Incorporating Person-generated Health Data and Digital Clinical Measures into PCOR Infrastructure

Bray Patrick-Lake, MFS
Senior Director, Strategic Partnerships

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Person-Generated Health Data (PGHD) enables continuous monitoring of health outcomes at the individual level, to better understand and measure a person’s experience with health and disease.
With individuals increasingly taking charge of their health, PGHD will eventually include all personal health data.
The richest data about patients’ experience with disease is mostly invisible to the healthcare system.

- Better characterization and understanding of living with the disease
- Better understanding of disease progression
- Earlier identification of at-risk individuals
- Real world, objective QoL and ADL measures
- Pattern detection for public health
Case study: Connecting directly to patients provides unprecedented resolution into asthma control and the true disease burden in everyday life not captured by traditional RWE

Both Individuals

- Persistent moderate/severe asthma
- Currently taking LABA/ICS
- Adhering to physician-prescribed treatment
- Non-smokers
- Use the same brand of wearable device

| Note: time asleep data is objectively-derived from wearable devices; comparison is illustrative only and not controlled for any variable |

- Reports waking up often (every night or almost every night) when asked how often they wake up at night due to asthma symptoms
  - 49% time asleep while in bed over last 90 days
- Reports waking up 2 or fewer days per month when asked how often they wake up at night due to asthma symptoms
  - 96% time asleep while in bed over last 90 days
Disease Event and Progression Modelling

- Detect, describe, and predict disease events and changes in health status
- Measure disease progression and recovery over time

CASE STUDY: AUTOIMMUNE FLARES

Objective

Describe, detect, and predict flare events in an autoimmune condition using wearable and survey data

- Identify behavioral changes leading up to and following a flare
- Assess whether behavioral deviations can detect and predict flare events

Results / Impact

- Enabled flare detection using easily measured changes in behavior
- Quantified flare impact and recovery over time
Recovery Modeling:
The most discriminative variable between faster (0-2 months) vs. slower (>3 months) recovery at 4 weeks follow up is the 95-th percentile of 30-min rolling sum of steps over week 1 as compared to baseline, which can be seen as a continuous and individualized version of the 6-min walk test.

Fig. 3. Estimated trajectories of daily number of steps across 3 self-reported recovery time groups in subsequent weeks from 12 weeks before to 26 weeks after surgery. The upper plots show absolute values of activity, the bottom plots show change with respect to the model-estimated baseline. Vertical plot panels correspond to 3 lower limb surgery types: bone fracture, tendon or ligament repair, and knee or hip replacement. The color of a point/line corresponds to the self-reported recovery time group. The “week 0” label (x-axis) denotes a 7-day period starting on a self-reported surgery day.

SOURCE: PREDICTING SUBJECTIVE RECOVERY FROM LOWER LIMB SURGERY USING CONSUMER WEARABLES. KARAS ET AL., KARGER DIGITAL BIOMARKERS
PGHD allows measuring burden of acute conditions invisible to the healthcare system, and its unfolding through time.

ADAPTED FROM: INFLUENZA SURVEILLANCE USING WEARABLE MOBILE HEALTH DEVICES. BRADSHAW ET AL., ONLINE JOURNAL OF PUBLIC HEALTH INFORMATICS, MAY 2019

NOTE: BASED ON 124K SURVEY RESPONDERS WHO REPORTED INFLUENZA SYMPTOMS IN 2018
Study goal: Understand utility of Person-generated Health Data (PGHD) for early detection, monitoring, and management of COVID-19 in everyday life.
In order for PGHD and digital clinical measures to achieve their potential in accelerating clinical research, enhancing clinical care, and improving public health we must:

- Ensure digital clinical measures are well understood and trusted
  - common ontology, standards, data collections schemes, meta data collections schemes, and data provenance schemes
- Develop broadly accepted evidentiary frameworks for clinical care, clinical research, and public health
- Develop incentives that reduce barriers to collaboration – promote data and measure use and re-use, reward innovation
- Advance data rights and ELSI work to support the appropriate balance between individual protections and public benefit, ensuring that individuals are well informed and protected against discrimination from their digital specimens

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Bray Patrick-Lake, MFS
Strategic Partnerships
Evidation Health, Inc.
Bpatricklake@evidation.com