

Towards a minimum information set needed to define patient-facing digital health technology for outcomes research

Annette Champion¹, Zsombor Zrubka², Anke Holtorf³, Rosella Di Bidino⁴, Jagadeswara Rao Earla⁵, Artem Boltyenkov⁶, Masami Tabata-Kelly⁷, Carl Asche⁸, Anita Burrell⁹

¹Healthcare Research Insights, Inc, Lake Forest, IL, USA; ²Óbuda University, Budapest, Hungary; ³Health Outcomes Strategies GmbH, Basel, Switzerland; ⁴Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Roma, RM, Italy; ⁵Merck & Co, Rahway, NJ, USA; ⁶Siemens Medical Solutions USA Inc, Malvern, PA, USA; ⁷Brandeis University, Waltham, MA, USA; ⁸University of Utah, Salt Lake City, UT, USA; ⁹Anita Burrell Consulting LLC, Flemington, NJ, USA

Objectives

Umbrella terms for **Digital Health Technology (DHT)** (digital health, eHealth, mHealth, telehealth/telemedicine) are insufficiently defined for health economics and outcomes research (HEOR). Definitions of secondary terms for DHTs lack information about PICOTS (population, intervention, comparator, outcome, timing, and setting) and health system or technology frameworks. We aim to **develop a minimum information set to define patient-facing DHTs for HEOR purposes**.

Methods

A **scoping review** (PubMed, EMBASE, Cochrane Library, EconLit; 2015-2020) identified systematic reviews containing DHT definitions. **Qualitative content analysis (QCA) of secondary DHT definitions** was performed using variables from PICOTS, Shannon-Weaver information model, Agency for Healthcare Research and Quality (AHRQ) quality domains, World Health

Methods (continued)

Organization (WHO) DHT classifications and information on technology and geography. From the QCA, a **two-level framework for definitions including domains and subcategories was proposed**. To generate feedback on the proposed framework, a two-round, modified Delphi survey has been initiated. ISPOR members with DHT expertise have been recruited to volunteer for an **online Delphi survey to develop a consensus** on a minimum information set for patient-facing DHT definitions.

Results

Sixty-eight unique secondary DHTs were found in 77 papers; 84% had a single definition. Most frequent definitions were for telerehabilitation (11), electronic health record (6), electronic consultation (5), and telemonitoring (5). **Among 24 QCA variables, only four (intervention, message, technology, and system) contained information in >50% of definitions.** For the **Delphi survey round 1**, PICOTS and three technology-related domains with 28 associated subcategories

Results (continued)

were proposed (Table 1). Input from eighteen round 1 respondents, forming a **diverse Delphi panel with a range of demographics and professional experience**, was used to revise the framework for round 2 consensus building.

Table 1 Delphi Survey Round 1 Proposed Framework	
Domain	Subcategories
Population	Target Population/Diagnosis; Demographic Characteristics; Special User Characteristics
Intervention	Key Function/Purpose; Modality
Comparator	Model of Care; Alternative Digital Health Interventions; Usual Care Alternatives
Outcomes	Health Benefits; Improved Care Structure or Process; Social/Societal Benefits; Safety; Non-health Related Risks; Efficacy, Convenience, and Economic Benefits
Timing	Timeliness; Frequency and Duration of Intervention
Setting	Care Setting; Patient Location; Geographic Scope
Information	Message; Data Management
Communication	User; Interaction Pattern; User Experience
Technology	Channel/ Medium; Device; Software; System

Conclusions

Definitions of umbrella and secondary DHTs contain insufficient information for HEOR use. We propose that by **extending the PICOTS framework, both medical and technological aspects should be specified**. By involving ISPOR members, a **minimum information set is under development** to initiate discussion with other stakeholders.