The ethical examination of non-validated closed-loop deep brain stimulation treatments in psychiatric surgery

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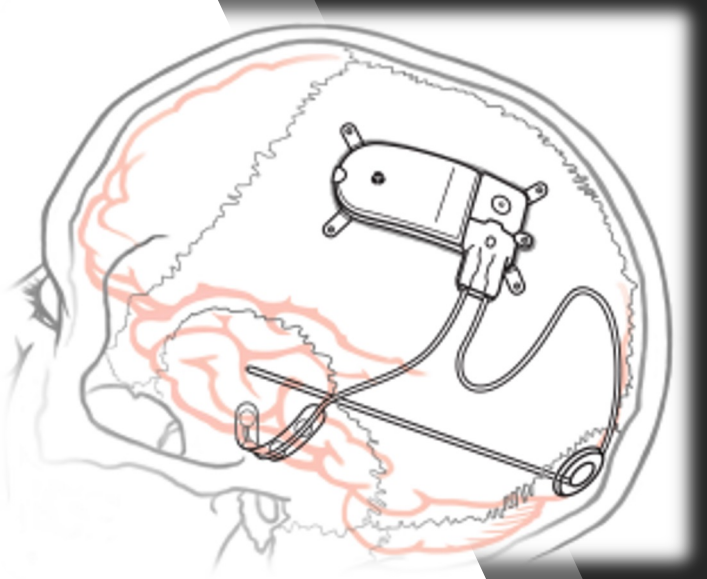


("RNS [Responsive Neurostimulation] System Physician Manual" 2021)

Neuro-oncology & Personalized Medicine Comparison:

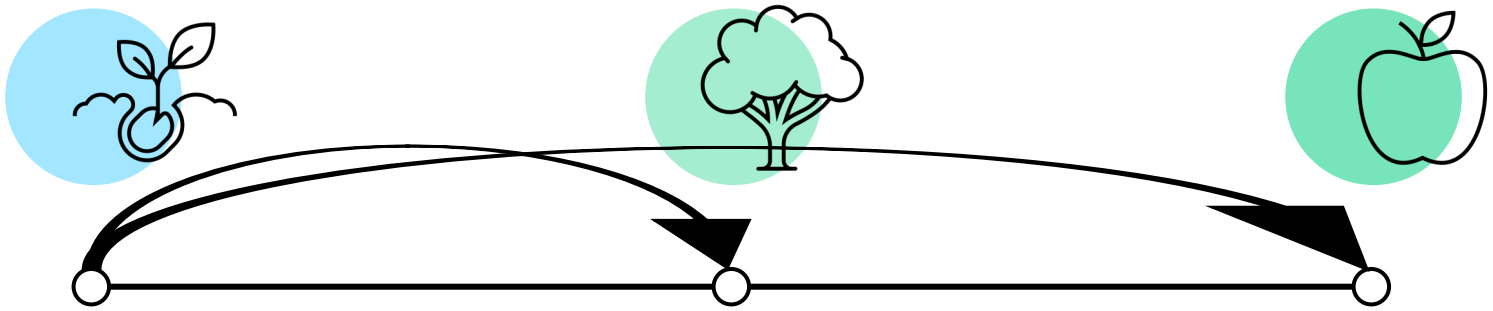
Per (Levine 2016) "*denoting the potential to devise and prescribe therapies based on molecular, and genetic information quasi-unique to the patient and the patient's tumor as well as therapies developed using cell line or rodent tumor model screens of drug candidates*".

Closed-loop Deep Brain Stimulation Personalized Characteristics (Stevens & Gilbert 2020):

- Local field potentials/electrocorticography
- Stimulation frequency/electrical potential
- 'Personalized algorithm'

Contemporary definition of surgical “innovation”:

“*Surgical innovation in both the research and the clinical paradigm may contain untested novel ideas, but innovation in research is aimed at generating generalizable knowledge, while innovation in clinical care is aimed at improving the outcome of the individual patient. When new surgical procedures are implemented in patients, generating universal knowledge thus coincides with the aim of ameliorating the suffering of the individual patient* (Zaki et al. 2019, 5).”



Non-validated Trial(s)

- Personalized treatments for individual patient betterment with logistical challenges limiting/prohibiting Randomized Control Trials.

Clinical Research

- Conducted for the generation of generalized knowledge.
- Ideally, relies on Randomized Control Trials.

Evidence-based Medicine

- Validated treatments or historical standards-of-care with varying levels of evidence.

What's the methodology of these dual-role non-validated trials?

Qualitative, ethnographic, 'real-world data', N-of-1, registry database, and/or legal/regulatory approaches.

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- Questions?
  - Email me at stevenia@ohsu.edu.

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