RAD-PD: Registry for the Advancement of DBS in Parkinson's Disease

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Objective:

To describe a deep brain stimulation (DBS) registry proposal for the purpose of improving DBS therapy and outcomes for Parkinson's disease (PD) patients.

Background:

- Considerable evidence favors DBS over continued best medical management when bothersome motor complications are present in PD
- Variability in outcomes are not well understood, best practices are not well-defined, and prospective, long-term health economics data and comparisons of treatment techniques are lacking.
- Randomized trials are impractical to investigate these questions.

RAD-PD was conceptualized with the following goals (Fig. 1):

1. Identify the best practices surrounding DBS therapy
   - Patient selection
   - Operative factors
   - Post-operative management
2. Identify the adverse effects (and determinants) of DBS therapy
   - Surgical/peri-op
   - Long-term device-related
   - Falls
   - Hospitalizations
   - Death
3. Identify the health economics and disparities related to DBS therapy
   - Motor outcomes
   - Non-motor outcomes
   - Treatment costs
   - QALY/ICER

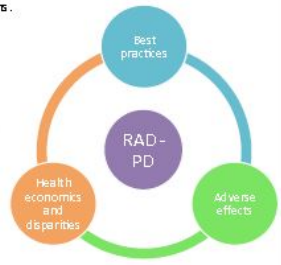

Fig. 1: Goals of RAD-PD

Methods:

- A survey of potential clinical sites (members of the Functional Neurosurgical Working Group) investigated which clinical data are routinely captured (Table 1)
- With contribution from multiple stakeholder groups, a RAD-PD proposal was developed as a quality improvement effort (Table 2)
- Proposed infrastructure is described in Table 3
- A large and heterogeneous PD cohort undergoing DBS will be prospectively and comprehensively characterized using a standard assessment battery and image analysis.

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Results

Table 1. Survey results (Number of responding sites = 25)

Most commonly assessed PD scales		Completed by <50%	Not assessed by any sites
MDS-UPDRS III	96%	Non-motor symptoms	Operative risk
MDS-UPDRS I, II, IV	70-77%	Impulse control disorders	Patient satisfaction
Hoehn & Yahr Staging	91%		
MoCA	85%		
PDQ-39	68%		

Table 2. Quality Improvement (QI) Registry Design

Must include	Does not include	Can support research functions
• Clearly defined quality measures • Specific data elements to calculate these measures • Continuous data collection • Sharing performance on quality measures with participants	• Clearly defined sample size • Clearly defined endpoint	• Secondary analyses • Linkage to other datasets (e.g., Medicare) • Some sites participate in "sub-studies" with additional data collection • Access to a de-identified dataset to answer additional research questions

Table 3. Proposed Registry Infrastructure

Parkinson Study Group/PRESIDIO	Neurotargeting/ CranialCloud	Neuropoint Alliance	Michael J. Fox Foundation	Clinical Sites
Steering Committee	Data repository and storage	Regulatory management	Patient retention	Patient recruitment and retention
Credentialing investigators / sites	Standardized image processing and analysis	Registry site management (contracting, onboarding, support) (clinical coordinating center)	Collaboration with Rancho Biosciences – data dictionary standardization, merging datasets	Administer assessments and upload data
Site selection	Site technical support	Data management (database management, quality assurance, data analysis/ reporting) (data coordinating center)	Potential recruitment to Fox Insight, linkage to Neuroshare	
Conflict of interest reporting	[Individual site customizability]	ongoing funding	initial funding	
Annual investigator meeting		Site reimbursement and distribution		
Scientific Review Committee / DUAC		Scientific Review Committee / DUAC		

PSG

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Registry Design

- A comprehensive set of data elements (Table 4) was devised to be systematically captured and benchmarked for analysis in RAD-PD. The majority are patient reported outcomes.
- Dashboarding to participating sites will enable them to consider implementing changes in therapeutic strategies to improve the quality of DBS care and outcomes for PD patients.
- Clinician-measured and patient-reported outcomes and imaging will be gathered from over 1,000 participants at up to 40 clinical sites (Table 5) across 5 years of DBS therapy (Fig.2).

Table 4. Proposed data elements for RAD-PD

Demographic/Social	PD history / medical and surgical interventions	Motor function	Non-motor symptoms	QoL/ Health economics	Adverse effects
• Patient demographics • Key past medical history • Key social history • Modified Frailty Index	• Duration of PD • Age at surgery • PD meds • Device info • Surgical techniques • OR time • Hospital stay • Readmission • Stimulation parameters • Electrode position • IPG exchange	• MDS-UPDRS I, III, IV • H&Y • NPoQ questionnaire	• MDS-UPDRS II • MoCA • BDI II • GAD-7 • QUIP-RS • NMSS	• PDQ39 • EQ5D • Neuro-QOL Ability • Patient satisfaction • Medicare vs commercial insurance • PD-related ER or hospital admission	• Death or withdrawal • Falls • Suicide attempt • Hospitalizations • Device-related AEs • Electrode revision

Figure 2. Time points and patient reported outcomes

Table 5. Proposed Site Activity

	Criteria	Proportion for RAD-PD	Total # Sites	Goal annual enrollment
tier 1	16-30 implants/yr	75%	N=30	20pts/site
tier 2	<15 implants/yr	25%	N=10	6pts/site

Conclusions:

- RAD-PD is needed to prospectively capture standard and comprehensive assessments in a large PD cohort undergoing DBS
- With a QI design, the primary goal is improving DBS therapy and outcomes.
- Results will have broad applicability to a range of practice scenarios and patient characteristics.
- The infrastructure can be applied to other disease states where DBS is a viable treatment strategy.