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# Wearable activity sensors and patient-reported outcomes in total hip arthroplasty: a nested RCT

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[WWW.NSFCDMI.ORG](http://WWW.NSFCDMI.ORG)

- PROs have been selected as a means to measure outcomes in the value equation
  - Value= outcomes/cost
- Collecting PROs is costly, inefficient, inaccurate.
- Can we do better?

- Question:
  - Can data collected passively about an individual help *predict* both objective and subjective clinical outcomes following surgical intervention?
  - Which data?
  - Collected from what source?
  - Over what time frame?
  - How sensitive a change can it detect?

- IHI Triple Aim, ACA, Quality movement, Patient Centered Care Initiative, CMS:
  - Value=Outcomes/Cost
- Industry needs to prove VALUE to all stakeholders
  - How?
  - What are the valid end points to define value?
    - Quality > Cost

- Our primary aim is to determine if a set of passively collected patient generated data can predict the impact of total joint replacement surgery on clinical and patient reported outcomes
- Nested RCT sensitivity study
  - determine if these data points can measure the impact of pre-habilitation on clinical and patient reported outcomes by randomizing patients to the intervention.

- Secondary Aims
  - Validation of PROs using sensor data
  - Demonstrate feasibility, value and challenges of collecting and merging passively collected data (EHR, Web, Sensor)
  - Compare utility, reliability, sensitivity and predictive value of different sensor types

- Pilot, nested study model
- Recruit 20 patients
  - RCT: pre-hab vs. no pre-hab (CaptureProof.com)
  - PROs (VR-12, HOOS/KOOS, VAS, WOMAC) (Healthloop.com)
  - Clinical complications (Healthloop, EMR review)
- Quantify the patients
  - Sensors (iPhone, Fitbit, Motiv)
  - Public Data (ClarifyHealth.com)
  - EMR data (Gliimpse vs. Manual)
- Gather the data first, ask questions later
  - identify patterns and associations predictive of outcomes (as defined by correlation with absolute change in PROs and actual complications)

# Milestones & Timeline

- 2016
  - Q3: IRB, patient coordinator and data base set up
  - Q4: patient recruitment
- 2017
  - Q1: Data Acquisition begins
  - Q2: Early Q2, end trial
  - Q1-Q2: data collection
  - End Q2: end data collection
  - Q3 data processing
  - August 31: report out.



- Signal: can we use passively collected data to *predict* clinical outcomes?
  - How subtle a difference can data identify?
  - Is some data better than other data?
  - Can this data be as (more?) accurate than the patient (PRO)?
- If so, what can we do with that knowledge?
  - Feedback loops, prevention, intervention
    - Future studies

## Deliverables: PILOT STUDY

- Identify promising technologies for investment or future partnerships
- Clarify if a potential strategic thrust for CDMI and industry leaders could be to partner with the Tech, Device, and Analytics industries to better quantify the value equation in health care.

# Proposed Budget \$40,000

- Research Team (data acquisition)
  - K. Hwang; J. Patterson; J Barry; I Bendich; J Mlvihill; A. Pitcher; R. Southgate.
- Research coordinator (patient management)
  - 0.30 FTE x 9 months : \$20,000
- Pre-habilitation
  - CaptureProof
- Sensors
  - 500 per patient = \$10,000
  - Fitbit, Motiv, iPhone
- Data, PROs,
  - Healthloop = \$60/MD per month. \$1800
- Analytics and programming
  - \$5,000-10,000

- THANK YOU
- QUESTIONS?



- Hypothesis
  - Passively collected data can reliably predict patient reported outcomes following total joint arthroplasty
- Primary Aim
  - Determine which passively collected patient generate data points (or combinations thereof) currently available from various sensors and public data sets correlate with PRO results