"I figured we'd face that when we got there": Care Partners' Perspectives on Post-trial Device Maintenance in adaptive DBS trials

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BACKGROUND

- Participants in neural device trials frequently are accompanied by a dedicated care partner (CP; e.g., spouse, parent) who assists them during and after trials.
- CPs' lives are impacted in many ways by the participants' treatment-resistant health condition.
- CPs may also be uniquely impacted by trial participation and experience challenges related to post-trial device access and maintenance. However, little is known about CPs' views or experiences.
- **Current study:** Examined CPs experiences and perspectives regarding trial participation and post-trial access and maintenance of adaptive deep brain stimulation devices.

METHOD

- In-depth, semi-structured interviews were conducted with CPs (n=20) involved in an aDBS trial.
- Interviews focused on individual experiences in supporting a loved one in an experimental brain implant trial, including views on post-trial device maintenance.
- Interviews underwent thematic content analysis and major themes identified in preliminary analyses are discussed. Two CPs did not complete follow-up interviews and were excluded from final analyses.

RESULTS

Table 1. Participant Demographic Information

	Total Sample (n = 20)
Gender	Male 5 (26.3%) Female 14 (73.7%)
Race	White 17 (89.5%) American Indian/Alaska Native 2 (10.5%) Other 2 (10.5%)
Ethnicity	Latinx 2 (11.1%) Non-Latinx 16 (88.9%)
Relationship to patient-participant	Spouse 14 (73.7%) Mother 5 (26.3%)

Note: Some CPs did not complete all demographic information. Sums to greater than 100% as respondents were asked to select all that apply.

❖ **Acknowledgments:** We gratefully acknowledge the support of the National Institute of Mental Health, Award Numbers R01MH114854 and R01MH133657.

RESULTS

"What, if anything do you remember about how device removal or maintenance will be managed at the end of this adaptive DBS study?"

- **Only half of CPs (9/18) recalled explicitly having discussions** with the research team regarding post-trial procedures. Of those who did recall these conversations, three participants could recall having a conversation, but were unsure of the details related to post-trial care. Several participants **(7/18) noted that they didn't consider post-trial maintenance costs**, and **(6/18) specifically stated they were concerned about these costs**.

> *"I don't think it's ever been addressed. We just assume that between Medicare and our health insurance, that the original surgery was covered, and that anything relating to it after that it would be covered. Maybe we assumed wrong."*

"What do you think should happen to the device [at the end of the trial]?"

> *"Well, I feel like for a participant and if it's worked very well, as in [PATIENT]'s case, that everyone on the team would have input and as to continued use of the device and it staying in. And right now, I think we're at a place where we would say, yes. Gosh, the thought of him going backwards would be just unthinkable."*

- Most CPs **(14/18) strongly indicated that patient-participants should be able to keep the device** at the end of the trial if they are experiencing benefit. Several CPs **(7/18) noted that a device should be removed if the patient-participant requests** that it be removed or if the device is not helping, or is causing severe side effects. The majority of CPs also felt that in the event of removal, the research study team should cover these costs, as they saw explantation as part of the research process.

"How do you think removal of the adaptive DBS device should be paid for at the end of the study?"

- **The majority of CP (13/18) felt the research team should be responsible for the costs associated with device removal** if it was decided that the device should be removed at the end of the trial, with several discussing the idea of reciprocity between the study team and participants. However, we note that we did not query about CPs views regarding the responsibility of alternative stakeholders (i.e., device companies, insurance, etc.).

> *"Because she's a participant in the study, I would think that they would have to pay for it to take it out because again, that would be ... She got into this program because of the study, so if she wanted to get out of the program, I think this study should pay for any expenses of getting out of the program as well."*

"How do you think keeping the adaptive DBS device functioning at the end of the study should be paid for? Why?"

> *"I think, your insurance… It would be a health necessity. It would be essential for them. I don't see how that differs any more than the prescription you get for managing [condition]."*

- Most CPs **(12/18) felt that insurance companies** should be responsible for covering the costs of device maintenance, with some stating that they assumed insurance would cover associated costs. Some participants **(6/18)** indicated that the **parties responsible for the research** should cover these costs given the contributions of the patients to the research efforts.

CONCLUSION

- Consistent with previous work with patients, only half of CPs recalled post-trial discussions. This raises concerns about the amount of information individuals are processing during the consent procedures and emphasizes the need for to tools to improve that communication.
- These results also indicated that many CPs feel those benefiting from the data should be at least partially responsible for maintenance and removal of the device.
- Finally, it underscores that CPs and research subjects are not always aware of grant funding structures that limit researchers' ability to provide maintenance and device removal; disclosure of these may be important to include in the consent process.