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Advanced Neurotechnology and Informed Consent in Neurosurgery: Ethical and Legal Perspectives

The Challenge of Informed Consent in Neurosurgery

Obtaining informed consent is a legal and ethical requirement for all neurosurgical procedures. At the heart of informed consent is a "meeting of the minds" between the neurosurgeon and patient.[1] As surgical procedures and consent discussions have become more complex, there is a concern that this added complexity will reduce patient comprehension of the information being communicated. For example, when patients scheduled for deep brain stimulation (DBS) device implantation were interviewed, they reported a lack of retention and comprehension of the procedure despite the utilization of properly trained research coordinators relying on a standardized protocol.[2] These findings are consistent with earlier studies showing participants' difficulty recollecting discussions about post-trial care in experimental DBS trials.[3]

The challenge of informed consent is likely to become even more complex with the advent of advanced neurotechnologies that may utilize artificial intelligence (AI), such as Responsive Neurostimulation (RNS) for treatment-resistant epilepsy.[4] When advanced neurotechnology enter the clinic, it will remain the neurosurgeon's ethical and legal responsibility to communicate effectively with patients about the advanced neurotech device and the procedure to implant it.[5]

Legal and Ethical Foundations

United States courts have long recognized a patient's right to self-determination.[6] In a landmark 1914 case, Judge Cardozo held that "[e]very human being of adult years and sound mind has a right to determine what shall be done with [their] own body..."[7] Healthcare providers can be exposed to liability if they withhold information pertinent to the patient making an educated and informed choice.[5] This legal liability is typically grounded in the tort claims of battery and negligence. Ethically, an obligation for informed consent is founded in the principle of respect for autonomy.[8] The American Association of Neurological Surgeons Code of Ethics includes this principle of "respect for autonomy,"[9] and it is a core biomedical ethics principle as well. At a minimum, an ethical informed consent process should include discussion of the diagnosis, the surgical treatment along with its risks and benefits, as well as the alternative options, including doing nothing.[8]

While there is agreement that promoting patient autonomy by obtaining meaningful informed consent is necessary, there is significant confusion about what is legally required. While variances exist between jurisdictions, generally there are three legal standards used in the U.S., and these standards vary in the type and level of information that must be provided to the patient. These standards are: (1) what a reasonable physician would provide; (2) what a reasonable person would want to hear; and (3) the subjective standard test: what this particular patient would need to understand in order to make an educated decision.[8] In more than half of the U.S. the reasonable physician standard is used, but there is significant variation because these standards leave room for interpretation and may differ between jurisdictions applying them.[5,6] For instance, a patient's preferred level of understanding before proceeding with a procedure can depend on their values.[8] Neurosurgeons should be sensitive to the reality that what a patient desires from the consent process will depend on the patient's cultural background, preferred learning modality, and level of trust in the medical establishment. In particular, trust in the medical establishment may be eroded in marginalized populations and communities of color.[10,11]

Additional guidance and requirements from the Federal Policy for the Protection of Human Subjects (the "Common Rule") are applicable if the neurosurgery is part of research that is federally funded, federally conducted, or conducted by an institution that renders a broad Federalwide Assurance (45 C.F.R. Part 46).[12,13] Food and Drug Administration (FDA) informed consent requirements (21 C.F.R. § 50.20) may also be applicable. The Common Rule states that the informed consent process "must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized


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representative's understanding of the reasons why one might or might not want to participate."[13]

Informed Consent and Liability with Procedures Involving Advanced Neurotechnologies

Where informed consent does not conform to legal requirements, a remedy available to patients is a medical malpractice suit. Neurosurgeons are familiar with this possibility, as neurosurgery is a specialty that is among the most likely to be a defendant in medical malpractice suits.[14] Informed consent is not infrequently one of the pillars of a neurosurgery malpractice claim. A recent review found that in neurosurgery malpractice litigation, informed consent is raised in 8% to 43% of the cases.[15] When informed consent is litigated, at issue will be the duty to disclose all risks and alternatives, and whether a breach of this duty to disclose caused the harm.[6]

The ever-growing complexity of neurotechnologies with semi-autonomous functionalities, like RNS, will make it more difficult for a neurosurgeon to (1) fully understand the technology, and then (2) effectively communicate "all risks" of the implanted device during the informed consent process.

Fully understanding how new therapeutic and diagnostic neurotechnologies work is not necessarily in the purview of the neurosurgeons implanting them. While neurosurgeons will surely have a high level of familiarity with the devices, given the intricate engineering required for device fabrication "[n]o single neurosurgeon can master all these domains, as talented as [they] may be."[16] Yet the key defendant in malpractice claims will often be the neurosurgeon,[5,17] and there will be a need to become familiar with issues such as potential algorithmic bias and data privacy related to the implantable device.

Given the coming advances in implantable neurotechnologies that utilize AI, especially those with "black box" algorithms whose underlying mechanisms are poorly understood, we see a need for revisiting the standard of care as it relates to informed consent. Prior legal scholarship in AI shares these medical liability concerns and highlights the asymmetry in information between what we want a patient to know and what we can actually tell the patient due to an algorithm's "dynamic inscrutability."[18]

One additional possibility would be to consider an expansion of products liability claims in this space. In general, the warning defect doctrine holds that the distributor of a product remains liable for a party's injuries if the purchaser is not adequately warned about the product's risks.[6] Scrutiny could be given to the warnings provided to the surgical team by the manufacturer. Other alternative frameworks are possible, as is improving training for providers on the complexities of these technologies.[17]

Toward New Standards for New Technologies

Legal standards strike a balance between respecting the patient's autonomy to make an educated decision about a procedure, and recognizing that neurosurgeons cannot and should not be required to share with patients every detail of a complicated procedure and technology. Legal standards have shifted in the past, and they will need to be revised again in light of new neurotechnologies on the horizon.

Now is the time to begin a dialogue with a diverse range of stakeholders, including patients, community members, device manufacturers, neurosurgeons, insurers, and regulatory authorities along with neuroethics and neurolaw experts.[19] Central to the success of this collaborative process will be the inclusion of individuals at the historical margins of society due to their race, language, religion, and other identifiers. These patients' providers may leave them misinformed disproportionately, whether intentionally or not, and they may face other biases embedded in the neurotechnologies themselves.[10,11]

Meeting of the minds in informed consent requires a joint effort by neurosurgeons and patients. The process for defining informed consent standards in the wake of advancing neurotechnologies should similarly be grounded in deep and lasting engagement between clinicians, patients, researchers, and manufacturers.[20,21]

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References:

1. Wecht, J. Shinal v. Toms M.D. (2017).
2. Wexler, A. et al. Ethical Issues in Intraoperative Neuroscience Research: Assessing Subjects' Recall of Informed Consent and Motivations for Participation. *AJOB Empir. Bioeth.* 13, 57–66 (2022).
3. Lázaro-Muñoz, G. *et al.* Post-trial access in implanted neural device research: Device maintenance, abandonment, and cost. *Brain Stimulat.* 15, 1029–1036 (2022).
4. Boddeti, U., McAfee, D., Khan, A., Bachani, M. & Ksendzovsky, A. Responsive Neurostimulation for Seizure Control: Current Status and Future Directions. *Biomedicines* 10, 2677 (2022).
5. Hodge, S. & Steinhaus, M. The Ever-Changing Landscape of Informed Consent and Whether the Obligation to Explain a Procedure to the Patient May Be Delegated. *Ark. Law Rev.* 71, 727-760 (2019).
6. Schuck, P. H. Rethinking informed consent. *Yale Law J.* 103, 899–959 (1994).
7. *Schloendorff v. Society of the New York Hospital, 211 N.Y. 125 (1914).*

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