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Beyond “ensuring understanding”: Toward a patient-partnered neuroethics of brain device research

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Introduction

The work of Sankary et al. provides valuable insights into the experiences of participants exiting brain device research. Empirical bioethics research such as this is critical to understanding the range of perspectives and experiences of participants in these trials, to identifying shared and divergent viewpoints, and (ideally) to incorporating lessons learned into the conduct of future trials. We support many of their recommendations, including for clearer communication and advanced post-trial planning.

However, we encourage the authors – and the broader neuroethics community – to critically examine the recommendations proposed herein. For example, Sankary et al state that their findings, “suggest researchers and sponsors should ensure clinical trial participants understand what ongoing support and follow up care will be provided after exit from research,” (Sankary et al. 2021, 16). While such a proposed minimum standard is consistent with traditional notions of informed consent, it inherently treats the participants in this research as passive recipients of the standards and protocols deemed appropriate by the researcher. In this model, the participants’ primary role is simply to “understand.”

In this Open Peer Commentary, we suggest that their data *about* patients also speaks to a greater need for conducting studies *with* patients as engaged partners. We discuss the ethical basis for patient engagement in research and suggest opportunities to draw on existing models of patient-partnered research that could enhance the ethical conduct of brain device research. We also touch on potential pitfalls of patient engagement that remain in need of further examination.

Ethical and Empirical Rationales for Patient Engagement in Research

The growth of interest in patient engagement in research over the last decade cannot be overstated. A quick search of PubMed retrieves 797 publications using the term in 2021, compared to only 36 in 2011. These results are driven in part by the founding of many large, government-funded research organizations specifically focused on patient

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engagement, including the Patient-Centered Outcomes Research Institute in the United States, the Strategy for Patient-Oriented Research within the Canadian Institutes for Health Research, and the United Kingdom's Centre for Engagement and Dissemination within their National Institute for Health and Care Research. However, the roots of the current push for patient engagement in research, as well as the ethical arguments in support of it, date back many decades.

Historians trace the emergence of this paradigm to the concept of “action research,” coined by psychologist Kurt Lewin in the 1940's. Lewin sought to reframe research not as a distant academic exercise, but as a tool for understanding and solving the social problems perceived as most pressing by the affected communities themselves (Duran and Wallerstein 2018). These ideas were further developed by Latin American philosophers and activists in the 1970s, including Brazilian philosopher Paulo Freire. Freire and colleagues challenged the notion of research as a value-neutral exercise and sought to expose the potentially exploitative nature of the scientific enterprise. They saw the need to engage communities as partners – as opposed to objects – of research as a social justice imperative. They also challenged the ability of researchers to understand an objective reality without directly engaging with the subjective experiences of participants, pointing to community engagement in research as, “an indispensable component of the process of both learning and knowing,” (Freire and Macedo 1995). These ideas remain central to many contemporary models of patient engagement (Duran and Wallerstein 2018).

In addition to these ethical arguments, there is empirical evidence of the value of robust patient engagement for research success. For example, a systematic review comparing studies with and without patient engagement found that involvement specifically of people with lived experience of the condition under study was significantly associated with improved enrollment when compared to studies with no such engagement (Crocker et al. 2018). Further, both patients and researchers report that patient engagement contributes to research feasibility, acceptability, rigor, and relevance to the communities intended to benefit from the knowledge gained (Forsythe et al. 2019).

Meanings and Models of Patient Engagement in Clinical Research

Despite the proliferation of interest, the concept of patient engagement itself still suffers from an acute lack of clarity with regard to its meaning, as well as a diversity of conflated term, including, “participant engagement,” “patient participation,” and “patient involvement.” Indeed, a recent assessment of standards for patient engagement in research noted a “striking lack of clarity” in both the concept itself and its implementation (McCoy et al. 2018). In addition, the phrase patient engagement is often used to refer to the practice of engaging individual patients in making decisions about their own clinical care, which is a separate area of inquiry.

There are a range of contemporary research approaches focused on patient or community engagement, including collaborative research, community-based participatory research, participatory evaluation, and participatory action research, to name just a few. A comprehensive review of these many overlapping approaches is beyond the scope of

this commentary. However, the central, shared feature of these varying approaches is the involvement of representatives of the population on which the research focuses as members of the research team (Duran and Wallerstein 2018). For example, the Patient-Centered Outcomes Research Institute (PCORI) defines engagement as, “the meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders throughout the entire research process—from planning the study, to conducting the study, and disseminating study results,” (<https://www.pcori.org/engagement/value-engagement>). This and other approaches encourage researchers to engage in an ongoing partnership with patient communities in the development of knowledge (Duran and Wallerstein 2018; Forsythe et al. 2019).

Neuroethics and Patient Engagement – A Call for Change

Research on patient perspectives, such as that of Sankary et al., provides valuable tools to support patient engagement in neural device research. However, such work is not a substitute for patient engagement itself. Were patients directly engaged as partners in this research, their role would inherently shift from a passive one of simply understanding study protocols and procedures decided by researcher, to one in which they contribute directly to the design and implementation of such procedures. They would and should be involved in directly determining the obligations of researchers and funders, including in the post-study period. Further, reports suggest that many patients are willing and eager to engage in such discussions (Riggare, Stecher, and Stamford 2020; Welle 2022). Ongoing and robust patient engagement in brain device research could not only increase patient understanding but also ensure that concerns or objections patients may have to the planned study procedures are addressed at the outset of the study, leading to better outcomes for both the patients and the researchers.

Given both the ethical and empirical arguments for patient engagement, neuroethics can and should play a leading role in encouraging and facilitating robust patient engagement. In doing so, neuroethicists can draw upon established models and initiatives noted above. For example, PCORI’s engagement rubric emphasizes the importance of reciprocity, partnership, transparency and trust between researchers and participants – themes that resonate with the narratives of many of the participants in the work by Sankary et al. In addition, they emphasize the need for engagement throughout the research process, ideally even in the development and design of the study itself. Indeed, earlier patient engagement in brain device research may have avoided the circumstances witnessed in the recent workshop on post-trial responsibilities, sponsored by the BRAIN Neuroethics Working Group (<https://braininitiative.nih.gov/News-Events/event/brain-neuroethics-working-group-newg-workshop-continuing-trial-responsibilities>), in which patients with implantable brain devices a decade old were being asked for their perspectives on post-trial responsibilities. While this event was a critical starting point, it also highlighted the risks of deferring patient engagement far beyond when it was actually needed.

We recognize that engaging patients as partners throughout the lifecycle of brain device research is a significant undertaking—one that comes with potential pitfalls. Patient engagement raises concerns about financial conflicts of interest when patient groups are

sponsored by industry stakeholders, or when they engage in venture philanthropy, tying the health outcomes of their members to the financial success of their organizations (McCoy et al. 2017). There are also non-financial conflicts of interest, for example, when patients push for regulatory changes that could compromise the scientific integrity of research and, by extension, therapeutic options for future patients (Joffe and Lynch 2018). Finally, practical challenges include maintaining the infrastructure and human resources required for meaningful engagement and ensuring representation of diverse perspectives among patient representative (Forsythe et al. 2019). We view these challenges not as insurmountable, but rather as points to be worked through in a shift towards a patient-partnered approach to clinical neuroscience research.

In conclusion, Sankary et al. and others who have done work on assessing patient perspectives have laid the foundation for a patient-partnered approach by providing a window into patients' experiences in and expectations of research. Yet the time has come for neuroethics and neuroscience research to take the next step. We must move beyond viewing patients solely as providers of data whose role is simply understanding the protocol as planned, and toward a model of research that engages patients as partners throughout the lifecycle of neural device research.

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