North South Inter-Parliamentary Association

Briefing Paper for the sixth meeting of the North-South Inter-Parliamentary Association

Deep Brain Stimulation

5th June 2015

Background briefing prepared by the Research and Information Service (RaISe) of the Northern Ireland Assembly and the Library & Research Service of the Houses of the Oireachtas (*Tithe an Oireachtais*)

Glossary:

Parkinson's disease is a progressive disorder of the nervous system that affects movement. Parkinson's disease symptoms worsen as the condition progresses over time.[1]

Essential tremor is a nervous system disorder (neurological disorder) that causes a rhythmic shaking. It typically manifests in the hands but can occur anywhere in the body. While not usually a dangerous condition, it can get worse over time.[2]

Dystonia is a syndrome of involuntary muscle contraction and spasms that twists part or all of the body into involuntary postures and movements which are disabling. It affects one in young life or in older years. In children who are affected, it often affects their entire body.[3]

IPG - implantable pulse generator is a surgically implanted, battery-operated medical device similar to a heart pacemaker, roughly the size of a stopwatch. It delivers electrical stimulation to specific areas in the brain that control movement.[4]

Acronyms:

DBS – Deep Brain Stimulation

HSE – Health Service Executive

TAS – Treatment Abroad Scheme

HTA – Health Technology Assessment

IPG – Implantable Pulse Generator

HIQA – Health Information and Quality Authority

EPDA – European Parkinson's Disease Association

[1] http://www.mayoclinic.org/diseases-conditions/parkinsons-disease/basics/definition/con-20028488

[2] http://www.mayoclinic.org/diseases-conditions/essential-tremor/basics/definition/con-20034509

[3] Dr. Richard Walsh presenting to the Joint Oireachtas Committee on Health and Children on 6th November 2014.

[4] http://www.ninds.nih.gov/disorders/deep_brain_stimulation/deep_brain_stimulation.htm

1. Key Issues

Compelling arguments have been put forward by some stakeholders to support the establishment of an all-Island Deep Brain Stimulation (DBS) service. The report of the Oireachtas Joint Committee on Health and Children, which strongly supported an all-island approach to the development of DBS treatment services, summarises these as follows (emphasis added):

a) **Ready access** to a neurosurgical unit with the necessary expertise and equipment;

b) **The patient experience** in a Belfast setting will be far easier and post-operative management is superior and safer than accessing DBS in England;

c) In the long-term, an all-island approach will help to develop **a critical mass of** qualified neurologists, neurosurgeons and patients to sustain a DBS programme;

d) Local availability and awareness of DBS will **open it up to candidates** who are currently overlooked or reluctant to travel overseas to receive treatment;

e) From a governance perspective, medical staff would be able to engage in **multidisciplinary discussion of cases** pre & post-operatively;

f) Given that DBS is a rapidly evolving field, there is a need to **develop local expertise** in the medical and surgical management of DBS.

g) Such an approach is **cost effective** with respect to alternative treatment options in England.

However there are cost implications for Governments on both sides of the border. The Health Service Executive (HSE) in Ireland and Department of Health, Social Services and Public Safety in Northern Ireland have expressed the view that any decisions regarding the provision of a DBS treatment service on the island of Ireland will require a thorough cost-benefit analysis.

2. Introduction

Deep Brain Stimulation (DBS) is described as:[5]

> "…a surgical procedure for the relief of motor function symptoms in patients with movement disorders – including Parkinson's disease, essential tremor and dystonia – that are no longer adequately controlled by drug therapy."

DBS is only used when drug therapy fails and patients suffering from involuntary movements must first undergo a phase of attempting pharmacological therapy. At present there is no routineDBS surgery on the island of Ireland (some surgeries are performed on a case-by-case basis at the Royal Victoria Hospital, Belfast), so patients from Northern Ireland and the Republic are referred to centres in other jurisdictions for the procedure and follow-up care.

Patients from the Republic may be funded through the HSE operated Treatment Abroad Scheme (TAS), while patients from Northern Ireland can access the treatment through the Health and Social Care Board's Extra Contractual Referral process.

In October 2012 the Health Information and Equality Authority (HIQA) published a health technology assessment (HTA) which examined the feasibility of establishing DBS treatment in the Irish Republic.[6] However, while the report compared the cost of providing DBS treatment in Dublin with the existing TAS-funded service; it did not consider the cost savings which could be achieved if an all-island centre were established in Belfast.

This latter point was discussed by the Oireachtas Joint Committee on Health and Children who met Consultant Neurosurgeons, representatives of Parkinson's UK, the Parkinson's Association of Ireland, and the HSE to discuss DBS.[7] The Joint Committee's meetings on this issue culminated in a *Report on the potential benefits of an All-Island approach to Deep Brain Stimulation Treatment*, which was published in February 2015.[8] The Committee supported the establishment of an all-island DBS

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[5] http://www.hiqa.ie/publications/health-technology-assessment-national-deep-brain-stimulation-service-ireland

[6] ibid.

[7] These meetings took place on the 6th November 2014 and 4th December 2014. Links are available here http://oireachtasdebates.oireachtas.ie/Debates%20Authoring/DebatesWebPack.nsf/committeetakes/HEJ2014110600009?opendocument#K00200 and http://oireachtasdebates.oireachtas.ie/Debates%20Authoring/DebatesWebPack.nsf/committeetakes/HEJ2014120400003?opendocument#B00300

[8] http://www.oireachtas.ie/parliament/media/committees/healthandchildren/health2015/Report-on-Deep-Brain-Stimulation-Treatment--060215.pdf

service based in the Royal Victoria Hospital, Belfast. The Joint Committee's recommendations include:

- the appointment of two DBS nurse specialists, one located in Dublin and one in Belfast, to co-ordinate and manage patient support before and after the procedure, in order to facilitate an all-island service.
- that the HSE keeps the business case for the establishment of a second DBS treatment centre in the Republic under continual review, in light of the current improving economic situation, with such decisions being based on a positive cost-benefit analysis for all concerned.
- that the issue of DBS treatment be given further consideration at Ministerial Council level.

In a reasoned response to this report, the Minister for Health, Dr. Leo Varadkar, T.D. writes that the increase in number of patients who are assessed as likely to benefit from DBS, along with the number of patients availing of DBS treatment in Belfast:

> "…underpins the all-island service model as a viable and preferable alternative to reliance on treatment overseas."

This paper will draw from the reports mentioned above and outline the main issues around the provision of DBS on the Island of Ireland. The paper is structured as follows:

- Deep Brain Stimulation – definition, procedure and efficacy
- Current options available to patients seeking DBS
- Providing an all-Island DBS centre
- Conclusion

3. Deep Brain Stimulation – definition, procedure and efficacy

3.1 The DBS procedure

DBS is a reversible procedure and works by implanting an electrode in the brain to stimulate targeted areas controlling movement. Prior to the procedure, a neurosurgeon uses magnetic resonance imaging (MRI) or computed tomography (CT) scanning to locate the exact areas within the brain where electrical nerve signals generate symptoms.[9]

There are three components to DBS:[10]

- The electrode is inserted through a small opening in the skull and implanted in the brain.
- The extension (an insulated wire) is passed under the skin of the head, neck, and shoulder, connecting the electrode to the implantable pulse generator (IPG).
- The IPG is implanted under the skin near the collarbone. In some cases it may be implanted lower in the chest or under the skin above the abdomen.

There is some pioneering research into the use of DBS for conditions such as Anorexia, Obsessive-compulsive disorder (OCD), Depression and Dementia, however these are at a relatively preliminary stage.[11] DBS is mainly associated with three conditions: Parkinson's disease, Essential Tremor and Dystonia.

3.2 Incidence of Parkinson's disease, Essential tremor and Dystonia

Parkinson's disease accounts for approximately 74% of all referrals for DBS in the Republic while Dystonia and Essential tremor account for 11% and 15% respectively.[12]

[9] http://www.parkinson.org/parkinson-s-disease/treatment/surgical-treatment-options/deep-brain-stimulation
[10] Ibid.
[11] Delaloye, S. and Holtzheimer, P.E. (2014). Deep brain stimulation in the treatment of depression. *Dialogues in Clinical Neuroscience*. 2014 Mar; 16(1): 83–91. Accessed on 6th May 2015 at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3984894/
[12] http://www.hiqa.ie/publications/health-technology-assessment-national-deep-brain-stimulation-service-ireland

Speaking to the Committee on 6th November 2014, Dr. Richard Walsh, a consultant neurologist and clinical senior lecturer at Tallaght hospital, spoke of the incidence of these conditions and reported the following to the Committee:

Ireland

- Parkinson's disease affects more than 8,000 persons in Ireland at present.[13] Approximately one third of these have advanced Parkinson's disease;
- Approximately 1% of the population, maybe 5% of those over 65 years, are affected by Essential Tremor;
- Approximately 3,000 persons in Ireland are affected by Dystonia.

Northern Ireland

- Almost 4,000 people in Northern Ireland have Parkinson's Disease;[14]
- Approximately 1% of the population, maybe 5% of those over 65 years, are affected by Essential Tremor;
- Dystonia affects an estimated 70,000 people in the UK.[15]

3.3 Efficacy of DBS

DBS is shown to be effective in reducing involuntary movements associated with Parkinson's, Essential tremor and Dystonia. The Health Information and Quality Authority (HIQA) (2012) feasibility study notes:

> "There is good quality randomised controlled trial data that DBS is more effective than best medical treatment for patients with advanced dopamine-responsive Parkinson's disease who have severe motor symptoms that are no longer adequately controlled with medication. The quality of the evidence of effectiveness of DBS in dystonia and essential tremor is more limited, consisting mainly of observational study designs showing improvements in symptoms, as measured by validated dystonia and tremor scales."

The HIQA (2012) study also reports the following risks associated with the procedure: infection, device malfunction, cerebral haemorrhage, dyskinesias[16], axial symptoms, speech dysfunction, paraesthesia and behavioural and cognitive issues.

[13] It is estimated that 1 person in 500 has Parkinson's Disease.
[14] As reported to the Oireachtas Joint Committee on Health and Children by Ms. Nicola Moore of Parkinson's UK on 6th November 2014.
[15] http://www.nhs.uk/Conditions/dystonia/Pages/introduction.aspx
[16] Dyskinesia is the term used to describe unintended, involuntary and uncontrollable movements including: twitches, jerking, twisting or restlessness; it does not include tremor (EPDA, 2014).

3.4 Follow-up care

Post-surgery DBS patients require follow-up care at specified intervals. The first appointment usually takes place 6-8 weeks after surgery and is used to assess the patient's progress and, if required, adjust the stimulation.[17] The second appointment usually takes place 4-6 months after surgery and serves the same purpose. The next review will take place one year post-surgery, where a set of tests are conducted to enable comparison with pre-surgery data.

Other appointments will be required after this, including a long term follow-up appointment, where the tests administered in the one year follow-up are repeated to compare with baseline, pre-surgery data. The timing of this review differs, ranging from three to five years.[18] All of these follow-up appointments involve a Neurologist Specialist Nurse.

Over time IPGs will need to be replaced (due to battery failure). This requires patients to spend 1-2 hours in surgery as well as 1-2 nights in hospital. Staffing requirements include a surgeon, surgical registrar and two theatrical nurses.

[17] HIQA. (2012). Health technology assessment of a national deep brain stimulation service in Ireland: Technical Report. Accessed on 29th January 2014 at http://www.hiqa.ie/publications/health-technology-assessment-national-deep-brain-stimulation-service-ireland
[18] Ibid.

4. Current options available to patients and demand for DBS on the Island of Ireland

4.1 Northern Ireland

It is estimated that, currently, there are between 18 and 25 patients in Northern Ireland suitable for DBS.[19]

Northern Ireland does not have an established DBS service and patients are regularly referred to another jurisdiction, such as England, for the procedure. Patients in Northern Ireland can access the treatment through the Health and Social Care Board's Extra Contractual Referral process, which provides for circumstances where specialised care cannot be provided within Northern Ireland.

While there is a neurosurgical centre in the Royal Victoria Hospital, Belfast where DBS surgery can and has been performed; the necessary nursing support is not in place to co-ordinate the service and make it routinely available.

Recently, arrangements have been made enabling patients from Northern Ireland and the Irish Republic to receive DBS in the Royal Victoria Hospital, Belfast. Some stakeholders hope that this practice can be continued and expanded.

Figures provided by the Department of Health, Social Services and Public Safety in Northern Ireland[20] show that during the period 2011/12 – 2013/14 there were 7 approvals for treatment in Northern Ireland and 1 approval for battery replacement. In the same period there were 47 approvals for transfers outside Northern Ireland, 2 of which were for assessment only and 11 of which were for battery replacement.

There has not been any treatment for DBS within Northern Ireland for the 2014/15 period.[21]

4.2 Ireland

It is estimated that currently between 40 to 60 people in the Republic would be suitable for DBS.[22]

[19] These figures were provided to the Oireachtas Joint Committee on Health and Children on the 6th November 2014 by Dr. Gavin Quigley, consultant neurosurgeon, Royal Victoria Hospital Belfast.
[20] Provided to the Northern Ireland Assembly Committee for Health, Social Services and Public Safety on 6th February 2015 in advance of their meeting with the Oireachtas Joint Committee on Health and Children.
[21] Ibid.

At a meeting on 4th December 2014 Ms Angela Fitzgerald, Deputy National Director of the HSE told the Committee that there were waiting lists for DBS:

> "A number of patients, particularly at outpatient level, are waiting longer than 12 months."

At present, there is no DBS surgery in the Republic so patients may qualify for the Treatment Abroad Scheme (TAS), operated by the HSE. This allows patients access to proven treatments in another EU-EEA country or Switzerland (if these treatments are not available in Ireland). Patients seeking DBS must be assessed on an individual basis in order to benefit from TAS. Patients receiving DBS through TAS remain under the clinical management of their Consultant Neurologist in Ireland or the DBS service at the Dublin Neurological Institute.

The HSE sends patients to two centres in the UK: Oxford and Newcastle, for DBS treatment. Figures provided by Dr. Tony O'Connell of the HSE[23] show that over the period 2012 to 2014, the number of people referred to another jurisdiction through TAS for DBS treatment increased from 50 to 170, with a corresponding increase in costs from €400,000 to €1.5m. Dr. O'Connell also said that TAS had implemented initiatives to streamline the application process. The Parkinson's Association of Ireland predict that making DBS available on the island of Ireland would increase the number of patients receiving the treatment by over 50%.

Figures provided by the Department of Health in the Republic, [24] show the number of patient attendances for DBS treatment which took place in hospitals in another jurisdiction (2012-2015). These are as follows

Table 1: Total No. of Patient attendances

Year	2012	2013	2014	2015 Quarter 1
Number	72	55	93	26

Source: Department of Health

It should be noted that these figures relate to all visits, including some or all of the following: assessment, pre-op, surgery, post-op and follow up reviews.

[22] These figures were provided to the Oireachtas Joint Committee on Health and Children on the 6th November 2014 by Dr. Gavin Quigley, consultant neurosurgeon, Royal Victoria Hospital Belfast.
[23] Provided to the Oireachtas Joint Committee for Health and Children on 4th December 2014
[24] Figures provided in private correspondence to the L&RS. Note the same patient can attend more than once.

5. Providing an all-Island DBS centre on the Island of Ireland

5.1 Rationale for providing an all-Island DBS centre

5.1.1 Improving the patient experience

As the situation now stands, patients in advanced stages of illness must undergo DBS surgery overseas, a burden which many stakeholders believe is onerous. In addition patients must receive follow-up care overseas, necessitating even more travel. From the patient point-of-view it would therefore be preferable to access a DBS service closer to home.

Also if patients encounter post-operative complications it is advantageous to have a DBS service available locally. This issue was brought to the attention of the Oireachtas Joint Committee on Health and Children by Dr. Richard Walsh:[25]

> "If their battery fails, they get post-operative infections or there is a lead failure, there is a scramble to contact the neurosurgical centre to get them over. We have to scramble to get E112 treatment abroad approval. The patient sometimes sits in an accident and emergency department, in Dublin or elsewhere in the country, waiting for this urgent transfer to the United Kingdom."

The HSE National Clinical Programmes write that offering an all-island DBS service would be more equitable than the present situation, as many patients are unable to travel overseas.[26]

5.1.2 Existing surgical expertise

Dr. Walsh told the Committee that establishing a service in Northern Ireland is helped by the fact that the surgical expertise already exists there:[27]

> "…there is a good rationale for looking at an all-island approach because in Belfast there is a neurosurgical centre and surgeons, such as Mr. Quigley, who are performing these surgeries already."

[25] Oireachtas Joint Committee on 6th November 2014 where he outlined the rationale for a thirty-two county service in Ireland
[26] HSE. (2015). Response to the Joint Committee on Health and Children's report on DBS.
[27] Oireachtas Joint Committee on 6th November 2014 where he outlined the rationale for a thirty-two county service in Ireland

5.1.3 Potential savings

A further argument made for providing an all-Island DBS service refers to the potential savings which could be achieved. On 6th November 2014, Dr. Richard Walsh told the Committee that an alternative to DBS, 'pump therapy' is more expensive and is already funded by the HSE:

> "There is certainly an upfront cost in developing a centre, but the cumulative cost is significantly less than the alternative pump-based therapies. One could consider this therapy paying for itself after two years because we can reduce drug costs by between 50% and 60% after surgery."

The HSE National Clinical Programmes write that additional savings would be made by reducing the current duplication which exists in assessment and monitoring between service providers on the island of Ireland and overseas.[28] The Minister for Health, Dr. Leo Varadkar, T.D. states that:[29]

> "Using a coordinated approach to assess patients for suitability, using standardised protocols before referral to Belfast for surgery, will reduce, and possibly eliminate such duplication."

5.2 North-South collaboration

Dr. Gavin Quigley and Dr. Richard Walsh propose that an all-Island DBS service be established and run as a North-South collaboration, with patients undergoing surgery in the Royal Victoria Hospital, Belfast while the ongoing assessments are conducted by nurses in centres like Cork, Galway, Dublin and Sligo. Doctors Quigley and Walsh envision a second DBS centre being established in Dublin as numbers increase.

5.3 Costs and challenges involved in establishing an all-Island DBS centre

The HIQA (2012) feasibility study compared the costs involved in establishing DBS treatmentin the Republic with the cost of maintaining the current HSE funded Travel Abroad Scheme (TAS), whereby patients are referred to another jurisdiction, such as England. The study did not look at the costs associated with establishing a DBS centre in Belfast. The HIQA (2012) report noted the following challenges:

> "…building the clinical expertise and service capacity to meet current and future demand while ensuring that adequate access to high quality DBS services is maintained and existing services for other neurosurgical patients are not undermined."

[28] HSE. (2015). Response to the Joint Committee on Health and Children's report on DBS.
[29] Department of Health. (2015). Reasoned response from Minister Varadkar to the Joint Committee on Health and Children's report on DBS.

However, the study did not consider using the resources already available in the Royal Victoria Hospital, Belfast. According to Dr. Gavin Quigley:

> "The infrastructure exists in the Royal Victoria Hospital and we do not need equipment, staff or anything like that. However, we do need two nurses to co-ordinate things in order that we have one North and one South who would be responsible for assessments, following up patients, looking up data and making sure the whole thing is co-ordinated."

Other cost implications were noted in the HIQA (2012) report, as shown in Table 2. The table shows that the additional cost per patient over 10 years for an Irish DBS service is €20,898, i.e. an Irish-based service would be more expensive than the current TAS arrangement. Over five years, the incremental budget impact of a national DBS service would be €1.84 million more than the estimated €4.29 million to treat the same number of patients through the TAS.

Table 2: Discounted cost per patient

Scenario	Discounted cost per patient	€ over ten years (95% CI)
Irish service	65,726	(52,853 – 86,959)
Current service	44,664	(32,892 -65,308)
Difference	20,898	(5,447 – 36,540)

Source: HIQA (2012) feasibility study.

Note: Difference is calculated as the median across all simulations rather than the difference between the median calculated for each service

The authors also found that there would be considerable staff requirements associated with an Irish based service and write:

> "With the establishment of an Irish DBS service, the terms of TAS require that all patients currently receiving treatment abroad would have to be repatriated. Partly due to the repatriation of DBS patients, if an Irish DBS service is established there will be substantial resource implications in terms of staff, theatre time and bed days that must also be taken into consideration."

Speaking to the Joint Committee for Health and Children on 4th December 2014, Dr. Tony O'Connell of the HSE referred to possible savings to Ireland if a DBS service was available in Belfast. He said:

> "The indicative savings are of the order of €7,200 per case, with further savings envisaged over time particularly with the potential development of

> outpatient follow-up in the Irish system. It is expected there will be further savings in regard to the reduction in pharmaceutical costs associated with DBS as a result of the patients availing of the surgery. It is also anticipated that in time this service will be developed further, with the possibility that multidisciplinary out-patient follow-up clinics could be conducted in the South providing further convenience for the patients."

Dr. O'Connell said that while savings would be achieved under an all-Island model compared with referring patients abroad to the UK, establishing a completely new service would be more expensive because of set-up costs in Dublin.

In his reasoned response to the Joint Committee on Health and Children's report on DBS, the Minister for Health, Dr. Leo Varadkar, T.D. writes that in addition to the nurse-specialist posts, identified in the Committee's report, access to allied health professions would also be required, such as neuropsychology, clinical neurophysiology, speech and language therapy, physiotherapy, social services, anaesthesia and radiology.

However Dr. O'Connell also expressed reservations regarding costs. As noted in the Oireachtas Committee's report:

> "Dr. O' Connell also advised that HSE would continually review the option to develop a DBST service in the Irish health system, but that this would be based on cost-benefit analysis. On the provision of additional staffing / nursing support to help co-ordinate the service, Dr. O' Connell advised that while the HSE was generally supportive of growing the service, this was not provided for in the HSE Service Plan."

Similarly, the Department of Health, Social Services and Public Safety in Northern Ireland [30] write that while the Trust would be keen to further develop a DBS service, decisions on any way forward will be dependent on available resources and the outcome of work underway which is examining:

> "…the safety and sustainability and cost effectiveness of a local service and the wider resource position in 2015/16 and beyond."

[30] Provided to the Northern Ireland Assembly Committee for Health, Social Services and Public Safety on 6th February 2015 in advance of their meeting with the Oireachtas Joint Committee on Health and Children.

6. Conclusion

For people with illnesses such as Parkinson's disease, Essential tremor and Dystonia, DBS treatment can provide relief. However patients from Ireland and Northern Ireland are usually referred overseas for treatment as there is no routine DBS surgery available on the island of Ireland.

For patient well-being it would be preferable to offer these services on the island of Ireland, thereby removing the need for travel, which is identified as distressing for DBS patients. There are also some cost savings associated with having patients undergo DBS treatment in Royal Victoria Hospital, Belfast, which has already carried out some DBS procedures.

It is proposed by some stakeholders that North/South collaboration may use existing DBS resources in Royal Victoria Hospital and combine these with centres in the Republic, where follow-up care could be carried out.

Authorities on both sides of the border have, however, indicated the need for further cost-benefit analysis on this issue before deciding whether establishing an all-island DBS service is viable.