Evaluating the Quality of Clinical Evidence for Digital Health Solutions: Findings from PHTI Assessments

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Introduction

- Digital health solutions have the **potential to improve health and lower costs**, but purchasers often face an **information gap on their clinical impact**.
- The Peterson Health Technology Institute (PHTI) addresses this gap by providing independent, evidence-based assessments of these solutions' clinical benefits and economic impact.
- The evidence underlying these assessments is highly variable and has not been comprehensively evaluated.
- Our objective was **to characterize the clinical evidence** supporting published PHTI assessments.

Methods

- The analysis set included five PHTI assessments published through September 2025:
  - Diabetes (DM)
  - Musculoskeletal (MSK) disorders
  - Hypertension (HTN)
  - Anxiety & Depression (AD)
  - Opioid use disorder (OUD)
- Data was abstracted on study designs, study duration, and study quality.
- Abstracted data were analyzed using descriptive statistics.

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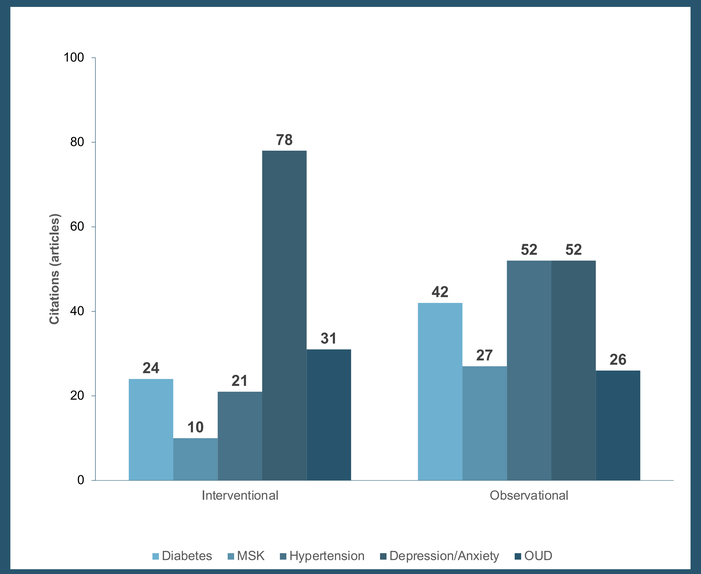
The evidence supporting PHTI assessments is substantial but heterogeneous, calling for more methodologically rigorous research on digital solutions.

Results

- Across PHTI assessments, 363 citations (articles) were reviewed, including 164 interventional and 199 observational studies (**Figure 1**).
- Among assessments that reported counts for comparative versus single-arm studies (HTN, AD, OUD), 41% were comparative and 59% were single-arm.
- Follow-up durations for included studies were generally short and vary by condition.
  - Follow-up durations in the MSK and AD reports most often reported outcomes at 6-12 weeks,
  - Follow-up durations in the DM, HTN, and OUD reports most often reported outcomes at 6-12 months.

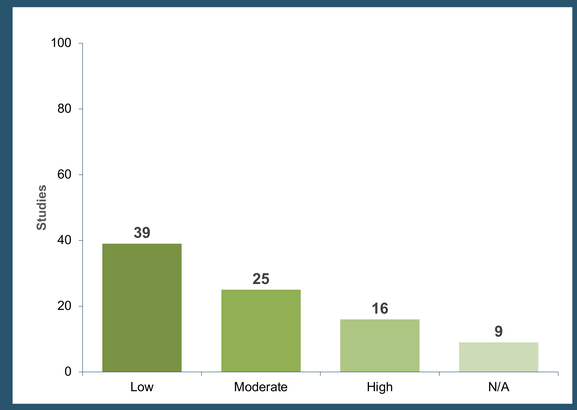
Figure 1. Study Design Types by PHTI Assessment



Key: AD – anxiety & depression; DM – diabetes; HTN – hypertension; MSK – musculoskeletal; OUD – opioid use disorder

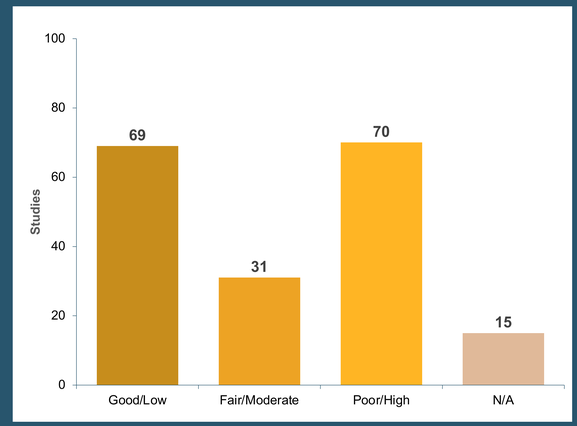
- A total of 250 unique studies were evaluated for risk of bias, including 80 studies assessed using RoB2 and 170 studies assessed using NOS.
- Approximately half of the studies (57%, n=142) were rated moderate or high risk of bias; 43% of studies were rated good or low risk of bias.

Figure 2. PHTI RoB2 Ratings Across Assessments



Key: RoB2 – A revised Cochrane risk-of-bias tool for randomized trials
*N/A: insufficient evidence to evaluate; these counts are not included in totals reported

Figure 3. PHTI NOS Ratings Across Assessments



Key: NOS – Newcastle-Ottawa Scale
*N/A: insufficient evidence to evaluate; these counts are not included in totals reported

Results cont.

- Across all assessments, 30 out of 51 (59%) companies submitted data for evaluation.
- The percent varied by assessment from a low of 32% in the DM assessment to 67% in the AD assessment.
- A relatively small share of company-submitted evidence met PICOs inclusion criteria across assessments (10%), ranging from 7% for AD to 18% for DM.
- Several companies, including Dario Health (DM, MSK, HTN, AD), Omada Health (DM, MSK, HTN), and Teladoc Health (DM, HTN, AD), were evaluated across multiple assessments.

Discussion

- The evidence underlying PHTI assessments is substantial but heterogeneous, with variability in study design, duration, and study quality.
- The heterogeneity in study design and high proportion of studies with moderate/high risk of bias can present challenges with interpretation and summarization of the body of accumulated evidence.
- Future research on digital solutions should prioritize rigorous methodology with appropriate comparators and adequate follow-up, when possible, to generate more robust and more widely generalizable evidence.

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