Deep Brain Stimulation as Clinical Innovation: An Ethical and Organizational Framework to Sustain Deliberations About Psychiatric Deep Brain Stimulation

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Deep brain stimulation (DBS) for psychiatric disorders needs to be investigated in proper research trials. However, there are rare circumstances in which DBS could be offered to psychiatric patients as a form of surgical innovation, therefore potentially blurring the lines between these research trials and health care. In this article, we discuss the conditions under which surgical innovation may be accepted as a practice falling at the frontiers of standard clinical care and research per se. However, recognizing this distinction does not settle all ethical issues. Our article offers ethical guideposts to allow clinicians, surgical teams, institutions, and institutional review boards to deliberate about some of the fundamental issues that should be considered before surgical innovation with psychiatric DBS is undertaken. We provide key guiding questions to sustain this deliberation. Then we review the normative and empirical literature that exists to guide reflection about the ethics of surgical innovation and psychiatric DBS with respect to general ethical questions pertinent to psychiatric DBS, multidisciplinary team perspectives in psychiatric DBS, mechanisms for oversight in psychiatric DBS, and capacity and consent in psychiatric DBS. The considerations presented here are to recognize the very specific nature of surgical innovation and to ensure that surgical innovation in the context of psychiatric DBS remains a limited, special category of activity that does not replace appropriate surgical research or become the standard of care based on limited evidence.

KEY WORDS: Deep brain stimulation, Ethics, Psychiatry, Surgical innovation

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The application of deep brain stimulation (DBS) to various medically refractory psychiatric conditions is under investigation, with further rigorous, blinded, randomized controlled trials required to conclusively demonstrate efficacy and safety.[1] Recommendations that DBS for disorders of mood, behavior, and cognition be confined to research trials are based on sound scientific and ethical reasons and recognize that evidence may not be adequately gathered and shared outside of clinical trials.[2] There should be no compromise on the goals of gathering sound evidence or on the ethical requirements for research activities (eg, proper protocol development and design, institutional review board [IRB] approval, informed consent of patients). However, there are circumstances in which DBS may be offered to patients as a form of surgical (or, more generally, clinical) innovation (ie, an innovative therapy justified solely by the pursuit of the patient's well-being). This is a possibility granted to practicing clinicians, analogous to off-label prescriptions, that should be recognized as such but nevertheless should be guided by high ethical standards to prevent innovative surgeries or informal research from prematurely influencing the standard of care.

Clinical innovation can be defined as "treatments in a clinical setting which have not been well-proven in a research setting."[3] Innovation is also sometimes defined simply by the absence of

ABBREVIATIONS: DBS, deep brain stimulation; **IRB,** institutional review board; **OCD,** obsessive-compulsive disorder

meeting a standard for research (ie, it is not research, but it has some of the hallmarks of research). The special status of clinical innovation (and similarly of surgical innovation) may be justified by the principle of beneficence and facilitated by a regulatory framework that allows the implementation of surgical innovations. Clinicians contemplating offering innovative care need to weigh several ethical issues carefully and strike a balance among the circumstances of the patient, the level of evidence for a given innovation, and the ethical principles and processes in place at their institution.

A decision to engage in innovative practice of this nature sets up many unique practical and ethical decisions, including those related to patient selection, target selection, surgical technique, data collection, publication of results, and follow-up (Table 1). It is in making these decisions that the personnel in DBS programs can benefit from addressing a set of important ethical questions.

This article aims to inform the ethical reflection of practicing DBS surgeons, members of DBS surgical teams, and others involved in assessing the procedure (eg, IRB members, bioethicists, hospital administrators) based on a collaborative endeavor between ethicists and a functional neurosurgeon leading a DBS program. First, questions stemming from common ethics case analysis methods were identified and tailored to the situation at hand to provide a general structure for our initial discussion (Table 2). Second, support for deliberation is offered in the text on issues in which either empirical or normative literature (or both) specifically informs ethical analysis.

TABLE 1. Case Study: A Fictional Patient With Intractable Obsessive-Compulsive Disorder[a]

BT is 32 y old with a 15-y history of treatment-resistant OCD. The patient's principal symptoms are obsessional thoughts related to a fear of self-embarrassment, particularly in conversation, and excessive worry about committing blasphemy. These thoughts now occupy >12 h a day. BT also exhibits compulsive mental checking behaviors. The patient's Yale-Brown Obsessive Compulsive Score is currently in the severe range (34).
BT has been hospitalized multiple times over the past decade for functional impairment and inability to cope. The patient has been treated unsuccessfully with several medication classes, including selective serotonin reuptake inhibitors (paroxetine, citalopram, fluvoxamine, sertraline, fluoxetine), benzodiazepines (clonazepam, temazepam), and antipsychotics (olanzapine, quetiapine, risperidone). BT has also failed a 2-wk course of intravenous clomipramine therapy and has participated in 15 sessions of cognitive behavioral therapy without noticeable benefit.
BT was forced to terminate university studies prematurely and has struggled to hold down employment. Currently, the patient lives in a group home, but the treating psychiatrist is worried that BT may soon require institutionalization at a psychiatric care facility. As a last resort, BT's psychiatrist wonders whether BT might be a candidate for psychiatric surgery and refers BT to a local functional neurosurgeon with expertise in DBS.
From an ethical perspective, should DBS be offered to BT as a form of innovative treatment? If the psychiatrist refers the patient, what kind of team and support should be available for the patient? Should the innovative procedure be carried out simply under the purview of the neurosurgeon, or does it require special ethics oversight? What conditions should be in place to ensure that the patient makes a meaningful and informed choice of whether to undertake DBS?

[a]DBS, deep brain stimulation; OCD, obsessive-compulsive disorder.

GENERAL ETHICAL QUESTIONS PERTINENT TO OFFERING PSYCHIATRIC DBS AS SURGICAL INNOVATION

Deciding to offer psychiatric DBS requires an understanding of the ongoing debate concerning its readiness for clinical application. There are promising results from early trials or cases of DBS in conditions such as depression,[4,5] obsessive-compulsive disorder (OCD),[6] and anorexia nervosa.[7] However, evidence needs to be obtained through stringent scientific and ethical means to avoid the same criticisms leveled at past attempts at surgery for psychiatric illness (ie, "moral blindness").[8]

Pursuing DBS in carefully regulated research trials ensures that patients are offered the greatest protection from unknown risks and that routine collection of scientific data concerning the safety and efficacy of psychiatric DBS is prioritized. Conversely, widespread clinical use outside of trials could unnecessarily expose patients to potential harms without contributing to generalizable knowledge about the risks and effects. Highlighting the value of research and respect for the principle of nonmaleficence, several authors argue that more widespread use of psychiatric DBS therefore is not currently legitimate.[9,10] Indeed, it would be troubling if DBS became a widely used intervention without strong supportive evidence in contemporary surgical practice, especially when history shows that some surgical innovations quickly incorporated into standard practice have been disproven later on or even have been shown to be harmful to patients.[11,12] Similar concerns that DBS for OCD will move prematurely from investigational to proven effectiveness under the auspices of a Humanitarian Device Exemption have been expressed.[2] Using the example featured in Table 1, we can ask the following question: What conditions need to be fulfilled in matters of consent or selection criteria to ensure that the patients' best interests are pursued?

The absence of treatment alternatives for psychiatric patients with refractory conditions could motivate innovative practice in the area of DBS as in other surgical specialties. A 2013 study of functional neurosurgeons revealed that patients with psychiatric indications are frequently already treated internationally by neurosurgeons with either DBS or stereotactic lesioning procedures.[13] In that study, 90% of neurosurgeons were optimistic about the future of neurosurgery for psychiatric disorders, but they believed that a significant limitation to the field was the reluctance of psychiatrists to refer patients for surgical intervention. This study could suggest a willingness to

TABLE 2. Some Questions to Tackle When Undertaking the Development of a Psychiatric Deep Brain Stimulation Program[a]

Should psychiatric DBS be offered as a form of clinical innovation?
No (eg, unknown risks and benefits; patients unable to give informed consent; premature in the absence of solid outcome data)
Yes (eg, unknown risks/benefits mitigated by exploring ethical considerations of widespread clinical use; patients capable of giving informed consent; premature use tempered by willingness to develop innovative care with potential for significant benefit to individual patients)
What are the ethical considerations when initiating a psychiatric DBS program?
What is the goal of the program (eg, offering a last-resort option to medically refractory psychiatric patients; contributing to knowledge about DBS in psychiatry [safety, efficacy, target selection]; treating the psychiatric population for which DBS has most evidence)?
What is the motivation for the program (eg, absence of viable options for refractory psychiatric conditions; compassion; hope for immediate patients and future impact beyond local community; reputational benefits for surgeon and/or institution; bias for innovative treatment despite lack of sufficient evidence; publication of research findings)?
Does the source of funding affect its ethical acceptability (eg, industry funding can generate conflicts of interest; should programs receive substantial public funding for a potentially ineffective procedure)?
How are team ethics and multidisciplinary team perspectives encouraged?
Do hierarchical relationships affect communication and ethical decision making (eg, tendency to mirror professional team hierarchy; should the neurosurgeon assume the traditional role of "captain of the ship"; level of collegial collaboration among team members)?
What types of methods are used to facilitate communication across team members (eg, briefing/debriefing policies; team-building exercises)?
Is everyone contributing to the ethics of decision making (eg, are different expertise and perspectives engaged; is patient care a collective responsibility; are individual responsibilities delineated; are procedures in place to aid in transferring responsibility between patient selection, surgery, and follow-up; are regular team meetings held to take into account member contributions; has a cohesive set of values been developed as a team to define patient care standards)?
Is there a process in place to sustain continuing ethics education and training (eg, type of format; by whom and for whom; when)?
What is the oversight for the psychiatric DBS program?
What is the oversight mechanism for the program (eg, individual team member [surgeon, psychiatrist]; peer-review mechanisms [eg, chief of department]; oversight committee; institution or IRB; funders)?
Is the program building from sufficient expertise and experience in DBS for movement disorders (eg, funding to increase capacity of existing staff who are familiar with DBS programming; funding to new staff trained specifically on managing psychiatric DBS patients; new oversight committee for psychiatric patients)?
How is the allocation of devices decided (eg, allocation of percentage off-label indications, with preference for standard indications; psychiatric DBS in separate category)?
Are there postsurgery obligations associated with innovations (eg, help for patient adjusting to new state of personhood; reintegration of patient into society; psychosocial cointerventions; device troubleshooting or removal; outcomes evaluation and data collection)?
How is informed consent handled?
Does the psychiatric patient approached possess the capacity to give informed consent (eg, patient unable to give informed consent; patient understand risks/benefits but cannot make complex decisions; alternative consent processes [with IRB, surrogate consent])?
Is vulnerability given due consideration (eg, are psychiatric patients considered intrinsically vulnerable; is vulnerability considered a dynamic property, with contextual and relational aspects; is vulnerability managed with correctives within the consent process)?
What is disclosed in consent (eg, known physical risks and side effects; known psychosocial risks and side effects; target selection and justification; surgeon's experience [with DBS itself; specific target; specific psychiatric population]; team's experience with DBS, target, psychiatric population; local vs national outcomes)?
Who is responsible and involved in the informed consent process (eg, surgeon; psychiatrist; psychologist; third-party consenter)?
How are risks/benefits expressed to patient (eg, risks overemphasized to counter possible overestimation of benefits; high degree of unknown risks; high degree of unknown long-term benefits)?

[a]DBS, deep brain stimulation; IRB, institutional review board.

offer innovative DBS but without clarity on guiding ethical principles or an understanding of interdisciplinary collaborations.

Competing interests may underlie the practice of surgical innovation such as patient welfare, prestige of carrying out a novel surgery, financial gain, previously promising experience with a particular surgical procedure, the opportunity to acquire new funding, and interest in being the first to publish results.[14] For this reason, any proposal for psychiatric DBS innovation must clearly articulate its goals (ie, what it will do) and principles (ie, why it should be done).

We suggest 2 foundational issues that must be considered: the goal of the intervention and who is responsible.

Goal of the Intervention

The best interest of patients should always be the principal goal of innovative psychiatric DBS, potentially accompanied by the pursuit of scientific knowledge. Furthermore, the goal of the intervention should be transparent, including the aspect of institutional approvals or ethics oversight committees (discussed below).

Who Is Responsible?

Typically, the head of the program (usually, although not always, the neurosurgeon) bears the ultimate responsibility for the activities and direction of the surgical program and for ensuring that other colleagues involved share a unified ethical vision of the program. With that said, all individual members of a psychiatric DBS intervention need to be cognizant of the unique ethical issues raised by psychiatric DBS. A Canadian study has suggested that trainees from diverse healthcare professions (eg, nursing, social work, physiotherapy) are not well prepared to handle many of the ethical issues associated with psychiatric DBS because, among other reasons, they may be unprepared to engage in ethical reflection, they have a limited understanding of issues associated with scientific uncertainty, and they may lack an interdisciplinary understanding about ethical issues.[15] This article suggested the need for tailored ethics training for staff members and an increased awareness of how the healthcare professionals' previous training shapes their process of ethical reflection.

MULTIDISCIPLINARY TEAM PERSPECTIVES IN PSYCHIATRIC DBS

There is a consensus in the literature, including a provisional consensus reached by members of the international psychiatric and neurosurgical societies,[1] that experienced multidisciplinary teams are mandatory for the ethical conduct of research on psychiatric DBS or for therapeutic DBS offered through a Humanitarian Device Exemption (ie, for OCD).[16,17] Multidisciplinary teams ensure that appropriate requirements for patient selection are met, that consent and capacity are established, that patients are holistically assessed, and that there are practitioners available to ensure a comprehensive program of preoperative and postoperative follow-up care (including psychiatric care and device programming).[1,10] Some authors have suggested that the inclusion of case-advisory panels would add psychosocial, ethical, and legal expertise to the evaluation of candidates for DBS[18] on the basis of experiences in the Parkinson disease DBS population.[19] Psychiatric patients may also face unique challenges with recovery such as rehabilitation back into the community or to the workforce[20] that may be met more readily by including the perspectives and professional services of social workers or community psychiatric teams, at least on an ad hoc basis.

To ensure that a final decision about any patient is arrived at in a balanced and consensus-based fashion, it has been suggested that "unanimous approval [of the team members] should be obtained before proceeding with the operation."[21] This underscores the fact that principles of accountability and transparency should underlie decisions made within the interdisciplinary DBS team. True inclusiveness requires more than merely a token survey of different multidisciplinary providers. Rather, team members should be actively included in the different aspects of ethical decisions of the intervention, including, as previously mentioned, its goal and justification. This type of joint ethical decision making can be facilitated by maximizing the moral agency of each team member and by paying attention to hierarchical relationships. Some evidence has shown that individual members of surgical teams possess different perceptions of their combined culture of teamwork, communication, and collaboration, and this has important implications for ethical decision making.[22-24] Multidisciplinary team participation in decision making should also help to offset the potentially disproportionate power and influence of the neurosurgeon that may influence patients to accept new or aggressive interventions.[25]

Broadly, teams planning to undertake psychiatric DBS must attend to the following.

Composition of Multidisciplinary Teams

Teams that are seeking to offer innovative treatment with DBS to psychiatric patients should be involved already in conducting DBS for movement disorders and should have expertise in the various aspects of presurgical, surgical, and postsurgical care for DBS patients, which share several similarities across different disease conditions. These include expertise in neuropsychological evaluation, neurosurgical DBS implantation, and DBS programming. A team involved in innovative psychiatric DBS should include, at a minimum, at least 1 psychiatrist who will be critically involved in screening potential candidates before DBS implantation and responsible and available for close postoperative follow-up and device programming. Often, psychiatrists are part of existing DBS teams that treat movement disorders; these psychiatrists may be ideally suited to assume a more central role in DBS for psychiatric indications. However, these same psychiatrists typically lack the necessary technical expertise and troubleshooting ability required to provide optimal care to patients after device implantation and should receive training in collaboration with experienced academic centers already carrying out experimental trials in psychiatric DBS. Besides psychiatrists, several other healthcare providers should be given due consideration in forming a psychiatric DBS team, including social workers, psychologists, and psychiatric nurses, among others.

Hierarchical Relationships and Decision Making in the Multidisciplinary Team Context

Traditional hierarchies within neurosurgical units must give way to collaborative interdisciplinary teamwork in the context of an innovative psychiatric DBS intervention. Members of the team should be given the opportunity to participate in decisions made about the intervention, particularly in screening for candidacy, surgical intervention, and follow-up and in setting the overall structure of the program. Such an approach recognizes that in the care of patients and in "a profession abounding with experts, no one person's expertise can always count for more" without dramatic consequences.[26] Improving team culture can also lead to better patient outcomes and fewer adverse events.[27] The team should openly discuss and agree on the core features and values of

the intervention that in turn will define patient care standards.[28] Team members should also participate in the development of any values statement or shared ethical approach for the overall DBS program. In addition, there should be a transparent discussion to delineate areas of individual responsibility within the group to ensure clarity about where expertise may need to be prioritized over perspectives.

MECHANISMS FOR OVERSIGHT OF INNOVATIVE PSYCHIATRIC DBS

Defining the mandate and goals of a DBS program will in turn help to determine the appropriate oversight mechanism(s) for innovation within that program. A position statement by the Society of University Surgeons hints at the undefined boundaries between standard research activities and innovations, such that some innovations would be "exempt from formal IRB approval, but would require some form of oversight and more-than-routine informed consent by the patient."[29] Different mechanisms have been suggested to ensure ethical oversight of any innovative program, including surgical innovation committees, conventional IRBs, independent ethical review, and departmental or peer review. The choice of IRBs as an appropriate body to conduct ethical oversight has been challenged by data indicating that few surgeons embarking on innovations seek IRB approval[30] and the suggestion that traditional mechanisms of oversight may inhibit innovation because they are inflexible or slow[31] or may be inadequate or ineffective, in part because of a lack of appropriate expertise among IRB members (L. Karpowicz, E. Bell, E. Racine, unpublished data, January 2016). It has been suggested that excessively inflexible oversight is unlikely to "lead to better care for patients"[32]; however, Bernstein and Bampoe[33] recommend that IRBs be involved in certain instances of innovation, depending on the newness of a procedure or the surgeon performing the procedure.

One of the most important roles played by oversight is to ensure that patients are informed of the novel aspects of the procedure and provided assurance that the procedure will be performed only with their free and informed consent. A meta-analysis of the literature on surgical innovation has identified a broad consensus about the necessity of special consent and disclosure for surgical innovations.[14] Disclosure about innovative aspects of the procedure or when a drug or device is being used off-label is considered necessary to ensure informed consent and to preserve the autonomy of patients.[29] Some authors have pointed out that mere disclosure of the novelty of a procedure may actually undermine a patient's evaluation of the risks and benefits of the procedure and therefore their consent because "for most of us whatever is 'new' is also 'improved.'"[14] This is especially worrisome given the frequent media exposure that accompanies innovative procedures[34] that have been reported to affect consent by patients.[35] Consequently, the high degree of unknown risks and potentially poor outcomes may need to be overemphasized during the consent process to offset an already favorable presentation.[25] These points notwithstanding, we (E.B. and E. R.) have previously suggested that too heavy a focus on disclosure to relieve the ethical tensions of innovations may create blind spots where other equally important actions can be taken to protect patients (eg, ensuring proper review of risks with neutral language to describe the procedure).[14]

Informed consent requires having a clear understanding of risks and benefits. In the case of psychiatric DBS, the consent is complicated by the presence of unknown risks resulting from the limited knowledge base at the time.[36] The risks of surgery itself include intracranial hemorrhage, infection, and death, which are rare, although the risks are also "arguably greater than any other available treatment in psychiatry."[37] One notable risk associated with chronic electric stimulation of the brain, although also associated with other forms of neurosurgical intervention, broadly involves the potential for psychological effects or impacts on personal identity.[9,20,38,39] As a result, the ethical question of whether and to what degree patients should be informed about the potential for psychological and identity effects must also be addressed, even though limited empirical data on these effects exist, with even fewer data on whether patients perceive these effects subjectively as good or bad.[9,40]

As a general principle, to better assess the risk-to-benefit ratio for patients undergoing innovative surgical procedures, data should be supplied for local outcomes compared with national ones.[41] This may be challenging in the case of rather unique and tailored psychiatric DBS intervention because there may be few national (or even international) comparators, and any attempt to disclose and discuss local outcomes may in fact bias the consent process because highlighting the rarity of the innovation could contribute to an overestimation of the benefits. In time, pooled data on outcomes may emerge and contribute usefully to consent discussions, and to achieve this, it has been suggested that oversight bodies could help to collect, evaluate, and share data. Many authors have reiterated the importance of capturing patient outcomes after surgical innovation.[29,31,32] However, when surgical innovation is meant to generate generalizable knowledge, formal ethics review and the standards of research ethics should apply. Currently, data on DBS outcomes are vulnerable to bias because of an excessive reliance on single-patient case reports or small case series that overrepresent positive outcomes.[42] Conversely, if preliminary outcome data from such studies are unfavorable, then a potentially beneficial therapy may be stopped dead in its tracks. To remedy these problems, Schlaepfer and Fins[42] have proposed that single-case studies should be reported to a registry and then possibly published as a data set to summarize positive and negative results.

Ethical Oversight for Surgical Innovation

Different mechanisms have been proposed to ensure flexible and context-sensitive mechanisms for the ethical oversight of surgical innovations. However, despite their face validity, none have been evaluated for their impact on innovation itself and their

ability to effectively address key ethical issues associated with surgical innovation. Relying on existing institutional structures (eg, IRBs) is a common option and would seem to be in line with the approval of DBS in cases of a Humanitarian Device Exemption (eg, OCD), in which IRBs are expected to supervise clinical testing of devices and to approve the use of the device.[43] However, IRBs should be consulted to determine whether they believe that oversight falls outside their mandate or responsibility. Other common alternatives are surgical innovation committees or other similar peer review mechanisms (eg, innovations are proposed and approved by the chief of the department or through a departmental peer review system).[31] Such an oversight strategy should consider the need for outside expertise (eg, surgical, legal, and ethical) in evaluation of the proposal, limits for the intervention (ie, 6-12 months), and expectations for evaluation and monitoring of outcomes and adverse effects, with the possibility that at any time the innovative intervention can be discontinued or referred to an IRB (ie, redesigned as a formal research study).[31] Lead members of the team should establish the openness of their departments and/or institutions toward innovative procedures well in advance, as well as any common policy in place.

ETHICAL CONCERNS RELATED TO CAPACITY, CONSENT, AND VULNERABILITY IN PSYCHIATRIC DBS

Within DBS teams, the general unfamiliarity of nonpsychiatrists in managing psychiatric patients may lead to unease about consent for such an invasive and innovative therapy. As we previously suggested, if psychiatric DBS teams are designed to be appropriately multidisciplinary, then this concern should be largely assuaged. Similar concerns, however, may be raised by IRBs or oversight committees that have been shown to deem psychiatric patients (compared with medical patients) to be more vulnerable, in need of further protections, and lacking the capacity to consent, especially to research.[44] However, empirical evidence demonstrates that patients enrolling in DBS trials make complex judgments about deciding to enroll.[45]

Capacity and Consent in Psychiatric Disorders

Empirical evidence gathered from patients with depression who entered into DBS clinical trials demonstrates a reasonable understanding of benefits and harms and a complex decision-making process that supports study participation.[45] This evidence, combined with the fact that a lack of capacity has been shown not to exist across all depressed or other psychiatric patients (eg, Okai et al[46]), should shift the burden of proof. Teams should focus their attention on the complete process of consent and be guided by the psychiatrist on the team. Teams may put a mechanism in place to revisit consent with patients to ensure ongoing consent.

Vulnerability in Psychiatric Disorders

Concerns about the recruitment of vulnerable patients in DBS have surfaced outside the scope of their ability to provide consent. Traditionally, vulnerability has been understood as a static state and an intrinsic property based largely on the susceptibility of a subject (and often a group of subjects) to being taken advantage of given his or her lack of decision-making capacity. However, if this is considered as a dynamic and relational property, vulnerability touches on important relational aspects beyond mere consent (eg, power differential between patient and surgeon, intimidating context resulting from the size of the interdisciplinary team). Correctives can be applied partly in the consent process but also more broadly within the different steps of the protocol (eg, identifying ways to reduce vulnerability and to advocate for management of potential sources of vulnerability by the team; collaborating with patient advocacy groups to level relational asymmetry).[47]

CONCLUSION

In certain circumstances, DBS for patients with psychiatric disorders is a form of surgical innovation. The proper delimitation of what constitutes innovative care is paramount to avoid a drift to informal research or the dissemination of clinical practices unsupported by evidence. However, there are situations when a neurosurgeon and his or her team members may contemplate offering DBS for a psychiatric indication to a patient who has no other good alternative treatment option. In such cases, special safeguards need to be in place, and a number of issues need to be recognized and addressed. They include addressing general questions about the following: the genuine innovative nature of the intervention (to avoid an unwarranted drift), ensuring the support of a multidisciplinary team, having proper oversight mechanisms in place, and dealing constructively with issues of decision-making capacity and informed consent. The considerations we present should help to usher in the responsible integration of psychiatric DBS when this is warranted.

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COMMENT

This article addresses a contemporary challenge in neurosurgery. Now that there are 2 failed pivotal trials for deep brain stimulation (DBS) for depression and a Humanitarian Device Exemption for DBS for obsessive-compulsive disorder, surgeons continue to find themselves in limbo regarding what to do when patients insist on attempting DBS therapy for refractory psychiatric illnesses. Given the long gap anticipated without any sure knowledge about the efficacy of DBS for certain psychiatric illnesses, how does a surgeon offer this as an innovative therapeutic attempt in an ethically rigorous way? The authors answer that there are careful ways to do so, and the tools to do this are already on hand. They highlight the framework and questions that have been developed in the literature to do this.

A particularly important point they raise is the need for programs to carefully articulate specific goals and philosophies about innovation. As well as being thorough, each team needs to be consistent in their approach to whether and how these innovations occur. Only by naming a specific philosophy of practice can the team then create metrics to guide programs when they are considering a new innovation. These are foundational ethical questions. Does this new attempt match our core values? Does the way we are doing this match our core values? Answering these questions will support fairness, transparency, and accountability.

Finally, the authors reinforce the value of consulting external experts to provide advice and validation of the appropriateness of an attempt for a novel intervention. We should provide important checks and balances in practice to allow new innovations to arise while safeguarding those who are potentially vulnerable for reasons of medical desperation. Healthcare privacy and professional conflicts of interest should not keep us from developing methods for creating these checks and balances.

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