in the context of research. Find out what only in research means on the NICE website.
- 1.2 Clinicians wishing to do deep brain stimulation of anterior thalamic targets for refractory epilepsy in adults should:
- Inform the clinical governance leads in their NHS trusts.
 - Give patients clear written information to support shared decision making, including NICE's information for the public.
 - Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these.
 - Audit and review clinical outcomes of all patients having the procedure. NICE has identified relevant audit criteria and has developed an audit tool (which is

for use at local discretion).

- 1.3 Patient selection should be done by a multidisciplinary team experienced in managing epilepsy including a neurologist, neurophysiologist and neurosurgeon.
- 1.4 The procedure should only be done in neurosurgery centres that specialise in managing epilepsy.
- 1.5 Further research should describe patient selection and clearly define the target area of the brain. Outcomes should include reduction in seizure frequency and improvement in the epilepsy seizure outcome scale, quality of life, reduction in concomitant medication and hospital admissions.

2 The condition, current treatments and procedure

The condition

- 2.1 Epilepsy is a neurological condition characterised by episodes of abnormal electrical activity in the brain which cause recurrent seizures. The seizures can be focal or generalised.

Current treatments

- 2.2 The main treatment for epilepsy is anti-epileptic drugs taken to prevent or reduce the occurrence of seizures. However, many people have drug-resistant (refractory) epilepsy. They experience frequent seizures and are at risk of status epilepticus and sudden unexpected death in epilepsy.
- 2.3 Surgery may be considered for refractory epilepsy. Surgical options include open surgical resection (such as lesionectomy, anterior temporal lobectomy or hemispherectomy) or disconnection (such as multiple subpial transection or

corpus callosotomy), neuroablation (using stereotactic radiosurgery, radiofrequency thermocoagulation or MRI-guided focused ultrasound) or neuromodulation (such as cranial nerve stimulation, deep brain stimulation or closed loop stimulation).

The procedure

- 2.4 Deep brain stimulation involves implanting electrodes into specific target areas of the brain. Although the mechanisms of action are not fully understood, the aim of the procedure is to reduce or suppress seizure frequency. A potential advantage of the procedure is its reversibility. It is an option for some patients with medically refractory epilepsy when resective surgery is not indicated.
- 2.5 The procedure is done using general or local anaesthesia. A stereotactic frame may be used. Imaging (MRI or CT) is used to identify the target area of the brain (most commonly the anterior nucleus of the thalamus but may include the centromedian thalamic nucleus, hippocampus and nucleus accumbens). One or more small holes are drilled in the skull and electrodes are implanted into the target area.
- 2.6 A neurostimulator is surgically placed into a subcutaneous pocket below the clavicle. The electrodes are connected to the neurostimulator by leads that are tunnelled under the skin of the neck and scalp. Postoperative imaging is usually used to confirm the location of the electrodes. A handheld remote-control programming unit is used to turn the neurostimulator on or off, adjust stimulation parameters, and monitor activity.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed

review of the evidence from 14 sources, which was discussed by the committee. The evidence included 3 randomised controlled trials (one of which resulted in 3 publications), 3 systematic reviews, 1 non-randomised comparative study, 1 case series and 4 case reports. It is presented in [table 2 of the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be reduction in seizure frequency and improvement in the epilepsy seizure outcome scale, quality of life, reduction in hospital admissions and reduction in concomitant medication use.
- 3.3 The professional experts and the committee considered the key safety outcomes to be device failure and off-target stimulation.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee noted that most of the evidence reviewed by the committee came from patients aged 18 years to 70 years.
- 3.6 The evidence reviewed by the committee included participants aged under 18. However, the CE mark certificate for the device is only indicated for adults. Therefore, in line with processes in the [interventional procedures programme manual](#), this guidance only relates to use of the procedure in adults.
- 3.7 The committee was informed that the efficacy of this procedure may vary by type of epilepsy.

ISBN: 978-1-4731-3834-6

Endorsing organisation

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