A Physician/Patient Hybrid Perspective on Biometric Monitoring Devices (BMD)

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Outline

• Objectives
• Background
  – Demographic
  – As Physician/Clinical Researcher
  – As Patient/Research Subject
• Parkinson’s Disease (PD) specific BMD considerations
• General BMD considerations
• Key Points for BMD development & utilization
Objectives

• Highlight key points for BMD development & use in clinical trials from my hybrid perspective

• Help ID and address “digital divides” & gaps in neurodegenerative disease research, care & support
Lessons Learned Violating the Golden Rules of Medicine & Clinical Research

• It is better to be providing care than receiving care
• It is better to be conducting clinical research than being the subject of research
• Having seen both sides of the care and research enterprises provides some perspectives you may find valuable
Demographic Background
Digital Evolution

• “Baby Boomer” or per my daughter an “Artifact”
• “Analog Artifact “Undergrad education predates digital revolution
• Slide rule
• First digital device purchased was a TI scientific calculator ~$400 in 1975 dollars

My digital pioneer classmates in the Original Facebook circa 1973
Digital Revolution Creeping Into Medicine by the End of Residency

• Pagers with dimes taped to clips to answer out of hospital calls from pay phones
• Department owned cell phone ("the brick") for some senior on call residents
• Introduction of computerized hospital Rx ordering
• Early PP rare, 35 mm slides, dual synched projectors standard for presentations
Physician & Clinical Research background

- Orthopedist w/ clinical epidemiology fellowship
- Designed and conducted academic clinical outcome studies, registry and Biotech GCP Phase 2-4 clinical studies
- 10+ years experience biotech clinical research & development
- FDA, EMA studies & approvals
- Electronic Data Capture (EDC) in some studies
Patient/Clinical Research Subject
Background

• PD diagnosis January 2006
• Clinical research subject in several trials including biomarker studies, 4 BMD studies
• DBS implant 2015, DBS study
PD Specific Considerations

• Multi-organ /system disease, not just a movement disorder
• Non-motor symptoms can be as important & disabling as movement symptoms, e.g. GI, speech, swallowing, sleep, cognition, mood, fatigue, pain syndromes, vision
• Disease progression generally involves increasing severity of symptoms in increasing number of systems, but extent /linkage/timing of co-morbidities variable
PD Specific Considerations

• Some of the non-motor symptoms challenging to measure with BMD’s only

• That, plus need to measure how symptoms affect patient function, may require active patient input into standardized PRO instrument(s) as well as “passive”/automatic collection of BMD data

• Possible model example – Patient diary with outpatient Holter monitor
Paradox/Challenge of Using Digital Devices for PD Patient Data Input

• Assessing traditional Activities of Daily Living (ADL’s) (e.g. walking, bathing, eating) well developed in clinical medicine & research

• Computers/smart phone devices are now essential part of daily functional activities, I term these “Activities of Digital Living”.

• PD markedly reduces ability & endurance to use digital devices

• Need better assessment, technology and support for PD patients & other patient populations to effectively use digital devices.
How Does PD Impact Use of Digital Devices?

- Tremors
- Dyskinesia
- Dystonia
- Bradykinesia
- Freezing
- Fatigue
- Posture – kyphosis
- Muscle & joint pain
- Speech difficulties, impair voice to text programs
- Vision, including reduced tears & blinking
- Standard touch screens & mice are problematic
Challenge of IT Development for PD Care and Research

• Breadth & progression of PD symptoms that affect digital tech use – ”Digital Devolution”

• Under recognized in both clinical and IT communities
  – Center of Excellence example

• Pharma/Biotech ≠ Info tech
  – Need to bridge “Two Cultures”
BMD Opportunities & Challenges

Opportunities

• Real time, continuous data
• Automatic collection
• Overcome recall bias
• Some data collection independent of patient education/”clinical sophistication” background
• Reduce observer variability

Challenges

• Noise to signal ratio, interpretation
• Establishing/validating clinical correlations
• Miss important symptoms/functional problems due to measurement or patient input difficulty
• Comfort/ease of use
• Device reliability
Is BMD a way to do traditional studies more efficiently or a way to do new types of studies?

• Both - potential to mitigate some operational and clinical risks

• Like EDC, has potential to make traditional types of studies more efficient, e.g. faster data collection, reduce missing data, reduce intra and inter observer variability, faster DB lock

• New types of data, potential for enhanced data analysis and interpretation, e.g. better measurement of progression rates, help identify rate predictors & sub-populations of “rapid progressives”, reduce false negative risks.
Conceptual Advantage of BMD

• Measure continuous change vs “step function”
• Capture disease progression/regression in real time vs. when patients come for scheduled visits or when become aware of symptom/functional changes
• Potential for “mapping/navigating” disease vs. static GPS coordinate like "point in time" description
• Help find “Holy Grail” – slow, stop, reverse disease progression
4 P’s for BMD Development & Use

• Be Practical
  – Pragmatic feasibility vs. academic perfection

• Be Persistent
  – New tech can help speed success, but therapeutic breakthroughs still require tenacity, time and money. Stay the course.

• Be Prepared
  – Chance favors the prepared mind. Learn from failures and unexpected observations. The potential of DBS was initially discovered serendipitously!

• Be Patient-Centered
How to be truly “Patient Centric”

- Measure what is important to patient
- Adapt technology to patients’ needs & abilities
- Pragmatic vs. Perfect
- Clinical validation & correlations initially and periodically
- Correlations with historical/existing lit & data