



Clinical Commissioning Policy: Deep Brain Stimulation For Chronic Neuropathic Pain

Reference: NHS England D08/P/b

Clinical Commissioning Policy: Deep Brain Stimulation for Chronic Neuropathic Pain

First published:

**Prepared by NHS England Specialised Services Clinical Reference Group for
Specialised Pain**

Published by NHS England, in electronic format only.

DRAFT FOR PUBLIC CONSULTATION

Contents

Policy Statement	4
Equality Statement.....	4
Plain Language Summary	4
1. Introduction	6
2. Definitions	6
3. Aim and objectives	7
4. Epidemiology and needs assessment.....	8
5. Evidence base	8
6. Rationale behind the policy statement	11
7. Criteria for commissioning.....	11
8. Patient pathway	12
9. Governance arrangements	16
10. Mechanism for funding.....	17
11. Audit requirements	17
12. Documents which have informed this policy	18
13. Links to other policies	18
14. Date of review	18
<i>References</i>	19
<i>Version Control Sheet</i>	Error! Bookmark not defined.

Policy Statement

NHS England will routinely commission deep brain stimulation for pain in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Throughout the production of this document, due regard has been given to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it.

Plain Language Summary

Long term pain is associated with significant suffering that can have a major negative impact upon quality of life. It is recognised that pain management services need to be available to support those with the most complex pain associated distress and disability.

Neuropathic pain has been defined as pain resulting from a disease or lesion of the nervous system, for example due to stroke or brachial plexus avulsion. It is often chronic (i.e. long term) and the response to treatment with medication may be poor. Patients may require very large doses of expensive pain medicines specific for neuropathic pain, the efficacy of which for certain neuropathic pains is frequently poor, and side effects, particularly cognitive impairment, are almost universal. Patients often face a life time of suffering which by most would be considered unacceptable in this day and age. Thoughts of and actual suicide and assisted death are real issues in this group of patients.

Deep brain stimulation (DBS) involves the implantation of a device that delivers small electrical pulses to specific parts of the brain that are involved in pain perception, with the aim of masking the pain by producing other sensations such as buzzing or warmth in the painful area. The device is somewhat like a heart pacemaker except that the wires, rather than running into the heart, go into the brain through small holes in the skull.

Randomised Blind Trials of DBS are not possible because deep brain stimulation needs to induce a perceptible sensation. Published reports suggest that DBS can be effective for neuropathic pain, but these are not from randomized clinical trials,; it is difficult to be sure exactly what proportion of patients would benefit and by how

much. There is also little data available on which to base estimates of cost-effectiveness. However, in carefully selected patients with involvement of a MDT and particularly if an appropriate trial of treatment stimulation is undertaken significant improvement in quality of life is acknowledged to occur.

In view of the above, this Policy recommends that routine funding for such procedures should be available but **only centres that meet very strict criteria** should be supported. Where DBS for pain is provided, it must be done under the care of a multidisciplinary team including neurosurgeons, pain physicians, and neuromodulation specialist nurses, with access to a neuro/pain psychologist. Referral to functional neurosurgery for DBS should come from specialist pain physicians after all other conventional methods of anti-neuropathic pain agents and cognitive techniques have failed. Patients should be thoroughly assessed by the whole team to ensure that they are suitable, and that they are realistic in their expectations of the treatment.

DBS is not a one off event. Follow up is required to maintain the system, to ensure continuing efficacy, and to produce clinical evidence regarding long term efficacy.

DRAFT FOR PUBLIC CONSULTATION

1. Introduction

This policy considers the use of Deep Brain Stimulation (DBS) for Chronic Neuropathic Pain and states the commissioning position for the funding of this intervention by the NHS.

Neuropathic pain is pain arising from an injury to the nervous system. Overall, 7-8% of the European population suffer from neuropathic pain. Symptom severity and duration are often greater than for other types of pain, and pharmacological treatment is unsatisfactory for many patients, either because it is ineffective or because the dosages required to alleviate pain cause intolerable side effects. For patients with very severe chronic neuropathic pain that is refractory to all other treatments, neuromodulation may offer an alternative option that may be able to induce analgesia without the problems associated with pharmacotherapy. DBS may be employed for a number of neuropathic pain states.

DBS is a surgical treatment involving the implantation of a medical device acting like a 'brain pacemaker', which sends electrical impulses to specific parts of the brain. By targeting specific areas (typically in the thalamus and periventricular grey matter) that play a part in pain perception, or related limbic areas that mediate the unpleasantness of pain, this method has been used in the treatment of chronic pain with success in selected patients, in particular those with pain after amputation, brachial plexus injury, post stroke and trigeminal neuropathy. Other successes include pain due to multiple sclerosis and spinal injury.

NICE have provided relevant interventional procedure guidance (IPG382: Deep brain stimulation for refractory chronic pain syndromes (excluding headache)). NICE indicated: "Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit." This was issued in May 2011. However high quality published trial evidence is still lacking.

2. Definitions

- Chronic pain: Pain that persists for more than 6 months.
- Neuropathic Pain: Pain caused by damage or disease that affects the somatosensory system
- Central neuropathic pain: Pain caused by a lesion or disease of the central somatosensory nervous system.
- Peripheral neuropathic pain. Pain caused by a lesion or disease of the peripheral somatosensory nervous system. See neuropathic pain note.
- Deep Brain Stimulation (DBS): This is the treatment being considered in this document. DBS involves the surgical implantation of a medical device like a 'brain pacemaker', which sends small electrical impulses to specific parts of the brain. DBS has provided therapeutic benefits for otherwise treatment-resistant movement disorders including Parkinson's disease, dystonia, and tremor, for all of which it has now received routine funding approval. DBS leads are placed in the brain in precise locations that depend on the type of symptoms to be addressed. The stimulation directly changes brain activity in

a controlled manner, the effects are reversible (unlike those of the surgical lesioning techniques that it has largely eclipsed). The deep brain stimulation system consists of three components: the depth leads (typically two in number) that are inserted into the brain, the implanted pulse generator (IPG) that contains a battery and circuitry to produce the stimulus current, and the extension leads that run subcutaneously to connect these together. All three components are surgically implanted inside the body. Experiences with DBS for movement disorders have established the safety and long term viability of all the technologies involved.

- Depth leads: These are thin cables containing several wires (usually four) which run to electrodes on the end of the lead that goes into the brain. Most commonly two leads are implanted, but sometimes only one, and very occasionally more than two may be needed.
- Implantable pulse generator (IPG): A device containing microelectronics and a battery to produce the stimulus current. The IPG can have either a non-rechargeable or rechargeable battery. The IPG can be programmed to deliver a precise electrical field to the nervous tissue; the patient using a hand held programmer can control it. The technology is similar to that of cardiac pacemakers and cochlear implants. The IPG is usually implanted in a similar place to a heart pacemaker, under the skin below the collar bone.
- Extension leads: These are cables that connect the depth leads to the IPG. They are designed to be extremely flexible as they have to withstand being flexed back and forth as the neck moves.
- Trial of Stimulation: Usually the implantation is done in two stages. At a first operation only the depth leads are inserted. They are connected to temporary extensions that pass out through the skin and run to a temporary external stimulus source. The system is then trialled, adjusting the external stimulus source as necessary to optimise the effect. At the end of the trial period, if the stimulation achieves pain reduction the system is completed with the implantation of the remaining components at a second operation. If ineffective, the depth leads are removed.
- UWNPS= University of Washington Pain Score
- BPI= Brief Pain Inventory
- MPQ= McGill Pain Questionnaire
- VAS Score = Visual Analogue Scale Score

3. Aim and objectives

The objectives are to establish:

- The evidence base of clinical and cost effectiveness and safety to support the use of DBS for patients with Chronic Refractory Neuropathic Pain?
- Given the evidence, what criteria should be used to identify suitable patients to be considered for DBS treatment?

- If the evidence base is not sufficiently robust, what steps should be considered to improve it before this policy is next reviewed? This stage is important and should be undertaken only if this condition is judged to be: clinically important; an area of high unmet need; the preliminary evidence base is promising and in this case has demonstrated a potential to provide clinically significant pain relief and improve suffering and distress.

4. Epidemiology and needs assessment

The prevalence of chronic neuropathic pain symptoms in the general population is estimated at 6-8% (Bouhassira, Torrance 2013) and this pain is typically more severe than chronic pain of non-neuropathic origin (median pain score of 7.0/10 for chronic neuropathic pain compared to 5.0/10 for chronic pain of non-neuropathic origin).

The incidences of new cases of certain common types of neuropathic pain have been quantified in the UK (Hall 2006). Annual incidences per 100,000 population are 40 for postherpetic neuralgia, 27 for trigeminal neuralgia (TGN), 1 for phantom limb pain, and 15 for diabetic neuropathy. This suggests some 40,000 new cases per year in England, and does not include several less well quantified indications for which pain DBS has been used, including brachial plexus injury, spinal injury, facial pain as a complication of dental work, and importantly central post-stroke pain (CPSP) which is thought to affect at least 10% of stroke victims.

Most cases of chronic neuropathic pain can be treated medically. However, some 10% of patients are truly refractory to medication. It is probable that only a small minority of even these patients would be candidates for deep brain stimulation. For example, there are a number of surgical options in TGN (microvascular decompression, percutaneous rhizotomy, Gamma Knife), and DBS would very rarely be a treatment for TGN itself. DBS may however be useful in the approximately 2% of patients in whom attempted surgical management of TGN with certain procedures such as injection via the foramen ovale are complicated by anaesthesia dolorosa, a condition of severe pain (often worse than the original pain) that is almost unmanageable by anything other than DBS.

The likely number of candidates for DBS is very hard to predict. A pragmatic estimate, extrapolating from the figures of the specialized neurosurgical centre that has done most of the UK's neuropathic pain DBS (Oxford) suggests a present caseload nationally of 80-100 cases/year. However referral of patients for DBS will be very dependent on referring clinician and patient awareness of the availability of the treatment, and formalised referral and treatment pathways have not been developed due to the fact that it has not been routinely funded to date.

5. Evidence base

The reference base-line for this was the NICE IPG guidance published in March 2011. This was based on an evidence overview prepared in June 2010 focusing on clinical DBS studies of good quality containing information on safety and/or efficacy.

These comprised 693 patients from 3 non-randomised comparative studies, 1 meta-analysis of case series and 5 case series. Publications included, dated from as early as the late 1970's.

Strongly positive commentaries were received from patients who had been treated by DBS.

NICE in 2011, endorsed the use of DBS for refractory chronic pain syndromes in patients selected by a specialised pain MDT, when other treatments had failed to control their pain, provided informed consent, clinical governance, patient information and audit arrangements were in place.

Keeping in mind the above NICE evidence review and Interventional Procedures Guidance recommendations, a further review was carried out using the NICE search strategy and the following studies identified:-

- a. Boccard et al prospectively evaluated 197 chronic neuropathic pain patients for DBS suitability of which 85 patients progressed to DBS. Reasons for not proceeding to DBS included lack of NHS funding (56), surgery declined (29), medical/psychological contraindications (22), not truly refractory (3). Of the 85 - 31 had post-stroke pain, 9 had phantom limb/stump pain, 7 had brachial plexus (BP) avulsion, 13 had spinal damage, 15 had cephalgia and 10 had miscellaneous causes. Of the 85, 74 were implanted following a successful trial. Of these only 59 had long-term data. The success of DBS (EQ – 5D health state) varied by etiology, being most successful following Phantom Limb and Post-Stroke. Overall it was 66.1% (39 patients) with a mean follow-up of 28 months for this subgroup. At 3 months post-DBS, VAS had improved by 50% SF-36 by 38%, MPQ by 38% and EQ – 5D by 27%. These improvements were statistically significant and were sustained throughout the first year. Four years after DBS, VAS and health-state improvements showed some decline although SF 36, MPQ and EQ – 5D improvements remained stable. Complications seen were IPG changes, device removal and infections. This study is the largest open-label study of DBS for pain and uses current DBS technologies and current standards for neuroimaging and stereotactic surgery.
- b. Pereira et al in a Portuguese centre treated 12 consecutive traumatic injury patients with DBS over 2009 – 2011. Patients were followed up for one year. The mean duration of symptoms before surgery was 20 ± 13.4 years. Eleven patients proceeded to full DBS implantation. Five patients were amputees and seven had Brachial Plexus Avulsions. Mean pre-op/baseline VAS scores were 8.2 ± 2.0 . At one month after surgery mean VAS scores improved by $60.1 \pm 27.3\%$, SF-36 improved by $30.1\% \pm 75.5\%$, UWNPS improved by $47.1\% \pm 33.3\%$ and BPI improved by $51.4\% \pm 33.3\%$. All improvements were statistically significant apart from SF-36 scores (except for physical functioning, physical role and bodily pain). Benefits demonstrated were sustained and remained significant at one year. Although both amputation and BPA subgroups showed significant improvements (as described above), amputation pain improved the most. No surgical complications or stimulation side-effects were noted.
- c. Gray et al examined the post-operative effect of DBS on quality of life, emotional well-being and cognition, by a neuropsychological assessment

carried out at least 6 months after patients had undergone DBS. Of 28 potential patients, 18 were available for the study. The sample's subjective post-op pain severity scores improved, significantly with mean reductions of 44.7% (BPI) and 50% (pain subscale of SF – 36). The latter however remained significantly different from a non-clinical sample. Statistically significant post-op functional improvements were also seen in FLP total disability scores of the order of 25.8%. Significant positive QOL improvements were shown in SF – 36 subscales for Physical role, Mental role and bodily pain. However although all SF – 36 sub scores showed an improvement, these were significantly impaired compared to non-clinical normative population data. Pre-operatively the sample's HAD – Anxiety and HAD- Depression scores measuring emotional well-being were both elevated compared with those of the non-clinical normative population. Following DBS surgery, the former scores were significantly reduced by 27.9% and 20.7% respectively. Whilst the reduction in the HAD anxiety score following DBS approached the population normative level, the post-operatively reduced HAD depression score remained elevated relative to the population level. Overall a positive effect with significant improvements in anxiety and mood were found. Post-surgery scores on all cognitive functioning measures were not significantly different from those of pre-surgery levels.

- d. Hunsche et al studied 4 patients suffering from intractable pharmaceutical therapy resistant thalamic pain affecting the whole hemi-body, lasting more than 2 years. Patients were assessed at 3, 6 and 12 months. Intra-operatively, all patients reported satisfying pain relief. In 2 patients a significant reduction of pain medication was achieved (50% reduction in 1 and 100% reduction in the other). In 1 patient successful pain relief vanished by the third month and only minor pain relief (10%) could be achieved. Overall 3 / 4 patients achieved long-lasting pain relief of more than 40%. This level of reduction in pain-intensity was demonstrable at 3, 6 and 12 months of follow-up post DBS. The study also demonstrated the feasibility of integrating tractography data into stereotactic planning of DBS in thalamic pain.
- e. Inference from trials in related areas suggests that DBS for pain is likely to be cost effective. Although initial costs are high, these are offset by reduced requirement for health care resources over time. A cost-utility analysis comparing spinal cord stimulation (SCS) to conventional medical therapy for chronic pain syndromes including failed back surgery syndrome (FBSS), chronic regional pain syndrome (CRPS), peripheral arterial disease (PAD) and refractory angina pectoris (RAP) showed significant economic advantages of SCS in terms of cost per quality adjusted life year (cost per QALY) with probability of cost effectiveness varying from 75-95% depending on pathology (Rizvi et al 2013). Incremental cost effectiveness ratio (ICER) for SCS varied between CAN\$ 9,293 (FBSS) and CAN\$ 11, 216 (CRPS) (Rizvi et al 2013). Evaluation of cost-effectiveness of DBS for Parkinson's disease also found significant benefits over best medical therapy, even after start-up DBS costs were accounted for (Eggington et al 2014).

Conclusions on Evidence

DBS for chronic neuropathic pain in selected patients by specialized centre MDTs

where pharmaceutical medications and other surgical treatments have had limited success, has demonstrated substantial efficacy in pain intensity but also bodily pain, physical functioning, physical role domains of QOL and emotional well-being. Greater efficacy has been reported for some aetiologies such as Brachial Plexus Avulsion, Post-Stroke Pain and Phantom Limb or Stump pain. This is based on an accumulative evidence base of nearly 1000 patients. However, the evidence is observational in nature and derived from cohort studies, case-series and reports. Drawbacks of the evidence would include heterogeneous case-mix of patients but also variability of stimulator technology, neuroimaging techniques, deep-brain sites stimulated and stimulation parameters.

Continued trials are encouraged:-

- To confirm findings of the positive experience of patients and clinicians from prospectively assessed cohort studies and case-series
- To address long-term issues of tolerance (reduction of efficacy with time), patient retention in long term follow up, and loss to follow-up

To identify predictors of long-term efficacy and investigate and overcome tolerance by subtle alterations of either pulse width, frequency, breaks in stimulation.

6. Rationale behind the policy statement

Chronic refractory neuropathic pain management represents a very considerable therapeutic challenge for patients with pain refractory to pharmacotherapy, who often present after other failed invasive pain interventions and neurosurgeries. There is an urgent unmet clinical need for additional effective treatment as often patients are so distressed as to contemplate suicide.

In its document IPG382, NICE states that "There is evidence that [DBS] is efficacious in some patients who are refractory to other forms of pain control".

Although the patients concerned are intensive users of healthcare resources including clinician time and prescription costs, and therefore there is the potential for successful treatment with DBS to be cost effective, there is at present a lack of robust economic evaluation demonstrating good value for the NHS.

From the above, it is considered that funding should be provided routinely but only in a few selected centres with the required experience and expertise. These centres should adopt a pathway as described in section 8 below and should be performing a minimum case volume (see section 9 below). Continued evaluation and further research gathered through appropriately designed trials and retaining patients in long term follow up is necessary. From a patient perspective, non funding will consign a significant number of people to a life time of unremitting pain which is considered unacceptable when this option is known to help some patients.

7. Criteria for commissioning

DBS for chronic neuropathic pain will be routinely funded by the NHS provided that:

- DBS for pain will be undertaken only in centres with sufficient expertise and case volumes taking equitable access into account.
- Safe and effective patient selection and management requires a multidisciplinary team (MDT) including all of the following:
 - Consultant Functional Neurosurgeons (at least two to enable cover of leave)
 - Consultant Pain Physicians (at least two to enable cover of leave)
 - Neuromodulation Nurse Specialists (at least two to enable cover of leave). The role of the nurse specialist is case management, liaison, support of intra-operative testing, and post-operative patient training and programming.
 - Consultant Neuro/pain psychologist to carry out pre-operative assessment.
 - Admin team support including secretary

The MDT should have access to or prior experience of all neuropathic pain treatments and neuromodulatory treatments so that alternatives including dorsal root ganglion and spinal cord stimulation can be considered.

- There should be 24 hour on call cover for emergencies from the neurosurgical unit.
- Centres should have a commitment to further research and evaluation of the technology.
- Centres should have a proven track record in research experience and an adequate research infrastructure as follows;
 - At least one surgeon with an academic 'University' position (full or part time)
 - R&D support for research within the department i.e. have been supported for at least one other clinical study in the past 5 years
 - A proven research track record including peer-reviewed publications in the field of pain research
- In addition, they should have a regular throughput of non-pain DBS cases in order to remain 'current' with the technique of DBS, because of the small numbers (such indicative numbers are specified in other DBS policies but a suggested number is 20 cases per year minimum)

8. Patient pathway

Historically, referral of patients from pain units to specialist centres for pain DBS was highly variable and dependent upon clinician awareness of the therapy. Once assessed for suitability by the implant centre, the success of funding applications via IFRs was dependent on local commissioner (formerly PCT) priorities. If funded, and

approved by the centre's MDT, surgery was offered. **The local factors have meant that there has been a great deal of inequality of access to treatment within the NHS in England.**

Patients who are felt to be candidates for DBS for chronic neuropathic pain should follow the pathway below.

1. Initial referral

The route into the service is via a specialist pain clinic, and this is where the patient should be initially referred from primary care or other specialties. It is critical that all other appropriate pain treatment options short of DBS have been explored (see below). Direct referrals from primary care to functional neurosurgery may be accepted in such cases, when patients have been discharged back to the community for lack of response by a specialised secondary/ tertiary care Pain clinic.

2. Pain clinic

Patients should only be regarded as potential candidates for DBS when all other conventional medical options have been tried and failed or at least considered and for good reason deemed inappropriate, under the supervision of a consultant pain specialist.

The patient must understand the reason for referral to the functional neurosurgery team and where possible should have been provided with some written or website information about DBS. The DBS centre should make leaflets or website addresses available to their usual referring pain clinics for provision to patients so that patients have an opportunity to read about DBS before coming to the functional neurosurgery clinic.

The referrer and local pain team should be prepared to continue to provide medical care to the patient who has been implanted with DBS (see follow up section below).

3. Functional neurosurgery clinic

The patient meets the neurosurgeon, neuromodulation specialist nurse, and functional neurosurgery team's pain physician. Deep brain stimulation is explained along with its aims, limitations and risks.

In order to proceed the patient must accept that:

- treatment will require an implantable device that will require some maintenance into the future. Hence patient commitment and compliance with monitoring and follow up will be essential.
- their condition has no cure but pain relief and functional improvement in physical and mental well-being can be achieved if the chronic pain condition can be improved upon.
- they undertake to cooperate to work with referral team and implanting centre to help achieve best outcomes.

4. Neuro/pain psychology assessment

This is required in all cases to ensure the patient's expectations of treatment are realistic and exclude psychological/psychiatric comorbidities that are likely to be prejudicial to efficacy. Post implant a pain management program may be indicated.

A previous history of psychosis, active suicidal ideation or behavior, major uncontrolled depression or anxiety, or serious cognitive deficits are exclusion criteria.

Involvement of the patient in unresolved litigation or compensation claims is known to be prejudicial to a good outcome in pain treatments and this is therefore also an exclusion criterion. Neuromodulation including deep brain stimulation should be deferred until all such proceedings have been resolved.

5. MDT

The NICE guidance states:

"Patient selection should be carried out by a multidisciplinary team specialising in pain management."

After assessment by pain physicians, neurosurgeons, and a neuropsychologist, all patients should be discussed at an MDT meeting where the decision as to whether to proceed with stage 1 surgery will be taken. At least one pain physician, at least one functional neurosurgeon, a neuropsychologist, and at least one neuromodulation specialist nurse must be present at the MDT meeting.

If it is believed that DBS is not in the best interests of the patient under consideration this will be explained to the patient and referrer and the patient will be discharged back to the referrer with a written letter.

6. Stage 1 surgery

For treatment of pain, the usual brain targets are the sensory thalamus (VP segment) and periventricular grey matter (PVG). Under local anaesthesia, a stereotactic frame is applied to the patient's head. A hole between 3 and 14 mm in diameter is drilled in the skull and, using the frame to guide it, the depth electrode lead is inserted to the target, with intraoperative test stimulation and verbal feedback from the patient to confirm optimal placement. Achieving somatotopic coverage (the generation of paraesthesias in the painful area) by test stimulation during awake surgery is important. The depth leads are attached to temporary extension wires which pass out through the skin in readiness for trialling, and the wounds are closed.

Siting of depth leads has a low risk of causing extradural or intracerebral haematoma. The incidence of neurological deficit due to haematoma after siting of depth leads is approximately 1 in 200. This would usually be apparent during initial postoperative recovery. Emergency CT scanning facilities and immediate access to emergency craniotomy must be available to cope with this eventuality.

7. Trial

Following stage 1 implantation there is an inpatient trial period during which an external pulse generator is used to try to achieve a satisfactory response. This is usually in the form of a paraesthesia that masks or replaces the patient's pain (typically a buzzing sensation similar to TENS when the sensory thalamus is stimulated, or a feeling of warmth when the PVG is stimulated). Success depends upon:

- correct somatotopic coverage (i.e. the stimulation effect is in the same body area as the pain)

- acceptability of the evoked paraesthesia
- substantial reduction in pain (which can often not be abolished completely)

The suggested minimum trial duration is 3 working days but if the team believe a longer trial is necessary (typically to avoid false negatives) it may be necessary to extend it.

Drug reduction may be a marker of successful stimulation. In particular reduction of the anti-neuropathic drugs may quickly occur during the trial. Opioid reduction may be slower in order to accommodate both post-surgical pain and the dependency that will have accrued.

8. Stage 2 surgery

Stage 2 is performed under general anaesthesia. The temporary extension wires are removed and discarded. A subcutaneous pocket is created for the IPG (typically placed subcutaneously in the pectoral region or anterior abdominal wall) and extension leads are passed under the skin from the pocket up to the scalp, and connected to the IPG below and the depth leads above. The IPG is then usually anchored within the pocket to prevent IPG rotation. Finally the IPG is interrogated telemetrically to ensure that the system is functioning correctly.

9. Postoperative management prior to discharge

- The IPG is programmed
- A postoperative analgesia plan is agreed with patient
- The patient is trained in handheld programmer operation, and in the recharging procedure if required
- The patient is taught how to use the therapy continuously or intermittently if appropriate
- Advice is given regarding suture removal
- Contact details of out of hours personnel at the implanting centre are provided

10. Follow-up

By implanting a DBS system, the implant centre takes on a long term responsibility to follow up the patient and provide maintenance of the system including reprogramming and IPG replacements as and when necessary.

While the functional neurosurgery for pain team will have its own consultant pain physicians who will manage the patient's medical treatment as they pass through the DBS pathway, it is not intended that the functional neurosurgery team's pain physicians will take on all the patient's long term medical pain care. Patients having DBS may still require pain clinic input from time to time and this remains the responsibility of their local pain team, with advice from the functional neurosurgery team when required. It is impractical for reasons of patient load (and frequently geographical distance) for the functional neurosurgery team's pain physician to take on the care of all patients having DBS.

Follow up management of the DBS system will usually be led by the neuromodulation specialist nurse, with input from the functional neurosurgeons and pain physicians when required. Pain medication reduction should be supervised by

the patient's local pain clinic, or the patient's GP if they are happy to do so.

Initial follow up is at 6 weeks and thereafter annually. Regular follow up is essential to outcomes assessment and data should be entered into the UK DBS registry.

It is recognised that patients may have come long distances to specialist centres for surgery and that repeated long journeys for follow up may be onerous, and that this may risk losses to follow up. In order to mitigate against this, follow up may be by telephone with the follow up dataset collected by post or online. In this situation programming may be done in the patient's local pain clinic, if the pain physician is appropriately trained.

9. Governance arrangements

DBS is an invasive procedure which has the potential to cause harm. Serious neurological harm is rare but complications such as implant infection, potentially leading to implant removal and consequent loss of therapy, are not uncommon. Both complication rates and outcomes are experience-dependent. DBS is a purely elective treatment and should only be carried out in centres which fulfill all the requirements below.

Referral

Referral should come from a specialist pain physician who has ensured that all appropriate treatments short of DBS have either been tried unsuccessfully, or at least considered and deemed inappropriate. Direct referral from primary care without the prior involvement of specialized pain services or self-referral, is not appropriate.

MDT

Safe and effective patient selection and management requires a multidisciplinary team (MDT) including all of the following:

- Consultant Functional Neurosurgeons (at least two to enable cover of leave)
- Consultant Pain Physicians (at least two to enable cover of leave)
- Neuromodulation Nurse Specialists (at least two to enable cover of leave). The role of the nurse specialist is case management, liaison, support of intra-operative testing, and post-operative patient training and programming.
- Consultant Neuropsychologist to carry out pre-operative assessment
- Secretary

The MDT should have access to or prior experience of all interventional treatments, both lesional (DREZ) and neuromodulatory (DBS, spinal cord stimulation, motor cortex stimulation) and possibly transcranial magnetic stimulation and intrathecal drug delivery as well as psychological and medical interventions.

There should be 24 hour on call cover for emergencies from the neurosurgical unit.

Volumes

Few UK DBS centres have extensive experience with DBS for chronic neuropathic pain, and while DBS for pain has not been routinely commissioned, case volumes have been low. If routinely funded then it is recommended that DBS for neuropathic

pain should be provided only at experienced centres treating at least 10 pain DBS cases per annum.

Audit

All cases will be recorded in the UK DBS registry (see section 11). Data to be captured include:

- pain treatment history (medications and interventions)
- indication (i.e. underlying cause of pain)
- assessment by MDT
- preoperative assessment (for selected cases)
- what was implanted
- complications
- outcomes

Benchmarking and comparison with other centres will be carried out annually.

Serious untoward incidents will also be reported following the individual Trust's usual reporting mechanism.

Research

All cases wherever possible should be entered into an appropriate clinical trial. Trials should be properly designed to maximize the usefulness of the data collected so as to inform future policy decisions, and should be registered as clinical trials in advance.

10. Mechanism for funding

Deep Brain Stimulation for chronic neuropathic pain is routinely funded by the NHS subject to the conditions and requirements set out in sections 7 and 9 above.

11. Audit requirements

The British Society for Stereotactic and Functional Neurosurgery (BSSFN) is developing a national registry for Deep Brain Stimulation which is expected to go live in early 2015. It will include DBS for all indications including pain.

All DBS centres will contribute all DBS patient activity to this registry.

Each implant centre will have access to, and retain ownership of, their own data for their own audit and revalidation requirements.

Nationally, anonymised data will be used:

- to provide aggregate data giving information about DBS as a whole in the UK, e.g. overall volumes and outcomes by indication. This will be useful to policymakers and those conducting observational research
- to provide early warning of device or batch faults
- to identify units that fall below minimum case volumes or are outliers in key performance measures including complication rates and outcome scores

12. Documents which have informed this policy

NICE GUIDELINES - Deep brain stimulation for refractory chronic pain syndromes (excluding headache) (IPG382)

13. Links to other policies

Policies in closely related areas include:

NHSCB/D03/P/b: Deep Brain Stimulation for movement disorders

TA159 (NICE): Spinal Cord Stimulation for Chronic Pain of Neuropathic or Ischaemic origin

14. Date of review

This policy will be reviewed in April 2016 unless information is received which indicates that the proposed review date should be brought forward or delayed.

References

Neuropathic pain in the general population: a systematic review of epidemiological studies.

van Hecke O, Austin SK, Khan RA, Smith BH, Torrance N.

Pain. 2013 Nov 26.

An observational descriptive study of the epidemiology and treatment of neuropathic pain in a UK general population.

Hall GC, Morant SV, Carroll D, Gabriel ZL, McQuay HJ.

BMC Fam Pract. 2013 Feb 26;14:28. doi: 10.1186/1471-2296-14-28.

Adams, J. E. and Y. Hosobuchi (1977). "Technique and technical problems." Neurosurgery 1(2): 196-199.

Akil, H., D. E. Richardson, J. Hughes and J. D. Barchas (1978). "Enkephalin-like material elevated in ventricular cerebrospinal fluid of pain patients after analgetic focal stimulation." Science 201(4354): 463-465.

Baskin, D. S., W. R. Mehler, Y. Hosobuchi, D. E. Richardson, J. E. Adams and M. A. Flitter (1986). "Autopsy analysis of the safety, efficacy and cartography of electrical stimulation of the central gray in humans." Brain Res 371(2): 231-236.

Deep brain stimulation for chronic pain: results of two multicenter trials and a structured review.

Coffey RJ. Pain Med. 2001 Sep;2(3):183-92.

Boccard, S. G., E. A. Pereira, L. Moir, T. Z. Aziz and A. L. Green (2013). "Long-term Outcomes of Deep Brain Stimulation for Neuropathic Pain." Neurosurgery 72(2): 221-231.

Thalamic deep brain stimulation for neuropathic pain after amputation or brachial plexus avulsion.

Erlick A, Pereira EA, Boccard SG, Linhares P, Chamadoira C, Rosas MJ, Abreu P, Rebelo V, Vaz R, Aziz TZ. Neurosurg Focus. 2013 Sep;35(3):E7. doi: 10.3171/2013.7.FOCUS1346.

Dieckmann, G. and A. Witzmann (1982). "Initial and long-term results of deep brain stimulation for chronic intractable pain." Applied Neurophysiology 45(1-2): 167-172.

Eggington S, Valdeoriola F, Chaudhuri KR, Ashkan K, Annoni E, Deuschl G (2014). "The cost-effectiveness of deep brain stimulation in combination with best medical therapy, versus best medical therapy alone, in advanced Parkinson's disease." J Neurol 261 (1): 106-16

Green, A. L., S. Wang, S. L. Owen, K. Xie, R. G. Bittar, J. F. Stein, D. J. Paterson and T. Z. Aziz (2006). "Stimulating the human midbrain to reveal the link between pain and blood pressure." Pain 124(3): 349-359.

Gybels, J. (1980). "Electrical stimulation of the brain for pain control in human." Verh Dtsch Ges Inn Med 86: 1553-1559.

Gybels, J. and R. Kupers (1990). "Deep brain stimulation in the treatment of chronic pain in man: where and why?" Neurophysiol Clin 20(5): 389-398.

Gybels, J., R. Kupers and B. Nuttin (1993). "Therapeutic stereotactic procedures on the thalamus for pain." Acta Neurochir (Wien) 124(1): 19-22.

Hamani, C., J. M. Schwalb, A. R. Rezai, J. O. Dostrovsky, K. D. Davis and A. M. Lozano (2006). "Deep brain stimulation for chronic neuropathic pain: long-term outcome and the incidence of insertional effect." Pain 125(1-2): 188-196.

Hamani, C., J. M. Schwalb, A. R. Rezai, J. O. Dostrovsky, K. D. Davis and A. M. Lozano (2006). "Deep brain stimulation for chronic neuropathic pain: Long-term outcome and the incidence of insertional effect." Pain.

Hosobuchi, Y. (1978). "Chronic brain stimulation for the treatment of intractable pain." Res Clin Stud Headache 5: 122-126.

Hosobuchi, Y. (1983). "Combined electrical stimulation of the periaqueductal gray matter and sensory thalamus." Appl Neurophysiol 46(1-4): 112-115.

Hosobuchi, Y. (1986). "Subcortical electrical stimulation for control of intractable pain in humans. Report of 122 cases (1970-1984)." J Neurosurg 64(4): 543-553.

Hosobuchi, Y. (1987). "Dorsal periaqueductal gray-matter stimulation in humans." Pacing Clin Electrophysiol 10(1 Pt 2): 213-216.

Hosobuchi, Y., J. E. Adams and R. Linchitz (1977). "Pain relief by electrical stimulation of the central gray matter in humans and its reversal by naloxone." Science 197(4299): 183-186.

Hosobuchi, Y., J. E. Adams and B. Rutkin (1973). "Chronic thalamic stimulation for the control of facial anesthesia dolorosa." Arch Neurol 29(3): 158-161.

Hosobuchi, Y., J. Rossier, F. E. Bloom and R. Guillemin (1979). "Stimulation of human periaqueductal gray for pain relief increases immunoreactive beta-endorphin in ventricular fluid." Science 203(4377): 279-281.

Jensen, TS., Baron R, Haanpaa M, Kalso E, Loeser JD, Rice AS, Treede RD (2011). "A new definition of neuropathic pain." Pain 152 (10) 2204-5

Kaplitt, M. G., A. R. Rezai, A. M. Lozano and R. R. Tasker (2004). Deep Brain Stimulation for Chronic Pain. Youmans neurological surgery. H. R. Winn. Philadelphia, Pa., Saunders. 3(197): 3118-3131.

Krauss, J. K., T. Pohle, R. Weigel and J. M. Burgunder (2002). "Deep brain stimulation of the centre median-parafascicular complex in patients with movement disorders." J Neurol Neurosurg Psychiatry 72(4): 546-548.

Kumar, K., C. Toth and R. K. Nath (1997). "Deep brain stimulation for intractable pain: a 15-year experience." Neurosurgery 40(4): 736-746; discussion 746-737.

Kumar K & Rizvi S (2013). "Cost-effectiveness of spinal cord stimulation therapy in management of chronic pain." Pain Med 14 (11): 1631-49

Levy, R. M., S. Lamb and J. E. Adams (1987). "Treatment of chronic pain by deep brain stimulation: long term follow-up and review of the literature." Neurosurgery 21(6): 885-893.

Marchand, S., R. C. Kupers, M. C. Bushnell and G. H. Duncan (2003). "Analgesic and placebo effects of thalamic stimulation." Pain 105(3): 481-488.

Mazars, G., L. Merienne and C. Cioloca (1974). "[Treatment of certain types of pain with implantable thalamic stimulators]." Neurochirurgie 20(2): 117-124.

Mazars, G., L. Merienne and C. Cioloca (1979). Comparative study of electrical stimulation of posterior thalamic nuclei, periaqueductal gray, and other midline mesencephalic structures in man. Advances in pain research and therapy. J. J. Bonica, J. C. Liebeskind and D. G. Albe-Fessard. New York, Raven Press. 3: 541-546.

Mazars, G., L. Merienne and C. Ciolocca (1973). "[Intermittent analgesic thalamic stimulation. Preliminary note]." Rev Neurol (Paris) 128(4): 273-279.

Mazars, G., R. Roge and Y. Mazars (1960). "[Results of the stimulation of the spinothalamic fasciculus and their bearing on the physiopathology of pain.]" Rev Prat 103: 136-138.

Mazars, G. J. (1975). "Intermittent stimulation of nucleus ventralis posterolateralis for intractable pain." Surg Neurol 4(1): 93-95.

Meyerson, B. A. (1983). "Electrostimulation procedures: Effects, presumed rationale, and possible mechanisms." Adv Pain Res Ther 5: 495-534.

NICE. (2011, March 2011). "NHS National Institute for Health and Clinical Excellence guideline IPG 382. Deep brain stimulation for chronic pain syndromes (excluding headache) <http://publications.nice.org.uk/deep-brain-stimulation-for-refractory-chronic-pain-syndromes-excluding-headache-ipg382>." 2012.

Pereira E. A.C., Boccard S.G.B. et.al. "Thalamic deep brain stimulation for neuropathic pain after amputation or brachial plexus avulsion." Neurosurg. Focus 35(3), in press.

Plotkin, R. (1982). "Results in 60 cases of deep brain stimulation for chronic intractable pain." Appl Neurophysiol 45(1-2): 173-178.

Ray, C. D. and C. V. Burton (1980). "Deep brain stimulation for severe, chronic pain." Acta Neurochir Suppl (Wien) 30: 289-293.

Richardson, D. E. and H. Akil (1977). "Long term results of periventricular gray self-stimulation." Neurosurgery 1(2): 199-202.

Richardson, D. E. and H. Akil (1977). "Pain reduction by electrical brain stimulation in man. Part 1: Acute administration in periaqueductal and periventricular sites." J Neurosurg 47(2): 178-183.

Richardson, D. E. and H. Akil (1977). "Pain reduction by electrical brain stimulation in man. Part 2: Chronic self-administration in the periventricular gray matter." J Neurosurg 47(2): 184-194.

Schvarcz, J. R. (1980). "Chronic self-stimulation of the medial posterior inferior thalamus for the alleviation of deafferentation pain." Acta Neurochir Suppl (Wien) 30: 295-301.

Shulman, R., I. M. Turnbull and P. Diewold (1982). "Psychiatric aspects of thalamic stimulation for neuropathic pain." Pain 13(2): 127-135.

Siegfried, J. (1987). "Sensory thalamic neurostimulation for chronic pain." Pacing Clin Electrophysiol 10(1 Pt 2): 209-212.

Tasker, R. R. and O. Vilela Filho (1995). "Deep brain stimulation for neuropathic pain." Stereotact Funct Neurosurg 65(1-4): 122-124.

Thoden, U., M. Doerr, G. Dieckmann and J. U. Krainick (1979). "Medial thalamic permanent electrodes for pain control in man: an electrophysiological and clinical study." Electroencephalogr Clin Neurophysiol 47(5): 582-591.

Tronnier, V. M. (2003). Deep brain stimulation. Pain research and clinical management ; v. 15. B. A. Simpson. Amsterdam London, Elsevier: 211-236.

Tsubokawa, T., Y. Katayama, T. Yamamoto and T. Hirayama (1985). "Deafferentation pain and stimulation of the thalamic sensory relay nucleus: clinical and experimental study." Appl Neurophysiol 48(1-6): 166-171.

Tsubokawa, T., T. Yamamoto, Y. Katayama, T. Hirayama and H. Sibuya (1984). "Thalamic relay nucleus stimulation for relief of intractable pain. Clinical results and beta-endorphin immunoreactivity in the cerebrospinal fluid." Pain 18(2): 115-126.

Tsubokawa, T., T. Yamamoto, Y. Katayama and N. Moriyasu (1982). "Clinical results and physiological basis of thalamic relay nucleus stimulation for relief of intractable pain with morphine tolerance." Appl Neurophysiol 45(1-2): 143-155.

Turnbull, I. M., R. Shulman and W. B. Woodhurst (1980). "Thalamic stimulation for neuropathic pain." J Neurosurg 52(4): 486-493.

Young, R. F. and T. Brechner (1986). "Electrical stimulation of the brain for relief of intractable pain due to cancer." Cancer 57(6): 1266-1272.

Young, R. F. and V. I. Chambi (1987). "Pain relief by electrical stimulation of the periaqueductal and periventricular gray matter. Evidence for a non-opioid mechanism." J Neurosurg 66(3): 364-371.

Young, R. F., R. Kroening, W. Fulton, R. A. Feldman and I. Chambi (1985). "Electrical stimulation of the brain in treatment of chronic pain. Experience over 5 years." J Neurosurg 62(3): 389-396.

Young, R. F. and P. C. Rinaldi (1997). Brain Stimulation. Neurosurgical Management of Pain. R. B. North and R. M. Levy. New York, Springer-Verlag: 283-301.

DRAFT FOR PUBLIC CONSULTATION