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Clinical Ethics in the Context of Deep Brain Stimulation for Movement Disorders

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Abstract

Objective: Discuss common clinical ethical challenges encountered in working with patients who are candidates for deep brain stimulation (DBS) for the treatment of motor symptoms of Parkinson's disease (PD).
Method: The relevant literature is reviewed and supplemented by descriptive, ethically challenging cases stemming from decades of combined experience working on DBS teams. We outline ethical arguments and provide pragmatic recommendations to assist neuropsychologists working in movement disorder teams.
Results: The goals of the pre-operative neuropsychological DBS assessment include: (1) identification of potential cognitive risk factors; (2) identification of relevant neuropsychiatric or neurobehavioral factors; (3) assessment of level of family support; and (4) systematic assessment of patient's and family member's goals or expectations for DBS. The information gleaned from the pre-operative neuropsychological assessment is highly relevant to the most commonly studied clinical ethics challenges encountered in DBS: (1) assessment of risk/benefit; (2) determinations regarding inclusion/exclusion; (3) autonomy; and (4) patient's perception of benefit and quality of life.
Conclusions: Neuropsychologists are particularly well poised to provide unique and important insights to assist with developing the most ethically sound practices that take into account patient's values as well as fiduciary responsibilities to the patient, the team, the profession, and the broader community.

Keywords: Parkinson's disease; Professional issues; Movement disorders

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Introduction

Ethics is about values. Ethical decisions become interesting and challenging when values are in conflict with one another and we need to give up one value to preserve another. One of the most well-known models for conceptualizing ethics is that articulated in the Belmont Report (1979) and further elaborated on by Beauchamp and Childress in their seminal book on bioethics (1994). Beauchamp and Childress outlined four principles in bioethics: (1) beneficence; (2) non-maleficence; (3) respect for persons (autonomy); and (4) justice. These principles have been highly influential and are reflected in the American Psychological Association's Code of Ethics (2016). In addition, the APA Code of Ethics emphasizes the concept of stewardship and fiduciary responsibilities to the patient, community, and discipline (i.e., Fidelity and Responsibility, Integrity). Despite the influence of these principles, they are often misunderstood and misused; too often the most important step of "specifying" in order to balance principles is ignored. In short, legitimate ethical analyses do not necessarily need to rely on the principlism outlined by Beauchamp and Childress or articulated by the APA but they should be systematic and result in relatively consistent practices over time (Yoder, 1998). Further, considerations of ethical dilemmas can be undertaken in plain language that describes things of central importance (i.e., values) for patients, families, healthcare providers, health systems, and society.

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Several ethically complex and challenging questions arise in the context of treating patients with movement disorders on a Deep Brain Stimulation (DBS) team. Patients electively undergo DBS in order to improve quality of life. Consequently, it is a highly personal decision that reflects the individual patient's values. DBS requires a neurosurgical procedure and ongoing stimulation with inherent risks and potential benefits—some of which are well established and others for which the data are not as clear. DBS differs in important ways from many other functional neurosurgical procedures in that the patient has an implantable device that must be programmed. Consequently, DBS requires a continued relationship with the team. The stimulation parameters are regularly adjusted over time to minimize deleterious side-effects while maximizing benefit, often in the context of an ongoing neurological/neuropsychiatric (or in the case of Parkinson's disease an ongoing neurodegenerative) disorder. The effect of DBS can be profound and immediate. Most often patients are awake during a portion of the surgery so that the surgical team can identify the best location for final placement of the DBS lead. Patients with Parkinson's disease (PD) undergo surgery in the "off" medication state which is often characterized by significant tremor, rigidity, and discomfort. When the stimulator is turned on and they experience the immediate effect of reduced tremor and other motor symptoms as if "a light switch was flipped"; patients voluntarily describe the experience as "miraculous". The immediate and "miraculous" experience of DBS as well as media accounts (Racine et al., 2007), can instill a false sense that DBS is a cure and contribute to unrealistic expectations. Finally, DBS is often reserved for patients with severe disease. Patients will often describe DBS as their last resort. This mentality can contribute to feelings of desperation which may affect the informed consent process. The combination of all of these unique factors can result in very complex and challenging ethical questions in the treatment of patients with movement disorders which contribute to concerns regarding vulnerability (e.g., Ford, 2009). Our goal is to examine some of the clinical ethical challenges that arise in working with patients on a Movement Disorder DBS team. We will provide pragmatic suggestions gleaned over the course of more than 35 combined years' experience in working primarily in a highly innovative, high volume DBS team that includes neurosurgeons, neurologists, psychiatrists, psychologists, neurophysiologists, nursing, and a dedicated clinical bioethicist.

Ethics in the Context of DBS for Movement Disorders and Team Decision-making

The DBS team is ideally constituted by members of several disciplines including neurosurgery, neurology, neuropsychology, advanced practice professionals and, often, psychology and psychiatry. The neuropsychologist is often in a special position to identify and elucidate ethical questions that can arise. The role of a neuropsychologist on a DBS team is to address four questions (Ford & Kubu, 2006; Rezai et al., 2008). First, the neuropsychologist evaluates neurocognitive function and identifies any potential cognitive risks associated with the proposed surgery. Included in that assessment is an evaluation of neuropsychiatric function with the goal of identifying any potential neuropsychiatric factors that need to be addressed and/or might complicate outcome. The third goal is to evaluate the level of family (or care partner's support) for DBS. Finally, the neuropsychologist should systematically elicit the patient's and family member's goals for DBS to help ascertain if those expectations are realistic. The goals of the pre-operative neuropsychological assessment are directly related to several of the potential ethical challenges that arise in the context of working on a Movement Disorder DBS team.

Clausen (2010) reviewed the DBS and ethics literature and identified five broad ethical questions relevant to clinical ethics in the application of DBS for the treatment of movement disorders: (1) Risk benefit analysis; (2) Inclusion/Exclusion Criteria; (3) Pediatric DBS; (4) Patient Autonomy; and (5) Quality of Life and Patient Benefit. His framework will be adopted to structure our discussion with the exception that we will not discuss DBS in children. (Adequate discussion of the ethical issues associated with pediatric DBS are beyond the scope of this paper and are not as relevant to most practicing neuropsychologists working on DBS teams.) We will focus on commonly encountered clinical ethical challenges of "particular relevance to neuropsychologists", the related ethical analyses, and pragmatic suggestions based on those analyses. DBS is most often used to treat motor symptoms of Parkinson's disease (PD); consequently, most of our discussion will focus on PD but parallel arguments may be made for other disorders.

Analysis of Risks and Benefits

PD is a disorder that is characterized by tremor, rigidity, akinesia, and postural instability (or the acronym TRAP). PD may also be associated with changes in cognition, mood, and personality either due to the underlying neuropathological changes associated with the disease, the sociocultural impact of living with the disorder, or the pharmacological or neurosurgical treatments used to address the motor symptoms (Alexander, DeLong, & Strick, 1986; Braak et al., 2006; Pandya, Kubu, & Giroux, 2008).

DBS has been demonstrated to be highly effective in treating many of the motor symptoms of PD and often results in medication reductions (particularly when the target is the subthalamic nucleus, STN) thereby contributing to reduced medication side-effects (e.g., dyskinesias, fatigue, potential cognitive side-effects) and burden (financial, frequent dosing) (Benabid, Chabardes & Mitrofanis, 2009; Deuschl, Schade-Brittinger & Krack, 2006; Weaver et al., 2009). For many patients, DBS has been truly life changing and significantly improved their quality of life by enabling them to continue to work, participate in valued activities, and maintain social relationships (Benabid et al., 2009; Deuschl et al., 2006; Weaver et al., 2009; Kubu et al., 2017).

However, DBS is not a panacea. It is typically viewed to be ineffective in addressing many non-motor symptoms and its' efficacy in treating some motor symptoms depends on the underlying cause of the symptom (e.g., gait problems). Furthermore, DBS is not without risk. The most common perioperative risk is hemorrhage whereas the most common hardware risks are infection, lead migration/misplacement, and lead breakage (Hamani & Lozano, 2006). The risk of cognitive decline is relatively minor in well selected patients (Elgebaly, Elfil, Attia, Magdy & Negida, 2017; Funkiewiz et al., 2004; Smeding et al., 2006; Voon et al., 2006; Woods, Fields, & Troster, 2002; Troster et al., 2017) with most studies demonstrating mild declines on measures of word fluency and less common mild declines on memory tests. Neurobehavioral risks following DBS for PD are also generally low when examined at the group level (Appleby et al., 2007; Temel et al., 2006) in well selected patients; however, there are compelling anecdotal cases illustrating that for some patients, the neurobehavioral changes may be more profound and can include mania/hypomania, apathy, pathological crying, and depression (Bejjani et al., 1999; Herzog et al., 2003; Kraak et al., 2001; Wojtecki et al., 2007). Further, DBS may negatively affect interpersonal relationships in some patients (Agid et al., 2006; Schüpbach et al., 2009).

Pre-operative neuropsychological assessment findings contribute to risk assessment. Patients who demonstrate neurocognitive impairments prior to DBS may be at greater risk for post-operative confusion (Abboud et al., 2015a; Pilitisis et al.,2005), longer hospital stays (Abboud et al., 2015a; Mikos et al., 2010), or verbal memory decline (Yaguez et al., 2014). The presence of MCI identified prior to DBS may be associated with diminished benefit at 6 months after surgery on a functional measure ($p = .065$) and reduced quality of life ($p = .051$) at 12 months following DBS surgery (Abboud et al., 2015a).

Pre-operative neurobehavioral symptoms may also be associated with potential risks associated with DBS. Two cases in which patients revoked consent intra-operatively due to neuropsychiatric symptoms are particularly interesting to highlight in this respect. In the first case, the patient became delusional in the operating room and was convinced that the surgeon was trying to control his brain. Eventually, the surgery was aborted (Parrent, personal communication). The second case involved a patient who revoked consent intra-operatively just prior to placement of the DBS lead presumably due to anxiety (Ford et al., 2007). After consultation with the patient, family, and bioethicist, the surgery was ultimately aborted. In both of these cases, the patient was exposed to several of the risks associated with DBS surgery with no benefit. Although avoiding this type of futile surgery is important, it is equally important to provide an opportunity for surgery to those who could be helped despite the presence of a possible risk of intra-operative revocation of consent.

Similarly, neuropsychiatric or neurobehavioral symptoms may be associated with post-operative risks. Pathological picking or trichotillomania may increase the risk of infection or, in severe cases, broken connecting cables (Machado et al., 2005). A history of impulse control disorders, including substance abuse, may place some patients at higher risk for those problems following surgery (Kasemsuk, Oyama, & Hattori, 2017). There are some data that suggest that suicide rates may be higher following STN DBS for the treatment of PD (Voon et al., 2008) but others have not found a higher risk (Weintraub et al., 2013); regardless, a history of a suicide attempt is a potential risk factor. Finally, personality characteristics, particularly those that may result in non-compliance to treatment recommendations may be associated with increased risk following DBS. For example, if a patient is non-compliant with attending post-operative programming sessions or reducing medications per the neurologist's recommendation, the post-operative course may be associated with reduced benefit and potentially increased harm.

The literature briefly summarized above illustrates the importance of neuropsychological assessment in the risk benefit analysis. Neuropsychological data and detailed information obtained through a careful clinical interview highlight cognitive and/or neuropsychiatric/behavioral factors that "might" increase risks. Neuropsychologists' responsibilities are to do no harm; yet which is the greater harm? DBS can reliably result in significant improvements in many motor symptoms of PD while reducing medication burden (costs, dosing frequency, and side-effects). This has been well established. However, there are some vivid anecdotal cases that serve as cautionary reminders. Neuropsychologists' fiduciary duties require that they are appropriately cognizant of the "potential" increased risk associated with some neurocognitive and neurobehavioral factors. It is critical to balance the compelling, vivid examples with the weight of the evidence documenting relatively minimal neurocognitive and neurobehavioral risk (Kubu & Ford, 2007). Balancing the risks of harm versus potential benefit is particularly complicated when the anecdotes are powerful and the data are limited.

Given their expertise in brain–behavior relationships and psychology, neuropsychologists can heavily influence decisions regarding candidacy. Neuropsychologists must be mindful of stewardship responsibilities, particularly the language used in written and oral communication as that can sway the team's decision making. Neuropsychologists must also be creative in proposing solutions that minimize risk rather than categorically deny potentially more vulnerable patients from a well-established treatment. Pragmatically, over the years our team has developed a number of practices to help further clarify and/or minimize potential risks. These potential solutions have emerged out of frank, open discussions with all team members that explicitly included consideration of conflicting values (see Table 1). Some representative scenarios and pragmatic solutions developed by careful consideration of various values and ethical analyses are illustrated in Table 2. Table 2 also includes representative scenarios and proposed solutions for the other broad clinical ethics domains we consider in this paper.

Inclusion and Exclusion

Candidacy for DBS surgery is best determined by an interdisciplinary team assessment that includes neurological, neurosurgical, neuroimaging, neuropsychological and, if needed, psychological/psychiatric assessments (Lang et al., 2006; Rezai et al., 2008). Candidates for DBS should have a 5 year history of severe idiopathic PD and a robust response to the dopaminergic medications. Response to dopaminergic medications is often assessed by having patients complete a standard motor examination while being in the practically defined "off" medication state (i.e., 12 hr without any medications). Following completion of the "off" testing, patients are provided with their PD medications and then re-tested in the "on" state. The discrepancy between these two scores is the best predictor of potential benefit associated with DBS (with the possible exception of tremor symptoms). All medical options should have been optimized before considering DBS and the patient should not demonstrate significant cognitive impairment, severe depression, psychotic symptoms, or other severe psychiatric symptoms (Defer, Widner, Marie, Remy & Levivier, 1999).

Although the above inclusion criteria hold for the majority of DBS candidates, some patients with PD may be ethically appropriate candidates even though they do not meet the full criteria. For example, consider a 55-year-old woman who is still working in an upper level executive position despite a relatively short history of PD. Her primary symptom is leg pain that she characterizes as deep muscular, wrenching pain. She is very sensitive to medication side-effects and develops significant psychiatric symptoms with agonists and suffers from significant dyskinesias with levodopa. Furthermore, to control her pain, she requires dosing every three hours including throughout the night. More recently, she has developed sudden offs which negatively affect her ability to work. The "off" medication UPDRS motor score is only 10 and her "on" medication score is zero. Importantly, her pain disappears in the "on" medication state. Although some might argue that she does not meet the inclusion criteria outlined above with respect to time since diagnosis and severity of her symptoms, our team would consider offering her DBS with the goal of improving her quality of life and helping her achieve her goals of reduced pain and reduced medication burden so that she could continue to pursue her career goals. This decision would be in line with the spirit of the above criteria while recognizing the morally significant difference in her specific circumstances that justifies an exception. However, prior to diverging from our typical process (per the above criteria), our team would need to articulate very clear reasons in support of that decision.

Exclusion criteria for DBS typically include frank dementia, uncontrolled psychosis, current severe depression, suicidality, marked substance abuse, and some neurosurgical and potential medical contraindications. Data from our center indicate that two of the leading reasons patients are not offered DBS are neurocognitive (32.7%) and neurobehavioral (21.3%) factors with smaller percentages of patients denied DBS due to unreasonable goals (9.8%) or limited support (1.6%) (Abboud et al., 2015b). Consequently, considering the four goals of the pre-operative neuropsychological evaluation, the neuropsychologist

Table 1. Examples of potential values in conflict in the context of clinical decision-making for DBS

(1) Do no harm vs. Help the patient
(2) Respect for patient's decision (autonomy) vs. Respect for team's (autonomy) obligation to do what they believe is safe
(3) Respect for patient's choices based on personal values (autonomy) vs. Respect for the broader needs of the community (Justice; e.g., potential increased costs associated with extra care.)
(4) Provide gold standard therapy for which the patient will likely be non-adherent vs. Provide a less effective therapy that does not require adherence (e.g., DBS vs. Ablation)
(5) Provide gold standard therapy with *potentially* greater risks vs. Provide less effective therapy with *potentially* fewer risks
(6) Keep patient safe by adding extra requirements/conditions vs. Fairness of not unduly burdening or restricting access to patients (e.g., imposing additional requirements or restrictions on patients)
(7) Fiduciary responsibility to the patient vs. Fiduciary responsibility to safeguard the field by minimizing likelihood of significant negative outcomes
(8) Do no harm vs. Professional integrity in light of limits of knowledge and literature
(9) Respect for individual's values and need for individualized assessment vs. Responsibility to communicate and contribute to the larger clinical research community
(10) Respect for patient's articulated choice vs. Respect for patient's values that are highlighted by family but unrecognized by the patient

Table 2. Common ethical challenges and pragmatic recommendations based on systematic ethical analyses

Ethical challenge	Pragmatic recommendations
Moderate cognitive impairments and/or impairments on tests (e.g., confrontation naming) that raise concern about a co-morbid neurodegenerative process	Re-evaluate the patient to ascertain reliability of the findings (possibly at an interval of months); confirm that the findings are not related to medication side-effects; alert the team of the possibility of increased risk of post-operative confusion so that the surgeon can appropriately plan (e.g., conduct a staged procedure, consider an alternate target, minimize OR time) and discuss with the patient and family the possibility of increased risk in informed consent process; consult with bioethics
Inability to cooperate during awake mapping with possible risk of revoking consent	Identify patients at increased risk in pre-operative evaluation including specific questions tailored at anxiety, panic attacks, delusions, etc; consult with psychiatry and psychology for further evaluation and treatment; consider including a psychologist in the OR to reduce anxiety Broer, Chapin, and Kubu (2008); consult with neurosurgeon who may consider alternate surgical procedures/practices that eliminate need for awake procedure
Compulsive picking, trichotillomania	Identify patients at potential risk for these low base rate behaviors by specifically inquiring about these behaviors in pre-operative neuropsychological interview; alert team so that extra precaution/plans are in place if the potential risks arise
Presence of significant impulse control disorders prior to DBS	Identify if the impulse control symptoms are directly related to dopaminergic medication burden by proposing a short trial off dopamine agonists to see if the symptoms abate; if symptoms improve, this may provide strong evidence to proceed with DBS in a target that will result in medication reduction. If the symptoms continue, consult with psychiatry with the goal of controlling the symptoms prior to re-consideration of DBS
Suicide risk	Assess for history of suicidal ideation and attempts as well as current suicide risk; consult to psychiatry and psychology; ensure psychiatric symptoms are controlled for a period of time prior to moving forward with surgery; ensure that patient is monitored closely by mental health professionals prior to surgery and for several months following surgery. Require patient to identify social support who can collaborate in identifying when the patient might need further mental health intervention related to suicidal ideation
Presence of severe psychiatric symptoms	Consult to psychiatry and psychology for pharmacological and behavioral review and treatment if needed; ensure psychiatric symptoms are well controlled for several months prior to moving forward with surgery; ensure that the patient is monitored closely by mental health professionals prior to surgery and for several months following surgery
Personality disorders	Identify if personality disorders are present and educate team; consult psychology; provide advice to other team members (particularly programmers) on how to work with patients with personality disorders. Evaluate whether a healthy therapeutic relationship is possible in the post-operative setting related to the match of personalities in the outpatient care providers. If there will not be a healthy working relationship (and work environment) consider helping patient find a provider group who would better suit the patient's style
History of non-compliance	Be alert to language/behavior (e.g., reports of self-medicating) or a history indicating a pattern of non-compliance; alert team; consider postponing surgery for a period of time in which the patient has the opportunity to demonstrate compliance to treatment recommendations; rarely, concerns surrounding non-compliance may result in the decision not to offer DBS
Dementia	Assess if potential medication side-effects and/or situational factors negatively affected performance; repeat the evaluation after a few months to ascertain the reliability of the findings (following medication reductions if necessary); review the patient again in the team meeting and proceed with surgery if scores have dramatically improved; if performance is stable, consult with bioethics and the larger team regarding the possibility of a palliative surgery with close follow-up; if performance has declined over time, the risks may outweigh the potential benefits
Lack of family support—instrumental	Problem solve to identify alternatives (e.g., short stay in a rehabilitation setting immediately following surgery, referral to a local neurologist well trained in DBS programming who can follow the patient following the first initial programming sessions); possibly consider an ablative procedure
Lack of family emotional support	Meet with the patient and family to fully address all questions and concerns surrounding DBS; if appropriate refer to psychology and recommend couple's therapy or family therapy; Bioethics consult. Problem solve to identify alternative ways of patient being emotionally supported
Unrealistic goals or expectations	Inquire about the specific behavioral goals the patient wants to achieve with DBS surgery and don't limit discussion solely to reducing specific symptoms as they may not fully capture the primary goals. Educate the patient and family in a mutual dialog about the potential benefits and limitations associated with DBS in the context of the patient's specific behavioral goals; consult to bioethics if necessary
Limits to autonomy associated with stimulation	Discuss among the treatment team the situation that might result in limits to autonomy; clarify the risks and benefits in the context of the patient's and family's values with appropriate respect to autonomy considerations for the patient, family, and treatment team; Consult with bioethics. Make tacit agreements with patient regarding situations in which the patient agrees that the team has the authority to turn off or change stimulation.
Outcome assessment	Systematically include patient-rated scales the reflect their individually defined goals/expectations as well as standard clinical research metrics; incorporate a multifaceted assessment of outcome

plays a key role in influencing the team's decision regarding a specific patient's candidacy for DBS. Similar to the inclusion criteria outlined above, there may be specific cases in which it would be ethically justifiable to offer a patient surgery despite the presence of one or more of the above exclusion criteria.

Dementia. Estimates of dementia in PD vary widely but more recent systematic reviews indicate that the point prevalence of dementia in PD is 25–30% (Aarsland et al., 2017). The majority of patients with PD will develop dementia if they survive more than 10 years following the diagnosis. Consequently, dementia is frequently encountered in a PD clinic and may be evident in a number of patients who present for DBS evaluation.

The presence of frank dementia should not always automatically preclude a patient from being offered DBS. The decision is trivial if a patient meets criteria for dementia and it is apparent from on/off testing that there is minimal likelihood of significant benefit associated with DBS. Consequently, the net benefit is negligible and the risks are presumably much higher (Farris, Ford, DeMarco & Giroux, 2008). Similarly, if the cognitive impairments are so great that there is concern that effective programming may not be feasible due to the patient's inability to reliably report benefits and/or side-effects then the net benefit is once again questionable. The more challenging cases involve those patients who meet criteria for dementia yet the likelihood of achieving a significant benefit and improvement in quality of life from DBS is very high (e.g., reducing a severe tremor). Excluding such patients in the absence of clear unequivocal data that the presence of dementia is associated with significant risk following DBS surgery poses a challenge to justice. Patients no longer have the potential of benefit if they are automatically excluded (Ford & Henderson, 2006). As Clausen (2010) argued "A hypothetical exclusion is linked to a 'moral duty' to examine whether the supposed potential risk can eventually be supported by empirical data" (p. 1154). It is unlikely that these data will be immediately available via a randomized control trial comparing DBS outcomes in patients regardless of pre-operative cognitive status, but studies with small case series of patients with mild dementia who are carefully studied may yield knowledge that help guide future decision making and, thereby, provide a basis from which to more appropriately make decisions regarding dementia as an automatic exclusionary criterion.

Our team has offered surgery to isolated patients with severe tremor who met criteria for mild dementia. After careful discussion and weighing the values of do no harm (in the context of imperfect knowledge regarding the real risks associated with a diagnosis of dementia) versus the highly likely benefit associated with reduced tremor, our team has offered a small number of these challenging patients neurosurgery with the goal of ameliorating suffering. This is offered with special attention to safeguards and process. The surgeon does all that can be done to minimize potential surgical factors (e.g., unilateral versus bilateral procedure, site, procedure-related, length of surgery, and anesthesia) associated with potential increased risk. The surgery is preceded by extensive discussions with the patient and family regarding the potential concerns modeling best informed consent processes. These discussions always include the neurosurgeon and, occasionally, the neuropsychologist and other team members. In addition, our team may include a formal bioethics consultation in these cases in which the bioethicist meets independently with the patient and family to identify goals and values and assist with decision-making in a way that mirrors those values. Not only does a case such as this require additional careful justification, it also requires the team to place additional assurances that this patient has the opportunity for good outcome. These assurances, may justifiably place more conditions on the patient and family that need to be met prior to surgery. The practice of placing additional conditions and safeguards is common when a patient has additional vulnerabilities and falls outside the usual criteria for surgery. In the case of patient with significant cognitive impairments, it can be ethically justifiable to require a patient to agree to be transferred to a skilled nursing facility for post-operative recovery as a condition of offering the surgery.

Neuropsychiatric disorders. A similar justice argument can be made for patients who suffer from severe depression (Ford & Henderson, 2006) or other neuropsychiatric disorders. Pragmatically, our team will not proceed with surgery unless severe psychiatric symptoms, such as psychosis, depression, or substance abuse disorders are well controlled. As noted in Table 2, we often require that a dedicated mental healthcare team is in place with regularly scheduled appointments prior to and following the DBS surgery to provide close, ongoing assessment in these potentially more vulnerable patients. We also partner with the family to help monitor these symptoms. Again, these are considered ethically justifiable requirements as conditions for providing DBS. They demonstrate due diligence in providing the patient a safe therapy by being assured that there are processes and professionals in place whose responsibilities are to identify and mitigate any harmful change in mood or neuropsychiatric status that might inadvertently ensue over the course of DBS (whether directly related to the therapy or not).

Family support. We (Ford & Kubu, 2006) and others (Bell, Mathieu, & Racine, 2009) have argued that DBS is an intervention that requires a network of support (usually family members) to assist with care in the immediate post-operative period, transportation to and from programming appointments, and ongoing care in the context of a neurodegenerative disorder. DBS centers are relatively rare and patients may need to travel significant distances to receive treatment. In addition, DBS surgery is only one part of the treatment. A well placed DBS electrode may be ineffective in the hands of an inexperienced programmer. Thus, the patient's and family's commitment to the DBS center may extend beyond the surgery. (Just as the DBS team's commitment to the patient and family extend beyond the initial surgery.) Consequently, it is important to include assessment of family support and ability to reliably travel to the DBS centers in the pre-operative candidacy evaluations. This highly practical consideration can lead to concerns regarding justice. Bell and colleagues (2009) aptly argue that to exclude patients without social support or easy access to DBS centers would "create additional disparities in the level of care of these patients, further disadvantaging them" (p. 579). In patients without such instrumental support and for whom it is unlikely that they will return for programming, it is ethically justifiable to offer ablative procedures that may be associated with greater risk (i.e., a permanent lesion) but can still provide substantial benefit. These factors would be carefully reviewed and discussed in the informed consent process.

Assessment of family support as part of the pre-operative DBS evaluation may also highlight important differences between family's and the patient's interest in DBS. Very rarely, we have encountered patients whose family members were pushing for DBS and the patient did not want to have surgery. In this situation, the ethical decision is clear: the patient should not undergo a neurosurgical procedure against their wishes. Careful conversations can uncover various types of subtle coercions. Conversely, patients may be very excited to pursue DBS whereas the family is adamant against it. This situation raises interesting questions: Does lack of family social support for this decision negatively affect outcome? Should patients be denied DBS if the family is not supportive of the decision? Discrepancies between the patient's and the family's interest in DBS may highlight important interpersonal relationship issues that might affect care. The lack of support for the patient's decision to pursue surgery should be differentiated from a lack of support to bring the patient to post-operative programming sessions and help them obtain the most benefit. In some instances, family members may disagree with the patient's decision to pursue surgery but will be willing to provide them the support in recovery. In ethical considerations, small distinctions such as between decision and post-operative recovery support are foundational to good evaluations.

Furthermore, discrepancies in decisions between the patient and family may suggest that further education and clarification regarding DBS is necessary. Limited family social support for the patient's decision to pursue DBS should not preclude the patient's candidacy. Counseling prior to and following DBS surgery may be recommended to help provide some measure of social support. This counseling can provide both educational and psychological benefit.

Goals. DBS is an elective neurosurgical procedure in which a patient chooses to undergo surgery to improve their quality of life. The patient's perception of quality of life may differ from the treatment team's metrics (Kubu & Ford, 2012; Kubu et al., 2017). It is important to fully understand the patient's goals in order to improve the informed consent process and ensure that DBS has the potential to address the patient's stated goals. Otherwise, the team runs the risk of a dis-satisfied patient due to unrealistic expectations (Bell et al., 2009; Clausen, 2010). These goals need to be placed in the context of the patient's and family's expectations of changes in function and activity, not just changes in physiology or symptoms. We elaborate on this point later.

Autonomy

Good informed consent processes model respect for autonomy balanced against professional fiduciary responsibilities to adhere to best practices. As Clausen (2010) states, informed consent in the context of DBS should include detailed discussion regarding the complexity of the procedure, possibility of being awake during some of the surgery, the requirements for programming, need for battery replacements, and a very clear discussion of the potential benefits and risks with careful consideration of the patient's and family's expectations and goals.

Bell and colleagues (2009) also discuss the perception that many patients and families view DBS as a "last resort". This may contribute to feelings of desperation which may be associated with increased vulnerability. As Bell and colleagues state "such situations need to be handled with extreme care because expectations and desperation may create challenges for free and informed consent" (p. 580). They go on to argue that respect for autonomy may be misinterpreted as solely the provision of a clear description of the potential benefits and risks associated with DBS and leave the decision to the patient. This implies that the treatment team's responsibility to the informed consent process is solely to convey information. Such an approach ignores the treatment team's fiduciary responsibility to the patient and larger community, including consideration of the principle of beneficence (cf. Bell et al., 2009). The treatment team has a responsibility to minimize the likelihood of significant negative outcomes not only for the individual patient but for the viability of the field. Scientific and popular media anecdotal reports of rare and extreme negative outcomes may prejudice patients and healthcare teams from considering a generally safe and beneficial treatment for many patients.

Patients, families, and healthcare professionals have different levels of knowledge about PD. All of these different perspectives need to be incorporated into the DBS informed consent process. This requires good communication, respect, and trust. Neuropsychologists can contribute to the informed consent process by highlighting potential issues that may limit the patient's autonomy (e.g., limited intellectual abilities, illiteracy, cognitive impairments related to PD) as well as highlight potential conflicts that might affect the informed consent process. For example, Bell and colleagues (2009) highlight how caregivers may try to influence the patient's decision to address their own goals by encouraging DBS in order to minimize caregiver burden or discouraging DBS in order maintain the patient's dependence on them. As Ford and Henderson (2006) note, it may be in the patient's best interest to include relatives in the decision-making process because they will often play a role in caring for the patient following surgery. However, the ultimate decision to undergo DBS should be the patient's without coercion. This respect for autonomy extends throughout the surgical process as we illustrated above in those patients who revoked consent in the midst of surgery.

Autonomy or respect for persons is not limited to the patient. The treatment team is also entitled to autonomy to make the decisions that they feel are most appropriate in light of their areas of expertise. Furthermore, although the decision regarding an individual patient's candidacy is a team decision; ultimately the decision to offer surgery is the neurosurgeon's recognizing that the management of the stimulation will be the responsibility of the neurologist and programming staff. The entire team needs to be aware of and accept the potential burden of having to follow patients for a long time. This includes patients whose behavior and relationship with the team is strained prior to surgery. There is a balance between accommodating diversity of patient personalities and assuring that healthcare providers operate in a non-hostile workplace. This fact illustrates the importance of the team's understanding of the potential post-operative and long-term follow-up environment. Ideally, a good relationship needs to exist between the patient and healthcare team through the entirety of the patient's therapy. If this is not possible, then a referral to another center can be ethically supportable.

Finally, there has been considerable discussion in the bioethics and philosophical literatures regarding challenges to autonomy following DBS. This has been based primarily on small case series or anecdotal cases illustrating significant changes in decision-making characterized by impulsivity, gambling, or hypomanic/manic behaviors due to stimulation (e.g., Frank et al., 2007; Herzog et al., 2003; Smeding et al., 2007; Leentjens et al., 2004; Mandat et al., 2006). We have experienced less striking cases in which patients had poor judgment that put them at greater risk of injury following successful treatment of their motor symptoms with DBS. For example, a patient might decide that following successful treatment of his tremor with DBS he can safely climb on a ladder to prune tall trees with a chain saw just like he has done throughout much of his life. However, he also has poor balance putting him at risk of falling from the ladder with a chain saw. Similarly, consider an elderly woman who demonstrates continued poor judgment with trying to walk without her walker and is at high risk of fracturing her hip. Prior to DBS, this was not a risk as she was unable to stand without support. In both cases, our team would debate extensively about our responsibilities to minimize harm while providing the best opportunity for the patients to improve their lives. We are aware that by successfully treating some symptoms of PD, we may increase the likelihood of incurring future injuries due to the combination of increased mobility in the context of poor judgment. We often consult with a clinical bioethicist. Ultimately, in cases like these, we may decide with the patients and their families to reduce the stimulation resulting in slightly reduced efficacy with the goal of minimizing the likelihood of potentially greater harm associated with falls. These vignettes illustrate classic examples of trade-offs and balancing in competing values.

Risks to autonomy are not just limited to those associated with active stimulation. For example, consider the case of a man with PD who underwent DBS and developed poor judgment over the course of his PD but was doing well with good family support. Problems arose after the family member died who had been his primary support. He became involved with a group of people who took advantage of him and would allegedly turn off his DBS stimulator leaving him in a frozen, painful state to extort money from him. Unfortunately, many patients with dementia are vulnerable to similar kinds of abuses. Thankfully, other family members became involved and a guardianship was established to protect him. Such cases are very rare in our collective experience and we include them simply to illustrate some of the challenges to autonomy that might ensue in the context of DBS for the treatment of motor symptoms of PD. This latter case also highlights the need for ongoing family (or other care partner) support.

Quality of Life and Patients' Benefit

DBS is an elective neurosurgical procedure that a patient choses to undergo to improve quality of life—a concept that is inherently highly personal and value-laden. Best informed consent entails having a clear understanding of the patient's goals, and we would argue family's goals, for DBS to provide an opportunity to clarify expectations if necessary.

This is particularly important in the context of media stories that falsely imply that DBS is curative (Racine et al., 2007). These portrayals may contribute to unrealistic expectations (i.e., a "miracle") that then lead to disappointment. Agid and colleagues (2006) described a set of patients whose appreciation of outcome following DBS was much lower than the significant improvements evident on standard clinical research measures of motor symptoms and quality of life. This widely cited paper highlighted a "satisfaction gap" that others have pointed out (e.g., Maier et al., 2013; Schüpbach et al., 2009).

There have been two studies that have prospectively assessed patients' goals for DBS. Maier and colleagues (2013) conducted a mixed methods study examining patients' expectations of DBS and their subjective perceived outcome in a group of 30 patients. Patients completed semi-structured interviews examining pre-operative expectations and post-operative subjective outcome 3 months following surgery. The qualitative data were analyzed and the patients were divided into three different groups based on post-operative subjective outcome (negative, mixed, and positive). Multiple comparisons were done within and between these three groups using routinely administered clinical research measures examining motor symptoms and quality of life. In addition, logistic regression analyses were conducted to identify predictors of subjective negative outcome. Eight patients reported a negative outcome, eight patients had a mixed outcome, and 14 described positive outcome. Significant improvements in motor function were evident for all groups indicating that marked improvement in motor function was not always associated with a subjective impression of positive outcome. Negative subjective impressions of outcome were related to pre-operative unrealistic expectations, lack of improvement on quality of life measures after surgery, and presence of pre-operative apathy and depression. These data once again support the role of pre-operative neuropsychological assessment in identifying opportunities for treatment or further education to potentially optimize perception of outcome from all perspectives.

Our group (Kubu et al., 2017) employed a mixed methods design in a group of 52 patients with PD who underwent DBS. Patients completed a semi-structured interview specifically inquiring about their symptom and behavioral goals prior to surgery and at two points following DBS surgery. Embedded in the semi-structured interview were visual analog scales (VAS) that provided quantitative measures of the patient's perceived symptom severity (or limits to participating in behavioral activities). This methodology allowed us to assess changes in the goals patients identified as most important over the course of DBS. Our data demonstrated that the most common symptom goals patients identified were improvements in tremor, gait, and non-motor symptoms whereas the most commonly cited behavioral goals related to interpersonal relationships, work, and avocational pursuits. The patient rated individual VAS severity measures were generally not significantly related to standard measures used to assess symptom severity and quality of life in PD at baseline suggesting that non-redundant and highly valued patient information is not captured in the most commonly administered clinical research metrics. Significant improvements following DBS surgery were evident on the patient reported scales (reflecting their unique goals for DBS) as well as the standard outcome measures. Our data suggest that novel and potentially important information may be gleaned by systematically investigating patients' goals. Interestingly, all of our patients indicated that they viewed DBS to be worthwhile and would do it again given the benefit of hindsight. Importantly, our data demonstrate that not all DBS patients experience a satisfaction gap.

Our outcomes may differ from those detailed at other centers because virtually all of our team members devote a significant amount of time with the patient individually to explicitly elicit and clarify patients' goals for DBS. The family's goals for DBS are also systematically assessed in the neuropsychological evaluation (if the family is present). These multiple discussions provide an opportunity for dialog and education to ensure that there is good understanding of what DBS can achieve and what it may not. Assessment of goals should not be limited to simple descriptions of the motor symptoms, for example, "reduce tremor" or "improve gait". Often it is the functional limitations that the motor symptoms exert on valued activities that negatively affect quality of life rather than the symptoms per se (cf. Kleiner-Fisman et al., 2010). For example, a patient may say that she wants to see improvements in her gait with the implicit goal of returning to running marathons or downhill skiing. Another patient may state that his primary goal is to reduce his tremor when his primary goal is to return to an active veterinary practice including surgeries. None of these underlying goals may be achievable despite statistically significant improvements in gait and tremor.

Finally, we have argued previously that assessment of outcome should be multifaceted and include patient specific derived metrics (similar to those outlined above) as well as functional, motor, psychiatric, cognitive, and quality of life measures (Kubu and Ford, 2012). These assessment should occur in the context of a deliberative, interdisciplinary team process that reviews patients' candidacy and examines outcome. Furthermore, we argue that time should be dedicated regularly for DBS teams to systematically review those patients for whom DBS was highly successful as well as those for whom it was not—by any or all metrics. Careful review of these exemplar cases may help identify best practices and opportunities for improvement thereby improving patient care, clinical outcomes, and research.

Conclusion

The neuropsychologist's role on a DBS team is to identify potential cognitive risk, highlight neuropsychiatric concerns, examine level of family support, and elicit patient's (and family's) goals. The information gleaned in the course of a neuropsychological assessment is critically important to several of the ethical challenges that may arise in the context of working on a DBS team. We have highlighted some of the ethical challenges that have arisen in our collective experience and provided pragmatic recommendations based on careful systematic ethical analyses taking into account often conflicting values. Undoubtedly, other challenges will arise as neuromodulation therapies continue to develop and expand to other populations. Neuropsychologists, by dint of their expertise in brain–behavior relationships, clinical psychology, and measurement, will continue to be important partners in articulating the most ethically sound practices that take into account patient's values as well as fiduciary responsibilities to the patient, the team, profession, and the broader community.

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Conflict of Interest

None declared.

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