National Institute for Health and Clinical Excellence

806 – Deep brain stimulation for refractory epilepsy

Consultation Comments table

IPAC date: Thursday 10 November 2011

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Specialist Adviser	**1**	Follow up MUST be in the context of MDts and not just by surgeons implanting. There must be independent assessment by other non-involved clinicians. Carer/care-giver/family quality of life should also be assessed.	Thank you for your comment. A new section 1.3 will be added to the guidance to state that patient selection and treatment should be done by an MDT.
2	Consultee 2 NHS Professional	**1**	All makes good sense. There may be individuals with learning disabilities Â - consent may be challenging	Thank you for your comment. The issue of consent in patients with learning disabilities is covered by DH guidance. Section 1.2 of the guidance will be changed to include patients and their carers.
3	Consultee 3 Voluntary Sector	**1**	Epilepsy Action agrees that this technology should be made available as an alternative therapeutic option to people with epilepsy. We agree about the need for special arrangements for undertaking the procedure but also note that this should be reviewed once more experience with the procedure is available. We agree about the need for further research as outlined.	Thank you for your comment.

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4	Consultee 4 Medtronic Manufacturer	**1**	Section 1.1 states "that there are well recognised and potentially serious side effects". It is imperative that the potential risks are highlighted, however, we suggest that this wording should be aligned with the safety recommendations observed in recently published IPGs for DBS in other indications. Specifically, IPG 381 and IPG 382 state "serious but well-known side-effects", and "serious but well-known risks", respectively. Risks associated with DBS Therapy for Epilepsy have been shown to be similar in nature to those for other DBS indications, and mostly non-serious in nature (Fisher et al., 2010).	Thank you for your comment. Section 1.1 of the guidance will be changed.
5	Consultee 2 NHS Professional	**2.1**	Clear	Thank you for your comment.

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6	Consultee 3 Voluntary Sector	**2.1**	We agree with the indications for treatments. This treatment is aimed at those with the most difficult to treat epilepsy. Of the 496,000 people with epilepsy in England (Epilepsy prevalence, incidence and other statistics, Joint Epilepsy Council of the UK and Ireland, September 2011) approximately 70% of the population with epilepsy could be seizure free with optimal treatment (JW Sander, The use of Antiepileptic drugs – Principles and Practice. Epilepsia 45 (Suppl 6): 28-34. 2004) This leaves 30% of the population, nearly 150,000 people, unlikely to gain seizure freedom using current anti-epileptic drugs (AEDs). This is a significant potential population for whom alternative therapies are required.	Thank you for your comment.
7	Consultee 2 NHS Professional	**2.2**	How long does the pulse generator remain implanted, what are the risks and complications of implantation?	Thank you for your comment. The Committee recognised that the generator implantation is intended to be permanent but will ensure that this information is included in the 'Understanding NICE Guidance' document. Explantation was necessary in some patients who experienced complications and details of time until explantation are given in the overview. The safety outcomes reported relate to all aspects of the procedure, including implantation.

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8	Consultee 4 MedtronicManufacturer	**2.2.1**	Section 2.2.1. We agree that the anterior nucleus of the thalamus is thought to be the most appropriate DBS target based on current evidence and CE label indication, however, we query the inclusion of the additional term dorsal nucleus. It is unclear what specific site in the brain is being referred to with the term dorsal nucleus i.e. this could be interpreted as the dorsomedial nucleus of thalamus, which is a different target with different connectivity and function to the anterior nucleus. Alternatively, dorsal nucleus could refer to the dorsal anterior nucleus, which is not a recognised term. In either case, we recommend that dorsal nucleus be removed from this sentence to avoid confusion. Additional comments on the IPG Overview document: What the procedure involves (page 3).	Thank you for your comment. The phrase ‘or dorsal’ will be removed from section 2.2.1 of the guidance.

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9	Consultee 4 MedtronicManufacturer	**2.2.1**	We welcome the reference to new emerging technologies with regard to devices with EEG sensors, also known as responsive brain stimulation. We would like to note, however, that this type of device is still experimental, and as such, we suggest they should be described within this document as currently under development, rather than developed. Validity and generalisability of the studies (page 21). We appreciate that electrode placement may induce a microlesion effect, however this has been described in the literature as a possible temporary effect introduced by surgical insertion of an electrode. We therefore have some concern that this phenomenon is being described as irreversible: "some of the intervention may not be reversible". To rectify this, we suggest either removal of this phrase, or an amendment of the text to reflect the possible temporary nature of microlesioning, consistent with the literature.	Thank you for your comment. These comments refer to the overview rather than the guidance document. The text of the overview will be amended as suggested by the consultee.
10	Consultee 2 NHS Professional	**2.3**	The efficacy looks encouraging but looks like the evidence base does not include systematic reviews or metaanlysis.	Thank you for your comment. The evidence base does not include systematic reviews or a meta-analysis.

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11	Consultee 3 Voluntary Sector	**2.3**	We agree with the key efficacy outcomes and suggest there should be a requirement to monitor and report on these on those undertaking the procedure. The clinical and cost effectiveness of this treatment should be based on the impact of potential seizure control on the quality of life of the individual, over a realistic time frame. This is particularly important in a chronic condition such as epilepsy, and it is vital that it should take into account both health and social care impacts and outcomes. These would access to or taking a full part in employment, social life, education, leisure activities etc. and the impact of the epilepsy on memory, behaviour, stigma.	Thank you for your comment. Section 1.2 of the guidance states that clinicians wishing to undertake DBS for refractory epilepsy should audit and review clinical outcomes of all patients having the procedure. Social inclusion will be added to the list of research outcomes in section 1.3 and to the Committee considerations in section 2.5 of the guidance. Cost-effectiveness is not within the remit of the Interventional Procedures Programme.
12	Consultee 2 NHS Professional	**2.4**	Important and pertinent information	Thank you for your comment.
13	Consultee 3 Voluntary Sector	**2.4**	We accept that, as with most new treatments for epilepsy, there may be serious risks involved. It is for the patient, in a fully informed consultation, to make a judgment whether the potential benefits outweigh the risks. The patient needs to be fully informed of the risks and possible advantages of this treatment? It is essential a key feature of the service delivery of DBS is access to information about the treatment is made available in suitable easy to understand format.	Thank you for your comment. Section 1.2 of the guidance states that clinicians wishing to undertake DBS for refractory epilepsy should ensure that patients understand the uncertainty about the procedure's safety and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.
14	Consultee 2 NHS Professional	**2.5**	agreed	Thank you for your comment.

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15	Consultee 3 Voluntary Sector	**2.5**	We would like to reinforce the points made that treatment that could reduce the frequency or severity of seizures in this group. It could reduce the risk of SUDEP. Data from a pooled analysis of risk factors indicate that the higher the frequency of tonic-clonic seizures, the higher the risk of SUDEP furthermore, risk of SUDEP is also elevated in male patients, patients with long-duration epilepsy, and those on antiepileptic polytherapy. (Shorvon et al, The Lancet, 2011) People with uncontrolled seizures have a 23-fold increased risk of SUDEP compared to people with fully-controlled seizures (Vlooswijk et al Seizure 2007) We would also note that being able to reduce medication may also reduce side effects of AEDs which can be severe, particular for individuals on polytherapy or high doses. There are also consequences for the health service of poorly controlled seizures. Epilepsy is the largest single source of one day admissions amongst neurological conditions in the North East of England. (North East Public Health Observatory, June 2009). Such admissions can reasonably be assumed to be a consequence of seizure activity.	Thank you for your comment. Section 2.5.1 of the guidance will be changed.
16	Consultee 4 MedtronicManufacturer	2.5	Reference Fisher, R., Salanova, V., Witt, T., et al. and the SANTE Study Group (2010), Electrical stimulation of the anterior nucleus of thalamus for treatment of refractory epilepsy. Epilepsia, 51: 899–908.	Thank you for your comment. This reference is included in table 2 of the overview.

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