

Deep Brain Stimulation – Ethical Considerations

Deep Brain Stimulation (DBS) has been proved to be effective in the management of Parkinson's disease, dystonia, and essential tremors. It works by blocking electrical signals from targeted areas in the brain¹ and the procedure can be reversed. Notwithstanding the fact that the stimulation can be turned off if it is ineffective or causes too many side effects, DBS raises some important ethical issues.

Human Dignity

Human dignity is a fundamental ethical value in Europe. In the context of human rights, human dignity expresses the intrinsic worth and fundamental equality of all human beings. It is bestowed equally to all human beings. The Council of Europe's Convention on Human Rights and Biomedicine, begins by stating that the dignity and identity of all human beings must be protected.² This is reflected also in Article I of the Charter of Fundamental Rights of the European Union which states that 'human dignity is inviolable. It must be respected and protected.'³ This means that not only should one refrain from interfering with an individual's private sphere but one should actively bring about conditions allowing individuals to live with dignity. By protecting human dignity one is also safeguarding other rights and fundamental freedoms.

Illness creates vulnerability and there is concern that this vulnerability can affect patients' rights and freedoms. This puts more responsibility on health care professionals to protect the dignity and rights of patients. The ethical principles guiding health care professionals in decisions relating to DBS include,- beneficence, proportionality, justice, subsidiarity and autonomy.

Beneficence

Beneficence is one of the core principles of healthcare. It is the duty of every health care professional to promote the well being of the patient and to prevent harm. Any treatment or intervention should serve the best interest of the patient.

Deep Brain Stimulation has been shown to benefit the patients by decreasing tremor, restore functioning and thus improving their quality of life and their dignity.

DBS is an invasive procedure and requires surgery. As with all brain surgery there are risks associated with this procedure such as haemorrhage, infection and pain. In addition there have been reports of side effects which include speech disturbance, impaired attention and learning, depression, mania, changes in behaviour including aggression, identity or personality changes, and compulsive actions (gambling).⁴

¹ National Institute of Neurological Disorders and Stroke. Deep Brain Stimulation for Parkinson's Disease, Information Page.

² Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regards to the Application of Biology and Medicine. Oviedo, 1997 .

³ European Union, Charter of Fundamental Rights of the European Union. Nice, 7-12-2000; ch 1 Dignity, art 1.

⁴ Piasecki S, Jefferson JW. Psychiatric Complications of Deep Brain Stimulation for Parkinson's Disease. J Clin Psych.2004;65:6.

Since DBS is invasive and presents more than minimal risk, the expected benefits and risks should be carefully assessed for each individual patient.

Principle of Proportionality

One of the issues that needs to be addressed is whether there are sufficient reasons for using DBS despite the fact that it is invasive and considerable side effects are predicted. On what basis are decisions to be taken when an intended treatment implies possible harm, like foreseeable unpleasant side effects? The principle of proportionality has been found to be helpful as a guide to ethical decision making. The principle has been proposed as a guide to decision making in end of life issues⁵ and in ischemic stroke⁶.

For Knauer the principle of proportionality is the fundamental principle of all ethics since every act may result in negative effects.⁷ Several interpretations of this principle can be distinguished. These are the relationship between positive and negative outcomes, the importance of the objective, relevance of means, most favorable option⁸ and how reasonable it is for the person concerned.⁹

Relationship between positive and negatives outcomes

The principle of proportionality acknowledges that all actions have positive and negative effects but accepts the risk of negative effects as long as the positive effects are proportionally beneficial. A treatment can be given if the therapeutic outcomes from such a treatment outweigh the negative effects. For DBS to be recommended and performed the benefits perceived must outweigh the side effects, with regard to the patient's individual situation. Risk-benefit assessment for side effects such as small impairment of executive functions and verbal learning and memory yields a net positive result. However, such cognitive declines following DBS may be intolerable for patients suffering from dementia.¹⁰ Moreover, risk benefit assessment requires ongoing review as new data becomes available through research.

The importance of objective

The principle of proportionality is grounded in the relationship between the intended action, and the objective sought. It places an emphasis on the proportionality of the

⁵ Quill TE, Dresser R, Brock DW. The Rule of Double Effect: a critique of its role in end-of-life decision making. *N Engl J Med.* 1997;337:1768-71.

⁶ Furlan AJ, Kanoti G. When is Thrombolysis Justified in Patients with Acute Ischemic Stroke? *J.Am Heart Ass.* 1997;28:214-8.

⁷ Kaczor C. Double-effect reasoning from Jean Pierre Gury to Peter Knauer. *Theological Studies.* 1998; 59.

⁸ Hermeren G. The Principle of proportionality revisited: interpretations and applications. [Med Health Care Philos.](#) 2011 Nov 1

⁹ Jesuit Refugee Service Europe. Principle of Proportionality. www.detention-in-europe.org.

¹⁰ Muller S, Christen M. Deep Brain Stimulation in Parkinsonian Patients—Ethical Evaluation of Cognitive, Affective, and Behavioral Sequelae. *AJOB Neuroscience.* 2011; 2(1): 3–13. doi: 10.1080/21507740.2010.533151

actions that are used.¹¹ The intended action aims to achieve something envisaged as a value for example alleviating pain, reducing tremors or improving the quality of life. If in the process there are a number of side effects, the intervention is ethical if it achieves the value that is being sought. Unintended but foreseen consequences are side effects which may be justified according to the circumstances.¹² In accordance with the principle of proportionality the intervention needs to be proportional to the objective it aims to achieve, even if there are inevitable side effects.

The objective of an intervention describes the therapeutic outcomes that the intervention aims to achieve. Hence these therapeutic outcomes influence both the clinical validity and ethical justification of that intervention. Instruments that measure the clinical aspect and quality of life are useful to assess the outcomes of DBS.

Studies have revealed that the outcomes of DBS for Parkinson's disease were a decrease in the severity and duration of immobility and dyskinesias and a significant and clinically meaningful improvement in quality of life in patients under 75 years of age with advanced Parkinson's Disease¹³. A review of studies on quality of life revealed evidence that DBS had a positive impact on the quality of life of patients with Parkinson's disease and other movement disorders.¹⁴

Volkman et al¹⁵ used the Unified Parkinson's Disease Rating Scale (UPDRS, a clinical scale that measures the progression of Parkinson's disease) and Sickness Impact Profile (SIP, to assess quality of life) to evaluate a group of patients who have been followed up for at least 3 years after DBS. Overall, the study found that DBS was linked to significant early improvements in patient quality of life but, despite lasting motor improvements, there was loss of initial benefits in quality of life. This loss may only affect certain patients and can be due to many factors. Studies are thus needed to identify factors associated with better long term outcomes in quality of life. Findings of studies revealed differences in improvement in each quality of life sub group. Whereas improvements were seen in motor functions, there was no significant improvement in communication, cognition and social support.¹⁶ As standard quality of life instruments evade some aspects of patient benefit, it might be useful to supplement them with open in depth interviews to provide a more accurate picture of patient outcome.¹⁷

¹¹ European Group on Ethics. Ethical Aspects of ICT Implants in the Human Body. Brussels, 16-03-2005.

¹² Quill TE, Dresser R, Brock DW. The Rule of Double Effect: a critique of its role in end-of-life decision making. *N Engl J Med.* 1997;337:1768-71.

¹³ Deuschl et al. A Randomized trial of deep brain stimulation for Parkinson's disease. *N Engl J Med* 2006;355:896-908.

¹⁴ Diamond A, Jankovic J. The effect of deep brain stimulation on quality of life in movement disorders. *J Neural Neurosurg Psychiatry.* 2005;76:1188-93.

¹⁵ Volkman J, Albanese A, Kulisevsky J, Tornqvist A, Houeto J, Pidoux B, Bonnet A, Mendes A, Benabid A, Fraix V, Blercom NV, Xie J, Obeso J, Rodrigues-Oroz MC, Guridi J, Schnitzler A, Timmermann J, Gironell A., Molet J, Pascual-Sedano B, Reñcrons , Moro E, Lang J., Lozano AM, Bentivoglio AR., Scerrati M, Contarino MF, Romito L, Janssens M, Agid Y. Long-term effects of pallidal or subthalamic deep brain stimulation on quality of life in Parkinson's disease. *Movement Disorder* 2009;24(8): 1154-61.

¹⁶ Limosin P. Quality of life and influence of ageing with deep brain stimulation. *European Neurological Review, Supplement.* 2008;3 (2):19-21.

¹⁷ Clausen, J. "Ethical brain stimulation - neuroethics of deep brain stimulation in research and clinical practice.", *The European journal of neuroscience.* 2010; 32, 7:1152--1162.

Relevance and non excessiveness of means

After identifying an objective for using an intervention, one should establish whether this intervention is actually necessary and relevant. An intervention is chosen because it is necessary to reach an objective and is relevant under the given circumstances. This is meant to prevent inappropriate and /or excessive applications of that action.

When the manner in which an objective is sought is excessive or counterproductive, the action is disproportionate.¹⁸ The action lacks proportionate reasons. Decisions to perform, or reverse the procedure should be based on proportionality. One does not have an obligations to perform the procedure or to continue with the procedure if that procedure is disproportionate to the expected benefit. DBS can be disproportionate if the patients are not physically and mentally capable of tolerating the surgery and/or the stimulation. For this reason careful assessment of patients is necessary to safeguard patients from the increased risks of DBS.

Candidates for DBS are those patients whose condition has not been controlled by pharmacological treatment and are judged to have a good probability that the intervention will benefit these patients. Such patients should be “physically, cognitively and emotionally capable of tolerating surgery and participating in their own postoperative care”¹⁹ Assessment of patients should involve an interdisciplinary team. Among other things the assessment should identify possible co-morbidities associated with neurological and mental disorders. Patients with depression, anxiety and mania are often excluded to protect them from severe side effects.

Can DBS be used on healthy persons for non therapeutic purposes, for example as neuroenhancers? It is not completely impossible that DBS can contribute to human enhancement. Research shows that DBS can improve spatial memory and cognitive capacities.²⁰ Should such procedures be used to improve the memory of healthy people, taking into consideration the invasiveness of the procedure and the associated risks? Would the intervention be proportionate to the outcomes it aims to achieve?

Most favorable option

The principle of proportionality requires that one needs to establish whether there are less severe, less excessive or more cost-effective means of achieving a specific therapeutic outcome.²¹

Quill claims that an agent needs to assess the negative effects of acceptable actions that produces a specific therapeutic outcome so as to choose the alternative that produces the least negative effects.²² Thus one will be evaluating which of the various

¹⁸ Kaczor C. Double-effect reasoning from Jean Pierre Gury to Peter Knauer. *Theological Studies*. 1998; 59

¹⁹ Bell E, Mathieu G and Racine E. Preparing the ethical future of deep brain stimulation. *Surgical Neurology*. 2009;72: 577-586.

²⁰ Suthana, N., et al. [Memory Enhancement and Deep-Brain Stimulation of the Entorhinal Area](#). *N. Engl. J. Med*. 2012;**366**:502-10.

²¹ Principle of proportionality. Art 3, EU Amsterdam Treaty. 1999.

²² Quill TE, LeeBC, Nunn S. Palliative Treatments of last resort: choosing the least harmful alternative.. *Ann Intern Med* 2000;132:488-93.

alternatives is relatively good.²³ Accordingly, only when other treatment options which are less burdensome and less invasive fail to control the patient systems, should DBS become an alternative option that can be chosen.

Reasonable

A patient has the right to determine what they will accept as beneficial and what they consider to be burdensome. How reasonable a procedure is from the patient's point of view, taking into consideration their goals and values are in line with principle of proportionality .

The person concerned can reasonably be expected to consent to have the intervention in question after assessing the burden of the intervention and the negative and positive outcomes.

The concept of burden is broad and has to be individually assessed. It can include aspects such as discomfort, the invasiveness of the procedure, the surgery itself (physical and emotionally), frequency of monitoring and adjustments, the effect on other members of the family, and postoperative care.

Whether certain side effects can be tolerated or compensated or whether they can cause suffering depends on how they are going to impact on the patient's life, on his work, social activities, plans for the future and psychologically. Small cognitive declines may be intolerable for some patients as they might interfere with their professional activities and personal values.

Patient preferences determine whether DBS is reasonable or not. There is thus a relationship between the principles of proportionality and autonomy.

Guide to decision making

The EGE opinion on ICT implants²⁴ for health purposes specify that implantation of these devices should be guided by the principles that:

- a. the objective is important,
- b. the necessity of the implant to achieve the objective,
- c. it is the least invasive and cost effective method of achieving the objective.

The five approaches of the principle of proportionality mentioned above taken together can be a better guide to decisions on whether or not to perform DBS.

Equitable Access.

Deep brain stimulation is an expensive treatment. In accordance with the principle of justice, patients who need this type of treatment should have equitable access to it.

²³ Shimizu T. Non-consequentialist Theory of Proportionality: With Reference to the Ethical Controversy over Sedation in Terminal Care. *J of Phil and Ethics in Health Care and Medicine*. 2007;2:4-21.

²⁴ European Group on Ethics. Opinion of the European Group on Ethics in Science and New Technologies to the European Commission, Ethical Aspect of ICT Implants in the Human Body. 16-3-05.

This would enable them to live an active meaningful life, and to enjoy the same opportunities in the course of their life.

Article 3 of the Convention for the Protection of Human Rights and Dignity of Human Beings with Regard to the Application of Biology and Medicine states that “taking into account the health needs and available resources” appropriate measures should be taken to provide equitable access to health care of appropriate quality.

The Explanatory report to this Convention explains that by ‘equitable’ one means the absence of unjustified discrimination and implies ‘effectively obtaining a satisfactory degree of care’. This means that patients, independent of their age, disability, social position or economic resources, should have access to DBS depending on their health care needs.²⁵ Care should be taken not to exclude patients who can benefit from DBS because of strict patient selection criteria to safeguard them from serious side effects.²⁶

In the face of scarcity of resources, one needs to prioritise, and priority should be given to those who have the greatest need for this procedure. These include those who are seriously impaired and who therefore would benefit most from such a procedure.

Subsidiarity and Autonomy

Patients have a right to participate in decisions that directly affect them in line with their dignity. This is within the principle of subsidiary and autonomy. DBS can only be performed after the patient has given his or her voluntary and informed consent to this procedure.

Patients undergoing DBS should be given clear, evidence based and truthful information, about the procedure and alternative treatments available, in a manner they can accurately understand, to enable them to make informed decisions. Such information can be provided in the form of a manual.

Patients need to receive information about:

- the procedure – what it involves,
- the programming of the neurostimulator, on how the neurostimulation will be adjusted depending on how their condition progresses and their response to pharmacological treatment; that it will be carried out on the patient, and not virtually without the patient’s knowledge.
- the postoperative care to be given;
- the expected benefits, incidence of risks and side effects of the procedure, its implications on personal identity and relationships, and its limitations,
- that the procedure does not cure the condition nor stop its progression,²⁷
- the possible consequences if the procedure is refused,

²⁵ ibid

²⁶ Ford PJ and Hendersen JM. Functional neurosurgical intervention: Neuroethics in the operating room. In *Neuroethics. Defining the issues in theory, practice, and policy*, ed. J. Illes, 2006;213–228.Oxford: Oxford University Press.

²⁷ Schermer M. Ethical issues in Deep Brain Stimulation. *Neurosci.* 2011; 5: 17.doi: [10.3389/fnint.2011.00017](https://doi.org/10.3389/fnint.2011.00017)

- circumstances when the procedure can be reversed.

There are situations whereby patients although they are personally capable of taking decisions, bring in their relatives or partner into the decision making process. There can also be instances when patients might decline to receive information and leave the decision in the hands of their consultant. This is also within patients' rights. The significance of the risk of DBS underscores the responsibility of consultants to counsel patients undergoing the procedure, and to formulate the patients' perception of the risk benefit ratio.

Through an open dialogue, patients will be able to understand the information given and assess the risks, benefits and limitations of the procedure according to their personal goals and values. The patients' decision depends on their point of view, on the type of risks they can tolerate and on what they will accept as beneficial. Patients have the right to object to an intervention, and to ask for the procedure to be reversed (if this is technically possible) without prejudice to their informed consent.

An important consideration is patients' vulnerability due to the effect the disease has on them and how this vulnerability may affect their freedom to give their consent. Patients and their relatives may be desperately looking for a solution so as to improve their or their relative's condition, quality of life and aspirations for the future. This is especially so when the condition is progressing and pharmacological treatment is no longer effective. Patients may feel that they have no option but to consent to undergo the procedure.²⁸

Another important consideration is the fact that media reports may raise patients' hopes and expectations of DBS. These unrealistic expectations that patients and their family might have need to be addressed by the consultant during the consent procedure.

Minors and Persons not able to consent

The Council of Europe Convention on Biomedicine and Human rights (Oviedo Convention), Articles 6 and 7 lay down specifications which must be followed in situations whereby an intervention needs to be carried out on persons who are not able to consent including minors.

DBS for neurological disorders in children deserves extra attention. Children are an extremely vulnerable group, and one needs to carefully assess whether there are sufficient reasons for using DBS in accordance to the principle of proportionality. In line with the precautionary principle, since research in children is limited, there needs to be successful treatment outcomes established in adults. Moreover, such treatment should only be performed within well-designed and independently reviewed research protocols.²⁹

An intervention on children necessitates the informed consent of the legal representative of the minor. Art 6 of the Oviedo Convention states that the "opinion of the minor shall be taken into consideration". Due importance is given in this article to the rights of children to be involved in decisions which are going to affect them,

²⁸ Schermer M. Ethical issues in Deep Brain Stimulation. *Neurosci.* 2011; 5: 17. doi:

[10.3389/fnint.2011.00017](https://doi.org/10.3389/fnint.2011.00017)

²⁹ *ibid*

depending on their maturity. Focquaert argues that it is crucial that the decision-making procedure is a shared process between minor, their legal representatives and medical experts³⁰.

Patients suffering from occasional debilitating psychiatric disease deserve also extra consideration. Assessment of decision making capacity and its implications for informed consent should involve an interdisciplinary team.³¹

Freedom from external control

Respect for patients' autonomy entails freedom from external controls and influence.

Adjustment of neurostimulations needs to be made depending on how the disease progresses and the patient's response to treatment. These should be done for the patient within a patient – doctor relationship. Such adjustments should not be made remotely without the patient's knowledge. This is in line with the principle of respect for the dignity of the patient

Advances in technology carry with them certain risks which might allow individuals to be located, and which might allow data in these devices to be read and modified remotely by entities managing electronic links. Both circumstances are in conflict with the data protection rules³².

Duty of Care

Appropriate care following DBS should incorporate follow-ups to closely monitor patients for risks and to manage them. This is within the obligations of healthcare professionals to provide care and to take positive steps to protect patients from harm when scientific findings have revealed plausible risks.

Such follow ups should also take into account information provided by the patients and by their spouses or caregivers, so as to evaluate outcome from the patients' perspective. These follow ups will also contribute to increase knowledge on the nature, extent and incidence of side effects. Assessments of quality of life and motor function are important to establish outcomes following DBS. Such data are needed to conform to the principle of proportionality. There is currently concern that side effects are not yet measured and evaluated sufficiently as the methods used measure subtle cognitive changes.³³ Deliberations on the benefits and risks of different therapeutic options become much easier if side effects of these new interventions are known³⁴ This is also

³⁰ Focquaert F. Paediatric Deep Brain Stimulation: A Cautionary Approach. *Integr Neurosci*. 2011; 5: 9. doi: [10.3389/fnint.2011.00009](https://doi.org/10.3389/fnint.2011.00009)

³¹ Muller S, Christen M. Deep Brain Stimulation in Parkinsonian Patients—Ethical Evaluation of Cognitive, Affective, and Behavioral Sequelae. *AJOB Neuroscience*. 2011; 2(1): 3–13. doi: 10.1080/21507740.2010.533151

³² European Group on Ethics. Opinion of the European Group on Ethics in Science and New Technologies to the European Commission, Ethical Aspect of ICT Implants in the Human Body. 16-3-05

³³ Muller S, Christen M. Deep Brain Stimulation in Parkinsonian Patients—Ethical Evaluation of Cognitive, Affective, and Behavioural Sequelae. *AJOB Neuroscience*. 2011; 2(1): 3–13. doi: 10.1080/21507740.2010.533151

³⁴ Christen M, Bittlinger M, Walter H, Brugger P, Muller S. Dealing With Side Effects of Deep Brain Stimulation: Lessons Learned From Stimulating the STN. *AJOB Neuroscience*, 2012; 3(1): 37–43.

in line with the principles of beneficence and nonmaleficence and with the precautionary principle. This principle entails the responsibility of continuous risk assessment with regard to the impact of relatively new interventions like the use of DBS in patients.³⁵

Diseases such as Parkinson's can have a profound impact on the patient to the extent that the patient might no longer seem the same person. They can disturb the psychological continuity of personal identity. The successful treatment of these disorders can bring about personality changes which can be perceived differently by different patients. Some patients might have difficulty with psycho-social adjustment after DBS, especially with regards to relationships and self perception. A period of adaptation and psycho-social support are necessary both for patients and their family to enable them to cope with these changes.³⁶

Concluding Comments

Deep Brain Stimulation is an innovative area which also holds promise for the treatment of certain psychiatric conditions and Alzheimer disease. There are important knowledge gaps and ethical concerns that need to be addressed. These include the impact on personal identity and autonomy of human beings, epigenetic changes in the brain, and the use of DBS as a neuroenhancer.

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³⁵ European Group on Ethics. Opinion of the European Group on Ethics in Science and New Technologies to the European Commission, Ethical Aspect of ICT Implants in the Human Body. 16-3-05.

³⁶ Schermer M. Ethical issues in Deep Brain Stimulation. *Neurosci.* 2011; 5: 17.doi: [10.3389/fnint.2011.00017](https://doi.org/10.3389/fnint.2011.00017)