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

Nina S. Hsu[1], Saskia Hendriks[1,2], and Christine Grady[2]
[1]NIH NINDS, Bethesda, MD; [2]Dept. of Bioethics, NIH, Bethesda, MD

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)

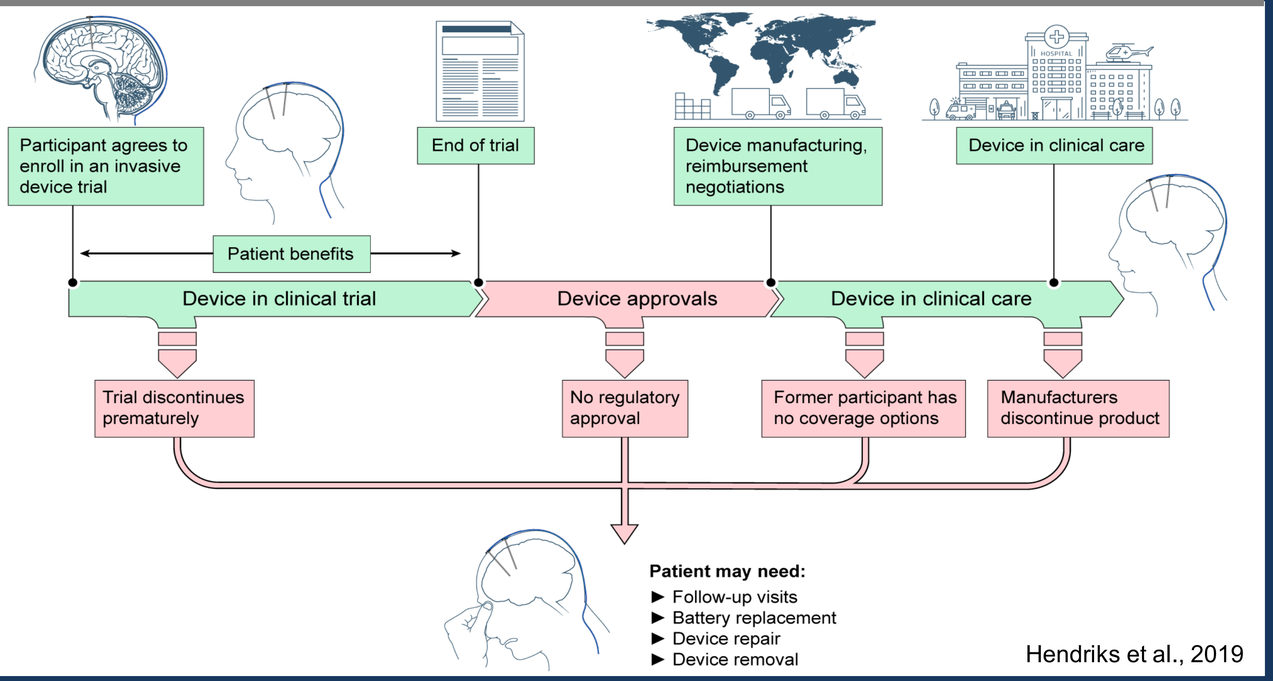
Current, many of these needs are inconsistently met, resulting in anxiety for patients and in some cases, high out-of-pocket costs or losing device access.

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

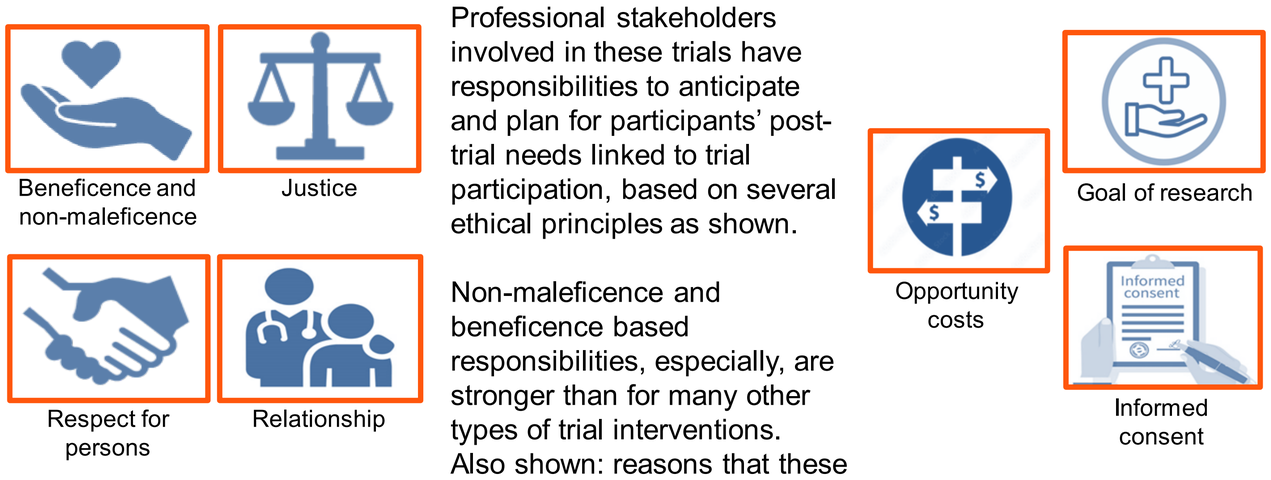
- Patients
- Researchers
- Research institutions
- Device manufacturers
- Funders
- Regulators
- Public and private health insurers
- Bioethicists

Research-related care needs – different scenarios



Hendriks et al., 2019

Underlying bioethical principles



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.

Workshop goals

This NIH workshop aimed to convene stakeholders together to discuss solutions to some of the key remaining challenges, including:

- Identifying post-trial needs
- Assessing the extent to which post-trial needs are covered
- Determining what post-trial needs should be facilitated
- Considering strategies for addressing unmet needs

The goal was to discuss reasonable expectations for research-related care plans that could eventually inform guidelines and best practices for the research community.

Acknowledgements

- Workshop panelists and participants
- NIH workshop steering committee
- NIH leadership
- BRAIN Neuroethics Working Group members

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"I've had this device for ten years. For me, this device is not an experiment anymore. We know this works. This is the only thing that did work. If I need a battery replacement or a lead fixed or any one of those things… it's a way to keep me alive. It's not an experiment anymore. We know that this works." (Patient-participant)

"When I first had the surgery, it was either that or, you know, death. So, I really didn't have that many options. I really wasn't thinking about the future too much, to be honest…Now, 3 years in, with a battery that is said to last 15 years, I'm thinking about what will happen 20 years from now." (Patient-participant)

Workshop highlights

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

Workshop Agenda
Workshop Summary
Videocast Day 1
Videocast Day 2

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

Currently, only emergency care and specialist follow-up visits are routinely covered for patients with health insurance. Many other needs are not consistently met.

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.

There are no perfect solutions and workshop participants noted initial 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

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

Selected Further Readings

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