

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

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Objective:

To describe a deep brain stimulation (DBS) registry 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 three goals (Fig. 1):

1. Identify the best practices surrounding DBS therapy

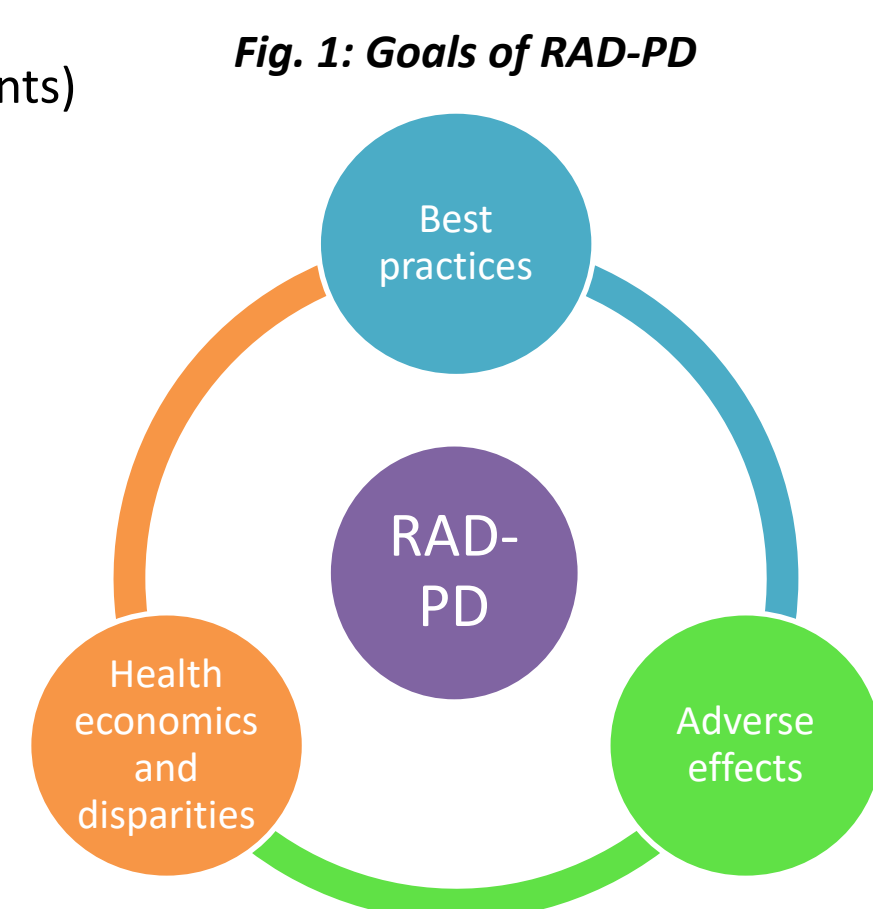
- Patient selection
- Operative factors
- Post-operative management

2. Identify the adverse effects (and determinants) of DBS therapy

- Surgical/peri-op
- Long-term device-related
- Falls
- Hospitalizations
- Death

3. Identify health economics and disparities related to DBS therapy

- Motor outcomes
- Non-motor outcomes
- Treatment costs
- QALY/ICER



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)
- Planned 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
MDS-UPDRS I, II, IV	70-77%	Operative risk
Hoehn & Yahr Staging	91%	Patient satisfaction
MoCA	85%	
PDQ-39	68%	

Table 2. Quality Improvement (QI) Registry Design

Must include	Does not include	Can support research functions
<ul style="list-style-type: none"> • Clearly defined quality measures • Specific data elements to calculate these measures • Continuous data collection • Sharing performance on quality measures with participants 	<ul style="list-style-type: none"> • Clearly defined sample size • Clearly defined endpoint 	<ul style="list-style-type: none"> • 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. Registry Infrastructure

Parkinson Study Group/FNSWG	Neurotargeting/Cranial Cloud	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 FoxInsight	
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		

Registry Design:

- A comprehensive set of data elements, primarily patient reported outcomes (Table 4), will be systematically captured and benchmarked for analysis in RAD-PD.
- Dashboarding to participating sites will enable them to implement changes in therapeutic strategies to improve the quality of DBS care and outcomes for PD patients.
- In the first 2 years of RAD-PD, clinician-measured and patient-reported outcomes and imaging will be gathered from nearly 500 participants at 20 clinical sites (Table 5). Data collection across 5 years of DBS therapy is planned (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
<ul style="list-style-type: none"> • Patient demographics • Key past medical history • Key social history • Modified Frailty Index 	<ul style="list-style-type: none"> • Duration of PD • Age at surgery • PD meds • Device info • Surgical techniques • OR time • Hospital stay • Readmission • Stimulation parameters • Electrode position • IPG exchange 	<ul style="list-style-type: none"> • MDS-UPDRS I, III, IV • H&Y • NFOG questionnaire 	<ul style="list-style-type: none"> • MDS-UPDRS II • MoCA • BDI-II • GAD-7 • QUIP-RS • NMSS 	<ul style="list-style-type: none"> • PDQ39 • ED5D • Neuro-QoL Ability • Patient satisfaction • Medicare vs commercial insurance • PD-related ER or hospital admission 	<ul style="list-style-type: none"> • Death or withdrawal • Falls • Suicide attempt • Hospitalizations • Device-related AEs • Electrode revision

Figure 2. Time points and patient reported

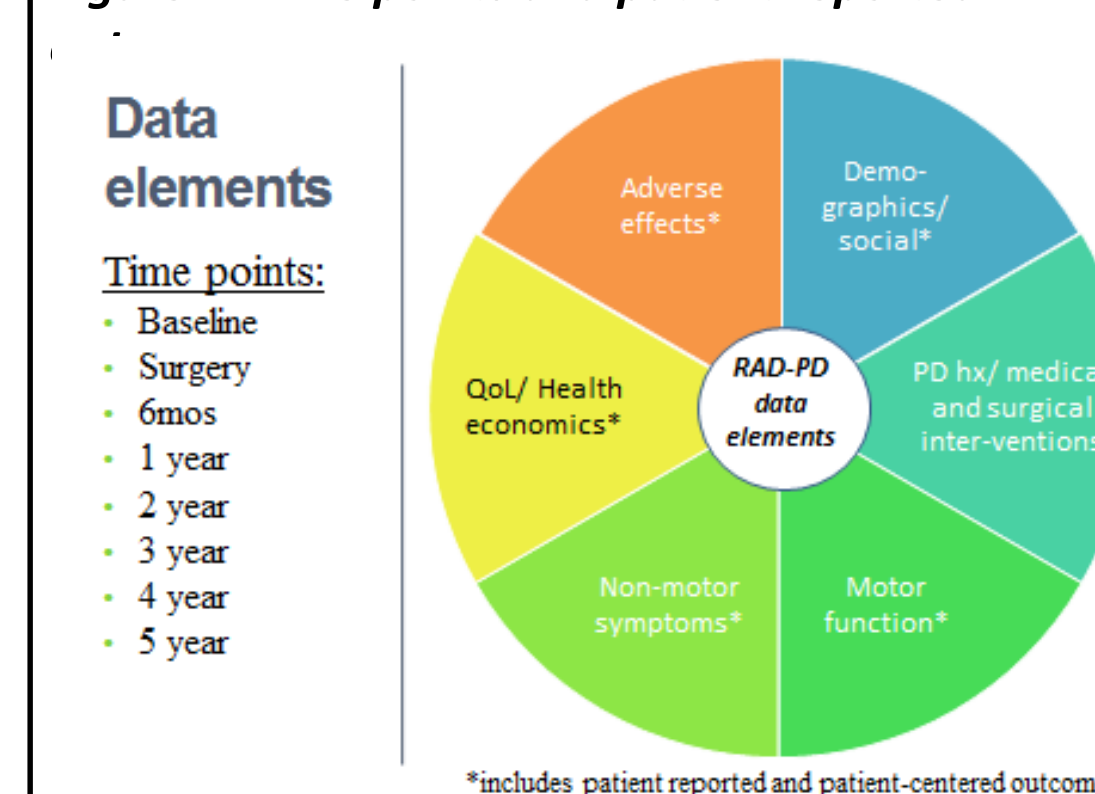


Table 5. Proposed Site Activity and Enrollment

	Criteria	Proportion for RAD-PD	Total 20 sites	Goal annual enrollment
tier 1	16-50 implants/yr	75%	N=14	20pts/site
tier 2	<15 implants/yr	25%	N=6	6pts/site
Enrollment: Year 1 = 158; Year 2 = 316 (Total = 474 subjects)				

Conclusions:

- RAD-PD is an approved PSG and MJFF study and will 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 across a range of practice scenarios and patient characteristics.
- The infrastructure can be applied to other disease states where DBS is a viable treatment strategy.