Appendix 6 The PICOTS-ComTeC framework

The PICOTS-ComTeC framework aims to help with the formulation of specific and detailed definitions to allow identification of comparable DHIs delivering essentially the same effect and comparators that deliver similar effect but differ in relevant determinants of value. While focusing on DHI's value to patients, PICOTS-ComTeC can be used in many situations, such as writing study reports; framing clinical, financing or development decision questions; formulating research questions for evidence syntheses or applying for approval or reimbursement. PICOTS-ComTeC can augment descriptions of DHIs when used in parallel with general reporting guidelines or evaluation frameworks. We suggest that the main domains: population, intervention, comparator, outcome, timing, setting, communication, technology, and context should be considered and specified if appropriate, while the 32 subcategories can be used flexibly to add optional detail. If feasible, authors should refer to established classifications when specifying details for the items or provide additional information if pertinent.

Item	Explanation	Details of the digital health intervention
Population Domain	Characterization of patients/ population(s)	**P**
• Target Population/ Diagnosis	Diagnosis/ condition/ population (may be more than one)	
• Demographic Characteristics	Socio-demographics of population (e.g., age, gender, education)	
• Special User Characteristics	DHI relevant user characteristics (e.g., digital literacy, PC access)	
Intervention Domain	Description of DHI Intervention including key components and interactions	**I**
• Key Function/ Intended Use	Intended function (e.g., online screening to identify high-risk patients)	
• Modality	Design elements to achieve key function (e.g., behavioral, communication)	
• Limits of intervention	To specify those situations or thresholds where the DHI can be used, and beyond which the DHI should be replaced by face-to-face care	
Comparator Domain	Non-DHI(s) or alternative DHI(s) with same function	**C**
• Model of Care	Current model of care and/or clinical pathway, may be redesigned by DHI	
• Alternative Digital Health Interventions	DHI(s) with the same purpose (e.g., smart phone vs PC retinal screening)	
• Usual Care Alternatives	Usual treatment or care (e.g., compare with paper-based surveillance)	
Outcomes Domain	Outcomes relevant to patients and other stakeholders	**O**
• Health Benefits	Clinical and patient reported outcomes	
• Improved Care Structure or Process	Health care system improvements (e.g., access to care, adherence to guidelines, patient health literacy, self-management)	
• Social/ Societal Benefits	Humanistic, social, or societal effects (e.g., DHI could improve social support, or reduce stigma of a condition)	
• Safety	May reduce health related risks or improve patient safety	
• Non-health Related Risks	Non-health related risks including data privacy (e.g., unauthorized access and use of personal data)	
• Efficacy, Convenience, and Economic Benefits	DHIs could deliver the same outcome with greater efficiency, or less effort	

Item	Explanation	Details of the digital health intervention
Timing Domain	Timing and duration of treatment and follow-up	T
• Timeliness	Timely delivery of services could improve outcomes (e.g., telestroke DHI to shorten time to thrombolysis could improve survival)	
• Frequency and Duration of Intervention	Increased DHI use may improve outcomes (e.g., increased use in cardiac rehabilitation associated with greater weight-loss)	
Setting Domain	DHIs may increase access to or improve quality of health care. Potential benefits may vary by setting.	S
• Care Setting	Settings where DHI may be useful include pre- and post-hospitalization, emergency care, primary and community care.	
• Patient Location	DHIs can bring care to the patient's location (e.g., in-home hospital care during COVID-19, public kiosks providing access to nurses).	
• Geographic Scope	DHIs can improve access to health care (e.g., rural Alaska). Culture may limit use (e.g., telehealth differences in Brazil vs Canada).	
Communication Domain	DHIs may have different users with different roles. Function impacts frequency of interaction (e.g., post-surgical vs routine monitoring).	Com
• User	DHI users may vary (e.g., activity monitoring for patient lifestyle modification involving healthcare providers, or support groups).	
• Message	Unit of information collected and communicated by DHI (e.g., text, diagnostic image, or machine-readable data) impacts function.	
• Interaction Pattern	Differences in interactions (e.g., synchronous (real-time) or asynchronous) could impact outcomes in critical situations.	
• User Experience	Improving user experience may improve outcomes (e.g., when human factors were considered in digital interface design).	
Technology Domain	Use of different technologies (i.e., communication channel, device, software, or system) may impact DHI performance.	Te
• Channel/ Medium	Channel selection may impact patient access and DHI effectiveness (e.g., DHIs that exclude patients without telephone access).	
• Device	DHIs involve devices or user interfaces that may vary in cost and accessibility (e.g., patient access to mobile phone vs PC)	
• Software	Algorithms (e.g., for machine learning) and software components (e.g., for security) used by DHIs may affect performance.	
• System	Compatibility with data standards (e.g., FHIR) and interoperability with larger healthcare systems may affect DHI potential.	
• Data Management	Considerations include data quality, timeliness, interoperability (e.g., with EHR), security, patient privacy, and legal requirements.	
Context domain	Capture additional information that may influence the usability, access, or overall value of DHIs.	C
• Regulatory status	The relevant regulatory category and authorization status for the DHI to identify appropriate comparators. (E.g., FDA approved or investigational)	
• Medical / legal liability	Specify if certain legal provisions influence the availability or effect of the DHI. (e.g., can a medical expert give advice or only tests results can be communicated)	
• Financing	Specify if certain reimbursement or financing rules or pricing schemes influence the availability of functionality of the DHI. (e.g., in-app purchases, free from health service provider, subscription fee etc.)	

When using PICOTS-ComTeC, please cite the following publication.

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