Model of Care

DEEP BRAIN STIMULATION FOR THE TREATMENT OF MOVEMENT DISORDERS

Contents

1 EXECUTIVE SUMMARY

The purpose of this document is to propose a model of care for the treatment of people with medication refractory movement disorders in the NSW public health system.

The model of care provides an outline of the surgical component (deep brain stimulation) of a detailed multidisciplinary process of assessment and treatment for clinically eligible public patients in NSW public hospitals.

Parkinson's disease, dystonia and tremor are neurological conditions most visibly characterised by disordered movement. Parkinson's disease affects approximately one person in 100 over the age of 50 years and causes significant disability in many sufferers. Generalised dystonia is relatively uncommon but causes moderate to severe disability in the majority of sufferers. Tremor is the most common movement disorder but causes significant disability less frequently.

These disorders respond to a varying range of medications and interventions. However, the diseases are degenerative and treatment is designed to ameliorate symptoms rather than provide a cure. Modern neurosurgical techniques for the treatment of movement disorders, particularly Parkinson's disease, have become widely accepted and are effective and worthwhile for selected patients.

Neurosurgical therapy with deep brain stimulation is a proven treatment modality that provides major symptomatic benefit for patients for whom medications are no longer effective.

Deep brain stimulation for the treatment of Parkinson's disease is eligible for reimbursement under the Medical Benefits Schedule. In 2006, the Commonwealth accepted and endorsed a Medical Services Advisory Committee report recommending public funding (Medical Services Advisory Committee, 2006). Medical Benefits Schedule funding can be accessed in an inpatient setting by:

- Private patients in private hospitals
- Patients who elect to be private patients in public hospitals

Currently deep brain stimulation therapy with highly trained and experienced specialist movement disorder neurologist/neurosurgical teams is available to private and self-insured patients at three centres in NSW: North Shore Private Hospital, St Vincent's Hospital and Westmead (Public) Hospital.

An adequately funded public program for deep brain stimulation surgery is the most equitable way of delivering such services to eligible patients. The proposed model of care sets out a pathway for patients with Parkinson's disease and movement disorders in the NSW public health system.

The model of care was developed by the former Greater Metropolitan Clinical Taskforce Movement Disorders/Deep Brain Stimulation Working Group (the membership of the working group is set out in Appendix 8.1). The Agency for Clinical Innovation is now responsible for the development of the model.
Three members of the Greater Metropolitan Clinical Taskforce Movement Disorders/Deep Brain Stimulation Working Group were also members of a national working group (the Australian Deep Brain Stimulation Referral Guidelines Working Group) that published the Australian referral guidelines for deep brain stimulation for Parkinson's disease (Silberstein, et al., 2009).

The development of the model of care was predicated on:

- Evidence on the efficacy and safety of deep brain stimulation from current literature;
- Consultation with stakeholders;
- Visits to the three movement disorder clinics providing deep brain stimulation in NSW at Westmead Hospital, North Shore Private Hospital and St Vincent's Hospital and review of the services provided

The model of care is supported by guidelines, developed by the Australian DBS Referral Guidelines Working Group (Review Group) a group of Australian deep brain stimulation neurologists and neurosurgeons.

The model of care provides direction for professionals treating people with Parkinson's disease and other movement disorders.

2 PARKINSON'S DISEASE, DYSTONIA AND TREMOR

2.1 Parkinson's disease

Parkinson's disease is a progressive neurodegenerative disorder characterised by symptoms caused by a loss of dopamine, predominantly from the basal ganglia of the brain. Loss of dopamine causes bradykinesia (reduction in, and slowness of movement), rest tremor, muscular rigidity, shuffling gait and flexed posture. Although recognised as a movement disorder, additional clinical manifestations include autonomic, sensory, sleep, cognitive and psychiatric disturbances. Parkinson's disease usually responds to replacement of dopamine (with Levodopa) for the first few years but management then becomes more difficult (GMCT Neurosurgery Network, Movement Disorders Working Group, 2007). Parkinson's disease may present at any age, although it is most prevalent in later life, affecting 1 % of the population over the age of 55 years. Between 53,200 and 72,200 Australians are currently affected (Silberstein, et al., 2009).

2.2 Dystonia

Dystonia is a disorder characterised by sustained or repetitive involuntary muscle contractions, frequently causing twisting movements with abnormal postures. Dystonia symptoms can range from minor contractions in an individual muscle group (focal dystonia) to severe and disabling involvement of multiple muscle groups (generalised dystonia) resulting in varying degrees of disability. It almost invariably arises in infancy or childhood. Dystonia is relatively uncommon (approximately 1:1000) but causes moderate to severe disability in the majority of sufferers (GMCT Neurosurgery Network, Movement Disorders Working Group, 2007).

2.3 Tremor

Tremor is the most common movement disorder and can arise from many different causes. Essential tremor is the most common, and may affect up to 10% of people as they age. It is a progressive disorder, which has a dramatic increase in prevalence in the 70 and over age group. It predominantly affects the upper extremities and the ability to maintain posture and perform tasks such as picking up a glass. Elimination of the tremor potentially allows people with the disorder to return to a high level of long-term functioning. Tremor can also be caused by underlying disease such as multiple sclerosis or brain trauma.

3 TREATMENT

3.1 Parkinson's disease

Dopamine replacement therapy provides substantial therapeutic relief for most patients over a period of years. In a minority, tremor is resistant to treatment, even at high doses. Longer-term dopamine replacement therapy is associated with the development of motor complications: motor fluctuations and dyskinesia.

When patients develop motor fluctuations, they spend part of the day with therapeutic alleviation of symptoms and part of the day when pharmacologic therapy is ineffective and symptoms are prominent. Over time, the window of therapeutic benefit gradually narrows. After 5 years of dopamine replacement therapy, nearly half the patients experience motor fluctuations and dyskinesia.

Deep brain stimulation has become an important adjunctive therapy in the treatment of dopamine-replacement-therapy-resistant tremor and medication refractory motor fluctuations and dyskinesias.

A small proportion of people with Parkinson's disease will be suitable for surgical intervention using deep brain stimulation. Generally, deep brain stimulation benefits those who are cognitively stable, have a well-preserved but erratic response to dopamine and lack significant co-morbidities.

3.2 Dystonia

Both generalised and focal dystonia can be resistant to medical and/or botulinum toxin therapy. People with primary generalised dystonia who are normal in all other respects can particularly benefit from deep brain stimulation. Deep brain stimulation may also be beneficial for some forms of secondary dystonia, which arise because of a cerebral injury or as part of a more widespread neurological disorder (eg cerebral palsy).

3.3 Essential tremor

Patients with moderate to severe essential tremor obtain a very modest benefit from medication.

Although rare, severe, disabling essential tremor is often completely resistant to medical therapy. Deep brain stimulation may offer the only chance of functional improvement (Silberstein, et al., 2009).

4 WHAT IS DEEP BRAIN STIMULATION?

Deep brain stimulation is exactly as the name implies – a structure deep within the brain is stimulated. Stereotactic guided neurosurgery is the technique used to insert stimulating electrodes into specific nuclei deep within the brain. Once positioned, the electrodes are connected to a permanent neurostimulator implanted into the chest wall. An appendix to the New Zealand Ministry of Health's assessment of deep brain stimulation by Dr D McAuley gives a good general description of the surgery (Ministry of Health, 2008).

The choice of the specific nuclei is dependent on clinical parameters (GMCT Neurosurgery Network, Movement Disorders Working Group, 2007) - see Appendix 8.4 for details.

The implantation process is carried out by a neurosurgical team experienced in movement disorder surgery, The team most commonly includes a neurosurgeon, operating room registered nursing staff, neurologist / neurophysiologist, anaesthetist and radiographer. The procedure takes between 7 and 10 hours, but may take as little as 4 hours depending on technique.

Test stimulation is used during the procedure to confirm the effectiveness and lack of side effects, and to guide accurate electrode placement. The movement disorder neurologist usually commences stimulation 1 to 7 days post-operatively. Programming (stimulation) is individualised to the clinical requirements of each patient and optimal levels may take up to 12 months to achieve. Stimulation parameters vary depending on the target nucleus and the level of a patient's disability.

Stimulators in general have a limited battery life depending on factors such as required stimulus intensity, electrical impedance, stimulus frequency and the battery model. The battery cannot be replaced; rather, a new implantable pulse generator unit must be inserted in exchange for the old unit. This is a simple surgical procedure and does not require further cranial surgery or surgical adjustment of the leads from the head to the upper chest where the stimulators are placed.

Optimal provision of deep brain stimulation therapy requires a multidisciplinary approach with neurological, neurosurgical, psychiatric, neuropsychological, biomedical engineering and specialist nursing input as well as specialised imaging and neurophysiological recording expertise and equipment (a full list of necessary specialist staff is set out at Appendix 8.5).

The major benefits of deep brain stimulation are to provide a more constant and predictable therapeutic benefit than medical therapy alone. Such patients may achieve:

- Reduction in "off" severity
- Increase in "on" time
- Reduction in dyskinesia
- Suppression of medication-refractory tremor
- Simplification of medication regime
- Reduction in medication dosage
- Improvement in performance of activities of daily living
- Improvement in quality of life (Silberstein, et al., 2009)

Deep brain stimulation is a modifiable and largely reversible therapy. These qualities underpin the greater safety and efficacy of this therapy compared with ablative surgery. However, as for all surgical procedures, deep brain stimulation surgery has the potential for adverse events and complications. There are three categories of complications:

- Those related to the surgical procedure, for example, haemorrhage, ischemic lesions and seizures
- Those associated with the device, for example, electrode displacement, skin erosion or infection and mechanical problems
- Those related to stimulation, for example, paraesthesia, muscle contraction, pain, and abnormal eye movements, (these are generally mild and can usually be controlled with stimulator adjustment) (Silberstein, et al., 2009).

5 COST EFFECTIVENESS OF THE TECHNOLOGY

A cost effectiveness analysis was undertaken to compare the costs and benefits of the provision of deep brain stimulation for people with Parkinson's disease to a do-nothing scenario or maintenance of the status quo (Policy and Technical Support Unit, 2010). Three options were analysed against the status quo option.

The cost effectiveness analysis showed that there is strong evidence that the provision of deep brain stimulation for people with Parkinson's disease is a cost-effective alternative to current sole therapeutic pharmacological regime.

The analysis also noted the major health and quality of life benefits for patients who undergo deep brain stimulation therapy.

The cost effectiveness analysis showed that providing deep brain stimulation for clinically appropriate public patients would result in an overall cost saving to the NSW health system. Over 9 years, the savings per patient could be as high as $233,000. Around 90% of the savings are generated by changes in pharmaceutical consumption, which can be reduced by up to half.

6 CURRENT VERSUS THE PROPOSED PATIENT PATHWAY

Currently, in NSW, except for a small number of private patients, people with movement disorders are treated medically.

6.1 Proposed patient management pathway

Patients are referred by their treating neurologist to one of the public movement disorder clinics in NSW. Early referral of patients with motor fluctuations and dyskinesias to an experienced deep brain stimulation team for assessment of suitability for deep brain stimulation is encouraged, as this permits optimal timing of surgery (Silberstein, et al., 2009).

The referral includes detailed information from the patient's records establishing the diagnosis, describing the patient's progress with pharmacological treatment, the complications the patient is experiencing and the indications for possible surgery.

After initial appraisal, patients undergo an extensive work up to assess suitability for surgery in a movement disorder clinic by a specialist team, which includes a movement disorder neurologist and neurosurgeon experienced in deep brain stimulation. The team may also include other specialists such as a movement disorders nurse, movement disorders neurologist, neuro-psychiatrist, and neuropsychologist, depending on the team's usual protocol. This process aims to determine the likely benefit and risks of the procedure on an individual basis.

The patient is admitted to hospital and a preoperative MRI scan of the brain is performed. A Levodopa challenge test, baseline Unified Parkinson's Disease Rating Scale assessment and Modified Parkinson's Disease Quality of Life questionnaire are also performed in the case of patients with idiopathic Parkinson's disease. Relevant accepted baseline Disability Scale scores are established for other disorders. Appendix 8.3 shows examples of these scales.

Clinical best practice for the Levodopa challenge recommends admission of the patient to hospital, because cessation of Levodopa is very disabling for patients and their

carers. In the future, it may be possible to incorporate hospital in the home support into the model of care for patients undergoing a Levodopa challenge.

Once approved for surgery and after pre-operative consultation with a neurosurgeon and anaesthetist, the patient undergoes an initial surgical procedure to insert the intracerebral electrodes and a subsequent second surgical procedure to insert the implanted pulse generators and connect the electrodes. This surgery is performed in two stages because the patient is awake throughout the insertion of the electrodes and undergoes a general anaesthetic for the insertion of the pulse generator. The implantation procedures are carried out by neurosurgical operating teams experienced in movement disorder surgery. The combined procedures take up to ten hours to complete.

Post operatively, stimulation parameters are adjusted by a movement disorder neurologist.

Post-operative programming of the implanted pulse generator may need to continue for up to two weeks. The majority of this work can be performed with the patient attending as an outpatient. During this time, the patient learns how to control the implanted pulse generator with further input from the movement disorders nurse. Post-operative Unified Parkinson's Disease Rating Scale and Modified Parkinson's Disease Quality of Life or other relevant disability scale assessments are repeated.

Each patient will require review in a movement disorders clinic at six-monthly intervals at which time the implanted pulse generators' programming parameters and battery state will be checked and adjusted if necessary. Some patients may require review more often depending on their clinical requirements. In addition, Unified Parkinson's Disease Rating Scale, Modified Parkinson's Disease Quality of Life or other disability scale assessments are repeated.

A summarised pathway including time for each stage is at Appendix 1.1.

6.2 Patient selection

The Australian deep brain stimulation referral guidelines (Silberstein, et al., 2009) clearly illustrate the clinical eligibility inclusion and exclusion criteria for non-movement disorder neurologists and general practitioners who require some direction when deliberating on referral of a patient to a movement disorder specialist neurologist.

The common indications for consideration of deep brain stimulation are:

- Patients with motor fluctuations and or dyskinesia who do not achieve satisfactory symptom control with optimised medical therapy
- Patients with medication refractory tremor
- Patients who are intolerant of medical therapy
- Patients with a combination of the above

Four main co-morbidities may influence the decision to proceed with deep brain stimulation. Contraindications from each category may be absolute or relative depending on severity:

- Significant cognitive impairment/decline
- Significant refractory psychiatric co-morbidity

- Significant medical co-morbidity
- Pre-existing affective and anxiety disorders

The New Zealand Ministry of Health also sets out detailed indications for deep brain stimulation in its *Assessment of the Business Case for a Deep Brain Stimulation Neurosurgical Program for Movement Disorders* (Ministry of Health, 2008).

7 NEXT STEPS

The implementation and operation of publicly funded deep brain stimulation services in NSW depends on acceptance, planning and funding of the model of care by the Department of Health.

Guidelines for implementation and systems and processes for service delivery and appropriate evaluation and monitoring of the program, will be developed if the model is funded and accepted.

However, it is proposed that a full database of patients will be implemented and maintained by each movement disorders clinic.

8 APPENDICES

8.1 GMCT movement disorders/deep brain stimulation working group and ACI Neurosurgery Network members

Prof Michael Besser	Neurosurgeon
Dr Ray Cook*	Neurosurgeon
Ms Lyn Farthing	Network Manager, Neurosurgery, ACI
Dr Victor Fung	Neurologist, movement disorder specialist
Dr Michael Hayes	Neurologist, movement disorder specialist
Professor Donald MacLellan	State Program Director, Surgery, NSW
Ms Laraine McAnally	CNC Parkinson's disease, movement disorders and epilepsy
Dr Martin McGee-Collett	Neurosurgeon
Dr Neil Mahant	Neurologist, movement disorder specialist
Ms Kate Needham	Executive Director ACI
Dr Brian Owler	Neurosurgeon
Dr Malcolm Pell*	Neurosurgeon
Dr Paul Silberstein*	Neurologist, movement disorder specialist
Dr Stephen Tisch	Neurologist, movement disorder specialist
Dr Hunter Watt	Chief Executive, ACI
*Also members of the Australian Deep Brain Stimulation Referral Guidelines Working Group	

8.2 Pathway details

(GMCT Neurosurgery Network/Movement Disorder /DBS Working Group, 2009)

Patient Journey for Deep Brain Stimulation

From Referral to Admission	Months
Public	
Private	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
Time from GP/Neurologist referral to initial assessment with Movement Disorder Neurologist	
Time from initial assessment until review at DBS clinic	
Time from 2nd DBS Clinic visit until review by neurosurgeon, psychiatrist, neuropsychologist; formal Dopa challenge, MRI +/- sedation (3-6 months)	
Time from initial assessment until review by neuropsychologist, psychiatrist, formal dopa challenge, MRI +/- sedation (1-1.5 month). Patient is added to surgery waiting list.	
Pre-op assessment with neurosurgeon	
Time from neurosurgical review until admission for DBS	

Notes – Public

60 - 80% of patients from the initial assessment proceed to review at the DBS clinic

90-95% of those patients go onto the surgical waiting list.

100% of patients on the surgical waiting list proceed to surgery.

Many patients referred for initial assessment do not meet criteria or choose not proceed.

Major delays are due to the limited availability of clinical neuropsychology, psychiatry and MRI +/- sedation or general anaesthetic

Notes – Private

A small proportion of patients do not proceed to surgery.

Patients are reviewed 4-8 wks prior to admission by neurosurgery.

Pts are reviewed 4-8 wks prior admission by anaesthetist if indicated.

Included in 2 days pre-op is r/v by DBS RN re surg/post-op expectations, completion of quality of life questionnaire.

Pre-surgical Preparation	Days
Public	
Private	-7 -6 -5 -4 -3 -2 -1 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
Pre-admission clinic; anaesthetist, neuro registrar, RN, ECG, Chest Xray	
Admission, adjust medications, 3T MRI +/- sed., RN, Bloods, ECG, Chest Xray	
Admission. (Some pts may require admission 1-2 days before for withholding of PD meds).	
Length of stay (maximum length of stay shown)	

Day of Surgery	Hours
Public	
Private	**7** 15 30 45 **8** 15 30 45 **9** 15 30 45 **10** 15 30 45 **11** 15 30 45 **12** 15 30 45 **13** 15 30 45 **14** 15 30 45 **15** 15 30 45 **16** 15 30 45
Start procedure, application	
stereotactic frame	
Post application CT	
Transfer to theatres	
Computerised surgical plan	
Draping, incision, burr hole	
Target mapping	
Electrode insertion	
Re-drape	
Previous 3 steps & wound closure	
General anaesthetic	
Subcut of lead, IPG	
Recovery	For an hour post completion of second surgery

Notes

There were negligible differences between the sectors regarding the day of surgery.

First post-op night pts are monitored in ICU/neuro HD (this is extended if clinically warranted).

Parkinson's medications are reduced; pt transferred to ward; IVABs for 3 days; mobilisation; normal diet; daily r/v with neurology & neurosurgery; stimulation and meds adjusted as required; r/v by DBS CNC; education on hand held programmer; discharged 7 to 14 days post-op; medications and stimulation parameters set prior to discharge; f/u with neurology, neurosurgery, DBS CNC, 4-12 consults in first yr; ongoing f/u with referring neurology; equipment check recommended every 6-12 months

8.3 Examples of scales and assessments

(GMCT Neurosurgery Network, Movement Disorders Working Group, 2007)
Unified Parkinson's disease rating scale (UPDRS)
http://www.mdvu.org/library/ratingscales/pd/updrs.pdf

Hoehn and Yahr staging of Parkinson's disease
http://neurosurgery.mgh.harvard.edu/functional/pdstages.htm

Schwab and England activities of daily living scale
http://www.ncbi.nlm.nih.gov/books/NBK27460/

Unified dystonia rating scale (URDS)
http://www.mdvu.org/library/ratingscales/dystonia/udrs_r1.pdf

The Fahn-Marsden (BFM) scale: movement
http://www.mdvu.org/library/ratingscales/dystonia/bfm_scale.pdf

Tremor Assessment Form

Patient name:	Date:
Dominant hand: R L (circle one)	Physician:

Description of tremor

Location	Severity	When present?
Face/Chin		R P K
Voice		R P K
Tongue		R P K
Head/Neck		R P K
Trunk		R P K T
Right Arm		R P K T
Left Arm		R P K T
Right Leg		R P K T
Left Leg		R P K T
	0 = none 1 = mild 2 = moderate 3 = severe 4 = incapacitating	R = resting P = postural K = kinetic T = task-specific

Current medications for tremor

Medications	Dose	Frequency

Patient's response to therapy

Patient's level of difficulty with:

	working		speaking		writing
	dressing		fine movements		depression due to tremor
	pouring		hygiene		anxiety due to tremor
	eating		drinking		embarrassment
	involvement in social functions				

Archimedes Spiral

Left hand	Right hand
Physician rating	Physician rating
Severity: 0 = none 1 = mild 2 = moderate 3 = severe 4 = incapacitating	

Line Drawing

R ●	●
L ●	●

Left hand	Right hand
Physician rating	Physician rating
Severity: 0 = none 1 = mild 2 = moderate 3 = severe 4 = incapacitating	

Handwriting sample

Speech and Voice Exam

Conversational speech	Physician rating
Count to 10	Physician rating
Sustained "eeeee" for 5 seconds	Physician rating

8.4 Target intracerebral structures for deep brain stimulation

(GMCT Neurosurgery Network, Movement Disorders Working Group, 2007)

Structure	Effect post stimulation	
The ventral intermediate nucleus of the thalamus (Vim)	Effective in suppressing contra-lateral limb tremor, eg if the left side of Vim is stimulated, the effect is seen on the right side of the body.	This is the main stimulation target for tremor. VIM deep brain stimulation in ET has been shown to reduce significantly limb and neck tremor.
The globus pallidus internus GPi	Dramatic reduction in dyskinesias and rigidity; variable effect on tremor and akinensia.	Most common implantation site for the treatment of dystonia. Implantation techniques and post operative care is similar for that described in Parkinson's disease, however, improvements may occur over a much longer period
The subthalamic nucleus (STN)	Bilateral STN stimulation has been shown to improve tremor, rigidity, akinensia and gait disturbance and facilitate a reduction in drug therapy.	Surgical treatment of choice in the majority of Parkinson's disease patients who are referred for deep brain stimulation

8.5 Multidisciplinary movement disorders team

Optimal provision of deep brain stimulation requires a multidisciplinary approach with neurological, neurosurgical, psychiatric, neuropsychological biomedical engineering and specialist nursing input as well as specialised imaging and neurophysiological recording expertise and equipment. Team members could include:

- Neurologist –specialising in movement disorders and DBS
- Neurosurgeon - skilled in stereotactic procedures with extra expertise in movement disorders
- Neurophysiologist - specialising in DBS
- Nurse - movement disorder Clinical Nurse Consultant
- Psychiatrist – specialising in neuropsychiatric complications of movement disorders
- Anaesthetist
- Assistant surgeon
- Neuro-radiologist
- Rehabilitation physician
- Allied health, including physiotherapist, speech therapist, social worker, occupational therapist, dietician, psychologist
- Neuropsychologist
- Biomedical engineering
- Neurophysiology recording expertise

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