The Evidence DEFINED Framework

A Rigorous, Rapid Approach to Assess Clinical Value for Digital Health Products (DHPs)

Goals

1. Facilitate rapid & rigorous DHP evidence assessment in organizations
2. Guide digital health solutions to providers who wish to drive product adoption

In Scope

- ✔ Generating defensible recommendations regarding adoption levels that may be appropriate for a DHP
- ✔ Assessing clinical evidence for digital health interventions through a rapid, rigorous, consistent process

Out of Scope

- ✖ Decisions for individual patients, caregivers, or clinicians
- ✖ Products that serve diagnostic functions exclusively
- ✖ Evaluation in critical domains other than clinical evidence (eg, patient experience, product design, data security, etc.)

Process

The Evidence DEFINED Framework is comprised of the following steps:

1

Step 1. Screening
Each organization defines and screens for absolute requirements (eg, compliance with data privacy standards, appropriate reading levels, absence of clinical red flags, etc.). This avoids investing effort in DHPs that are not candidates for adoption.

2

Step 2. Apply an established method designed for non-digital products
Apply an established evidence assessment framework that was developed for non-digital interventions (eg, GRADE). Many stakeholder organizations already use such frameworks routinely for evidence assessment in non-digital domains.

3

Step 3. Apply the Evidence DEFINED supplemental checklist
Apply the Evidence DEFINED supplemental checklist (Table 2) to address considerations unique to DHPs or requiring greater vigilance in digital health.

4

Step 4. Make actionable recommendations
Apply evidence-to-recommendation guidelines (Table 3) to generate a defensible recommendation regarding levels of adoption that may be appropriate for the relevant DHP.

Target Audience

Designed to support digital health evidence assessment within stakeholder organizations including:

- Payers
- Pharmacy Benefit Managers
- Health Systems
- Pharmaceutical Companies
- Trade Organizations
- Professional Medical Societies

Source: https://dimesociety.org/access-resources/evidence-defined