Researchers Perspectives on Ethical Considerations in Adaptive Deep Brain Stimulation Trials

Katrina A. Muñoz M.B.E., Kristin Kostick Ph.D., Clarissa Sanchez M.P.H., Lavina Kalwani, Laura Torgerson M.S., Rebecca Hsu, Demetrio Sierra-Mercado Ph.D., Jill O. Robinson M.A., Simon Outram Ph.D., Barbara Koenig Ph.D., Stacey Pereira Ph.D., Amy McGuire Ph.D., J.D., Peter Zuk Ph.D., Gabriel Lázaro-Muñoz Ph.D., J.D., M.B.E.

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 (1,4). 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 other 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 store neural data. Thematic content analysis was utilized to identify themes in researcher responses to six different questions (see Table 1).

RESULTS

8 Central Themes in Researcher Responses:

- Data Privacy and Security Issues (91%)
- Autonomy and Control Over Stimulation (57%)
- Personality and Identity (30%)
- “In the study where we’re manipulating mood potentially, the goal is to improve mood, which most people would say would be a good thing. But then at some point, do you give somebody a new mood that changes their personality? There are a lot of ethical issues behind potentially manipulating people’s mood and personality [be]cause that could be a good thing or a bad thing” (R_010).

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

<table>
<thead>
<tr>
<th>Concern Area</th>
<th>Autonomy and Control Over Stimulation</th>
<th>Personality and Identity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Privacy and Security</td>
<td>17 (57%)</td>
<td>24 (32%)</td>
</tr>
<tr>
<td>Risks and Safety</td>
<td>9 (39%)</td>
<td>10 (43%)</td>
</tr>
<tr>
<td>Informed Consent and Adequate Patient Understanding</td>
<td>30 (65%)</td>
<td>17 (34%)</td>
</tr>
<tr>
<td>Automaticity and Device Programming</td>
<td>61 (17%)</td>
<td>4 (13%)</td>
</tr>
<tr>
<td>Advances in Biomarker Validity</td>
<td>9 (34%)</td>
<td>39 (35%)</td>
</tr>
<tr>
<td>Patient Selection and Candidacy Considerations</td>
<td>78 (17%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Table 2. Percentage (%) of Respondents (n=23) who Discussed Main Ethical Concerns related to aDBS

NEXT STEPS

CONCLUSION

- Researchers highlighted many pressing concerns. While some were relevant to conventional DBS and aDBS, most were exacerbated by distinct features of aDBS.
- The automatic nature of stimulation spark 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.

References


Acknowledgments

Research for this article was funded by the BRAIN Initiative-National Institutes of Health (NIH), parent grant R01MH114884 and supplemental grant R01MH114884-S1 (Lauro-Muñoz, McGuire, Goodman). The views expressed are those of the authors and do not necessarily reflect views of NIH, Baylor College of Medicine, Rice University, the University of Puerto Rico, or UC San Francisco.