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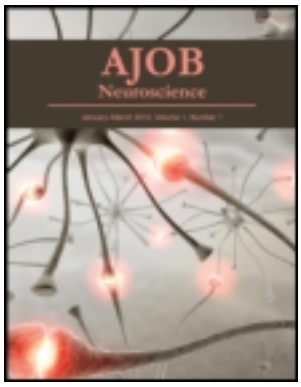

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Justice and Equity in Trials of Deep Brain Stimulation for the Treatment of Addiction and Overeating

Wayne Hall [a] & Adrian Carter [a]
[a] University of Queensland Centre for Clinical Research
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are themselves manipulated by DBS, since DBS arguably alters not only first-order emotions, but *all* emotions—even those interconnected with deeply held beliefs and values.

If a patient's feelings about food, drugs, playing with children, and even DBS are manipulated, then so are the patient's beliefs—since beliefs and emotions are intimately and inextricably connected. Therefore, post-DBS, the patient is not without controlling influence over her or his beliefs and evaluative judgments, and cannot grant autonomous authorization to the effects of that procedure. The patient fails to meet all of Faden and Beauchamp's (1986) criteria for informed consent. Even when a patient has the decisional capacity to provide informed consent to undergo DBS for treatment of addiction and substance abuse, the patient will lack the capacity thereafter to consent to the global changes in personality and emotional experience that result.

There is an important follow-up question, though: Does the presence of a controlling influence invalidate consent granted post DBS to continue stimulation? Faden and Beauchamp state, "There may be compelling policy or moral justifications in some contexts for adopting consent requirements that establish a threshold below the level of substantial autonomy, in effect treating less than substantially autonomous consents as valid or, more precisely, effective consents" (1986, 241). Increased well-being, better family life and more fulfilling relationships, job security, and other perks of substance-abuse-free living may be compelling enough reasons to continue DBS when the patient consents to even radical changes in personality. However, we should be reluctant to call this informed consent as it is traditionally understood as "autonomous authorization," since DBS is, arguably, a controlling influence over the patient's emotions and, therefore, even deeply held beliefs.

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Justice and Equity in Trials of Deep Brain Stimulation for the Treatment of Addiction and Overeating

Wayne Hall, University of Queensland Centre for Clinical Research
Adrian Carter, University of Queensland Centre for Clinical Research

Pisapia and colleagues (2013) argue that there is sufficient scientific evidence to warrant trials of deep brain stimulation (DBS) to treat addiction and discuss some of the ethical issues involved in conducting such trials, concentrating on patient selection and informed consent. We have elsewhere argued in detail why we think that trials of DBS in addiction are premature (Carter and Hall 2011). We have also provided guidelines on the ethical conduct of clinical trials of DBS for use by those who are unconvinced by our arguments (Carter et al. 2011).

This commentary focuses on important ethical issues in trialing DBS in addiction that Pisapia and colleagues do not discuss, namely, justice and equity. These issues arise because DBS is a very expensive procedure: It costs more than US$50,000 for the initial surgery and there are recurrent costs of over US$10,000 per year to replace batteries,

Address correspondence to Wayne Hall, University of Queensland, Centre for Clinical Research, Herston Rd, Herston, 4029, Australia. E-mail: w.hall@sph.uq.edu.au

monitor patient progress, maintain electrodes, and adjust stimulation parameters to ensure that any therapeutic effects are maintained (Baltuch and Stern 2007). The costs of DBS, including the additional and ongoing costs of regular research assessments, makes it very expensive to conduct trials of DBS for addiction, or indeed any other indication.

DBS will also be a very expensive treatment to provide if clinical trials indicate that it is safe and effective in treating addiction. Researchers who embark on clinical trials therefore need to consider the ethical issues that will arise in making the difficult decisions about who will have access to this form of treatment, if it is approved. This discussion has obvious implications for patient selection in trials and for the type of justification that is often provided for doing these trials.

THE OPPORTUNITY COSTS OF TRIALING DBS FOR ADDICTION

We would argue that a higher priority should be given to funding clinical trials of less expensive, less invasive, and equally promising approaches to the treatment of addiction, such as implantable forms of opioid agonists or antagonists for heroin dependence (Krupitsky et al. 2011; Kunoe et al. 2009; Ling et al. 2010) or opioid antagonists for alcohol dependence (Lobmaier et al. 2011). These treatments are likely to benefit many more addicted patients if they prove to be effective than will DBS. Such trials would be much cheaper and easier to conduct in large enough samples of patients to properly assess their therapeutic value. DBS, by contrast, is likely to be conducted on a small scale with publications of small patient series, the results of which may be difficult to interpret. The same argument can be made for trialing simpler and probably much more cost-effective treatments for obesity, such as newer forms of bariatric surgery, in preference to DBS (Vos et al. 2010).

Pisapia and colleagues do not discuss the opportunity costs of trialing new indications for DBS as against ensuring that trials of DBS for intractable psychiatric and neurological disorders are large enough to be informative. Neurosurgical teams, and the multidisciplinary teams that are required to assess and support patients undergoing DBS, are expensive and consume scarce resources. In many specialist DBS research centers these resources are often already involved in trials of DBS for indications such as intractable depression and obsessive compulsive disorder. It would be an arguably better use of these resources to ensure that these trials are completed before we embark on trials of DBS in yet another condition.

There are other opportunity costs of conducting more clinical trials of new indications for DBS. One foregone opportunity is expanded access to DBS for patients with Parkinson's disease (PD). A recent controlled trial indicates that offering DBS earlier in a PD patient's illness may produce larger benefits by delaying disease progression and improving quality of life (Schuepbach et al. 2013). This outcome makes DBS an even more cost-effective intervention for PD than delaying its use until dopamine replacement medication no longer controls motor symptoms. The scarcity of the expertise required to expand the use of DBS in PD may well constrain the capacity of most treatment systems to undertake clinical trials of DBS for new indications.

THE COSTS OF PROVIDING DBS

If DBS proves successful in treating intractable cases of addiction, its costs will limit the number of addicted patients who can benefit from it, even in developed countries with good neurosurgical infrastructure. The most likely results are that very few addicted patients will benefit from DBS; these are unlikely to include the persons with the most severe addictive disorders who have been used to justify trials of DBS in addiction (e.g., Stephens et al. 2012). The provision of DBS could well be at the cost of increasing access to cheaper forms of treatment for addiction to which many addicted persons do not now have access.

Stephens and colleagues (2012) have provided an economic argument for trialing DBS in addiction. They argued that trials of DBS were warranted in heroin addiction because DBS would be a cost-effective intervention if it was only half as effective as methadone maintenance treatment (MMT). They used the positive results of DBS in PD to argue that this was likely to be the case. We question the assumption that the results of DBS in Parkinson's patients can simply be transferred to an addicted population. Parkinson's patients are not ambivalent about controlling their movement disorders in the way that heroin-addicted individuals are about heroin use. Heroin-addicted individuals will attempt to subvert the effects of methadone and naltrexone in order to occasionally use heroin. We would expect them to also find ways of modulating stimulation parameters to allow drug use (e.g., by misreporting craving when stimulation parameters are adjusted or finding other ways to control their stimulation).

A more significant problem with their analysis is that their estimates of the costs of untreated heroin addiction come from the United States, where criminal justice costs comprise 57% of the total. As we have argued previously, in using these costs, Stephens and colleagues are implicitly endorsing the use of DBS as a crime control measure (Hall and Carter 2012). We do not believe that this was their intention, but it is an unintended consequence of using these figures to justify trials of DBS.

Addiction affects approximately 5% of the adult population in any year (Kessler et al. 2005), and a much larger proportion if nicotine dependence is included as an indication, as some advocates of DBS seem to suggest. Even if we allow that only a minority of these persons would be candidates for DBS, there are a large number of potentially addicted patients who would be eligible for DBS. The likely excess of demand over supply raises the following question: Which addicted individuals will have access to DBS? The answer will depend critically on how this treatment is funded.

If DBS is funded on a user-pays basis, as is likely in the United States, then only that minority of the addicted

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population with health insurance or substantial private income will have access. This will certainly not include the heroin users who figure in Stephens and colleagues' economic modeling, namely, street heroin users who engage in crime to fund their drug use, most of whom end up in the prison system. If DBS is approved for use in publicly funded health care systems, then the number of patients who receive it will be tightly rationed to limit health care costs. Managing patient demands for access to DBS (if it is approved for clinical use) will be a major challenge for health care managers and staff.

The likely limited future access to DBS raises a major justice issue for clinical trials: Is it ethically acceptable to trial an expensive treatment procedure that will be used to treat very few highly selected patients when the majority of addicted patients now lack access to cheaper, effective forms of treatment? The lack of access to treatment also raises an ethical issue in obtaining consent to participate in trials of DBS. The offer of a place in the trial will provide a large implicit incentive to participate, namely, access to an expensive form of treatment about which unrealistic expectations of benefit are likely to be generated by the media (Bell et al. 2010), when these patients would be otherwise unable to access other forms of addiction treatment.

CONCLUSIONS

Advocates of trials of DBS for addiction need to pay much more attention to the opportunity costs of these trials and the serious issues of resource allocation that will arise if these trials suggest that DBS is an effective treatment. One has to question the use of data on the high costs of untreated heroin addiction to justify trials of DBS when (if successful) a tiny proportion of the affected population will benefit, and very few of those addicted persons in whose interests DBS is supposedly being trialed. This is an especially worrisome feature of these proposed trials when so many addicted persons do not yet have access to less expensive forms of effective treatment.

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