This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Novel neurotechnologies: intervening in the brain* between 1 March 2012 and 23 April 2012. The views expressed are solely those of the respondent(s) and not those of the Council.


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**Nuffield Council on Bioethics – Novel Neurotechnologies: Consultation response for the part Neurostimulation (DBS)**

*11. Have you used neurostimulation and if so, with what consequences? Please describe your experience.*

No (neither for myself as a treatment nor as an "applicator")

*12. If you have not used neurostimulation before, under what circumstances would you do so?*

I would use DBS both for established indications (e.g. Parkinson's disease; PD) as well as for novel indications if ordinary treatment cannot lead to symptom relief.

In particular, I would opt for early stimulation in the case of PD, i.e. I do not consider DBS as a "last resort treatment" given the well-established fact that is superior to best medical treatment.

*13. Under what circumstances do you think it might be acceptable to use neurostimulation in non-medical context (that is to say, not for the treatment of a disease or disability)?*

Due to the surgical risks that go along with DBS and the stress of a brain surgery lasting several hours, I do not see any need and/or any motivation for someone to undergo such a procedure for non-therapeutic purposes.

In particular, DBS for non-therapeutic purposes should certainly not be paid by any health insurance.

*14. Are there any particular ethical or social issues associated with neurostimulation?*

There are indeed several ethical issues that are involved in DBS:

First, in our research we have obtained indications that the referral practice for DBS interventions may be conservative in several countries (e.g. Christen & Müller 2012), i.e., some patients do not get the optimal treatment. However, this point needs further backing by more solid data. In particular, one should investigate whether this finding results from a justified skepticism regarding possible adverse effects of DBS, or whether it reflects lack of knowledge or prejudice in the referring stakeholders and/or patients. Research on this issue should complement the current international discussion with respect to the optimal time window and criteria for referring patients to a DBS center.

Second, one has to be aware that the decision problem for DBS is complex, as both the disease as well as medication-based alternatives have an impact on the patient's affection, behavior and cognition (in particular in the case of PD; Müller & Christen 2011). Therefore, the patients should be supported in evaluating the risks and the expectable benefits with regard to their individual situation (professional activity, social situation, psychological condition, and plans for the future) and personal values. The counseling of the patient about all risks of DBS should include considerations on the difficulty of predicting and evaluating possible side effects. It should include the risk of partnership and professional problems. The counseling necessitates a balance of optimism with reality. Since DBS is often used as a last resort procedure, expectations and desperation may create substantial challenges for free and informed consent.

Third, although the beneficial effects of DBS for the established indications in some movement disorders is well established, there is still a need to assess the long-term benefit of the intervention including evaluations by third parties (e.g., close relatives) and cost-benefit comparisons. We found that the side effects of DBS interventions are not yet measured and evaluated sufficiently. Our

analysis (Christen et al. 2012) reveals that the majority of methods used investigate subtle cognitive changes that may be statistically significant but whose relevance for the patients is unclear. Only a minority of investigations focus on the self-assessment of the patients, and even less on the assessments of their caregivers. This methodological bias implies blindness for certain side effects. We expect that this problem will be aggravated if DBS is used to treat psychiatric disorders as depression or addiction, since interpersonal relationships play a crucial role in overcoming these disorders.

Fourth, the adaptation of the stimulation parameters should not only optimize motor functions, but additionally aim at saving or restoring the patient's autonomy and compatibility with his or her surroundings. Especially, stimulation parameters that induce mania, loss of control over sexual drive, drug abuse, and criminal behavior must not be selected, even if the patient requires them. Advance directions should be established to deal with such adverse events.

Fifth, DBS may be a promising tool for the therapy of various diseases. However, alternatives should still be valued as well. For example lesion procedures – performed either by microsurgery or by radiosurgery (e.g., Gamma Knife) – could remain an option for some special patient groups, e.g., for patients who would be non-compliant with the long-term follow-up after DBS, for patients who could neither tolerate the stress of a wake-operation nor an operation under full anesthesia, and for patients who could not accept any devices in their body

For further information, see:

- Christen M, Müller S: Current status and future challenges of deep brain stimulation in Switzerland. Swiss Medical Weekly 142: w13570.

- Christen M, Bittlinger M, Walter H, Brugger P, Müller S. Dealing with Side Effects of Deep Brain Stimulation: Lessons Learned from Stimulating the STN. AJOB Neuroscience 3(1): 37-43.

- Müller S, Christen M: Deep Brain Stimulation in Parkinsonian patients – Ethical evaluation of stimulation-induced personality alterations. American Journal of Bioethics - Neuroscience 2(1): 3-13.

*15. What would robust and effective regulation of research in this area look like? Is more or less regulation needed? Please justify your response.*

Generally, the current research regulation system (at least in most countries) seems to be adequate to deal with research in DBS, as this technique does not pose completely novel problems. For enhancing informed consent, we proposed the development of a "living database" that contains the consecutive, standardized outcomes of all DBS treatments of a multitude of neurosurgical centers. This database should be available online and be continuously updated. An independent organization, optimally a patient organization, should organize the database; it should be supported scientifically and financed by public resources.