

# National Institute for Health and Clinical Excellence

319 – Deep brain stimulation for tremor and dystonia (excluding Parkinson’s disease)

## Comments table

IPAC date: 16 June 2006

<b>Consultee name and organisation</b>	<b>Section no.</b>	<b>Comment no.</b>	<b>Comments</b>	<b>Response</b> Please respond to all comments
The Dystonia Society	<b>1 – Provisional recommendations</b>	1	The text should read ""a multidisciplinary team - from an accepted centre of Neurological clinical excellence.""	The Committee agreed to add the following words to the end of section 1.2: ‘specialising in the long-term care of patients with movement disorders’.
Individual respondent – patient	<b>1 – Provisional recommendations</b>	2	I had procedure performed November2004. Although it took several months to see any improvement with several changes in settings I am now much improved and know this operation was the right step for me. I have had no complications. My comment on the use of a multidisciplinary team would be to agree- I only saw my neuro surgeon with no involvement of physio etc	Thank you, your comment has been noted.

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Individual respondent – carer	<b>1 – Provisional recommendations</b>	3	1.2 Patient selection should be on the basis of improving quality of life not just absolute improvement in rating scale. Post operative management using a multidisciplinary team where continuity of the personnel involved in programming of the stimulation is essential to identify the sometimes small changes in response which can provide useful indicators as to the programming protocol. This is particularly important for Dystonia patients where there is often a variable time lapse between stimulation changes and a visible change of symptoms.	Thank you, your comment has been noted.
South Gloucestershire PCT	<b>1 – Provisional recommendations</b>	4	Given that this is a complex procedure with significant uncertainty about effects beyond 10 years, the question arises of what the "normal arrangements" should be particularly around patient consent? Which disciplines are essential in the assessment of candidates for DBS?	The Committee agreed to add the following words to the end of section 1.2 'specialising in the long-term care of patients with movement disorders'.
Individual respondent – clinician	<b>2.1.4 – Indications</b>	5	Point 2.14 When tremor is resistant to drug monotherapy, combinations of drugs can be tried, but this can lead sometimes to side-effects from polypharmacy. This can interfere further with a patient's activity of daily living.	The Committee agreed at section 2.1.4 to replace the words 'most patients with tremor benefit from' with 'tremor can be treated by'.
Individual respondent – clinician	<b>2.1.4 – Indications</b>	6	2.15 Thalamotomy and pallidotomy are rarely performed for the management of tremor and dystonia, especially for bilateral disease, because there is a risk to speech and cognition when these permanent lesions are performed bilaterally.	The guidance states that these procedures MAY be used. This guidance is not intended to be a guideline on management of the condition in question. The Committee considered this point but decided not to change the text.

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The Dystonia Society	<b>2.2 – Outline of the procedure</b>	7	My understanding for DYT1 dystonia sufferers is that the insertion of the fine wires into the skull is ONLY done under general anaesthesia, not least because the total procedure can take 8 hours, requires a brain scan and by the definition of generalised dystonia the patient is liable to sudden and uncontrollable movements. For DYT1 dystonia the position of the target area is known exactly from a prior brain scan and the electrodes are inserted on the basis of that information.	At section 2.2.2 the Committee agreed to delete the following sentence: 'This part of the procedure is usually carried out under local anaesthetic'.
Individual respondent – patient	<b>2.2 – Outline of the procedure</b>	8	The outline in 2.2.1 is very technical in description. Section 2.2.2 states that the “pulse generator” pulse generator is in the chest wall, my own generator is my abdomen, and ought to be indicated.	NICE’s ‘Understanding NICE guidance’ information for patients leaflet will explain the description of the procedure in easy-to-understand terms.  The Committee agreed to change section 2.2.2 to read ‘Wires are tunneled subcutaneously into the chest or abdominal wall, where they are connected to a pulse generator’.
Individual respondent – patient	<b>2.2 – Outline of the procedure</b>	9	I had a severe head tremor and a slight torticollis but the tremor was the part I found most distressing and socially limiting. This has now almost gone apart from times of stress/anxiety. The electrodes are in the globus pallidus and the whole operation was performed under a general anaesthetic	The Committee agreed to add a sentence to the end of section 2.2.2: ‘Local or general anaesthesia may be used for this procedure’.

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South Gloucestershire PCT	<b>2.2 – Outline of the procedure</b>	10	Further information needs to be added to this section on the long term maintenance required. The current wording underestimates what DBS involves.	This guidance is not intended to be a guideline on management of the condition in question.
Individual respondent – carer	<b>2.2 – Outline of the procedure</b>	11	2.2.2 Performing the procedure on Dystonia patients should be given the option of general anaesthesia as due to the time lapse between stimulation and change in symptom there is no advantage to performing the operation under local anaesthesia. Performing the operation for Dystonia under general anaesthesia enables the completion of both the electrode implantation and the stimulator implantation in one session and accordingly is less traumatic for the patient.	The Committee agreed to add a sentence to the end of section 2.2.2: ‘Local or general anaesthesia may be used for this procedure’.
Individual respondent – carer	<b>2.2 – Outline of the procedure</b>	12	2.22. The procedure of wire insertion for dystonic patients may have to be performed under general anaesthesia because a dystonic patient may continue to have twisting or discomfort during this part of the surgery if under local anaesthetic.	The Committee agreed to add a sentence to the end of section 2.2.2: ‘Local or general anaesthesia may be used for this procedure’.
Individual respondent – patient	<b>2.3 - Efficacy</b>	13	It seems to me that DBS does work for Dystonia, but as in my case not as well as I thought it would. The operation has stopped the movement in my neck and I am virtually pain free.	Thank you, your comment has been noted.
South Gloucestershire PCT	<b>2.3 - Efficacy</b>	14	Comment in 2.3.3 is important and raises the question of whether the judgement in 1.1 is appropriate	Thank you, your comment has been noted.

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Individual respondent – patient	<b>2.3 - Efficacy</b>	15	Some Patients with toticollis (for instance) do not seem to have the same benefits as generalised dystonia, depending on the age of the person, and any muscular deformity that may have occurred. My own dystonia has reacted well to DBS	Thank you, your comment has been noted.
Individual respondent – carer	<b>2.3 - Efficacy</b>	16	2.3.2 it should be remembered that even a relatively small change in rating scale or global disability score can have a dramatic effect on the individual quality of life.	Thank you, your comment has been noted.
Individual respondent – patient	<b>2.4 - Safety</b>	17	I think that it is a very safe procedure. I did however have to have further surgery after I banged my head and fractured a lead, I have also had to have my neurostimulator changed after 2 years and it is ready for changing (subject to funding) again after a further 2 years	The Committee agreed to add a section 2.2.3 reading ‘further operations may be required for replacement of the generator’.
South Gloucestershire PCT	<b>2.4 - Safety</b>	18	There are significant safety concerns. Should the recommendations in this guidance include limiting provision of DBS to a limited number of specialist units with sufficient expertise?	The Committee agreed to add the following words to the end of section 1.2: ‘specialising in the long-term care of patients with movement disorders’.
Individual respondent – patient	<b>2.4 - Safety</b>	19	The number of replacement generators, i.e. every two years or so, could mean that the human body will reject eventually. Although the research is on-going for rechargeable generators/stimulators which should alleviate the frequency of operational replacements.	The Committee agreed to add a section 2.2.3 reading ‘further operations may be required for replacement of the generator’.

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Individual respondent – patient	<b>2.5 – Other comments</b>	20	My age is 51. The condition started when I was 9 but not diagnosed until 22. This procedure is very new and so, by definition, there are many older patients with advanced DYT1 dystonia that could currently benefit. That is not to contradict the point that the younger, the better, from a reduction of symptoms and the reduction of skeletal damage (ostio arthritis in my case) caused by the repetitive muscle spasms	Thank you, your comment has been noted.
Individual respondent – carer	<b>2.5 – Other comments</b>	21	2.5.3 my daughter had the operation aged 17 (Feb 2003) I have seen a remarkable improvement in her well being not just physical but mentally, reducing the considerable drug regime which was made possible as a result of the improvements post op has also made huge difference in her alertness.	Thank you, your comment has been noted.

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Individual respondent – patient	<b>2.5 – Other comments</b>		I was 45 when I had DBS and think that it has given me a new lease of life. I have had to have botox twice since my surgery (when my neurostimulator required changing) and I am fortunate not to have to take any other form of medication.	The Committee agreed to add a section 2.2.3 reading ‘further operations may be required for replacement of the generator’.
South Gloucestershire PCT	<b>2.5 – Other comments</b>		There is no reference to current arrangements for specialist commissioning of DBS. I do not feel that the evidence around safety and efficacy is clear enough to justify the rather non-specific guidance provided in section 1 - should more be done to address uncertainties about safety and efficacy (particularly long term), and to manage the clinical risks?	Your comment has been noted, however this is outside remit of NICE’s interventional procedure guidance.