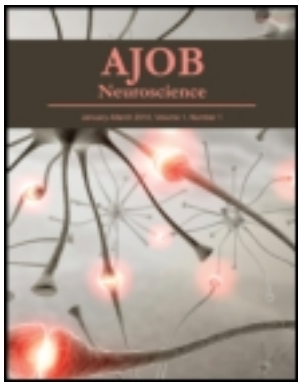

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Rethinking Vulnerability

Farah Focquaert [a]
[a] Ghent University

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Rethinking Vulnerability

Farah Focquaert, Ghent University

The aim of deep brain stimulation (DBS) for treatment-resistant depression (TRD) is to provide relief for individuals who due to the very nature of their disease may be faced with (a history of) suicidal ideation and suicide attempts. It is not unlikely that DBS for TRD, which is currently experimental in nature, will become standard treatment sometime in the (near) future for patients who have failed conventional treatments (i.e., psychotherapy, medication, and electroconvulsive therapy). If such a scenario will indeed present itself, it is of the utmost importance that the procedure is safe for *all* the individuals in this patient group. Provided that the necessary safeguards are put in place (e.g., an informed consent process that gives specific and sufficient attention to the elevated suicide risk; pre- and postoperative monitoring and treatment), is it ethical to exclude TRD patients with a history of suicidal ideation and suicide attempts from having *safe* access to DBS treatment? It can been argued that "under the assumption that DBS would be an efficacious treatment, one might do harm to patients not only by performing DBS, but also by *not* performing it" (Synofzik and Schlaepfer 2011, 10–11; also see Focquaert 2011).

Investigational studies and clinical trials for DBS are performed within scientific research settings that are subject to the most stringent ethical review demands. If we exclude individuals with a history of suicidal ideation and suicide attempts from participating in DBS TRD research studies, we exclude them from having access to a maximally protective setting in which the safety and efficacy of a potential treatment can be tested. More importantly, by the same token, we exclude these individuals and future patients with the same history from having access to sufficiently *safe* treatments (i.e., tailored to the needs of their specific vulnerabilities) in case DBS were to become standard treatment for TRD. Their exclusion may be considered unfair compared to individuals with no such history.

Unfortunately, both performing and *not* performing clinical DBS treatment in TRD patients with a history of suicidal ideation and suicide attempts can be considered problematic when DBS has only been tested in individuals with no such history. Performing treatment means exposing these patients to an increased risk (due to the untested nature of the procedure in this subpopulation of TRD patients compared to TRD patients with no such history), and *not* performing treatment means denying these patients a potentially effective treatment for their untreatable condition. Medical experts may decide to exclude TRD individuals with a history of suicidal ideation and suicide attempts from receiving DBS treatment because of the increased risk. This would indeed be the reasonable choice to make if the procedure has not been tested in this subpopulation, although it may just as easily be considered unfair to allow these patients to suffer tremendously if a potential treatment exists. Also, even if ethical guidelines by medical experts suggest excluding these patients from receiving DBS treatment, what guarantee do we have that (some of) these individuals will not be offered such treatments? A potential widening of eligibility criteria, once we leave the maximally protective environment of the research setting in which ethical review is essential, is not unthinkable. If DBS has only been tested on individuals with no history of suicidal ideation and suicide attempts, it is likely that the treatment program will not be adequately equipped to care for patients that suffer from such a history (e.g., the capacity to monitor and treat suicidal ideation, plans, or intent to self-harm in patients). TRD patients with such a history, who can be considered the most vulnerable individuals in this patient group, are thus put at an increased risk if they are offered DBS and do opt for DBS compared to TRD patients with no such history.

In sum, there are good ethical reasons why TRD individuals with a history of suicidal ideation and suicide attempts should not be categorically excluded from participating in investigational studies and clinical trials aimed at procuring a safe and efficacious treatment for their untreatable condition. At the same time, we are faced with a pressing need for uniform eligibility criteria in case of DBS TRD. The data on postoperative suicidal ideation, suicide attempts, and deaths should urge us to look more carefully at the informed consent process and the requirement of preoperative and postoperative monitoring and treatment to adequately address suicidal ideation and (previous) suicide attempts. DBS TRD research protocols should indeed ensure that patients are fully aware and sufficiently educated about postoperative suicidality risks. Enrolling TRD individuals with a history of suicidal ideation and suicide attempts most definitely requires additional safeguards and may require third-party consent due to the heightened vulnerability of these individuals (Lipsman et al. 2012). Although categorically excluding TRD patients with a history of suicidal ideation and suicide attempts from enrolling in investigational studies and clinical trials is ethically questionable, it is obviously also ethically questionable to include patients with *current* suicidal ideation involving plans or intent to self-harm. For example, it is likely that current suicidal ideation may alter patients' ability to judge the risks and benefits of an untested procedure like DBS, as well as render patients more prone to therapeutic misconceptions.

Address correspondence to Farah Focquaert, PhD, Bioethics Institute Ghent, Department of Philosophy and Moral Sciences, Ghent University, Blandijnberg 2, 9000 Gent, Belgium. E-mail: Farah.Focquaert@ugent.be

REFERENCES

Focquaert, F. 2011. Pediatric deep brain stimulation: Parental authority versus shared decision-making. *Neuroethics*. doi:10.1007/s12152-011-9098-4

Lipsman, N., P. Giacobbe, M. Bernstein, and A. M. Lozano. 2012. Informed consent for clinical trials of deep brain stimulation in psychiatric disease: Challenges and implications for trial design. *Journal of Medical Ethics* 38: 107–111.

Synofzik, M., and T. E. Schlaepfer. 2011. Electrodes in the brain—Ethical criteria for research and treatment with deep brain stimulation for neuropsychiatric disorders. *Brain Stimulation* 4: 7–16.