

Five Ethical Considerations for Patient-Participant Selection and Consent: BRAIN and DBS

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1. Be Careful of Ockham's Razor
2. Not All Brain Diseases Respond Similarly
3. Dispel Media/Societal Mythology
4. Vulnerability: Not So Fast with Assumptions
5. Patients as Collaborators

BE CAREFUL OF OCKHAM'S RAZOR

Brain models as more complex and not more reductive

- More difficult task in consenting subjects (education)
- Complex disorders/systems have unexpected side-effects (difficult to predict risk)

Oversight of research

- Proper expertise in neurosciences avoids over and under protection
- Balance with efficient processes

(see discussion of research impediments in Kelly et al Neurology 2014;82:1465–1473)

NOT ALL BRAIN DISEASES RESPOND SIMILARLY

Same technology have very different time courses

- Deep Brain Stimulation [DBS] for Tremor (immediate), DBS for Dystonia (slow)

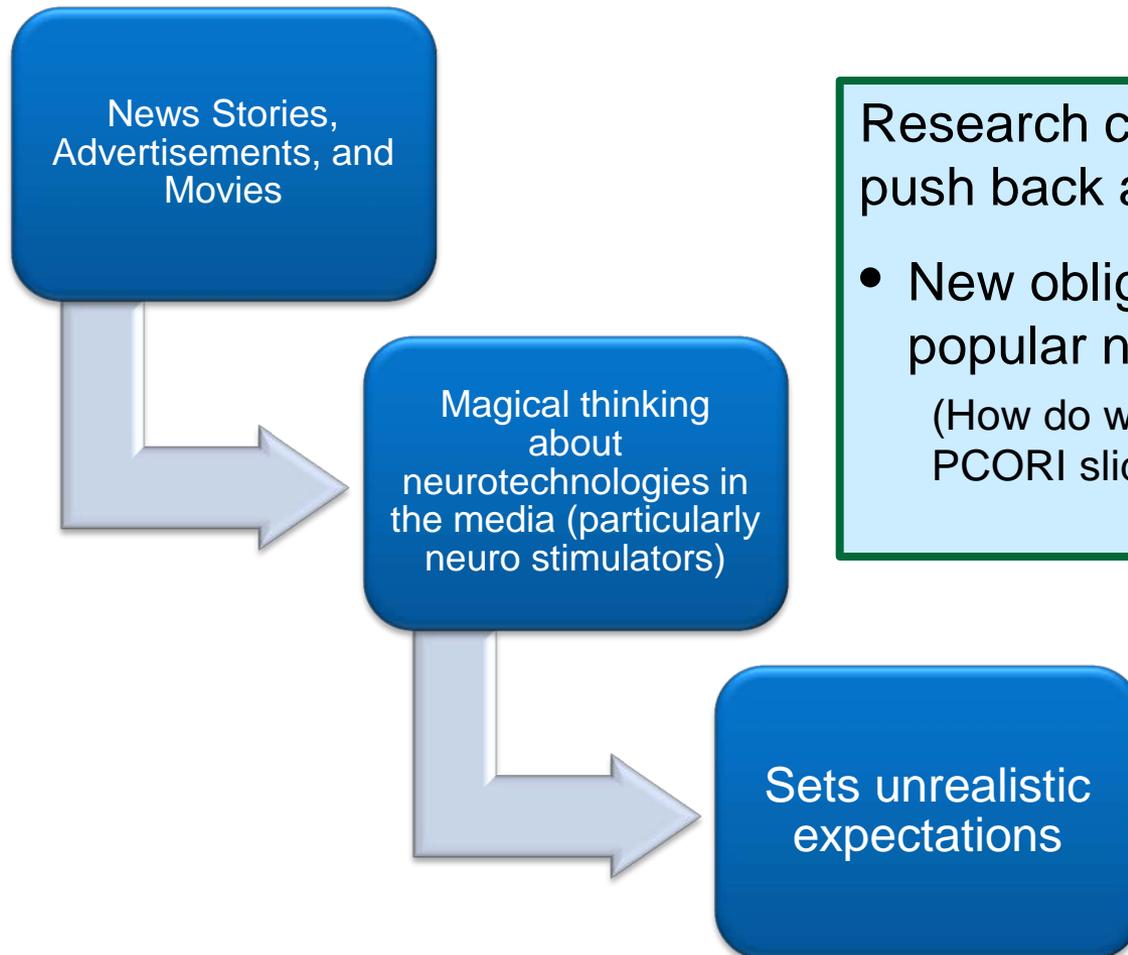
Some interventions will only potentiate other therapy

- DBS for Obsessive Compulsive Disorder:
 - Allows for normal brain plasticity and opportunity for conventional behavioral therapy to be effective

Some illnesses are better addressed by less/non-physically/chemically direct modes

(McGrath et. al. JAMA Psychiatry. 2013;70(8):821-829.)

DISPEL MEDIA/SOCIETAL MYTHOLOGY



Research consent processes should push back against these myths

- New obligation: account for popular narratives
(How do we know which narratives? See PCORI slide)

(See Racine et. al. Camb. Q. Healthc. Ethics. 2007;16(3):312–316; Gilbert and Ovadia. Frontiers in Integrative Neuroscience 2011;5 (16))

VULNERABILITY: NOT SO FAST WITH ASSUMPTIONS

Must be clear on what type of vulnerability

(Ford PJ. Law Med. Ethics. 2009; 37(1):73–83)

Should not disadvantage vulnerable from advances

(Fins JJ. Nature Rev. Neuro. 2003;4: 323-327)

Mental health diagnosis does not necessarily make a person more vulnerable.

(Bell et al. Camb. Q. Healthc. Ethics. 2014;23(3):361-8.)

VULNERABILITY: NOT SO FAST WITH ASSUMPTIONS

What kinds of risks/harms are too much?

- Allowing a subject to return to a minimally unconscious state and lose “self” in an On/Off DBS protocol?

(Schiff ND et al. Nature. 2007;448(7153):600-3)

- Risk of death may be justifiable in some mental illnesses research.
 - Some Mental Illnesses have a mortality risk in themselves

PATIENTS AS COLLABORATORS

Avoid assumptions about meaningful outcomes

- Do patients want more control over their DBS?
- Most wanted less control in our study (Kubu et. al., in preparation)

Patient Centered Research Outcomes

- Ask the stakeholders what makes life better?
- Create outcomes that matter to patients

Patient as Collaborator

- Brain studies often rely on patient reported data
- Need to be respectful of this effort

