

mHealth Webinar Supplemental Slides

**All slides are *DRAFTS* meant only to facilitate
public comment on topics not covered in the webinar
held on June 26, 2017**

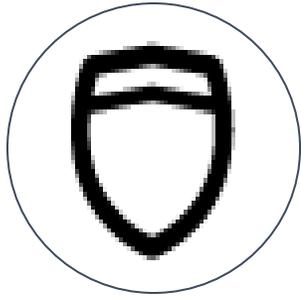
Topics Addressed in the Webinar:

- Contribution of mHealth data for novel real-world evidence generation
 - Role of NEST in encouraging the inclusion and use of mHealth in evidence development for medical devices
- Ways to think about different types of person-facing mHealth technologies, software, and data
- Recommendations for advancing person-facing mHealth adoption and usage
 - User engagement
 - Researcher/sponsor needs
 - mHealth company incentives
- Overarching challenges in digital health data: Current work and resources
 - Best practices for patient-consumer informed consent
 - Data linkages and interoperability
 - Accommodating diversity of apps and wearable technology
 - Fit-for-purpose: validation and reliability of data
- Recommended next steps to advance consumer/clinical mHealth technologies as a viable source of reliable data for evidence generation

Additional Topics to be addressed in the Action Plan

- Contribution of mHealth data for novel real-world evidence generation
 - Role of NEST in encouraging the inclusion and use of mHealth in evidence development for medical devices
- Ways to think about different types of person-facing mHealth technologies, software, and data
- Recommendations for advancing person-facing mHealth adoption and usage
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- Recommended next steps to advance consumer/clinical mHealth technologies as a viable source of reliable data for evidence generation

Digital Health - Overarching Challenges



Consent for data sharing and usage



Data linkages and interoperability



Diversity of mHealth technologies



Usability of data analysis and output to end users



Consent for Data Sharing and Usage

- Current practice for different types of trials
 - Traditional randomized clinical trials
 - Adaptive and registry-based trials
 - Current practice in postmarket
 - When is consent needed? (e.g., public health authority, quality measures)
- How to balance patient autonomy and privacy with consent for broad longitudinal research?
 - Informed yet frictionless participation in research
 - Yearly opt-out reminders?
- What issues change with virtual studies using mHealth?
 - Telehealth
 - Technology disparities

Consent for Data Sharing and Usage

Efforts:

- [PCORI](#)
- [ONC](#)
- NIH
 - [All of Us Initiative](#)
- Research organizations
 - [Sage Bionetworks](#)
 - Apple's ResearchKit
 - [PatientsLikeMe](#) – Patient-focused Research Network
 - CROs
- Others?

Data linkages and interoperability

Challenges:

- Lack of a widely adopted standardized framework for electronic healthcare record interoperability
- How to facilitate mHealth data sharing and aggregation across proprietary platforms
 - Standardized APIs - what information could be sent? (e.g. hardware, software version, raw sensor data)
 - Uniquely identifying consumer apps and wearables
- Keeping patient security and privacy standards up-to-date with mHealth software and hardware upgrades
- Others??

Data Linkages and Interoperability

Current efforts:

- **ONC**
 - [Proposed Interoperability Standards Measurement Framework \(April 2017\)](#)
 - [ONC and Accenture project funded by the Patient-Centered Outcomes Research Trust Fund to develop a policy framework for the collection and use of PGHD through 2024](#)
- **[HL7 Mobile Health Work Group](#)**
 - Mobile Health Application Interoperability Review
 - Cross-Paradigm Implementation Guidance for Medical Device Data Sharing with Enterprise Health Systems
 - FHIR for Device Data Reporting
 - Consumer Mobile Health Application Functional Framework (cMHAF)
 - Mobile Framework for Healthcare Adoption of Short-Message Technologies (mFHA)
- **[Personal Connected Health Alliance](#)**
 - Continua Design Guidelines for end-to-end interoperability of personal connected health devices and systems
 - Continua Product Certification for PCHAlliance members
- **IHE mHealth**
 - [Mobile access to Health Documents Technical Framework Supplement](#)
- **[IEEE Medical Devices Standards \(11073\)](#)**
- **[CDISC standards for regulatory submissions to FDA CDER and CBER](#)**
- **Industry data aggregation**
 - [Apple HealthKit, ResearchKit, CareKit](#)
 - [Google Fit](#)
 - [Samsung Health](#)
 - [Microsoft HealthVault](#)
- **[Open mHealth](#)**
 - Open standards for data storage, integration, and sharing
- **Others?**

Diversity of mHealth Technologies

1) Challenges in measurement and technology standards development and adoption

- Rapid pace of device and software innovation, as well as increasing development of multisensory devices
- Black box between raw data collection and pre-processing (e.g. piezoelectric signals to step counts)

Diversity of mHealth Technologies

2) Challenges in mHealth technology reliability and validity

- Evidence on reliability within and between proprietary models
- Evidence of empirical effectiveness of consumer mHealth devices
 - Accuracy in basic measurements
 - Relationship to health outcomes
- Matching stakeholder's real world evidence requirements for reliability and validity with current mHealth evaluation tools and capabilities

Diversity of mHealth Technologies

Resources and Efforts:

- Published research and systematic reviews
- Consumer Technology Association Health and Fitness Technology Subcommittee
 - Sleep Monitors, Physical Activity Monitoring, Consumer EEG Working Groups
- International Medical Device Regulators Forum
 - Software as a Medical Device (SaMD) Group

Draft Use Cases

Understanding Variation in Outcomes (Draft)

Total knee replacement results in significant variation in functional outcomes, even after adjusting for surgical factors and other risk factors. Patient-reported exercise diaries were piloted as a potential way to adjust for differences in adherence to recommended exercise schedules.

- 90% of patients in pilot study completed 9 week exercise log, recording at least 3 days/week

Data from Tele-Technology for Clinical Use (Draft)

- Kaiser Permanente allows patients to talk to a doctor remotely while using a stethoscope, digital thermometer and otoscope to check their own symptoms under observation of the physician.
- Acreo Swedish ICT has developed an inexpensive prototype instrument that looks like a business card and can analyze blood and saliva samples.
- Validic allows data from non-connected devices to be digitized and collected through smartphone photographs.

Using the Fitbit to Identify Patients at Risk for Surgical Complications (Draft)

Thirty-eight patients wore the Fitbit Zip activity tracker for 7 days before and 21 days after abdominal cancer surgery during this feasibility study at Wake Forest University. The study sought to find out whether patients would use the devices and whether the activity data could be used to predict patients who were more likely to have complications from the surgery.