

# Mapping definitions of patient-facing digital health intervention in published frameworks against the PICOTS-ComTeC minimum information framework

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## Objectives

Despite published guidelines and frameworks for standardizing the reporting, evidence generation and assessment of **digital health interventions (DHIs)**, concerns persist about the quality of definitions used in DHI studies. We **compared and mapped the definition domains of DHI assessment frameworks against those of the consensus-based PICOTS-ComTeC** (Population, Intervention, Comparator, Outcomes, Timing, Setting, Communication, Technology and Context) **minimum information framework for defining patient-facing DHIs for HEOR.**

## Methods

PICOTS-ComTeC was developed as a flexible tool for defining patient-facing DHIs for HEOR purposes. **Sixteen widely used frameworks were mapped to the 9 domains and 32 subcategories of PICOTS-ComTeC.** The CHEERS framework, although not specific to DHIs, was included because it establishes standards for reporting health economic evaluations. Reviewer pairs mapped an average of 2 frameworks to PICOTS-ComTeC and agreed on a consensus mapping, which was then examined by a third reviewer, focusing on PICOTS-ComTeC domains that did not match. Descriptive statistics were used to characterize the overlap between these frameworks and PICOTS-ComTeC.

## Results

		P	I	C	O	T	S	Com	Te	C
CONSORT EHEALTH	Consolidated Standards of Reporting Trials of Electronic and Mobile HHealth Applications and onLine TeleHealth	●	●	●	●	●	●	●	●	●
iCHECK - DH	Guidelines and Checklist for the Reporting on Digital Health Implementations	●	●	●	●		●	●	●	●
MARS	Mobile Application Rating Scale	●	●					●	●	
mERA (WHO)	Mobile Health Evidence Reporting and Assessment Checklist	●	●		●	●	●	●	●	●
TECH	Target user, Evaluation focus, Connectedness and Health domain (TECH) systematic mHealth app reviews	●	●					●	●	
Evidence DEFINED	Evidence in Digital health for Effectiveness of Interventions with Evaluative Depth	●		●	●			●	●	●
DHA (Australia)	Assessment framework for mHealth apps. Australian Digital Health Agency	●	●		●		●	●	●	●
RIZIV (Belgium)	Mobile medical applications. National Institute for Health and Disability Insurance (RIZIV) Belgium.	●	●	●	●	●	●	●	●	●
HAS (France)	Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care	●	●		●	●		●	●	
Digi-HTA (Finland)	Digi-HTA process for digital health technologies	●	●	●	●		●	●	●	●
DiGA (Germany)	Fast-Track Process for Digital Health Applications	●	●	●	●	●	●	●	●	●
NICE (UK)	Evidence Standards Framework for digital health technologies (ECD7)	●	●	●	●	●	●	●	●	●
CDISAH (WHO)	Classification of Digital Interventions, Services and Applications in Health	●	●	●	●	●	●	●	●	●
VF-DHT	Value Framework to Assess Patient-Facing Digital Health Technologies That Aim to Improve Chronic Disease Management	●			●			●	●	●
CEN-ISO/TS 82304-2	Standard on labelling the quality and reliability of health and wellness apps	●	●		●		●	●	●	●
CHEERS 2022	Consolidated Health Economic Evaluation Reporting Standards 2022	●	●	●	●	●	●			●

## Conclusions

**PICOTS-ComTeC (Population, Intervention, Comparator, Outcomes, Timing, Setting, Communication, Technology and Context) is a comprehensive, yet flexible and versatile framework** that allows the identification of comparable DHIs and the selection of comparators that deliver similar effects to patients.

## References

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