EDITORIAL

An ethical framework for deep brain stimulation in children

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DEEP brain stimulation (DBS) is increasingly considered for the treatment of refractory neurodevelopmental conditions affecting children.²⁵ In 1999, Coubes and colleagues were among the first to report on the use of pediatric DBS for primary dystonia.⁹ Since then, pediatric DBS has gained considerable traction, with several case series reported.^{25,29} Although dystonia remains the most common indication for pediatric DBS, the technology has also been applied to treat epilepsy⁴⁴ and Tourette syndrome.³⁸ More recently, DBS of the nucleus accumbens and amygdala have been reported for self-injurious behaviors.^{34,41}

The majority of the evidence for DBS in children has been derived from the adult literature, in which the procedure has been shown to be safe and effective for an increasing number of indications.³⁷ However, pediatric DBS has many substantial differences, with important bioethical, social, and legal considerations. First, patients and their caregivers represent a uniquely vulnerable population. Second, given biological differences between adults and children, the procedure in pediatric populations can be considered a surgical innovation and is still investigational for all indications. Third, the natural history of a disease within the context of a child's neuromuscular and cognitive development must be factored into treatment decisions. Furthermore, the surgical risks and technical nuances of DBS differ from those in adults. Thus, evidence from the adult DBS literature may not be readily translatable to pediatric populations.

With the exception of *DYT1* dystonia (for which there is level II-2 evidence⁴⁵), all indications for DBS in pediatric patients are in the early stages of investigation; thus, the procedure represents a surgical innovation, i.e., a procedure that “departs in a significant way from standard or accepted practice.”¹¹ Surgical innovations are charac-

terized by evolving techniques, outcome measures, and patient selection.³¹ Three systematic reviews and meta-analyses (two manuscripts currently under review and one paper in press¹⁰) have described the conduct of DBS in pediatric populations (Table 1), all emphasizing significant heterogeneity and the need for prospective studies to guide patient selection. The framework we describe here is intended to be applied to DBS in children in all settings, most of which are presently experimental or under the realm of surgical innovation. Ultimately, the most basic ethical principles protecting research subjects flow from the Nuremberg Code (1948), the Declaration of Helsinki (1964), and the Belmont Report (1979); however, in children with a medically complex condition who may benefit from novel investigational treatments, a more targeted framework is needed.^{11,14,43}

Herein we expand on differences in the conduct of DBS between adults and children and the unique ethical challenges they pose. First, we describe ethical issues raised by the vulnerability of the patient population, the novelty of the application of DBS for expanding indications in children, and the conduct of the procedure in children despite limited evidence. We then propose a bioethical framework for the evaluation of children for DBS. Although ethical issues may figure more or less prominently depending on the individual patient and the indication, the framework we put forth may be generalized to shape personal, institutional, and social policies regarding DBS in children. It is not our intention to prescribe the steps and thought process for carrying out pediatric DBS, but rather to advance dialogue regarding the ethical underpinnings of this promising technique in children.

The Population: Ethical Challenges in Vulnerable Patients

The pediatric population being considered for DBS is

TABLE 1. Systematic reviews and meta-analyses of DBS in exclusively pediatric populations

Authors & Year	Indication	No. of Subjects (total no. of studies)
Elkaim et al., 2018*	Primary & secondary dystonia	Primary: 173; secondary: 139; myoclonus: 9 (72)
Coulombe et al., 2018 (in press)	Tourette's syndrome	58 (21)
Yan et al., 2018*	Epilepsy	40 (21)

* Manuscripts currently under review.

complex and vulnerable, requiring a high level of case-specific ethical appraisal. Ethical criteria for DBS in vulnerable adult populations have been published:²⁴ 1) adequate discussion of patient selection, 2) provision of an evidence-based rationale that exceeds a standard of reasonableness, 3) demonstration of the disease burden, 4) transparency in informed consent, 5) multidisciplinary review of individual cases, 6) adequate oversight of all aspects of the research, and 7) routine scheduled evaluations focused on ethical aspects of the trial design.²⁴ While many of these principles apply to the conduct of DBS in children, several unique pediatric considerations should be recognized.

Children may not be able to articulate their wishes due to intellectual immaturity or neurocognitive disability, leaving caregivers to make difficult decisions. In cases in which the child has not yet declared their interests, decisions are based on the child's presumed best interest rather than their right to autonomy and self-determination.^{1,20} Such decision-making spans not only the perioperative period, but also subsequent decision points such as device programming, further treatment, and potential revisions.²⁰ Depending on the child's age and abilities at initial intervention, he or she may begin assuming a greater role in subsequent decision-making, an evolution that all stakeholders within the circle of care must anticipate.

There is no accepted age at which children are deemed competent and capable of medical decision-making. Competence is more often associated with prior experience rather than a specific age.^{2,20} Beginning at age 7 years, children with a prior surgical history are often asked to participate in decision-making.¹ In the case of DBS, there is usually no prior experience, and few such cases have been performed; therefore, advice and experience from family support groups with related experience are limited. Children with prior non-DBS surgical experience might participate better in consent discussions regarding general surgical risks, but would be unlikely to have added insight into the specifics of undergoing DBS.

In some cases, there is a dilemma between early versus delayed intervention to allow the child to better participate in decision-making. A delay in treatment may result in undue harm from disease sequelae, such as musculoskeletal deformity from spastic conditions,^{6,28,29} worsening epilepsy, and so forth. Early intervention is most warranted for conditions with strong evidence such as primary *DYT1* dystonia, but is less indicated where evidence is hetero-

geneous such as in secondary dystonia.²⁵ The concept of "double jeopardy" may apply: First, these children suffer as a result of their disabilities, and second, lower priority is given to treatments that may improve their quality of life.¹⁸ A "relational" view of decision-making holds that treatment (and evidence for and against intervention) should be considered within the context of the child's subjective experience with the illness.^{12,20,39} Consultation with medical bioethicists may be prudent to maintain the strictest standards for patient care.

The Procedure: Known and Unknown Risks of Surgical Innovation

Although DBS for movement disorders in adults is an accepted treatment option, in children it still represents a surgical innovation, even for the most common indication, dystonia. As mentioned above, an innovation is defined as a procedure that significantly departs from standard or accepted practice and is characterized by evolving techniques, outcome measures, and patient selection.^{11,31} The extent to which a surgical innovation deviates from standard practice is directly related to the extent to which it requires ethical oversight and regulation.⁵

Before proposing DBS for a pediatric patient, the health team should recognize that the risks, and often the benefits, of the procedure are not well understood. Available data are limited to small case series with specific institutional protocols that are poorly generalizable to other centers. Risks of the procedure may be higher in children when that procedure is performed using protocols derived from adult DBS. For example, early case series on pediatric DBS have reported higher rates of infection ranging from 5% to 33%, as compared to approximately 5% with adult DBS.^{22,29,35} Since then, two series in which the pulse generator was implanted at a later date both reported an infection rate of 0%.^{21,33} Furthermore, DBS leads and batteries are sized for use in adults, and the risks of skin erosion and hardware fracture seem to be higher in children.^{25,29} An appreciation of the ways in which a standard procedure in adults (i.e., DBS) may be an innovative intervention in children is critical to determining the extent of ethical oversight required for its use in clinical and experimental indications.

Surgical innovations are also associated with evolving outcome measures.³¹ Current instruments used to measure the success of DBS treatment may not be ideal, even for the most widely studied indication, dystonia. Originally created to assess primary torsion dystonia in adults, the Burke-Fahn-Marsden Dystonia Rating Scale (BFMDRS) has been adopted for pediatric use and is now the most commonly reported measure of dystonia impairment.⁷ Intended for use in secondary dystonia, the Barry-Albright Dystonia Scale (BADDS) is also frequently cited.⁴ These scales often fail to capture a child's experience with illness (i.e., dystonia). For example, a recent study highlighting this showed that DBS improved individualized functional goals in the absence of significant changes in BFMDRS scores in children with secondary dystonia.¹⁶

Despite the uncertainties introduced by evolving techniques, patient selection, and outcome measures, clinicians have an obligation to apply DBS in appropriately selected

candidates. Future studies will aim to clarify the extent to which pediatric DBS deviates from the adult equivalent, as well as the minimum level of evidence required before acceptance of the procedure.¹⁹

The Element of Time: Interaction Between Disease Course and the Child's Development

Timing plays a much larger role in pediatric DBS. Unlike in adults, when the decision to proceed with DBS involves ensuring that the disease is truly refractory to other treatments, the pediatric neurosurgeon must also factor in the child's development. The most common indication for pediatric DBS is dystonia, for which early intervention seems to yield better motor improvements.^{25,30} In treating secondary dystonia due to cerebral palsy, those treated before skeletal maturity improved in their BFMDRS scores by 38%, while those treated after skeletal maturity improved by only 9%.³⁰ Early interventions for dystonia likely mitigate contractures and may prevent or inhibit fixed deformities from developing.^{21,30} Advantages of early intervention must be counterbalanced by the various challenges associated with DBS in a younger child.

Ethical challenges are also presented by diseases with an unknown natural history. In Tourette syndrome, a tic disorder whose treatment has shown promising results in adult DBS series, pediatric cases often spontaneously remit in adolescence, making early DBS less appealing.^{23,25} While most guidelines recommend against DBS for Tourette syndrome in children for this reason, the result is that a subset of children must endure years of unnecessary suffering until their disease is deemed to be nonremitting.^{36,40} Moreover, anorexia nervosa, a common and severe condition often beginning during adolescence, is associated with a high rate of treatment resistance and death and may therefore be amenable to earlier DBS.²⁶

The Technical Nuances: Ethical Challenges Introduced by Technical Considerations

Technical nuances in children may also present ethical challenges. One example of this is the need for general anesthesia in children, which may preclude microelectrode recordings, potentially decreasing the accuracy of lead placement. In adults, lead misplacement is the chief cause of suboptimal outcomes with DBS.¹³ There is reasonable case-control evidence from adults with Parkinson's disease that awake and asleep DBS yield similar results.⁸ This comparison has not yet been performed in children. Awake DBS has been successfully performed in many children over the age of 10, although it requires innovative strategies such as an intraoperative child-life specialist and preoperative relaxation training.²⁹

In children under the age of 7, the location of DBS electrodes can also change with head growth. The deepest lead should be placed slightly ventral to the target in children with further head growth anticipated.²⁷ Similarly, extra wire should be loosely looped in the subcutaneous pocket to avoid lead fracture with growth.

Stimulation parameters also introduce an element of uncertainty in children, for whom no standardized protocols exist.²⁹ In adults, common stimulation settings have

been demonstrated to be safe through autopsies on patients who had chronic DBS.²⁹ Safety data of this nature are not available in children. Consent discussions for pediatric DBS should outline the limitations of our current state of knowledge, especially as regards the safety profile and long-term effects of stimulation. An ethical obligation of the scientific community is to facilitate the standardization of pediatric DBS protocols, including programming.

The ethical challenges associated with these procedural differences highlight the importance of appreciating and communicating that pediatric DBS is novel not only because of the age group, but also because the basic technical procedure is still being refined.

The Evidence: Translating From Adult to Pediatric Populations

Although children are biologically different from adults, the evidence used to guide pediatric DBS is largely derived from adult data. Stimulation parameters for dystonia DBS were adopted from the adult Parkinson's disease experience, with most patients receiving > 100 Hz of stimulation.³ In a relatively large case series, Alterman et al. demonstrated that dystonia may respond well to much lower-frequency stimulation, i.e., 60 Hz.³ Stimulation frequencies and voltages have been demonstrated to be safe in adults, causing only mild gliosis, but such reports are not available in children.²⁹ Despite a few prior successful treatments, clinicians should be aware and communicate to families that there is simply not a strong body of evidence regarding the use of these devices in children, yet.

Because the evidence for pediatric DBS remains in its infancy, the neurosurgeon is often acting as a clinician and scientist concurrently. "Therapeutic misconception" occurs when study participants fail to recognize the potentially competing roles and obligations of the treating physician as both clinician and scientist.³² Patient populations that hold particularly negative views about their health are at higher risk for therapeutic misconception.¹⁷

Various strategies can be implemented to circumvent knowledge gaps and mitigate the risk of therapeutic misconception. The Fort Worth pediatrics program in Texas uses institutional board review to ensure that patients and families are adequately informed and fairly selected.²⁹ The program also uses an independent nurse to perform a parallel consent process. Regardless of the institution-specific process, each case should be carefully considered by a multidisciplinary group, factoring in whatever degree of input the child is capable of providing along with the decision of a competent substitute decision maker.

Ethical Framework for Pediatric DBS

Ethical frameworks function as scaffolding for public, institutional, and personal views toward an existing problem.¹⁵ Ethical frameworks include common themes that transcend individual challenges, such as access, accountability, autonomy, client centeredness, collaboration, efficiency, equity, evidence, prevention, public involvement, quality, responsibility, sustainability, and protection of the vulnerable.¹⁵ Given the ethical challenges unique to the conduct of DBS in children, we propose a bioethical

TABLE 2. Guidelines for the ethical conduct of DBS in children

Research design & conduct in the child's best interest
Hypotheses, outcomes, & procedures viewed in a developmentally relevant context
Realistic discussion of what is known & what is unknown regarding the risk profile in pediatric DBS; weighing the decision to proceed with & the timing of DBS vs other treatments with better known efficacy & risk profiles
Cautious application of adult data to the design of pediatric clinical trials
Diligently report methods & results to the neurosurgical community in the spirit of collaboration

framework centered around five primary expectations that may serve to advance dialogue regarding pediatric DBS (Table 2).

Expectation 1: Protection of the Child's Best Interest

Decisions and clinical hypotheses and their testing should be made in the spirit of the child's best interest. Since children are often unable to declare their treatment preferences because of immaturity or disability, treatments that support their development and decrease their suffering should be emphasized. An examination of a child's best interest may also encompass benefit to caregivers.⁴² For example, reduced dystonia may facilitate the delivery of care and hygiene to the child by their caregivers, thus providing a net benefit. Although DBS research, for instance, in the form of clinical trials, is primarily designed to test an intervention that may benefit future patients, surgical trials are inherently accompanied by a reasonable expectation of benefit to the individual subject. Efforts to uphold the highest standards of ethical principles and mitigate therapeutic misconception during the conduct of clinical trials involving DBS in children are paramount.

Expectation 2: Decisions Made Within the Developmental Context

The use of DBS in children should be viewed through a developmental lens. The treating team should have a clear concept of the expected trajectory of the child's illness, their development, and how the proposed treatment fits within this larger picture. The timing of any proposed treatment should be clearly justified based on these factors, such as trying to prevent contractures from developing in the case of dystonia. For example, in refractory Tourette syndrome, the benefits of intervention should be weighed against an unknown and potentially favorable natural history. A holistic approach encompassing the child's medical, psychiatric, and social comorbidities and position should inform the presurgical discussions.

Expectation 3: Mitigating "Relative" Known and Unknown Risks to the Individual Child

Relatively little is known about the risks of DBS in pediatric patients and how they differ from those in adults, and all members of the treating team should be aware of this. In the conduct of pediatric DBS, the child's rela-

tive experience with illness must be weighed against uncertainty to minimize known and theoretical risks. The child's subjective experience should dictate the degree to which DBS can and should be pursued for an accepted or investigational indication.

The known benefits and harms of a child's current treatment, as well as their subjective experience of illness, should be balanced against the relatively unknown risks and benefits of DBS. For example, intrathecal baclofen therapy is an established, effective treatment for secondary generalized dystonia. The point at which DBS should be considered represents a balance of its unknown risks (and benefits) relative to the efficacy and tolerance of the established treatment (intrathecal baclofen). Presently, in most cases, the balance tips toward DBS when other treatments have become ineffective or harmful despite significant suffering due to the illness. As better data emerge, the decision to proceed with and the timing of the intervention is expected to be associated with less uncertainty and to pose fewer ethical dilemmas.

Expectation 4: Avoidance of Overreliance on the Adult Literature

The treating team and caregivers must be constantly cognizant that "children are not small adults." In addition to the unique risk and benefit profiles, the diseases manifested in children differ significantly from those in adults, as does a child's perception of illness. Incumbent on the treating physician is the need to approach pediatric DBS as uncharted territory and to take on the burden of demonstrating reasonable evidence for and against all elements of the treatment.

Expectation 5: Communicate and Collaborate With Other Practitioners

Each lesson learned in the pre-, intra-, and postoperative phase of DBS in the pediatric setting is extremely valuable and should be disseminated to the larger clinical community. Both positive and negative results require discussion and publication. For instance, given the heterogeneity of outcomes following secondary dystonia, it is incumbent upon the medical community to better define the ideal surgical candidates. A frank review of complications must also occur, with institutional oversight. Such practices have already improved outcomes following DBS in children.^{21,33} Although small case series still provide valuable data, emphasis should be placed on collaborative registries, with standardized, prospective outcome reporting. Collaboration to harmonize protocols between institutions will be necessary to produce larger, more generalizable case series.

Conclusions

Current evidence for the use of DBS in children is limited to case reports and case series. Early results for pediatric DBS have generated enthusiasm for the expansion of its indications. Herein we have outlined some of the key ethical issues in implementing DBS in the pediatric population, as well as an ethical framework to guide neurosurgeons when considering DBS for accepted or experimental indications.

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Disclosures

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