Researcher Perspectives on Ethical Considerations in Adaptive Deep Brain Stimulation Trials

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BACKGROUND
Interest and investment in closed-loop or adaptive deep brain stimulation (aDBS) systems have quickly expanded due to this neurotechnology’s potential to more safely and effectively treat refractory movement and psychiatric disorders compared to conventional DBS (3,4). However, the defining features of aDBS that make it promising (i.e., automatically adjust stimulation, store neural data), may exacerbate certain neuroethics concerns (e.g., felt authenticity of affective states, patient privacy) (4). Few studies have examined stakeholder perspectives about ethical issues in aDBS research and next generation DBS devices.

METHODS
To help fill this gap, we conducted semi-structured interviews with researchers involved in aDBS trials (n=23) to gain insight into the most pressing ethical questions in aDBS research and any concerns about specific features of aDBS devices, including devices’ ability to measure brain activity, automatically adjust stimulation, and measure and store neural data, thus utilized to identify themes in researcher responses to six different questions (see Table 1).

RESULTS
8 Central Themes in Researcher Responses:

- Autonomy and Control Over Stimulation (57%)
- Patient Selection and Consideration (30%)
- Post-Trial Access to Care and Device Maintenance (39%)
- Personality and Identity (30%)
- Privacy and Security Issues (91%)
- Informed Consent and Adequate Patient Understanding (74%)
- Automaticity and Device Programming (65%)
- Risks and Safety (83%)

Table 1. Percentage (% of Respondents (n=23) Who Discussed Main Ethical Concerns Related to aDBS

- "I think the main concerns would be privacy of the data. We stream these data to external computers. Someone's data is now [...] it could be considered personal health information, in a way. Eventually, we may be able to decode specific things about that person's privacy and their personality from that data. So, we do have to consider it as personal health information, even if it's de-identified..." (R_011).
- "There's the fact that we just don't know that much about DBS and how it works. That's the danger of doing any kind of experiment on humans directly, even though it's pretty well understood, what the random risks are" (R_006).

Table 2. Percentage (%) of Respondents (n=23) Who Discussed Specific Ethical Concerns Related to aDBS

- "My concern is that it might stimulate when it's not supposed to, causing [an] unwanted side effect. Or the opposite, if it's not stimulating when it's supposed to cause the patient unnecessary suffering. Those are glitches that, as we develop these techniques, hopefully will not be an issue. But those are concerns that I have from an ethical perspective" (R_020).

NEXT STEPS
- Minimize Cybersecurity Vulnerabilities
- Advance Biomarker Validity
- Promote the Balance of Device Control
- Enhance Patient Knowledge & Ongoing Informed Consent

CONCLUSION
- Researchers highlighted many pressing concerns. While some were relevant to conventional DBS and aDBS, most were exacerbated by distinct features of aDBS.
- Due to the need to measure and store neural data, aDBS researchers raised concerns about protecting the privacy of neural data and preventing unwanted third-party access to data.
- The automatic nature of stimulation sparked risk and safety concerns about the experimental nature of identifying biomarkers to automatically adjust stimulation outside the clinic as well as concerns about patients’ ability to properly consent to continuous alterations in stimulation.

Our findings therefore suggest that the technical features that give aDBS advantages over conventional DBS systems also raise distinct issues.

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ACKNOWLEDGMENTS
Research for this article was funded by the BRAIN Initiative-National Institutes of Health (NIH), parent grant R01MH114854 and supplemental grant R01MH114854-01S (Lázaro-Muñoz; McGuire, Goodman). The views expressed are those of the authors and do not necessarily reflect the views of the NIH, Baylor College of Medicine, Rice University, the University of Puerto Rico, or UC San Francisco.

Questions Explored:

1. How do you think about the current status of aDBS, where do you think we are going with aDBS research?
2. From a non-medical perspective, what are the key concerns you think that need to be addressed and why?
3. How confident are you about patients' autonomy in making decisions about their own DBS?
4. As you know, an important component of aDBS is that it can be adjusted based on the patient's brain activity. What, if any, ethical concerns do you see with this approach?
5. The adaptive DBS systems automatically change stimulation based on the patient's behavior. What ethical concerns do you have with this approach?
6. The adaptive DBS systems have demonstrated improvement in their ability to adjust stimulation based on the patient’s brain activity. What ethical concerns, if any, do you have with this approach?