Health technology assessment of a national deep brain stimulation service in Ireland

Executive Summary

11 October 2012
About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is the independent Authority established to drive continuous improvement in Ireland’s health and personal social care services, monitor the safety and quality of these services and promote person-centred care for the benefit of the public.

The Authority’s mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.

- **Social Services Inspectorate** – Registering and inspecting residential centres for dependent people and inspecting children detention schools, foster care services and child protection services.

- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health Technology Assessment** – Ensuring the best outcome for people who use our health services and best use of resources by evaluating the clinical and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.

- **Health Information** – Advising on the efficient and secure collection and sharing of health information, evaluating information resources and publishing information about the delivery and performance of Ireland’s health and social care services.
Foreword

Deep brain stimulation (DBS) is a surgical procedure for the management 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. In the absence of a DBS service in Ireland, patients are currently referred to DBS centres abroad for assessment, surgery and follow-up care. Funding for eligible patients is provided through the Treatment Abroad Scheme.

In September 2011, the Health Information and Quality Authority (the Authority) agreed to undertake a health technology assessment (HTA) on the provision of DBS services in response to a request from the National Director of Quality and Patient Safety in the Health Service Executive (HSE). The purpose of this HTA was to examine the implications of a national DBS service in Ireland for current and future patients and the resource requirements and costs of such a service compared to the current service provided through the Treatment Abroad Scheme.

Work on the HTA was undertaken by an Evaluation Team from the HTA Directorate of the Authority. A multidisciplinary Expert Advisory Group (EAG) was convened to advise the Authority during the conduct of this assessment.

The Authority would like to thank its Evaluation Team, the members of the EAG and all who contributed to the preparation of this report.

Dr Máirín Ryan

Director of Health Technology Assessment
Health Information and Quality Authority
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The membership of the EAG was as follows:

Mr John Caird, Consultant Neurosurgeon, Children’s University Hospital, Temple Street, Dublin

Mr Martin Flattery, Head of HTA Research and Planning, Health Information and Quality Authority*

Ms Carole Goggin, Clinical Nurse Specialist, Dublin Neurological Institute at the Mater Misericordiae University Hospital, Dublin

Dr Davida de la Harpe, Assistant National Director, Health Intelligence, Health Service Executive

Dr Patricia Harrington, Head of Assessment, Health Information and Quality Authority

Prof Dan Healy, Consultant Neurologist, Beaumont Hospital, Dublin

Ms Maria Hickey, Chairperson, Dystonia Ireland

Mr Joe Lynch, CEO, Parkinson’s Association of Ireland

Prof Tim Lynch, Consultant Neurologist, Dublin Neurological Institute at the Mater Misericordiae University Hospital, Dublin

Dr Fiona Molloy, Consultant Neurophysiologist, Beaumont Hospital, Dublin

Mr Patrick Moran, Information Scientist, Health Information and Quality Authority

Dr Deirdre Mulholland (Chair), Head of Standards & Methodology, Health Information and Quality Authority

Mr Gavin Quigley, Consultant Neurosurgeon, Royal Victoria Hospital, Belfast

Dr Conor Teljeur, Mathematician/Statistician, Health Information and Quality Authority
Organisations that assisted the Authority in providing information, in writing or through meetings, included:

Health Service Executive (HSE)
Frenchay Hospital, Bristol, UK
John Radcliffe Hospital, Oxford, UK
Dystonia Ireland
Parkinson’s Disease Association of Ireland
Medtronic
St. Jude Medical
The Centre for Innovation, Technology & Organisation, University College Dublin

Members of the Evaluation Team:

Members of the Authority’s Evaluation Team included: Martin Flattery*, Dr Patricia Harrington, Patrick Moran, Dr Linda Murphy, Michelle O’Neill, Dr Conor Teljeur and Dr Máirín Ryan.

* Martin Flattery left the Authority in February 2012

Conflicts of Interest

None reported.
Executive Summary

1. Background

On 21 September 2011, Dr Philip Crowley, the National Director of Quality and Patient Safety in the Health Service Executive (HSE), requested that the Health Information and Quality Authority (the Authority) undertake a health technology assessment (HTA) on the provision of a national deep brain stimulation (DBS) service for the treatment of selected movement disorders in adults.

DBS is 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. At present, patients deemed suitable for DBS are routinely referred to UK DBS centres for treatment. Funding is provided through the Treatment Abroad Scheme (TAS) for persons entitled to treatment in another European Union/European Economic Area (EU/EEA) member state under EU Regulation 1408/71 and in accordance with the procedures set out in EU Regulation 574/72. The need for a national DBS service has been questioned based on the increasing volume and cost of referrals through the TAS.

Since 1997, it is estimated that over 130 adults have been funded to receive DBS care through the TAS. While enabling eligible patients to have prompt access to beneficial treatment in recognised DBS specialist centres, the scheme is not without its disadvantages. Patients must be able to travel overseas for initial assessment, surgery and ongoing follow up, incurring travel costs for the patient and potentially for a travel companion for patients unable to travel without assistance. The need to travel may also exclude otherwise eligible patients who are unable to make this journey. There are also logistical issues and difficulties for patients experiencing adverse effects or complications subsequent to their surgery that necessitate a return journey to the overseas DBS centre.

2. Objectives

The terms of reference for this HTA were to:

- Describe the epidemiology and evidence of clinical effectiveness and safety of deep brain stimulation for relevant conditions (selected movement disorders in adults, specifically Parkinson’s disease, dystonia and essential tremor)
- Estimate the demand for a national deep brain stimulation service for relevant conditions.
- Describe the organisational issues associated with the setting up of a high quality national DBS service within the health system in terms of the resources and organisational structures required.
- Perform an economic analysis of the provision of a national DBS service compared to the current practice of providing this therapy through the Treatment Abroad Scheme and estimate the budget impact of provision of such a service.
- Consider any ethical, legal or social issues relating to a national deep brain stimulation service.

3. Methodology

This HTA was conducted using the general principles of HTA and employing the processes and practices used by the Authority in such projects.

In summary:

- The Terms of Reference of the HTA and the specific questions to be addressed were agreed between the Authority and the HSE.
- An Expert Advisory Group (EAG) was established and an evaluation team was appointed comprising internal Authority staff.
- A review of relevant scientific literature was performed to summarise the available clinical evidence on the effectiveness of the technology and to identify guidelines and service standards for its provision in other healthcare systems. The results of the literature review were combined with input from the Expert Advisory Group to develop a service specification estimating the likely resource requirements of a national DBS service. The estimated demand for DBS services in Ireland was based on epidemiological data for movement disorders in adults along with DBS service utilisation rates in comparable populations elsewhere.
- Data were obtained from a range of Irish and international experts where required. This included dossiers submitted by commercial companies manufacturing DBS devices.
- The likely costs and budget impact over five years for the Irish healthcare system were assessed. A cost-minimisation analysis was performed based on the assumption that a national service would operate to similar quality standards to those governing the provision of the DBS services currently accessed abroad and hence that patients would achieve equivalent safety and efficacy outcomes. Data to support the economic evaluation were obtained from a literature review, manufacturers, UK DBS centres, Irish databases and expert opinion. Endorsement of all inputs was sought from the EAG.
A review of the patient-related, organisational and ethical considerations concerning the provision of a national DBS service compared to the current service provided through the TAS was also undertaken.

4. Results

4.1 Clinical effectiveness and disease burden

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. Risks associated with the treatment include infection, device malfunction, cerebral haemorrhage, dyskinesias, axial symptoms, speech dysfunction, paraesthesia and behavioural and cognitive issues. A decision has been taken by the HSE to routinely fund the use of DBS for the treatment of selected movement disorders in adults (specifically medically-refractive Parkinson’s disease, dystonia and essential tremor); therefore, the clinical effectiveness of DBS for these conditions was not the focus of this assessment.

At present, Parkinson’s disease accounts for approximately 74% of all referrals for DBS for movement disorders in Ireland, with dystonia and essential tremor accounting for 11% and 15%, respectively. Currently there are no reliable methods of determining the number of people with movement disorders in Ireland eligible for DBS. One method of estimating the likely demand for a national service is to examine the numbers of patients treated within the English public health service where public funding for DBS is generally restricted to the movement disorders of interest in this HTA. Assuming comparable population prevalence rates to England for Parkinson’s disease, dystonia and essential tremor, a national DBS service would treat approximately 19 new patients with movement disorders each year. This is more than the current average of 13 new patients per annum undergoing surgery via the TAS, indicating a potential underuse of DBS services. The could be caused by a number of factors including difficulties for patients in travelling abroad, constraints in receiving an appointment with a consultant neurologist or a decreased level of referrals from a neurology service lacking in experience in assessing and referring patients for DBS treatment.

There is a growing body of evidence describing the use of DBS in a range of indications beyond those included in this HTA (including chronic pain, epilepsy, depression and obsessive-compulsive disorder). Future demand for DBS services may increase due to its routine use for indications other than movement disorders.
4.2 DBS service specification

An exploration of the potential resource requirements of a national DBS service was conducted based on input from the EAG, the TAS office and with reference to published literature on service standards. DBS is a long term treatment for a chronic condition; long term surveillance and support are required and demand for the service is cumulative. International service standards for a high quality service include specifications for integration of care; informed consent; the patient experience; access to services; age-appropriate care; the resources, expertise and volume of care required to maintain a high quality service; and the use of a team-delivered approach that audits outcomes. These factors must all be considered in the design of a national service.

Challenges that exist in relation to the establishment of a national service include the development of a multi-disciplinary team of appropriately trained professionals with the support services required to provide the volume of care expected, in accordance with appropriate quality standards. In addition to initial set-up, a DBS team must have and be able to maintain the competencies needed to offer the most appropriate care according to the individual patient needs. International standards for excellent care specify an annual minimum of 15 new DBS assessments and 10 new DBS surgeries per specialist centre, with transition plans recommended for new centres so they may develop their services safely while building up the number of patients treated. There is an existing level of neurological and neurosurgical DBS experience within the Irish healthcare service gained from the small number of DBS procedures undertaken both in the private and publicly funded system since 2008. However, it may be anticipated that it may take a number of years for a new national service to scale up to meet the anticipated demand for DBS surgery.

Potential efficiencies that could be realised with a national DBS service compared to the existing services funded through the TAS include a reduction in the administrative burden associated with the TAS, a potential for some inpatient appointments to be carried out on an outpatient basis and streamlining of neurological reviews due to a proportion of patients needing to attend only one neurologist rather than an Irish-based neurologist and a UK-DBS specialist. The latter may not be possible for all patients, some of whom would continue to see their local (non-DBS trained) neurologist for regular reviews with additional appointments being scheduled with a national DBS centre.
4.3 Economic evaluation

A cost-minimisation analysis was undertaken using the perspective of the publicly funded health and social care system; costs were restricted to the direct costs to the HSE and excluded costs to the patient and wider societal costs. As the economic model incorporates a number of assumptions, the results are subject to a degree of uncertainty. This uncertainty was explored by varying key parameter inputs within a range of plausible values.

It was estimated that providing DBS services in Ireland will increase the cost to the HSE by €20,900 per patient over 10 years; the estimated current median cost per patient for the existing TAS-funded service is €44,700 over 10 years. Over five years, the incremental budget impact of a national DBS service is estimated at €1.84 million more than the €4.29 million required to fund the same number of patients (i.e., at a rate of 13 new patients per annum) through the TAS. The budget impact analysis includes costs generated by patients repatriated from services abroad in addition to costs for new patients.

The relative contribution by private health insurance companies to the cost of DBS care for patients with private health insurance is a significant factor in the cost difference between a national DBS service and the existing service. Under current financial arrangements, private health insurers reimburse the full cost of inpatient care provided to insured patients through the TAS, but reimburse inpatient care delivered in Ireland at a per diem rate. In a scenario analogous to a single payer system, where the full cost of DBS care for an individual patient is entirely borne by one provider, the cost difference between the service delivery models is reduced to €4,100 per patient over 10 years. If altered so that the HSE could recoup the full cost of inpatient care for private patients (e.g., a DRG-based payment system), providing DBS services in Ireland would cost the HSE an additional €1,900 per patient over 10 years compared to a service funded through the TAS. In sensitivity analyses, changes to the relative contribution by private health insurance companies to the cost of DBS care for patients with private health insurance substantially influenced the estimated five-year budget impact of the different service delivery models and could potentially render a national programme more affordable than in the base case analysis. Any changes in the cost of DBS devices to the HSE as a result of price negotiation are also likely to impact significantly on the cost-effectiveness of a national service.

Provision of a national DBS service would have resource implications for staff, imaging services, theatre time and surgical bed days. Assuming no increase in patient numbers, a national service would generate an additional 112 hours of neurosurgical theatre time, 227 surgical bed days and 74 outpatient neurology appointments per annum.
The potential for increased demand for DBS surgery for movement disorders in a national DBS service has been noted. The cost difference per patient for DBS care in Ireland compared to the UK is not impacted by the number of patients treated. Potential for increases in the five-year budget impact may be mitigated by two factors: the ability of a new national service to scale up from treating 13 to 19 new patients per annum in the short to medium term, and the potential for cost offsets for the HSE due to reductions in healthcare utilisation subsequent to successful DBS surgery for the cohort heretofore unable to avail of DBS due to the requirement to travel.

4.4 Patient-related, organisational and ethical considerations

The TAS enables timely access to specialised DBS services in other European countries for eligible Irish patients. However, the requirement to travel can place a significant financial and logistical burden on the patient and their family and precludes otherwise eligible patients who are unable to travel from accessing beneficial care.

Maintaining continuity of care for patients receiving treatment and long-term follow-up from two multi-disciplinary teams in different countries is a challenge for the current scheme whereby DBS services are located outside Ireland. To ensure the provision of a safe and integrated service, it is critical that there are clear governance arrangements for the coordination of care and clarity and accountability for each element of care. Continued dialogue between referring clinicians and the TAS is required to ensure that logistical difficulties associated with accessing urgent care at overseas DBS centres can be minimised for patients experiencing complications while still ensuring that the relevant clinical governance arrangements required in the operation of the TAS can be maintained. The rights of patients applying to the TAS, the welfare benefits available to them and the approval and appeal processes, should be clear and consistent to ensure fairness, equity of access and to reduce stress associated with the application process.

The establishment of a national DBS service would have implications for existing DBS patients, for future DBS patients and for other neurosurgical patients. Patients who have previously undergone DBS surgery and are currently receiving care in the UK would, under the terms of the TAS, have all future DBS care repatriated to a national DBS centre if established. This would reduce the logistical and financial burden associated with travel on these patients. However, appropriate infrastructure and planning would be required to ensure continuity of care and that existing standards of care received by these patients are maintained.

Ethical issues around equity of access would be addressed by a national DBS service for the subset of otherwise eligible Irish patients unable to access care due to their
inability to undertake the necessary overseas travel. As noted, it is anticipated that the potential demand for DBS surgery would increase with a national service, not least due to this cohort being newly able to access care. For these patients and other future DBS patients, appropriate infrastructure and planning would be required to ensure that timely access to elective surgery could be maintained by a national DBS service. Under the current TAS-funded model, estimates of the total time from referral by a neurologist to undergoing surgery range from 8 to 13 months. The potential for a national DBS service to provide comparable access is of particular concern given the acknowledged capacity constraints in the existing Irish publicly-funded neurological and neurosurgical services, as reflected by lengthy waiting lists for outpatient appointments and elective surgery.

There are potential opportunity costs associated with a national DBS service for other neurosurgical patients and other healthcare users that could generate new ethical issues around equity of access and justice. A national DBS service providing 13 new DBS surgeries a year would, without additional resources or realignment of the service, displace 26 existing neurosurgical procedures and add further to waiting lists for these patients. This HTA has also estimated that, based on current financing arrangements, a national DBS service is likely to cost the HSE more than the existing service funded through the TAS. Assuming a finite healthcare budget, a new national DBS service would necessitate reallocation of resources, potentially diverting resources from other effective treatments.

The use of DBS for indications other than the specific movement disorders examined in this HTA is the subject of considerable international research. Through the current TAS process, the HSE has a mechanism to restrict the availability of DBS to those indications for which reimbursement has been agreed. In a prospective national service, the range of indications for which DBS is used may change as decisions regarding the type of patients to be treated are usually made at a local level and at the discretion of the treating clinicians. Without additional resources, any expansion in the range of conditions treated may result in reduced access to DBS for patients with Parkinson’s disease, dystonia or essential tremor.

5. **Conclusion**

A national DBS service will cost the HSE more per patient treated (€20,900 more over 10 years) and result in an increase in the overall costs of the service (€1.84 million more over five years) compared to the estimated €4.29 million to treat the same number of patients abroad via the TAS. A key factor in this analysis is the impact of private health insurance. Under current arrangements, a greater proportion of costs can be recouped from private health insurance companies for insured patients if DBS is provided abroad rather than in Ireland. In a scenario analogous to a single payer system, where the entire cost of DBS care for an
individual patient is entirely borne by one provider, the difference in cost between the two service delivery options is greatly reduced. It is likely that a national DBS service would also result in an increase in the number of patients with movement disorders undergoing DBS, from approximately 13 to 19 new cases a year. However, the initial growth of a new national DBS service is likely to be constrained by the need to build local capacity and expertise.

Potential benefits to patients from having a national DBS service include the elimination of the logistical and financial demands associated with overseas travel, improved continuity of care and reduced administrative burden. Challenges that exist in relation to the establishment of a national DBS service include 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.