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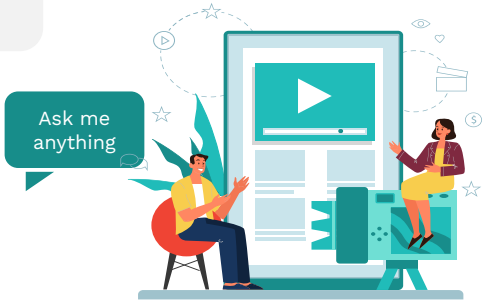

JMIR Publications
Advancing Digital Health & Open Science

Recommendations for Defining and Reporting Adherence Measured by Biometric Monitoring Technologies

May 12th, 2022 11am ET

Iredia Olaye PhD, MSc, MS
Fellow
Weill Cornell Medicine, Cornell

Jessie Bakker, MS, PhD
Executive VP of Medical Affairs
Signifier Medical Technologies

Isaac Rodriguez-Chavez,
PhD, MHSc, M.Sc.
Senior Vice President
Icon

Ali Ciger
Vaccines Country Lead
Pfizer Germany

Carrie Northcott, PhD
Director, Project Lead
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Mia Belovsky, BS
MD Candidate
Sidney Kimmel Medical

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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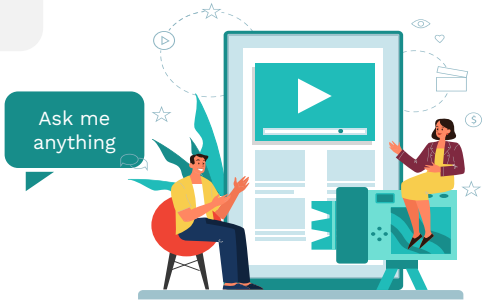

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Disclosures

- JPB (Signifier Medical Technologies and Philips)
- LB (Novartis)
- RC (Verily Life Sciences)
- AC (Pfizer and Ali Ciger Ventures UG [haftungsbeschränkt])
- KLF (K Health, Trusst Health Inc, InquistHealth, and Social Wellness)
- ESI (Koneksa Health)
- CJM (Astra Zeneca and Abbvie)
- CAN (Pfizer)
- IRRC (ICON plc)
- BV (Byteflies)

All other authors indicated no disclosures

Background

- Biometric monitoring technologies (BioMeTs): Connected digital tools that process data captured by mobile sensors using algorithms to generate measures of behavioral or physiological function
- Suboptimal adherence to data collection procedures or a study intervention is often the cause of a failed clinical trial (Eysenbach, 2005)
- If we build it, will they come?

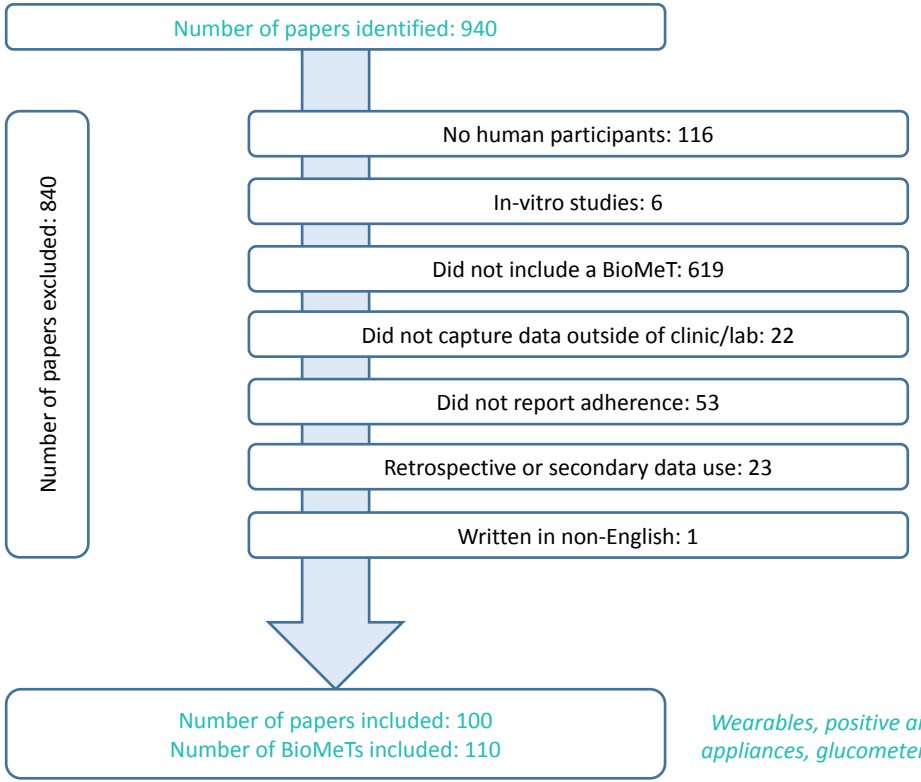
Objectives

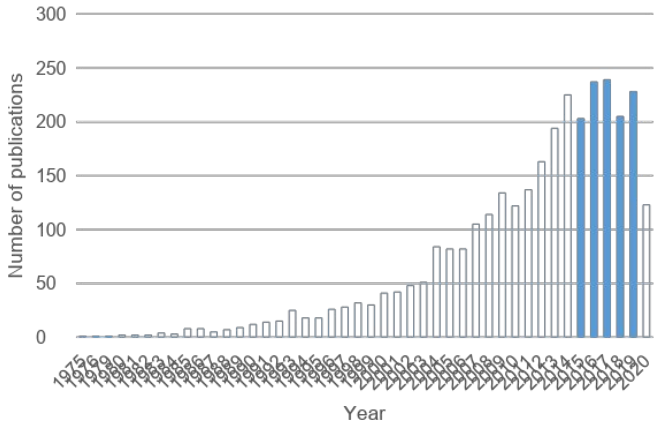
Conduct a systematic literature review of published studies reporting adherence captured by BioMeTs to:

- identify studies that have used these tools to capture adherence to data collection procedures and/or study interventions
- describe the various methods used to measure adherence
- compare the definitions of adherence reported in the literature

... then use this information to identify gaps and compile recommendations for investigators

Systematic review





Wearables, positive airway pressure devices, smart clothing, blood pressure monitors, smartphones, oral appliances, glucometers, ingestibles, implantables, smart scales, patches, exercise equipment, and more…

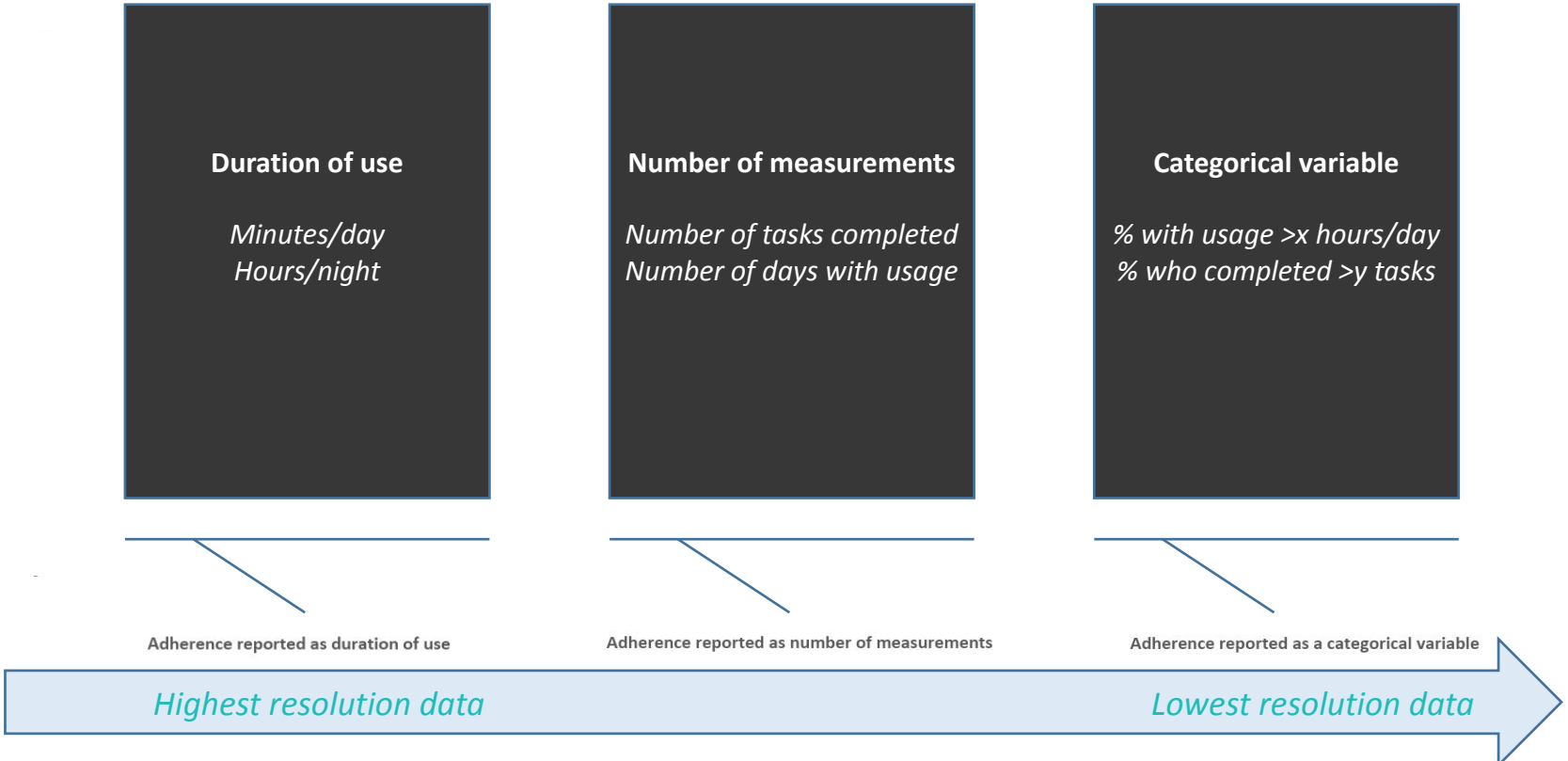
Adherence data

PASSIVE: Designed to be used continuously
Example: Fitness trackers

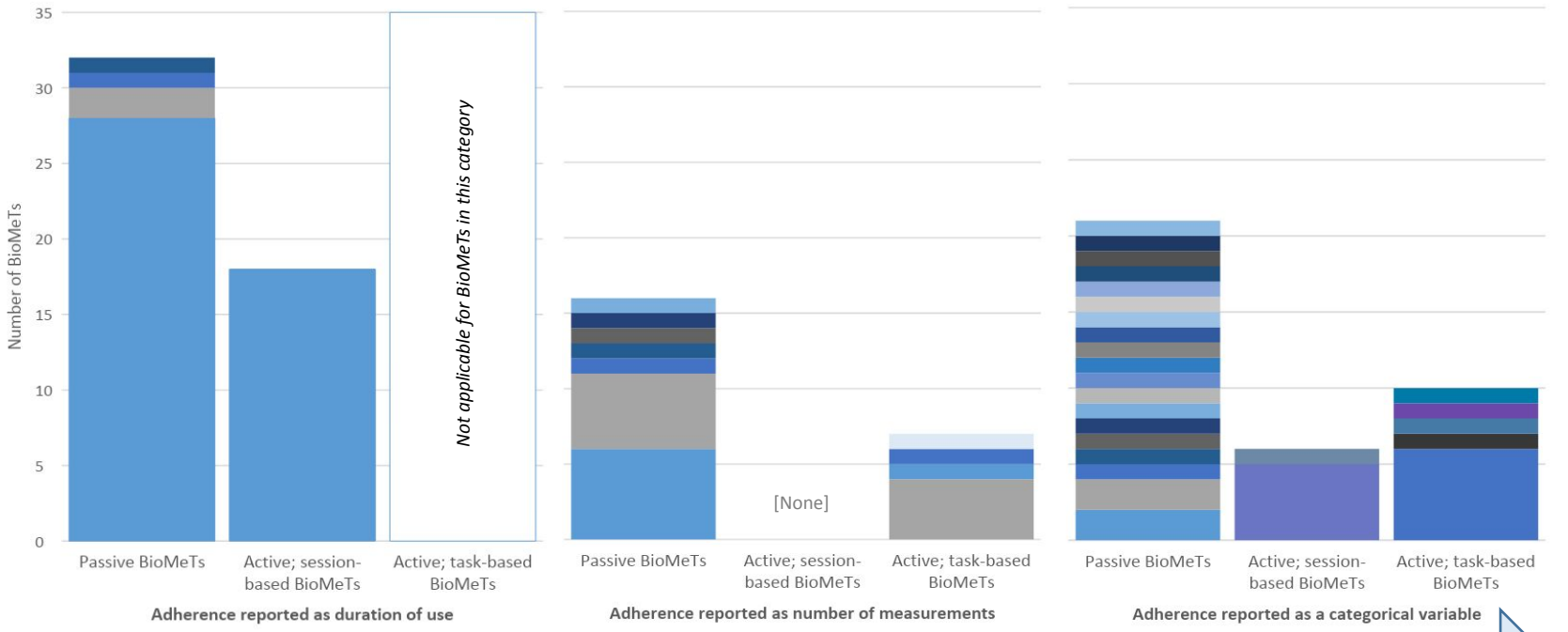
SESSION-BASED: Designed to be used during sessions
Example: Connected exercise equipment

TASK-BASED: Designed to be used as a one-off task
Example: Connected weight scales

Adherence data



Adherence data



*Heterogeneity of adherence data **increased** as resolution of adherence data **decreased***

Gaps and Recommendations

Gap 1: Sensor-based adherence data were not reported in 29.9% of screened manuscripts

- **Recommendation 1:** Develop and/or use BioMeT sensors to capture sensor-based adherence data in addition to their primary purpose

- **Recommendation 2:** Collect and report adherence data that are a direct reflection of actual use, rather than a surrogate

Gap 2: BioMeT manufacturer or model & software information missing for 10% and 68% of tools

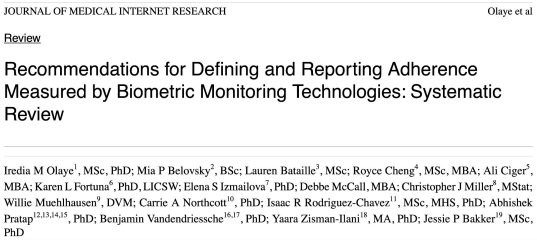
- **Recommendation 3:** Provide a clear description of the sensor or sensors capturing adherence data
- **Recommendation 4:** Describe the algorithm or algorithms that convert sample-level measurements into a measurement of adherence

Gap 3: Heterogeneity of adherence definitions increased alongside decreasing resolution of adherence data

- **Recommendation 6:** Report primary adherence as a continuous variable of time for passive or session based BioMeTS
- **Recommendation 7:** Report primary adherence as a continuous variable of time for task based BioMeTS
- **Recommendation 8:** Categorical adherence data are reported with continuous adherence data
- **Recommendation 9:** Categorical definitions of adherence should be based on clinical validation data

Key Takeaways

- With **increased consistency and reporting** of adherence and associated data elements, it will become possible to meta-analyze adherence data to identify determinants
- Understanding determinants of adherence allows for the development and testing of **targeted interventions** to optimize adherence
- Increased adherence to BioMeTs will ultimately improve the quality and efficiency of clinical trials



JOURNAL OF MEDICAL INTERNET RESEARCH Olaye et al

Review

Recommendations for Defining and Reporting Adherence Measured by Biometric Monitoring Technologies: Systematic Review

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Full paper available at *Journal of Medical Internet Research*:
https://www.jmir.org/2022/4/e33537/

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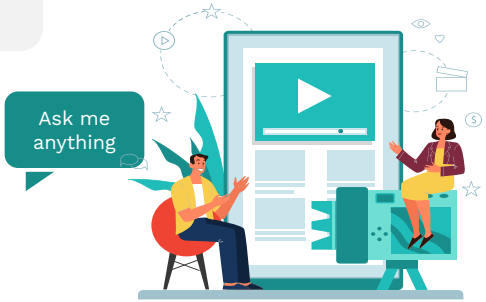

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May, 2022

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