Continuing trial responsibilities in implanted neural device trials: convening diverse stakeholders to facilitate research-related care

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Research-related care needs, after a trial has ended

Patients who participate in clinical trials of invasive neural devices may have medical needs related to their trial participation after the trial has ended, including, for example:

- Patients experiencing clinical benefits from the device may want to keep it, and may need:
  - Routine follow-up with a specialist
  - Device maintenance, including hardware and software (e.g., batteries)
  - Acute medical care relating to device complications (e.g., bleeding)

Current, many of these needs are inconsistently met, resulting in anxiety for patients and in some cases, high out-of-pocket costs or losing device access.

Professional stakeholder groups have a shared responsibility to facilitate research-related care needs, but it remains unclear how this may be specified and operationalized in practice.

Convening diverse stakeholders

- Patients
- Researchers
- Research institutions
- Device manufacturers
- Funders
- Regulators
- Public and private health insurers
- Bioethicists
- Device manufacturers
- Public and private health insurers
- Bioethicists
- Professional stakeholders involved in these trials have responsibilities to anticipate and plan for participants’ post-trial needs linked to trial participation, based on several ethical principles as shown.

- Non-maleficence and beneficence based responsibilities, especially, are stronger than for many other types of trial interventions. Also shown: reasons that these responsibilities may be limited.

Potential post-trial needs:
- Continued device access if the patient is benefiting
- Follow-up care and maintenance, including:
  - Specialized clinician access
  - Compatible software and hardware
  - Emergency care
- Coordination of care
- Device explantation/replacement
- Psychological support
- Clarity about future access to care and associated costs
- Accessibility of research records for new providers

Stakeholders consider several factors for determining coverage:
- “Success” of the device
- Whether the participant has insurance and which insurance
- FDA approval of device (i.e., devices have an Investigational Device Exemption (IDE))
- Sufficiency of data to qualify for CMS/private health insurance coverage
- Financial resources and leadership support from stakeholder groups
- Ability of patients to coordinate care

Workshop conclusions
- First discussion to include this breadth of stakeholders
- Importance of early multi-stakeholder conversations to plan for and support post-trial care
- Early, critical step for defining and managing reasonable expectations for post-trial care plans

Workshop highlights

- Workshop panelists argued that professional stakeholders have a shared responsibility to facilitate more post-trial care needs than what is currently being provided, given the risks and benefits involved in these trials, as well as dependency of patients on these devices.

- Workshop panelists noted that there are no perfect solutions and that there are several realities that responsibilities may have limited. Proposed strategies to address unmet needs include:
  - Collaborative stakeholder agreements to divide responsibilities and cover certain parts of care
  - Stakeholder contributions to post-trial care-related insurance funds or escrow
  - Longer-term follow-up studies
  - Early negotiations with healthcare institutions and payors (e.g., CMS)
  - Informed consent language around post-trial care needs

Selected Further Readings