Researchers' views on perceived risks of device removal following brain implant research

Demetrio Sierra-Mercado[1,2], Peter Zuk[1], Kistin Kostick[1], Laura Torgerson[1], Rebecca Hsu[1], Jill Oliver Robinson[1], Katrina A Muñoz[1], Clarissa Sánchez[1], Simon Outram[4], Lavina Kalwani[3], Barbara Koenig[4], Stacey Pereira[1], Amy McGuire[1], Gabriel Lázaro-Muñoz[1].

[1]Center for Medical Ethics & Health Policy, Baylor College of Medicine, [2]Dept of Anatomy & Neurobiology, Univ of Puerto Rico School of Medicine, [3]Institute for Health & Aging, University of California San Francisco, [4]Dept of Anthropology, History, and Social Medicine, University of California San Francisco.

Introduction: Research with brain implant devices such as adaptive deep brain stimulation (aDBS) systems has led to ethical discussions about device removal, including who ought to cover the financial costs of removal upon study conclusion (Sierra-Mercado & Zuk et al., 2019). A related question about device removal is how to assess the risks involved, including physical risks such as hemorrhage and infection (Patel et al., 2015, Chen et al., 2017).

1. Methods

Using in-depth, semi-structured interviews, we examined DBS/aDBS researcher (n=23) perspectives on perceived risks regarding post-trial device removal.

2. Results

Perceived Risks: Physical

- Researchers largely believed that the physical risks of removing the neural components of the device outweigh the potential benefits of removal, citing the broad risks associated with neurosurgery.
  - As noted by one researcher: *"…risk of surgery, including infection".*
  - Another researcher stated that *"…of course, with every surgery there's a risk of infection. There's the risk of anesthesia. There's all kinds of these additional risks".*

Physical Risks of Removal
• Similar risks to implantation: coma, paralysis, seizures, pain
• Medications for general anesthesia (heart attack, death)
• Components break and complications of surgery
• Damage to brain tissue, blood vessels
• Temporary or permanent neurological complications

Perceived Risks: Financial Risks

- Researchers highlighted financial risks associated with medically necessary or elective removal. Some grants cover removal costs, sometimes in the case of elective removal, but often only during the grant period.
- Insurance will cover medically needed explantation, but the participant may still need to pay a high deductible. Notably, some participants may lack insurance.
  - *"...that is a concern for patients and we are in a unique position with our grant that we have funding to cover the cost of the surgery and the implant, and in some instances the removal as well. So, if it is done for research related purposes, the grant will cover the cost of that removal at the end of the study if it is determined necessary or that it wasn't beneficial to the patient. Now, if they're off study and they decide to remove the device... once they're off study... the cost transfers to them."*
  - *"Once the study ends, if you want removal..., we'll try to bill your insurance, but if they don't cover it, then basically the participant assumes that cost or the patient at that point-"*

Financial Burdens
• Removal costs around $13,000 (1)
• Insurance company generally not obligated to cover costs
• Clinical visits for infections, allergies, or tissue damage (1,3)

Perceived Risks: Opportunity Costs

- For participants who do not receive desired level of benefit, leaving the neural components of the device implanted but deactivated is typically recommended over removal.
- Given this, other researchers highlighted that leaving the device implanted could be risky because it would impede the patient from some clinical evaluations.
  - One researcher stated a *"[primary risk is a brain tumor necessitating MRI, that requires an MRI that they cannot have with the implant]".*

Perceived Risks: Psychological

- In cases of psychological distress, a few researchers suggested that removal count as medically indicated rather than as elective.
  - *"if it's not bothering you... turn it off and leave it in".*
  - *"That having the device in there was problematic, just knowing that there's a device in there. Whether it was doing something or not, just the fact that there was something there, discomfort related to a device."*
- Arguably, these responses could suggest that if it is bothering the patient, device removal is favorable.

Perceived Risks: Other unknown long-term risks

- Leaving a device implanted but deactivated may itself involve other unknown long-term risks.
  - *"Well, we want to do research to understand and to improve therapy, but at the same time we're offering therapies that are not the standard of care, that have some unknown risks and possibilities that patients cannot possibly understand, no one can predict what a patient will experience after the device is implanted and what might be the motivation for having it removed. So I think patients are, in some regard, committing to something that they don't know, they cannot know 100% about.*

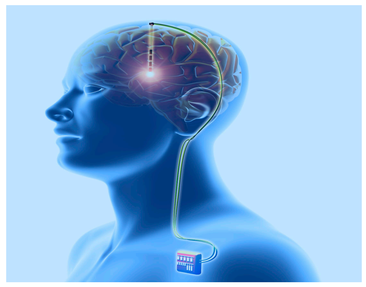
Regardless of the perceived risks of the researchers, they did emphasize that it is ultimately the patients' choice and that they would fulfill the patients' informed desire although it is the participant who may have to pay for it.

- *"… If it's worth it to you to not have it in your body then, certainly, we'll do it. But just make sure you understand the risks of taking it [out], as opposed to, the risks of keeping it in [but turned off]."*

Conclusion: There was broad agreement that removing neural components of the device carried risks associated with neurosurgery. However, researchers expressed various views on the acceptability of taking these risks. Researchers also appealed to distinct categories of risk relevant to device removal:

1) Physical
2) Financial
3) Opportunity costs
4) Psychological
5) Other unknown risk of long-term dormant device

Researchers expressed a commitment to honoring a participants' informed preferences for device removal. A more exhaustive analysis of both medical and non-medical risks associated with device removal will help to ensure that participants' preferences are fully informed.



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