BRAIN Initiative
Neuroethics Working Group Pre-Meeting for Continuing Trial Responsibilities Workshop

Perspectives from Patients and Caregivers

February 15, 2022

Virtual Meeting

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Executive Summary

On February 15, 2022, the Neuroethics Working Group (NEWG) of the Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Initiative held a pre-meeting for a 2022 Continuing Trial Responsibilities Workshop. The workshop will focus on research-related care responsibilities for participants in clinical trials involving implantable neurological devices and will include perspectives from the National Institutes of Health (NIH), health insurers, device manufacturers, patients, caregivers, patient advocates, researchers, regulators, and bioethicists. Furthermore, the workshop topics will reflect the collective belief that key stakeholder groups involved in clinical trials hold a shared responsibility to facilitate research-related trial care, yet how that care should be facilitated remains unclear.

During this series of pre-meetings, NINDS will convene relevant stakeholders to gather information that will shape the Continuing Trial Responsibilities Workshop. This pre-meeting featured the perspectives of patients, caregivers, and patient advocates. Topics highlighted as relevant to this stakeholder group included (1) enhancing communication among patients, research teams, and device manufacturers, (2) shifting the financial burden of post-trial medical needs and insurance challenges away from patients, and (3) responding to evolving technology and maintaining older technologies.

Enhancing Communication

Improving communication among patients, their families, researchers, providers, and device manufacturers can improve ongoing research-related trial care for the patient. Currently, patients must undergo informed consent processes before entering into a clinical trial; however, these interactions often do not sufficiently address expectations and outcomes of the trials, which causes patients to feel a sense of uncertainty throughout the process. Sharing expectations and decision points with patients and their families can help alleviate that uncertainty by increasing patient awareness of the possible outcomes of the trial, as well as of circumstances in which they may have choices to make related to their care. Currently, patients are not always involved in choices regarding their care—including those made during surgery or related to technological advancements that may impact future care—leaving patients and caregivers unsure of what to expect when receiving even routine medical care related to their device.

Clinicians should be also responsible for communicating information that is necessary for maintaining continuity of care; for example, clinicians may relocate or retire, leaving patients without a local clinician with experience or expertise related to a medical device. Clinicians must ensure that patients and families are referred to a suitable alternative clinician so that patients received continued access to appropriate medical care.

Enhancing communication with patients can also ensure that patients and families receive up-to-date information about the implanted medical device. Often researchers and device manufacturers learn more about a medical device throughout a clinical trial, and sometimes those findings can directly impact future patient care. For example, clinical teams may find that

the device is not compatible with other medical technology or that the device requires more frequent battery changes, both situations that will likely impact research-related care throughout the patient's life.

Communication among clinical trial teams, manufacturers, and patients can be enhanced through the designation of a patient advocate, who is tasked with ensuring that patients are aware of clinical trial expectations, outcomes, and choices, as well as helping patients and families navigate research-related care needs (such as obtaining insurance coverage and remaining aware of new research insights related to the implanted medical device).

In addition to enhancing the patient's knowledge of a medical device, improving communication can also enhance the clinical trial process. Patients provide a unique perspective, one with lived experience of both a disease and the medical device, and thus can provide the clinical team with insights that cannot be acquired elsewhere. Incorporating patients as advisors to clinical trial teams can help improve clinical trial design to best serve those whom the trial aims to benefit—the patients.

Shifting the Financial Responsibilities of Patient Medical Needs and Navigating Insurance Challenges

Current post-trial practices leave patients, caregivers, and families to handle the administrative and financial burden of future medical needs, as well as the ongoing burden of the disease. When patients enter into a clinical trial, they are accepting the risks of a novel medical device. Patients believe that accepting that risk, as well as helping scientific progress, are sufficient reasons to be compensated in the form of coverage of their financial medical needs by the device manufacturers and researchers responsible for implanting the device.

One of most pressing post-trial medical needs related to implanted devices is proper battery functioning, which, in some cases, requires frequent battery change surgeries. The burden of undergoing those frequent surgeries—typically for the rest of the patient's life—can be reduced or balanced by the knowledge that the financial costs of those surgeries will be incurred by the research and manufacturing teams, rather than the patient.

When the researchers or device manufacturers will not cover these financial costs, patients and their families must hope that their insurance plans will cover their medical needs. In most cases, patients must justify the need for medical coverage related to their implanted device, without support from clinical teams or device manufacturers. When an insurance plan does not cover the medical costs, the high cost of medical care can leave patients and families in debt for many years. Because these expense relate to life-sustaining medical care that enables a better quality of life that could be achieved with the devise, rather than to elective activities, patients believe the costs should be treated as such by insurance companies.

Evolving Technology and Maintaining Older Technologies

The medical device field has grown significantly over the past few decades. Whether a patient has a medical device that was implanted more than 20 years ago or last week can impact their

post-trial care needs; for example, older devices may require more frequent battery replacement surgeries, whereas newer devices may contain rechargeable batteries and require less frequent surgeries. For patients with older devices, the burden posed by the need for frequent surgeries is coupled with the uncertainty of whether manufacturers will continue to support their device. For example, device companies may discontinue a device or a part (e.g., a battery as no longer financially feasible to produce. These decisions can negatively impact patients who rely on that device to live, and leave patients to ascertain how they will ensure that their device continues to functioning properly.

New technologies or advancements in current technologies can improve patient care, but those advancements can also jeopardize the ongoing use of current medical devices. Balancing the development of emerging technology with the need to maintain current devices is imperative to caring for patients now and in the years to come.