Pressing Ethical Issues in Considering Pediatric Deep Brain Stimulation for Obsessive-Compulsive Disorder

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Background

OCD is the first psychiatric disorder for which DBS has received an FDA Humanitarian Device Exemption (HDE). Given the HDE approval of DBS for adults with OCD and encouraging evidence that has since emerged (1), exploration of DBS for OCD may expand to adolescents in the future.

- More than 100,000 adolescents in the U.S. suffer from refractory OCD who could potentially benefit from pediatric DBS (pDBS) (2).
- There is already a precedent for the transition of DBS in adults to children and adolescents in the case of pDBS for dystonia which is available on an HDE basis for children ≥ 7 years old (3).

However, the risk-benefit analysis of pDBS for OCD may be more complex and raise different ethical questions compared to pDBS for dystonia.

Methods

To gain insight into the most pressing ethical issues related to offering pediatric DBS for OCD, we conducted semi-structured interviews with clinicians (n=25) caring for pediatric patients with refractory OCD. Interview transcripts were coded with MAXQDA 2018 software and then analyzed using thematic content analysis to identify the content and frequency of emergent themes.

Results

<table>
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<tr>
<th>Capacity to Consent &amp; Quality Decision-Making (80%) *</th>
<th>Evidence, Unknowns &amp; Risk-Benefit Analysis (68%) *</th>
<th>Bias, Coercion &amp; Conflicts of Interest (28%)</th>
<th>Access (24%)</th>
<th>Refractory Status &amp; Exhaustion of Other Treatments (20%) *</th>
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<td>“I think the number one thing is just this issue of consent and assent and doing something to a child's brain that they not necessarily want done” (021).</td>
<td>“…the unknowns with regards to effects on brain development, and in terms of using this in adolescents, what potential side effects could arise [...] Those are major issues” (020).</td>
<td>“Does the person who’s recommending it have any sort of affiliation with the device maker, or some kind of a research protocol that someone would fit into?” (015).</td>
<td>“Insurance could become an ethical dilemma where a child, which I feel would get benefit, parents in agreement, child is in agreement, and insurance does not cover” (023).</td>
<td>“Another issue is the degree that we have a good handle on what constitutes refractory OCD. The field has been really unclear [...] and I’ve seen a lot of different definitions” (013).</td>
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Note: * = themes unique to/exacerbated in pediatric compared to adult DBS setting

Five central themes were identified in clinician responses

Conclusions

Potential strategies to address pressing ethical issues include...

- Use of a shared decision-making framework and decision aid to guide decision-making triad (pediatric patient-caregiver-clinician) (4)
- Further research into the risks and benefits of pDBS for OCD and clinician participation in data registries
- Seek greater consensus on what constitutes “refractory” OCD to establish clear guidelines for patient selection

Acknowledgements & References

Research for this article was funded by the BRAIN Initiative-NIH, parent grant RF1MH121371 and supplemental grant 3RF1MH121371-01S1 (Lázaro-Muñoz, Blumenthal-Barby, Storch). The views expressed are those of the authors and do not necessarily reflect views of the NIH, Baylor College of Medicine, or Rice University.