Journal club presents:

EVIDENCE Checklist

Digital Biomarkers

EVIDENCE publication checklist for studies evaluating connected sensor technologies: explanation and elaboration.

Christine Manta[a, b] Nikhil Mahadevan[a, c] Jessie Bakker[a, d] Simal Ozen Irmak[e]
Elena Izmailova[a, f] Siyeon Park[g] Jiat-Ling Poon[h] Santosh Shevade[i]
Sarah Valentine[h] Benjamin Vandendriessche[j, k] Courtney Webster[l]
Jennifer C. Goldsack[a]

May 26th, 2021
11a ET

Jen Goldsack
Executive Director
Digital Medicine Society

Christine Manta
Head of Applied Sciences
Elektra Labs

Ray Dorsey, MD
Editor-in-Chief
Digital Biomarkers

Beth Kunkoski
Health Science Policy Analyst
FDA CDER

But first, housekeeping

- Please note today's session is being recorded
- To ask a question for discussion during Q&A, please:
    - Either 'raise your hand' in the participant window and moderator will unmute you to ask your question live, or
    - Type your question into the chat box
- Slides and recording will be available after today's session

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Quality of reporting in peer reviewed literature evaluating digital measurement products is **highly variable**

Inconsistencies in essential **metadata** and **variances in evaluation protocols** leads to **low confidence** in results and researchers unnecessarily **repeating work**

Bakker JP, Goldsack JC, Clarke M, Coravos A, Geoghegan C, Godfrey A, et al. A systematic review of feasibility studies promoting the use of mobile technologies in clinical research. NPJ Digit Med. 2019 Jun;2(1):47.

Badawy R, Hameed F, Bataille L, Little MA, Claes K, Saria S, et al. Metadata concepts for advancing the use of digital health technologies in clinical research. Digit Biomark. 2019 Oct;3(3):116–32.

A systematic review of studies evaluating mobile technologies in research found:

- Only 73% of studies reported the software used in the analysis
- Nearly 10% did not report the make and model of the technology
- There was substantial variation in documenting sensor modalities (e.g., “motion sensor,” “accelerometer,” “tri-axial accelerometer,” or “pedometer” without specifying the actual sensors contained within the product)

Bakker JP, Goldsack JC, Clarke M, Coravos A, Geoghegan C, Godfrey A, et al. A systematic review of feasibility studies promoting the use of mobile technologies in clinical research. NPJ Digit Med. 2019 Jun;2(1):47.

To speed the development and deployment of digital measurement products **worthy of our trust**, the **quality of reporting** of evaluation studies **must improve**

EVIDENCE Checklist

- 25-item checklist covers universal requirements for best research practices plus **unique considerations for reporting on connected sensor technologies and software**
- Developed by interdisciplinary group of **experts from the DiMe community** via a virtual workshop and subsequent rounds of asynchronous feedback
- **Structured similarly to existing publication checklists** such as PRISMA for systematic reviews and meta-analyses, CONSORT for randomized clinical trials, STARD for diagnostic accuracy studies, and STROBE for observational studies in epidemiology
- Intended to **promote high-quality reporting in studies where the primary objective is an evaluation of a digital measurement product or its constituent parts**

Manta, C., Mahadevan, N., Bakker, J., Irmak, S. O., Izmailova, E., Park, S., ... & Goldsack, J. C. (2021). EVIDENCE Publication Checklist for Studies Evaluating Connected Sensor Technologies: Explanation and Elaboration. Digital Biomarkers, 5(2), 127-147.

Unique checklist items for connected sensors and software

- Make and Model
- Selection Rationale
- Product Availability/Maturity
- Sensor Characteristics
- Form Factor and Wear Location
- Algorithm Description
- Software Version number and manufacturer
- Wear time
- Reference Standard
- Training for Staff and/or Participants

Manta, C., Mahadevan, N., Bakker, J., Irmak, S. O., Izmailova, E., Park, S., ... & Goldsack, J. C. (2021). EVIDENCE Publication Checklist for Studies Evaluating Connected Sensor Technologies: Explanation and Elaboration. Digital Biomarkers, 5(2), 127-147.

IN Scope for EVIDENCE

Type of study	Definition	Common distinguishing characteristics	Examples
Proof of concept	Conducts initial testing intended to indicate whether the use of a technology or the development of a digital measure may be feasible in a given context of use	Described as a pilot study with a small sample size and a short duration Evaluating a novel measure that does not have predefined protocols and acceptance criteria	Sensor-based measures of forgetfulness [14] Smartphone-based measures of eye tracking or gaze [15] Actigraphy to predict mood [16]
V3 Framework			
Verification	Measures the accuracy of sample level sensor data compared to a bench standard	No human subjects	Raw data from the ECG sensor is accurate, precise, and consistent [58]
Analytical validation	Determines the ability of a sensor and accompanying algorithm(s) to capture the behavioral or physiological concept accurately in an intended context of use	Comparison to a reference standard Measure has a defined protocol and acceptance criteria	Accuracy of heart rate variability compared with a traditional ECG and Kubios clinical grade software [59]
Clinical validation	Determines whether the digital clinical measurement is meaningful to answer a specific clinical question in a specific population	Measurement performance in healthy controls compared to those with the disease Identifies or predicts a meaningful change	Heart rate variability identifies the presence of autism [82]
Utility and usability	Evaluates the practical considerations of using the technology in an individual's daily life	Assesses whether all of the necessary features exist and how pleasant these features are to use	Assessing technical problems and the comfort of wearable devices [83]

X

Manta, C., Mahadevan, N., Bakker, J., Irmak, S. O., Izmailova, E., Park, S., ... & Goldsack, J. C. (2021). EVIDENCE Publication Checklist for Studies Evaluating Connected Sensor Technologies: Explanation and Elaboration. Digital Biomarkers, 5(2), 127-147.

OUT of scope for EVIDENCE

- Studies evaluating the performance of **electronic patient-reported outcomes or digital therapeutics**
- Studies evaluating performance of digital measurement products that **measure adherence to an intervention** such as smart pill boxes
- Studies using **animals, tissues or other biological specimens**
- **Systematic reviews and meta-analyses** of studies evaluating connected sensor technologies
- Studies evaluating **security, data privacy or operational considerations** of digital measurement products

Manta, C., Mahadevan, N., Bakker, J., Irmak, S. O., Izmailova, E., Park, S., ... & Goldsack, J. C. (2021). EVIDENCE Publication Checklist for Studies Evaluating Connected Sensor Technologies: Explanation and Elaboration. Digital Biomarkers, 5(2), 127-147.

DECISION TOOL

Is the study intended to evaluate a connected sensor technology?*

YES

NO

EVIDENCE Checklist

Evaluating Connected Sensor Technologies Checklist

Can the study be identified as POC, V3, U&U?

YES

NO

The EVIDENCE checklist applies.

Download the checklist below.

The EVIDENCE checklist does not apply.

For guidance on required elements for POC, V3 and U&U, reference the EVIDENCE manuscript.

For guidance on evaluating data rights and/or security, reference *The Playbook*.

The EVIDENCE checklist does not apply.

Note: It is critical to ensure that a connected sensor technology is evaluated in the context and population of interest before it is deployed in a clinical trial or clinical practice.

To evaluate the existing literature, use the EVIDENCE checklist to ensure you have all the information you need to proceed.

For guidance on characteristics to include in evaluation studies you may conduct yourself, reference *The Playbook*.

*__Connected sensor technologies__, also referred to as digital measurement product or Biometric Monitoring Technologies (BioMeTs), process data captured by mobile sensors using algorithms to generate measures of behavioral and/or physiological function.

POC = Proof of concept

Conducts initial testing intended to indicate whether the use of a technology or the development of a digital measure may be feasible in a given context of use

V3 = Verification, analytical validation, clinical validation

- Verification: Measures the accuracy of sample level sensor data compared to a bench standard
- Analytical validation: Determines the ability of a sensor and accompanying algorithm/s to capture the behavioral or physiological concept accurately in an intended context of use
- Clinical validation: Determines whether the digital clinical measurement is meaningful to answer a specific clinical question in a specific population

U&U = Utility & usability

Evaluates the practical considerations of using the technology in an individual's daily life

https://www.dimesociety.org/tours-of-duty/evidence

Resources

- EVIDENCE Webpage
  - Are you a journal editor interested in endorsing EVIDENCE? Contact us.
  - Have you published a study using EVIDENCE? Share it with us
  - Comments or suggestions for the checklist? Contact us.
- Manuscript in Digital Biomarkers with elaboration on checklist items and examples
- Decision tool for applying EVIDENCE to your study
- Downloadable version of the checklist to accompany manuscript submissions

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DIGITAL MEDICINE SOCIETY

Digital Medicine and the Future for Pharmacists

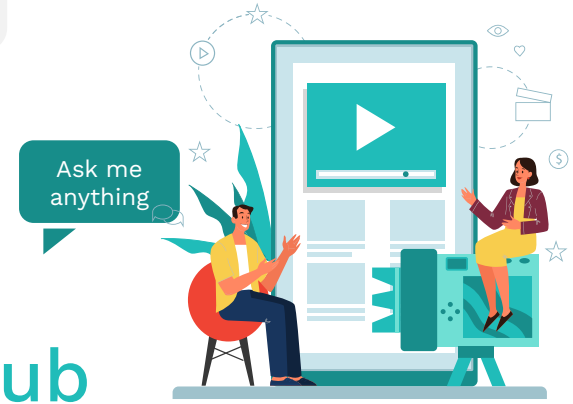
Thursday, June 10, 2021
12:00-1:00pm ET

Mel Odorzynski
COO, Aspen RxHealth

Gerald E. Finken, RPh
CEO & Founder,
RxE2, Inc

Moderator:
Smit Patel, PharmD
Director of Digital Medicine, DiMe

Virtual Journal club



Contextualizing Progress In The AI Revolution

June 24th, 2021
11a ET

David Shaywitz, MD, PhD

Founder
Astounding Healthtech

Lecturer on Biomedical Informatics
Harvard Medical School

THANK YOU

Jen, Christine, Ray and Beth

DIGITAL MEDICINE SOCIETY

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