



Definition of Implanted Neurological Device Abandonment

A Systematic Review and Consensus Statement

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Abstract

IMPORTANCE Establishing a formal definition for neurological device abandonment has the potential to reduce or to prevent the occurrence of this abandonment.

OBJECTIVE To perform a systematic review of the literature and develop an expert consensus definition for neurological device abandonment.

EVIDENCE REVIEW After a Royal Society Summit on Neural Interfaces (September 13-14, 2023), a systematic English language review using PubMed was undertaken to investigate extant definitions of neurological device abandonment. Articles were reviewed for relevance to neurological device abandonment in the setting of deep brain, vagal nerve, and spinal cord stimulation. This review was followed by the convening of an expert consensus group of physicians, scientists, ethicists, and stakeholders. The group summarized findings, added subject matter experience, and applied relevant ethics concepts to propose a current operational definition of neurological device abandonment. Data collection, study, and consensus development were done between September 13, 2023, and February 1, 2024.

FINDINGS The PubMed search revealed 734 total articles, and after review, 7 articles were found to address neurological device abandonment. The expert consensus group addressed findings as germane to neurological device abandonment and added personal experience and additional relevant peer-reviewed articles, addressed stakeholders' respective responsibilities, and operationally defined abandonment in the context of implantable neurotechnological devices. The group further addressed whether clinical trial failure or shelving of devices would constitute or be associated with abandonment as defined. Referential to these domains and dimensions, the group proposed a standardized definition for abandonment of active implantable neurotechnological devices.

CONCLUSIONS AND RELEVANCE This study's consensus statement suggests that the definition for neurological device abandonment should entail failure to provide fundamental aspects of patient consent; fulfill reasonable responsibility for medical, technical, or financial support prior to the end of the device's labeled lifetime; and address any or all immediate needs that may result in safety concerns or device ineffectiveness and that the definition of abandonment associated with the failure of a research trial should be contingent on specific circumstances.

JAMA Network Open. 2024;7(4):e248654. doi:10.1001/jamanetworkopen.2024.8654

Key Points

Question What definition for neurological device abandonment can be developed through consensus?

Findings This systematic review and consensus statement reviewed 734 articles published in the professional literature and found that 7 were relevant to or addressed the issue of neurological device abandonment. A multistakeholder group developed a consensus definition for neurological device abandonment inclusive of devices used in deep brain stimulation, vagal nerve stimulation, and spinal cord stimulation, including failures related to patient consent, support before the end of the device's lifespan, and safety concerns.

Meaning This study established a formal definition of neurological device abandonment, which may be important for development of guidelines, policies, and laws that collectively have the potential to reduce or prevent such abandonment.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Introduction

Patients who have received implanted neurological devices, such as deep brain, vagal nerve, and spinal cord stimulation, will be increasingly abandoned.^{1,2} This phenomenon of device abandonment will increase coincidentally with neurotechnology market growth as increasing types and sophistication of implantable devices are made commercially available, older iterations of neurotechnology become obsolete or more difficult to maintain, and health care insurance coverage fails to keep pace with these realities. The topic and definition of abandonment was recently debated at the Royal Society Summit on Neural Interfaces (September 13-14, 2023) and resulting therefrom, we reviewed the literature and developed a preliminary definition for implantable neurological device abandonment based on the existing data and experience of experts in the field.

Considering the expanding device abandonment phenomenon, we suggest that it will be critical to define shareholder and stakeholder groups and their respective needs and priorities within the expanding current and proposed environments of implantable neurotechnology use. As strongly advocated by the disability movement, the adage of “nothing about us without us” aptly characterizes active roles that shareholders and stakeholders³ should play in clinical trials conducted to generate evidence of safety and efficacy, as well as processes, guidelines, and laws required for sound commercialization, provision, access, monitoring, and economic support of extant and emerging devices.

The most important stakeholders are patients receiving these neurotechnology implants. This is because while the involvement of other shareholders and stakeholders will likely wax and wane over the utility lifetime of a device, the relationship of the patient with the device is perdurable; namely, it provides the patient with a means toward sustaining personal agency.⁴ Thus, although these devices are not generally considered to be life-sustaining or life-supporting in the absolute sense, we argue that their value in qualitative life sustenance and support cannot and should not be denied, neglected, or abandoned. In this study, we refer to patients and participants interchangeably. The authors recognize that these terms refer to the people living with neurological conditions and that there are many roles within the health ecosystem. The context of this study is for specific roles that people with lived experience have within the clinical and research environment present during the time of implant and management of their neurological device.

In this study, we sought to more clearly define involved stakeholders, their respective roles and responsibilities, and circumstances and premises that constitute abandonment of patients who have active implantable technologies that are intended to diagnose, treat, or otherwise mitigate neuropsychiatric diseases, injury, and conditions; therefrom, we sought to offer a standardized definition of abandonment of active implantable neurotechnological devices. Throughout, we use the term *abandonment* to mean a failure to actively support medical needs of patients who, through no fault of their own, do not possess the medical, technical, or financial capabilities to maintain the safe and effective use of a durable implanted neurotechnological device.

Methods

Following a Royal Society Summit on Neural Interfaces, a systematic review of articles in English using the PubMed search engine was undertaken to investigate extant definitions of neurological device abandonment (**Figure 1**). Articles were reviewed for relevance to neurological device abandonment in the setting of deep brain, vagal nerve, and spinal cord stimulation. An expert review group was convened to summarize findings, add subject matter experience, and apply relevant ethics concepts and any missing literature. The group proposed a current, operational definition for neurological device abandonment. The group also addressed device durability and insolvency of device companies. Data collection, study, and consensus development were conducted between September 13 to 14, 2023, and February 1, 2024. The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting guideline was used. Our PubMed review used the

search terms *abandonment and deep brain stimulation, abandonment and neuromodulation, abandonment and neurological devices, retention and deep brain stimulation, device malfunction and deep brain stimulation, device removal and deep brain stimulation, abandonment and vagal nerve stimulation, and abandonment and spinal cord stimulation.*

Results

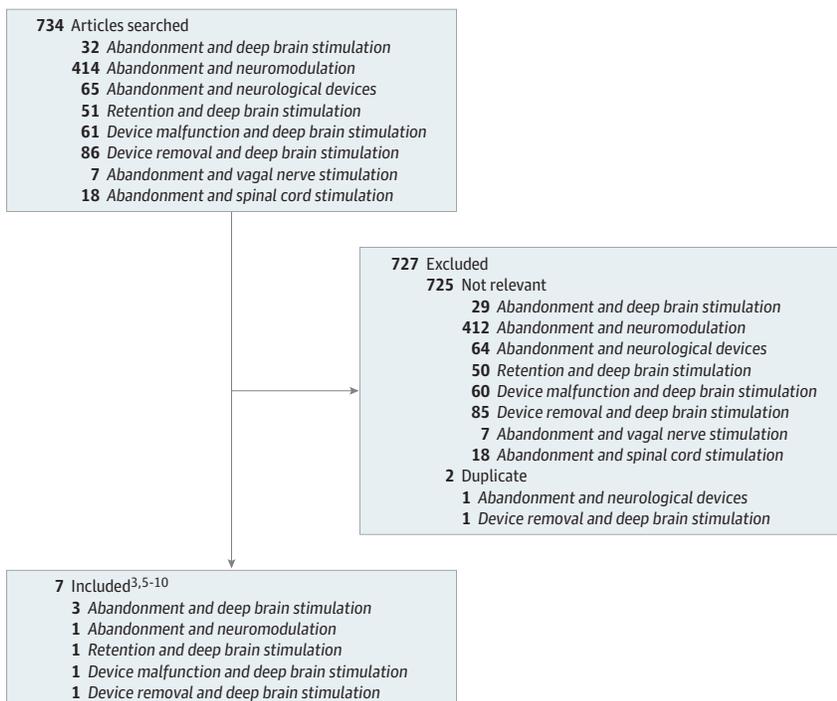
The expert consensus group consisted of 3 neuroethicists (F.G., G.L.M., and J.G.), 2 neuroscientists with experience in device engineering (S.P.D. and T.D.), 2 patients with implanted devices (S.P.D. and J.F.), 1 neurologist (M.S.O.), 1 neuropsychologist (C.K.), 1 neurosurgeon (who also founded a device company; J.E.), 1 neurological device regulatory specialist (T.M.), and 1 policy representative from the Royal Society (J.P.). One member of the group (S.P.D.) was counted as both a neuroscientist and a patient with a neurological device implant. Figure 1 summarizes the search strategy, which revealed that of 734 articles identified, 7 articles^{3,5-10} were related to or addressed neurological device abandonment.

The consensus group discussed findings and contributed additional professional and personal experience and other relevant peer-reviewed ethics constructs and articles to propose a preliminary comprehensive definition for neurological device abandonment. The group addressed stakeholders and their respective responsibilities and operationally defined the context of abandonment, whether clinical trial failure constituted abandonment, and if and to what extent shelving of devices impacts abandonment, as defined. Finally, based on the literature, discussion, and expert experience, the group proposed a standardized definition for abandonment of active implantable neurotechnological devices.

Stakeholders and Their Respective Responsibilities

In addition to the patient, key stakeholders include clinician-scientists, family members, and device manufacturers. All presumably share a common goal of improving patients' lives, yet various

Figure 1. Article Search Strategy



stakeholders may have additional incentives and aims that may not completely support or sustain patient benefit. For example, although the clinician's primary fiduciary responsibility is to the patient, clinician-scientists can have 2 fiduciary responsibilities: patient care and contributing to scientific knowledge, and these may be in tension if not frank conflict. Feinsinger and colleagues¹¹⁻¹³ have argued that clinician-scientists' primary responsibility is always to patients while contribution to scientific inquiry and knowledge is secondary. However, there is some ambiguity in defining if and how the pursuit of scientific inquiry may result in direct benefit to patients in a clinical trial, and it should be appreciated that negative trials may also be associated with potential benefits.¹⁴⁻¹⁶ Beyond the clinical and research encounter, it is important to acknowledge that device manufacturers have fiduciary responsibility qua fiscal responsibility to their boards and shareholders given that considerable resources have been invested in the development and funding of clinical trials.^{17,18} Finally, it should be recognized that device manufacturing companies also have a responsibility to ensure their own credibility and reputation.

Such variation in stakeholder fiduciary responsibilities can lead to situations in which patients have received a medical device that may be beneficial but ongoing access to the device and the expertise and finances required to manage the device may not be guaranteed after implant. We contend that this is especially problematic in the context of active implanted neurotechnology for several reasons. First, the severity of signs and symptoms of patients enrolled in clinical trials may render these individuals at somewhat more risk. Second, there are potentially greater risks associated with neurosurgical intervention and possible effects of neurostimulation on cognition, emotion, and behavior, which would require ongoing monitoring and intervention (eg, adjustment of device performance parameters). Third, failure to monitor and maintain the implanted technology could lead to recidivistic and perhaps rebound signs, symptoms, and effects in such patients, which may create additional burden and harms. Fourth, and as an undergirding ethical construct, longitudinal evaluation and maintenance of implanted devices are essential to the intended purpose of the trial (ie, to assess the safety, effectiveness, and relative efficiency of the technology,¹⁴ overarching goals of science via the acquisition of knowledge with intent to advancing public good, and essence of medicine: to provide right and good care of patients who are the subject of clinician moral and technical regard).^{19,20} More information on defining and sustaining fiduciary responsibility and country specificity can be found in the eAppendix in [Supplement 1](#).

Operationally Defining This Context of Abandonment

In general, medical abandonment is formally defined as an abrogation of clinical responsibility as incurred by a clinician's unilateral termination of their treatment of a patient in need absent provision of adequate notice to or support for the patient to obtain substitutional care. However, as it relates to abandonment of care in circumstances wherein a patient receives an implant of an active neurotechnological device, a standardized definition that fully and granularly captures and obtains the specifics of such dissolution of responsibility has not been established, to our knowledge. While issues described in this study may also be applicable to noninvasive neurological technologies, the nonindwelling nature of such devices fails to evoke many of the same concerns. Existing notions of what constitutes device abandonment may depend on the relative perspective and values of the clinician, patient, family member, device manufacturer, and insurance company. The Royal Society Summit on Neural Interfaces meeting (September 13-14, 2023) highlighted the need for an improved definition of implantable neurological device abandonment.

Patient experience has established several factors associated with abandonment, including lack of payer support for device maintenance and replacement, the paucity or complete absence of plans for continued provision, and the use of other investigational devices when companies dissolve or cease manufacturing or providing services for a particular product. These challenges emphasize a need for technology-related guidelines and policies to ensure services to sustain patient involvement and accommodate long-term patient needs.²¹ Furthermore, ethical concerns about neurotechnological device abandonment arise, at least in part, because neural systems are relatively

functionally and to some extent structurally plastic. Thus, the introduction of device hardware (eg, electrodes) into the nervous system parenchyma and the actual modulatory effect of such instruments can create alterations in neurological node and network activity, which may manifest as alterations in cognitive, emotive, or behavioral domains. Simple discontinuation of the function of the device can and has been noted to evoke changes in the pathology treated and aspects of individual capacity and agency.²²

Ensuring patient and participant awareness of these outcomes and the contingencies of continued care is paramount to the probity of obtaining their consent to participate in a clinical trial or agreement to receive an implanted device.^{23,24} Indeed, to uphold the ethical probity of any treatment or trial of such neurotechnology, genuine informed consent must address potential benefits, burdens, and risks associated with the specific device and patient understanding of associated outcomes that could arise.^{23,25,26}

Is Clinical Trial Failure Abandonment?

An important consideration in developing a realistic definition of device abandonment is that clinical trials often fail to achieve their desired outcomes. To be clear, trial failure is not abandonment. While the guiding maxim for clinical care is benevolence (ie, a desire to maximize the good), the undergirding principle of clinical research in reality is nonmaleficence (ie, nonharm), given that the intended idiosyncratic and more generalized goods of any research investigation remain uncertain through the course of the study.^{23,27-29} Therefore, overarching responsibility and measures to avoid harm afford a sound moral keel for any research enterprise despite the omnipresent chance of failure to achieve good ends as desired by intention and design. Trial failure can arise from safety concerns or lack of efficacy or effect, and hence discontinuation represents responsible action to avoid undue burden and harm.

However, for trial termination to remain contrary to abandonment and axiomatically nonmaleficent, it is essential for 3 things to occur. First, study participants should be informed about the possibility of discontinuance owing to such concerns about safety and inefficacy, as well as their relative assignment to treatment or control arms of the investigation. Although this information is important, patients may have difficulty understanding or retaining it. This can lead to possible therapeutic misconception and misperception by the patient of clinical abandonment.³ Second, participants should be notified if and when the trial is being terminated. Finally, researchers in charge of the study should provide participating patients resources and vectors for other therapeutics that meet accepted standards of care. To be sure, any definition of abandonment must specify these distinctions of trial failure vs abandonment.

It is critical to disaggregate and disambiguate a failed clinical trial from a failed potential therapy. Clinical trials of active implantable neurotechnologies offer unprecedented opportunities not only to afford possible benefits rendered by successful outcomes, but also to more thoroughly investigate mechanisms of devices in question and neural structures and functions they affect. This information can lead to foundational knowledge about brain-behavior relationships that may afford viable targets to alleviate research participant and subsequent patient suffering and debility. Accomplishing these goals depends on the trial design, including choice of outcome measures, modulation parameters, surgical site, definition of benefit, timeline to assess outcomes, power analyses, variability in research participant characteristics and sign or symptom presentation, differences in surgical approach, and relevant neurophysiology.¹⁴ Variables that may contribute to trial failure are provided in the eAppendix in [Supplement 1](#).

Shelving Devices and the Association With Abandonment

A more complex issue can arise when a particular implantable neurotechnological device is demonstrated to have efficacy in a clinical trial but then fails to translate to use in practice owing to stakeholder agendas. We refer to this circumstance as shelving. It can occur when an interventional approach is deemed to be implementable, safe, and effective but is prevented from being used in

clinical care owing to ongoing issues, tensions, or conflicts in corporate intellectual property control or other licensing agreements. This can occur when companies have breakdowns in relations with a clinician-inventor or when a change in commercial strategic direction for funding to support clinical translation leads to intentional buy and block impediment of further treatment. Although this may be explicitly contrary to fundamental ethical principles guiding humanitarian considerations, it is legal as a matter of fact. At present, there is no explicit pull mechanism to ensure rollout and provision of a proven therapy after a successful clinical trial. Thus, there is potential for abandonment for non-therapeutic or health economic reasons. See the eAppendix in [Supplement 1](#) for more information on shelving of devices.

Device Durability and Association With Abandonment

Given that these are new technologies, it is important to address the durability of any implanted device. Durability of a neurotechnology refers to the time that the device or system remains functional and effective without requiring excessive maintenance or repair throughout its span of use. This includes the device as a single entity and as a levelled iteration (eg, versions 1.0, 2.0, and beyond) or category (eg, unipolar deep brain stimulation electrodes vs multipolar electrodes) of a therapeutic tool. Given the rapid pace of development and progress in neuroscience and technological applications in research and clinical care, what works and may be considered as cutting edge or at least a viable standard of care today may not be regarded as state of the field or even adequately effective tomorrow.^{27,30} Patients should be informed of these possibilities and realities as an element of obtaining their consent so as to afford insight and judgment about future considerations of acquiring care as may be required and, thereby, avoiding abandonment, as mentioned previously.

Addressing Insolvency of Device Companies

Finally, there are numerous examples of neurotechnology companies becoming insolvent. For example, the commercial entity Neurovista (date of insolvency, August 2013), which was developing a first-in-human brain implant, declared bankruptcy, and patients who received implants with the technology felt betrayed. The sentiment was fortified by patient therapeutic expectations and by the perception that an unsettling break in trust had occurred. Recent reports provide evidence that 1 patient who was part of the trial compared the experience to a sense of loss or theft, stating, "They took away that part of me," which the individual felt compromised their agency and in this way left them abandoned to an absence of care.^{2,31} It is important to bear in mind that such devices are regarded as enabling technologies,^{23,27,32-35} and therefore, it is vital to consider and respect the degree to which some patients may identify with these devices as constituent to their identities and personalities.^{31,36-42} The distress they experience may in some cases be directly proportional to the effectiveness of the technology and their subjective relationship with it.

In cases of device maintenance or replacement (with repaired or newer versions), payers will surely play a role in determining sustainability of resources and services that can be provided to patients. We posit that any genuine discussion and actions toward defining and preventing neurotechnological device abandonment must address the value of payer conjunction to the enterprise in ways that are supportive and facilitative to positive, beneficent ends. Failure of this sector participation would render any such efforts toward these goals problematic at least, if not impossible in reality. Lessons learned from prior and current experience with the payer sector may serve as key pediments toward bridging extant gaps in the regnant system and conduct of health care support.²⁵

It should be noted that when explantation or removal of a device is necessary, it will be important to address challenges of who will pay for expenses incurred. To be sure, future efforts will need to clarify the status of abandoned devices (eg, defective devices, those no longer functioning after battery depletion, or functional devices providing waning benefit). Therefore, the safety and ethics of device removal will need to be determined for each case, with special considerations

afforded to whether a future upgrade in the software or change in management strategy could convert a nonfunctioning device to a functioning device.

Discussion

Toward a Standardized Definition for Abandonment of Active Implantable Neurotechnological Devices

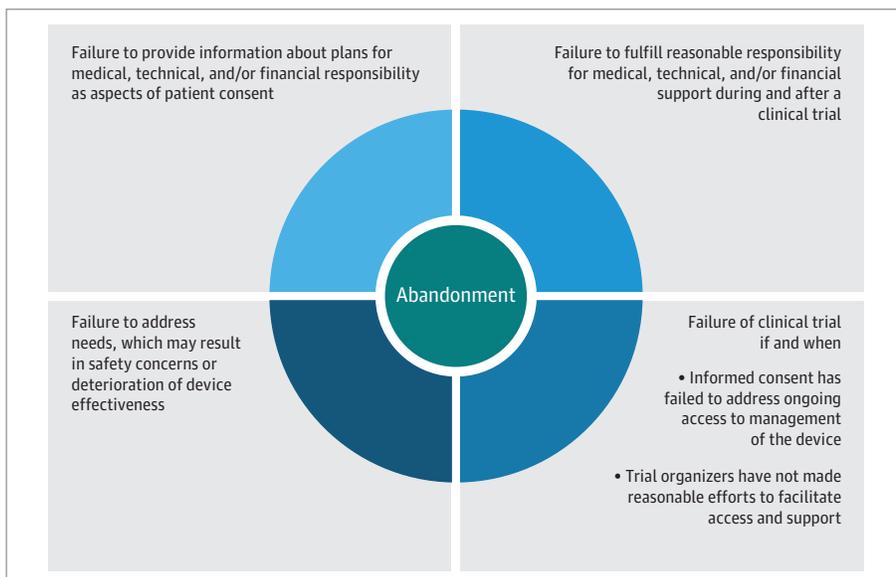
Apropos to the previously mentioned facts, factors, considerations, and concerns provided in this systematic review and consensus statement, we propose the adoption of a standard definition of abandonment of active implantable neurotechnological devices, which constitutes 1 of the following (Figure 2):

1. Failure to provide information relevant to (the existence or absence of) plans for medical, technical, and/or financial responsibility as fundamental aspects of patient consent during and after a clinical trial.
2. Failure to fulfill reasonable responsibility for medical, technical, and/or financial support prior to the end of an implantable device's labeled lifetime.
3. Failure to address any immediate needs (eg, infection or device programming) of the individual using the implanted device, which may result in safety concerns and/or the deterioration of device effectiveness.
4. Failure of a clinical research trial if or when (1) informed consent has failed to address ongoing access to and management of the implanted device (per 1) and/or such other devices that may be demonstrated as having equal or greater therapeutic value in the future and (2) individuals responsible for the trial have not made a reasonable effort to facilitate continued access to device and support for patients who benefit from the device.

Limitations

This study has several important limitations. First, because the field currently lacks a formal, accepted definition of device abandonment, it is possible that the literature review and expert group could have missed relevant aspects of abandonment. Second, the literature was sparse on this topic, and

Figure 2. Failures That May Constitute Neurological Device Abandonment



This figure addresses the 4 failures, any of which may constitute device abandonment.

thus it will be likely that as more publications become available, these works could help refine future definitions. Third, our review did not examine similar abandonment challenges in cardiac pacemaker and related technologies. However, we performed a review of 232 additional articles using the search terms *abandonment and pacemaker*, which revealed 41 relevant articles that afforded comparative illustration of abandonment challenges that were similar in cardiac and neural technology implant cases. These challenges included magnetic resonance imaging-induced heating of partially abandoned devices, infections, broken lead fragments, and capping of a disconnected device. We anticipate that challenges similar to those noted for cardiac pacemaker use would increase in number as more neurological devices are implanted. Hence, we posit that definitions and issues of device abandonment will continue to evolve and therefore will require ongoing attention as neurotechnologies are further developed and in the contexts of current practices.

Conclusion

In this systematic review and consensus statement, a comprehensive literature review on neurological device abandonment revealed that this ethical issue was largely buried within case reports, case series, and clinical trials. Dialogue like that recently conducted at the Royal Society, with the convergence of stakeholders and combined with experience has the potential to yield a more functional definition of neurological device abandonment. We opine that these tenets previously listed may afford a working basis for further consideration, discourse, and dialogue toward establishing a formal definition of abandonment of active implantable neurotechnological devices and guidelines, policies, and laws to prevent its occurrence. We encourage such discussion and welcome participation to advance such ends, especially as devices expand into neuropsychiatric indications.

ARTICLE INFORMATION

Accepted for Publication: February 27, 2024.

Published: April 30, 2024. doi:10.1001/jamanetworkopen.2024.8654

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Author Contributions: Drs Okun and Giordano had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: All authors.

Acquisition, analysis, or interpretation of data: Okun, Ekanayake, Kubu.

Drafting of the manuscript: Okun, Marjenin, Ekanayake, Gilbert, Doherty, Kubu, Lázaro-Muñoz, Giordano.

Critical review of the manuscript for important intellectual content: Okun, Marjenin, Ekanayake, Doherty, Pilkington, French, Kubu, Lázaro-Muñoz, Denison.

Administrative, technical, or material support: Ekanayake, Pilkington, Denison.

Supervision: Okun, Ekanayake.

Conflict of Interest Disclosures: Dr Okun reported serving as a medical advisor to the Parkinson's Foundation; receiving research grants from the National Institutes of Health (NIH), Parkinson's Foundation, Michael J. Fox Foundation, Parkinson Alliance, Smallwood Foundation, Bachmann-Strauss Foundation, Tourette Syndrome Association, and University of Florida Foundation; serving as principal investigator of an NIH Training Grant; receiving royalties for publications with Hachette Book Group, Demos, Manson, Amazon, Smashwords, Books4Patients, Perseus, Robert Rose, Oxford University Press, and Cambridge University Press; serving as an associate editor for the *New England Journal of Medicine Journal Watch Neurology* and *JAMA Neurology*; participating in continuing medical education and educational activities in the past 12 to 24 months on movement disorders sponsored by WebMD/Medscape, RMEI Medical Education, the American Academy of Neurology, the Movement Disorders Society, Mediflix, and Vanderbilt University; that grants from industry were received by the University of Florida and not Dr Okun; participating as a site principal investigator or co-investigator for several NIH-, foundation-, and industry-sponsored trials without receiving honoraria; and that research projects at the University of Florida receive device and drug donations. Dr Gilbert reported receiving a Royal Society bursary award to attend the Neural Interfaces Summit 2023 and grants from the University of Tasmania EthicsLab during the conduct of the study. Dr Doherty reported receiving devices for research studies from Innocon Medical and grants from Brain Research UK, the Inspire Foundation, and Innovate UK outside the submitted work and owning less than 1% of shares in Amber Therapeutics Ltd, London, which has subsidiaries Bioinduction Ltd (maker of the Picostim and Picostim DyNeuMo, Bristol, UK, in several first-in-human studies) and Finetech Medical Ltd (manufacturer of the Sacral Anterior Root Stimulator). Dr Kubu reported receiving grants from the National Institute of Mental Health (NIMH) during the conduct of the study and having a patent issued. Dr Lázaro-Muñoz reported receiving grants from the NIH. Dr Denison reported receiving supply devices for research from Amber Therapeutics during the conduct of the study and serving as nonexecutive chairman of Mint Neuro, which makes circuits for implants, and a consultant for Cortec, which develops neurotechnology. Dr Giordano reported receiving award UL1TR001409 from the NIH National Center for Advancing Translational Sciences through the Clinical and Translational Science Awards Program, a trademark of the Department of Health and Human Services, part of the Roadmap Initiative Re-Engineering the Clinical Research Enterprise, and National Sciences Foundation Award 2113811-Amendment ID 001 and support from the Henry Jackson Foundation for Military Medicine; Strategic Multilayer Assessment Branch of the Joint Staff, J-39, US Strategic Command, Pentagon; Asklepios Biosciences; and Leadership Initiatives. No other disclosures were reported.

Data Sharing Statement: See [Supplement 2](#).

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SUPPLEMENT 1.

eAppendix. Supplementary Data

eReferences.

SUPPLEMENT 2.

Data Sharing Statement