A State of the Technology Assessment for Deep Brain Stimulation

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BACKGROUND

• As the Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) initiative supports trans-NIH research aimed at transformative improvements in technology, it is useful to assess the pre-initiative state of a particular neurotechnology as a baseline for assessing future advancements.
• OSP partnered with the NINDS Office of Scientific Liaison to conduct a pilot of a baseline evaluation for a BRAIN initiative technology.
• One such technology, Deep brain stimulation (DBS) is an invasive neurostimulation technology used to treat several disabling neurological and neuropsychiatric symptoms.
• DBS uses a surgically implanted, battery-operated medical device to deliver electrical stimulation to specific areas in the brain, thus helping to regulate abnormal nerve signals that cause motor or cognitive dysfunction.

METHODS

The BRAIN initiative launched in 2014, and so several data sources were examined for data on the scientific landscape prior to 2014, including:
• Federal Portfolio Analysis (FY2010-14)
  o Analysis of the NIH grant portfolio via QVR, search of FY 2010-2014 grants with “deep brain stimulation” RCDC concept
  o RePORT for visualization of portfolio funding and IC distribution
  o QVR output of human vs animal subject codes
  o Topic visualization via RCDC PVIZ tool—clustering via thesaurus & raw text (not shown), and analysis of existing RCDC category representation
  o Search within Federal RePORTER for “deep brain stimulation”—Note that Federal RePORTER does not contain some federal agencies who may fund DBS research.
• Publication Analysis (including delay between funding and publication)
  o RePORT search of publication products from the DBS portfolio identified above (Grants in FY10-14, pub years unspecified)
  o PubMed search for “deep brain stimulation” MeSH term (FY05-15)
• Clinical Trial Analysis (FY04-14)
  o Search of Clinicaltrials.gov intervention field using “deep brain stimulation”
  o Trials identified by this search were further clustered by indication into larger categories and data cleaned
  o FDA Approval Analysis (FY04-15)
  o Search for “Deep Brain Stimulation” in the Devices@FDA.gov database, which includes Class I, II, and II device approvals, including Pre-market Approval (PMA) and Pre-market Notification (PMN) approvals
  o Devices@FDA database is not perfectly comprehensive with FDA PMA database, and contains both approvals and subsequent supplements
• Patent Analysis
  o Search for “Deep Brain Stimulation” via PatentsView tool

RESULTS

I. The NIH DBS Portfolio

Figure 1: A Total costs for NIH DBS awards by year, B: DBS research by type of subject, C: total costs by admin IC, D: Geographic distribution of DBS awards 2010-14, E: Map of existing, public RCDC Categories represented within 2010-14 DBS awards

II. A (Partial) Federal DBS Portfolio

DBS Projects in Federal RePORTER

The National Science Foundation (NSF): 17 DBS projects
  o Software for deep brain stimulation control
  o Modeling and optimizing patterns of stimulation
  o Understanding patterns of neural activity in disease and treatment
  o Anatomical guidance for electrode placement
The Veterans’ Administration (VA): 6 DBS projects
  o Ongoing DBS to treat stroke damage
  o Treating epilepsy
  o Improving DBS packaging and treatment for Parkinson’s
The Congressionally Directed Medical Research Program (CDMRP): 4 DBS projects
  o Treating tremors with DBS
  o DBS for mouse models of a subtype of Parkinsonism
  o DBS for rat models of focal dystonias
  o Improving walking gait after partial spinal cord injury

RESULTS

III. The DBS Publication Landscape

Pubmed Articles with MeSH term “Deep Brain Stimulation”

IV. DBS Clinical Trials by Indication

DBS FDA Approvals (and supplements)

Conclusions

• This analysis establishes a pre-BRAIN baseline for DBS research: An NIH portfolio with a majority of animal models and a substantial human component, other federal agencies doing specific, mission-oriented tech development and application, a clinical trial landscape dominated by Parkinson’s but slowly branching out, and Medtronic being the main player. In the short term, could see whether there is: 1. A shift in the NIH portfolio into new diseases/conditions and increased investment in biomedical engineering to optimize the technology; 2. Better synergy in the portfolios of federal agencies; 3. Increased publication and patent output; and 4. Increased number of clinical trials beyond Parkinson’s disease. In the medium to long term, might expect to see: 1. New DBS companies entering the market; and, 2. More FDA approvals for new indications which could be traced back to NIH-funded research.