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Abstract

This article suggests that investigation deep brain stimulation (DBS) for mental disorders raises few new bioethical issues. Although the scientific basis of the procedure may be both complex and largely unknown, addressing informed consent in such situations is a familiar problem. After reviewing the legal and moral background for investigating DBS and the scientific difficulties DBS faces as a potential treatment for mental disorders, the article focuses on informed consent and makes two primary suggestions. The study of DBS may proceed, but hyper-disclosure" of the complexities should be required for competent subjects or proper surrogates if the candidate is not competent, and the most rigorous standard for competence should be employed. Throughout, neuromodesty and caution are urged.

Comments

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Article

New Therapies, Old Problems, or, A Plea for Neuromodesty

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This article suggests that investigational deep brain stimulation (DBS) for mental disorders raises few new bioethical issues. Although the scientific basis of the procedure may be both complex and largely unknown, addressing informed consent in such situations is a familiar problem. After reviewing the legal and moral background for investigating DBS and the scientific difficulties DBS faces as a potential treatment for mental disorders, the article focuses on informed consent and makes two primary suggestions. The study of DBS may proceed, but “hyper-disclosure” of the complexities should be required for competent subjects or proper surrogates if the candidate is not competent, and the most rigorous standard for competence should be employed. Throughout, neuromodesty and caution are urged.

Keywords: bioethics, deep brain stimulation, informed consent, neuroethics, psychiatric disorders, psychosurgery

DBS for psychiatric disorders may be a new therapy, but the issues it raises, including autonomy concerns, are familiar in bioethics because the same issues have been raised previously for other medical and psychological therapies (see generally Morse 2004; 2009). The basic framework of benefit, harm, and autonomy is no different whether one is considering proven or experimental psychological, pharmacological, or physical interventions such as DBS. All interventions change the brain. The issue is how. Context matters, of course, and the hard work will be applying the general ethical parameters to the specific problems DBS will create. The ethical problems psychiatric DBS does and will produce stem from our lack of knowledge about the relation between the brain and complex human behavior, from lack of data about the effects of DBS, and from mostly innocent overclaiming about our knowledge that may undermine attempts to proceed cautiously (Morse 2005). Nonetheless, there is enormous agreement in both individual and expert group writings on both sides of the Atlantic about the ethical concerns and the types of restrictions that should be placed on DBS.

This article addresses the important background legal/ethical and scientific considerations. Then it turns to the problem of autonomy itself. Questions of harms and benefits are not discussed unless they bear directly on the autonomy problem. The basic conclusion is that DBS should continue under extremely strict constraints with competent patients who have been exquisitely fully informed and perhaps also with incompetent patients if there is proper substituted judgment consent.

ETHICAL AND LEGAL BACKGROUND

The related legal and ethical questions are political and metaethical: For example, how parentalistic versus liber-

tarian do we wish our regime to be and what meta-ethical commitments do we wish to make, if any? All commentators appear to concede that the usual framework of benefit, harm, and autonomy for thinking about the acceptability of any intervention, whether it is proven or experimental, is the appropriate framework. I expand those three categories to seven—efficacy, intrusiveness, side effects, potential for abuse to the subject and others, cost, distributional concerns, and autonomy—but the analysis is similar.

The problem is that none of these variables is self-defining with a consensual meaning. These terms are of varying vagueness and are capable of diverse broad and narrow interpretations. For example, writers have distinguished “moral autonomy,” the capacity to subject oneself to objective moral principles, and “personal autonomy,” a value-neutral ability of individuals to self-govern any aspect of their existence they deem important according to whatever goals or desires they choose or have. We might also characterize the distinction as between objective or virtue autonomy and subjective autonomy. Are there objective moral principles, however, and how would we discover them? Moreover, which form of autonomy one might privilege will depend on the strength of one’s preference for individual liberty. Should the conception of autonomy we adopt be a legal right, a normative ideal, or a set of basic factual capacities? The answer theoretically is all three, but as a practical matter it is a legal right and we must decide the contours of that right in the context of experimental DBS.

Let me provide an analogy from U.S. constitutional law. The Supreme Court is often asked to decide what process is due when the government seeks to infringe on a particular liberty and there is no specific provision in the Constitution to decide the question. For example, should someone about to lose welfare benefits for violating the terms of

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receiving those benefits be entitled to a formal hearing and, if so, what further protections should be provided at the hearing? The Supreme Court has adopted a three-part test for deciding such cases that balances (1) the importance of the interest at stake; (2) the risk of an erroneous deprivation of the interest because of the procedures used, and the probable value of additional procedural safeguards; and (3) the government's interest (*Mathews v. Eldridge* 1976). Although these are the right considerations, this balancing test has never been outcome determinative and is always elastic depending on the court's political and moral preferences.

The same will be true in any bioethical context. Deciding whether and when a proven or experimental intervention is permissible suffers from the same use of contested ethical and political concepts and from indeterminacy. We sometimes forget this when weighing considerations pro and con. Focusing on the correct considerations is only the beginning of the moral enterprise, however. Being sensitive to context and practice will be crucial.

Scientific Considerations

As Kuhn and colleagues (2009) wrote:

DBS for psychiatric patients is not a standard therapeutic method. Therefore, every application of DBS in a psychiatric patient somehow enters into the experimental domain and has to be justified by a thorough, in-depth analysis of benefits, risks and burdens. (S137)

Just so. In this context I think we should be especially cautious for the most basic scientific reasons. Autonomy, however it is understood, is preserved by the doctrine of informed consent. The question is what we can justifiably tell patients as they, or surrogate decision makers, decide whether the subject should undergo DBS. I begin with general considerations and then turn to the specifics.

The brain–mind–action connection is one of the hardest problems in science. Many think, for example, that explaining consciousness, which is a crucial aspect of our subjective experience and moral lives, may be the hardest problem in science, and some claim that it is beyond current human capacities to solve it (McGinn 1999). I am agnostic, but these are indisputably difficult problems. Although there has been substantial progress in understanding the neural correlates and some causes of certain types of cognition, at present we have no idea how the brain enables mental states and how action is possible (McHugh and Slavney 1998). For example, we would like to know the causal difference between a neuromuscular spasm and intentionally moving one's arm in exactly the same way, but we do not know the difference.

Many people hope that intertheoretic reduction of psychological states to brain states will help to solve the problem, but the intertheoretic reduction program has failed to explain mental states and social life. We cannot even accomplish the allegedly simplest reduction from chemistry to physics, and there is theoretical reason to believe that the reductionist program cannot succeed. In my opinion,

the most sophisticated current philosophy of science view about explaining complex human behavior—by which I mean mental states (including moods) and actions—is that a multifield, multilevel approach will be necessary (Craver, 2007). The astonishing advances in neuroscience, especially those fueled by the advent of functional magnetic resonance imaging (fMRI), have scarcely changed our currently modest understanding of the brain–mind–action connection. Future advances may do so, but that is a cautiously optimistic speculation about the future.

At present, most cognitive and social neuroscience studies on human beings, especially neuroimaging, involve very small numbers of subjects. Further, most studies average the neurodata over the subjects and the average finding may not accurately describe the brain structure or function of any actual subject in the study. Replications are few, which is especially important for law and policy. Policy should not be influenced by findings that are insufficiently established, and replications of findings are crucial to our confidence in a result.

The functional neuroscience of cognition and interpersonal behavior is largely in its infancy, and what is known is quite coarse-grained and correlational rather than fine-grained and causal (Miller 2010). Any language that suggests otherwise, such as claiming that some brain region is the neural substrate for the behavior, is simply not justifiable in most cases. There are also technical and research design difficulties that undermine valid inferences, but future advances may remedy this. Structural findings avoid some of the difficulties of functional imaging, but the meaning of findings is often not apparent and many of the positive findings may be the result of significance bias (Ioannidis 2011). We seldom know whether an anatomical difference is a cause, an effect, or just a correlate of the condition under investigation.

Now let me turn to some specifics regarding psychiatric disorders in particular. To study such disorders properly presupposes that the researchers have already identified and validated the diagnostic behavior under neuroscientific investigation. On occasion, the neuroscience might suggest that the behavior is not well characterized or is neurally indistinguishable from other, seemingly different, behavior. In general, however, the existence of psychiatrically relevant behavior will already be apparent. And if the behavior and the imaging data are inconsistent, we should virtually always believe the behavior. Actions speak louder than images.

If the behavioral data are not clear, then the potential contribution of neuroscience is large. Unfortunately, it is in just such cases that the neuroscience at present is not likely to be of much help. I term this the “clear cut” problem (Morse 2011). Neuroscientific studies start with clear cases of well-characterized behavior, so the neural markers might be quite sensitive to the already clearly identified behaviors precisely because the behavior is clear. Less clear behavior is simply not studied, or the overlap in findings for less clear behavior is greater between experimental and control subjects. For example, investigators have discovered various

small but statistically significant differences in neural structure and function between people who are clearly suffering from schizophrenia and those who are not. Nonetheless, in a behaviorally unclear case, the overlap between data on the brains of people with and without the disorder is so great that no imaging finding is yet sufficiently sensitive to be used for psychiatric diagnosis (Frances 2009).

To the extent that neural correlates for mental disorders have been identified, they tend to be nonspecific. That is, findings in similar regions of the brain have been identified with mental disorders as diverse as major affective disorders and schizophrenia. In the context of psychiatric DBS, a U.S. consensus conference concluded that “no single target has been validated or demonstrated to be superior to others in any disorder of MBT” [mood, behavior, thought] (Rabins et al. 2009, 932). Further, it is virtually impossible to do the type of randomized, controlled, blinded studies that are typically the gold standard. Finally, the types of patients who will agree to investigational psychiatric DBS will virtually certainly not be a random sample, even of intractable patients.

Some people think that animal translational models will offer solutions to some of the neuroscientific problems that hinder achieving the goals of psychiatric therapies, but we should not reach this conclusion too hastily. When we are dealing with essentially mechanistic phenomena, such as the movement signs of movement disorders, animal models may be of great help because we are dealing with pure mechanisms. Unless the reductionist program succeeds, however, we cannot treat mental disorders, even the most severe, seemingly culturally impenetrable, disorders, as pure mechanisms. They are part of psychological experience, which includes mental states and actions, and are aspects of whole people who are makers of and interpreters of meaning, who reflect on their own lives, and who are always shaped by interpersonal and social variables. Other animals do not have these capacities or do not have them to the same degree. I would argue that these differences often prevent adequate translation, even when the outward behavior of another animal—e.g., a grieving chimp—seems so familiar to us.

Over time, however, these problems may ease as imaging and other techniques become less expensive and more accurate, as research designs become more sophisticated, and as the sophistication of the science increases generally. There is also an open question of whether accurate inferences or predictions about individuals are possible using group data for a group that includes the individual. This is a very controversial topic, but even if it is difficult or impossible now, it may become easier in the future.

In short, at present we must admit that we do not understand the neural causes of major mental disorders or how DBS works when it seems to do so. Talk of “neuromodulation” as an explanation of its efficacy means nothing or very little because it is a conclusory, vague description, not a genuine explanation. The upshot of these considerations is that interventions based on justified hypotheses about which target to choose or about virtually any other aspect

of DBS are more problematic than one would suspect from reading the seemingly cautious literature.

We do not need scientific understanding of why some intervention relieves human suffering. If we discover empirically that something works, then we may be well justified in offering it, assuming that we reasonably understand the potential short and long-term harms. We do not have the database yet for the efficacy and harms of psychiatric DBS, but it is possible that we may in the future.

INFORMED CONSENT FOR PSYCHIATRIC DBS

The foregoing discussion suggests that obtaining informed consent to psychiatric DBS is exceptionally problematic. Even the most careful investigator is eager to learn more about the brain–mind–action connection, and all investigators would like to alleviate suffering. Thus, for even the most cautious investigator, it will be difficult not to overstate how much we know and how justifiably we can hypothesize.

Informed consent, the guarantor of autonomy, raises essentially two issues: who can provide it, and what must be provided to the patient or subject? To grant an investigator permission to violate the subject’s otherwise inviolable right to be left alone, in U.S. law the waiver must be knowing and intelligent, and it must be voluntary (Berg et al. 2001). Whether a waiver is competent depends on a number of factors, including the subject’s intelligence and rational capacities generally, the difficulty of the decision to be made, and the test for competence that will be applied. In the United States, three general legal tests have been identified for an adequate informed consent: factual feedback, appreciation, and rational manipulation. Factual feedback is satisfied if the subject can accurately repeat what he or she has been told. Appreciation refers to the subject’s ability to understand how the intervention applies in his or her case. Rational manipulation asks whether the subject can engage in a reasonable benefit–cost calculus about the intervention. Holding capacity and task difficulty constant, the outcome might be different depending on the test.

The issue of capacity is both factual and normative. What is the subject capable of doing and what should be required for exercising informed consent? A currently unresolvable difficulty, however, is determining what a subject is capable of doing. For example, we cannot distinguish people who can govern themselves properly from people who simply are not motivated to do so. At most, generally, we make inferences from the subject’s general behavior and from how well the subject seems to react to the decision at hand. We know from experimental work that people with depression, a prime psychiatric indicator for DBS, appear to be able to “pass” operationalized measures of the three major U.S. tests for competence to consent to treatment (Berg et al. 1996; Grisso and Appelbaum 1995). In the case of experimental DBS, the knowledge base is so thin that there is a strong argument that decision makers should choose the most demanding test, but note that choosing the most demanding increases the level of paternalism.

The prime danger for potential DBS candidates may be potentially poor exercise of the capacity the subject may have. If DBS should be reserved for intractable conditions that have failed to respond to all other, less invasive therapies, then the subject may be “overly” motivated to engage in DBS. A related concern is that DBS candidates may be especially vulnerable to the “therapeutic misconception,” the incorrect understanding that this experimental procedure will in fact ameliorate the subject’s suffering. Investigators must be especially vigilant about these concerns.

DBS raises the possibility of personality change. The implications of personal transformation over time is a familiar problem (Parfit 1984), but, once again, context matters. As experience with DBS for Parkinson’s disease has indicated, profound behavioral changes can accompany sudden, mechanically produced improvement in previously debilitating conditions (Haarh et al., 2010; Mayberg and Lozano, 2002). Despite the dramatic improvement, patients often are less than pleased, however, because such changes make reintegration in sociofamilial and professional life difficult (Agid et al. 2006). But even this context is somewhat familiar. People often voluntarily expose themselves to experiences that can transform them and their lives suddenly and mechanically, such as having open heart surgery and surgery for epilepsy. Whether and how often radical personality shifts of so-called “narrative personality” or identity will occur are open questions, and if they do, DBS may not be directly accountable.

Assuming such reintegrative or identity problems will occur with psychiatric DBS, as long as the subject is informed about the possibility and the transformed subject retains rational capacities, the potential for transformation should not be a bar to consent. Moreover, in the future we may be able to identify which patients are likely to experience such disruptions from psychiatric DBS and we may be able to mitigate the problems through targeted counseling (Schectman, 2010).

The possibility that the intervention will disable the person and undermine future autonomy does not seem high, but it is a potential outcome of many neurosurgical procedures and it is best handled by utterly full disclosure. For example, DBS for Parkinson’s disease causes some patients to lose their energy and ambition. Full disclosure of such risks for psychiatric DBS is once again hampered by our limited database, but this, too, can be fully disclosed, and experience with Parkinson’s disease does not suggest that frequent, massive disabilities should be expected.

My preferred solution for competent subjects is “hyper-disclosure.” I have a strong normative preference for permitting people to make unencumbered decision about how to govern their own lives and generally set the competence bar rather low. But subjects must be absolutely fully informed in this context in which we know so little. The complexity of the intervention, the expectations of the subject and significant others, the particulars of the operation, and all the other issues must be completely discussed and any potential subject on the margin of consent should be discouraged.

What if the potential subject is not competent to provide informed consent according to the governing competence standards, thus raising a genuine autonomy problem? One possibility is to bar DBS absolutely, but this may prevent obtaining knowledge in circumstances in which we might most need it and it may condemn the subject to needless suffering. Despite our lack of understanding of the mechanism of change, DBS does seem to alleviate psychiatric suffering in a nontrivial number of cases, which is why experimentation continues.

Assuming that incompetence is not an absolute bar, who should decide, and should we use a subjective or objective standard for substituted judgment? Again, these are familiar problems. Family members are usually best placed to make such decisions, but there can be an inevitable conflict of interest. If we are reasonably certain that the substitute decision maker is genuinely attempting to act in the subject’s best interest, should the decision maker try to determine what the subject would have wanted to do or use a more objective, reasonable person standard? In this instance, it is hard to know what outcome either standard would produce because the procedure is so experimental. Advance medical directives are unlikely to clearly cover such situations. I have a general preference for subjective standards because I prefer maximizing self-governance, but I have no strong view in this context. The difficulty of exercising substituted judgment by any standard suggests that incompetence should perhaps be an absolute bar, but I do not want to reach this conclusion yet. The possibility of substituted judgment in this context requires the most careful attention.

CONCLUSION

In sum, my proposal is for neuromodesty and all that this entails. The ethical questions are familiar and little different from those raised by any experimental procedure about which the knowledge and hypothesis base is so slim. As more data accumulate, however, the ethical issues specific to DBS will emerge more clearly.

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