

Improving healthcare decisions

Advancing the Definition and Reporting of Digital Health Interventions: From PICOTS-ComTeC to CHEERS-DHI

ISPOR Digital Health Special Interest Group

Friday, May 16 2025 | 10:00AM – 11:00AM



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Welcome and Introduction



The ISPOR Digital Health Special Interest Group

2023

Completed scoping review of published definitions of umbrella and secondary digital health terms PICOTS-ComTeC framework for defining digital

health interventions (DHIs) developed from a Delphi consensus study



Mapped items in established DHI frameworks and guidelines (and CHEERS) with PICOTS-ComTeC domains and subcategories





Presenters



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Presenter's Disclosure

Carl Asche is a Research Professor and the current Executive Director of the Pharmacotherapy Outcomes Research Center, Department of Pharmacotherapy, University of Utah College of Pharmacy.

Zsombor Zrubka is an Associate Professor and General Director of the University Research and Innovation Center at Obuda University

Annette Champion is President of Healthcare Research Insights, Inc., a consulting firm specializing in epidemiology and outcomes research and scientific communication.

The views expressed in this presentation are solely those of the authors' and do not necessarily reflect the views of their affiliated organizations.



Agenda

	Торіс	Presenter
1	Welcome and Introduction	Carl
2	PICOTS-ComTeC Rationale & Development	Zsombor
3	PICOTS-ComTeC Use Case & Mapping to Other DHI Frameworks	Annette
4	CHEERS-DHI Key Project	Carl
5	Audience Q&A	Carl



Audience Polling

- How familiar are you with the PICOTS-ComTeC framework for defining digital health interventions (DHIs)?
 - Attended previous ISPOR conference sessions
 - Read the Value in Health publication
 - Have used it in my work
 - Here to learn more

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PICOTS-ComTeC Rationale and Development



Digital health and AI development in perspective





Digital health and AI development in perspective





Digital Health in the Era of Ferment

337 000 apps

360+ DTX approved

140+ DTX reimbursed

30+ major digital health companies failing



Fragmented payer landscape



Diverse and vague terminology





The Development of PICOTS-ComTeC

Systematic review of definitions of four umbrella terms: 10 new definitions / year



Qualitative analysis of 67 secondary terms: 95 information patterns



A 3-round Delphi study for a minimum information framework to define patient-facing DHIs

18 experts from 7 geographic regions with diverse background



PICOTS-ComTeC Is A Flexible Framework to Define Patient-Facing Digital Health Interventions for HEOR

Population

- Target population / diagnosis
- Demographic Characteristics
- Special User Characteristics

Intervention

- Key function / Intended use
- Modality
- · Limits of intervention

Comparator

- Model of Care
- Alternative DHIs
- Usual Care Alternatives

Outcome

- · Health benefits
- Improved care structure / processes
- Social / Societal Benefits
- Safety
- Non-health related risks
- Efficiency, convenience and economic benefits

Timing

- Timeliness
- Frequeny and Duration of Intervention

Setting

- Care Setting
- Patient Location
- Geographic Scope

Communication

- User
- Message
- Interaction Pattern
- User Experience

Technology

- · Channel / medium
- Device
- · Software
- System
- Data management

Context

- Regulatory status
- Medical / legal liability
- Financing



PICOTS-ComTeC Was Published In Value In Health And On The EQUATOR Network Website



tents lists available at sciencedirect.com

The PICOTS-ComTeC Framework for Defining Digital Health Interventions: An ISPOR Special Interest Group Report

Zsombor Zrubka, PhD, Annette Champion, MBA, Anke-Peggy Holtorf, PhD, Rossella Di Bidino, PhD, Jagadeswara Rao Earla, PhD, Artem T. Boltyenkov, PhD, Masami Tabata-Kelly, MA, Carl Asche, PhD, Anita Burrell, MA

Objective: Dinital health definitions are abundant, but often lack clarity and precision. We aimed to develop a minimum information framework to define patient-facing digital health interventions Abundant, yet yaguely defined (DHIs) for outcomes research.

definitions in digital health represent a challenge for clinicians, Methods: Definitions of digital-health-related terms (DHTs) were systematically reviewed, followed by a content analysis using frameworks, including PICOTS (population, intervention, comparator, outcome, timing, and setting), Shannon-Weaver Model of Communication, Agency for Healthcare decision makers, developers, and researchers. Despite having several Research and Quality Measures and the World Health Organization's Classification of Digital guidelines/checklists for the rventions. Subsequently, we conducted an online Delphi study to establish a minimum standardization of evidence information framework, which was pilot tested by 5 experts using hypothetical examples. generation and assessment for

Results: After screening 2610 records and 545 full-text articles, we identified 101 unique definitions of 67 secondary DHTs in 76 articles, resulting in 95 different patterns of concepts among the definitions. World Health Organization system (84.5%), message (75.7%), intervention (58.3%), and technology (52.4%) were the most frequently covered concepts. For the Delphi survey, we invited 47 members of the ISPOR Digital Health Special Interest Group, 18 of whom became the Delph second, and third survey rounds were completed by 18, 11, and 10 respondents, r consolidating results, the PICOTS-ComTeC acronym emerged, involving 9 dom intervention, comparator, outcome, timing, setting, communication, technology, a 32 optional subcategories.

Conclusions: Patient-facing DHIs can be specified using PICOTS-ComTeC that facilita of appropriate interventions and comparators for a given decision. PICOTS-ComTec versatile tool, intended to assist authors in designing and reporting primary stud syntheses, yielding actionable results for clinicians and other decision makers.

Keywords: definition, bealth economics and outcomes research, patient-facing dis vention, PICOTS-ComTeC, systematic review. ATTIE HEALTH. 2024; 27(4):383-396

THEFT	maan	2024,	73(4)

Introduction

Digital health involves technologies including artificial intelligence (AI), virtual reality, digital therapeutics, wearables, remote ogy o monitoring, and software.1 Acknowledging the bewildering array tervent of terms in use,1-6 we denote these technologies as digital health their n interventions (DHIs). Technological advances, movement toward patient-centered care, and the COVID-19 pandemic have driven list for the adoption of DHIs,7:15 Although DHIs can potentially enhance on I decision making, equity, and access,^{36,17} concerns persist regarding the reporting quality and ambiguous terminology of DHI studies⁴ Several guidelines aim to standardize the methodological and

reporting quality of DHI studies. CONSORT-EHEALTH focuses on

Reporting and Assessment (mERA) checklist proposes a minimum

indomized controlled trials of DHIs21 The mHealth Evidence

ited 47 members i panel. The first, espectively. After ains (population, and context) and tes identification i is a flexible and ies and evidence gital health inter-	their personalized nature, complex technologies, and indiages to larger systems. This may restrict the validity of eridence syntheses. We introduce the PKODS ComTeC (gopulation, intervention, comparator, outcome, timing, setting, communication, technology, and context) framework, a newly developed, flexible, and versation to help the formulation of sufficiently specific and detailed definitions for patient science glaput deting in the states of the states of the deting in the states of the states of the states of the states of the states of the states of the deting of the states of t
ation set to the content, t, and technol- f mHealth in- ions to support eplication. ³⁸ The mes and Check- the Reporting Nigital Health tentations	To overcome the limitations of the terminology in digital headsh, the HCIDS-ConTeC framework of patient-facing DHs should be specified in sufficient detail, to allow the identification of comparable interventions and allow for the selection of appropriate comparators that deliver similar effects to patients; therefore, the fit development decision contexts, and development decision contexts. and specific research questions can be

digital health interventions (DHIs),

the identification of comparable

DHIs remains difficult because of

the reporting of realworld implementation studies.22 A checklist is available for DHI usability studies.23 The Digital Health Checklist for Researchers addresses ethics, data security, and privacy when selecting DHIs for research.24,25 The eHealth Resource Checklist guides the search

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The PICOTS-ComTeC Framework for Defining Digital Health Interventions: An ISPOR Special Interest Group Report

Reporting of patient-facing digital health interventions.

```
Reporting guideline
provided for?
(i.e. exactly what the
```

authors state in the paper)

```
Full bibliographic
```

reference

Language

Study design

PubMed ID

Reporting guideline acronym

Applies to the whole

Economic evaluations, Systematic reviews/Meta-analyses/Reviews/HTA/Overviews

Zrubka Z, Champion A, Holtorf AP, Di Bidino R, Earla JR, Boltvenkov AT, Tabata-Kellv M, Asche C, Burrell A. The PICOTS-ComTeC Framework for Defining Digital Health

Interventions: An ISPOR Special Interest Group Report, Value Health, 2024;27(4):383-

Intervention (exposure)

report or to individual sections of the report?

April 15, 2024 Record last updated on

306

English

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PICOTS-ComTeC

Reporting guidelines for main study types							
Randomised trials	CONSORT	Extensions					
Observational							
studies	STROBE	Extensions					
Systematic reviews	PRISMA	Extensions					
Study protocols	SPIRIT	PRISMA-P					
Diagnostic/prognost							
ic studies	STARD	TRIPOD					
Case reports	CARE	Extensions					
Clinical practice							
guidelines	AGREE	RIGHT					
Qualitative research	SRQR	COREQ					
Animal pre-clinical							
studies	ARRIVE						
Quality improvement	<u>t</u>						
studies	SQUIRE	Extensions					
Economic evaluations	CHEERS	Extensions					

Translations

Some reporting guidelines are also available in languages other than English. Find out more in our Translations section.

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PICOTS-ComTeC Use Case and Mapping to Other DHI Frameworks



PICOTS-ComTeC Use Case in Breast Cancer

- Identified 6 mobile apps used in the US for postoperative breast cancer care from studies in a scoping review
- PICOTS-ComTeC domains used to define mobile apps
 - Information from review supplemented by original studies and online searches
 - Differentiated between information about the app and the study
- Audience polling today to identify comparators using PICOTS-ComTeC

PICOTS-ComTeC domains

- Population
- Intervention
- Comparator
- Outcomes
- Timing
- Setting
- Communication
- Technology
- Context



Scoping Review of Mobile Apps Used in Breast Cancer Postoperative Care

REVIEW OPEN ACCESS

Mobile Applications in Breast Cancer Postoperative Care: A Scoping Review

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Keywords: breast neoplasms | mhealth | mobile application | postoperative care

ABSTRACT

Background: The utilization of mobile application in postoperative care for breast cancer patients has seen a significant rise in recent years. This study aimed to synthesize the literature to identify the features of breast cancer postoperative care mobile applications.

Methods: This scoping review was conducted using the framework developed by Arksey and O'Malley. All articles published from inception until July 25, 2024, were searched in the PubMed, Scopus, Web of Science, IEEE, and Cochrane databases. The quality of publications was evaluated using the mixed-methods appraisal tool (MMAT).

Results: A total of 999 publications were found, of which 28 studies were considered in this review. Out of these studies, 14 used native apps, 14 used hybrid apps. Nine features were used in applications, and Tracker, Tailored Education, and Community Forum were the most repetitive features. In five studies, various devices and sensors, like Bluetooth and GPS, were utilized in mobile applications to monitor physical activity, stress levels, heart rate, sleep patterns, and calorie intake.

Conclusions: Mobile applications for postoperative breast cancer care encompass a range of features. In a co-design approach, understanding patients' required features could help to develop usable applications to improve the postoperative care for breast cancer patients.

- Literature search identified 28 studies focusing on design and development of mobile apps
- Studies in 13 countries; US (6), Republic of Korea (4), Canada (3) and China (3) had the most studies
- Six US studies selected to illustrate use of PICOTS-ComTeC to identify comparators

Alidadi M, Rabiei R, Akbari A, Emami H, Laal Mousavi SM. Mobile Applications in Breast Cancer Postoperative Care: A Scoping Review. *Cancer Med.* 2024;13(24):e70444. doi:10.1002/cam4.70444



Six Mobile Apps Used in US Postoperative Breast Cancer Care

- A. Manage My Surgery (MMS)
- B. Creating Healthy Actions Through Technology (CHAT)
- C. Mi Guía (My Guide)
- D. The-Optimal-Lymph-Flow (TOLF) system
- E. Nuevo Amanecer (New Dawn)
- F. imPROVE platform



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PICOTS-ComTeC – Mobile Apps in Post-Surgical Breast Cancer Care in the US (page 1/2)							
	A. Manage My Surgery (MMS)	B. Creating Healthy Actions Through Technology (CHAT)	C. Mi Guía (My Guide)				
Population (study)	Breast cancer elective surgery patients	African American breast cancer survivors	Hispanic breast cancer survivors (BCS)				
Intervention	MMS mobile app for surgical planning, communication with provider, outcomes tracking	CHAT mobile app, patient daily ecological momentary assessments (EMA), tailored heath messages to improve physical activity and diet	My Guide mobile app (education & self-management program); tailored for Hispanic BCS				
Comparator (study control)	None	No tailored health messages	My Health app (health education)				
Outcomes (study)	PROMIS-29 Survey	Computer-based survey	General and disease-specific HRQoL, distress				
Timing (study)	12 months	2 months	6 weeks				
S etting	Outpatient	Outpatient	Outpatient				
Com munication	Between patients & providers, patient reminders	App provides tailored messages, recommendations	NM				
Technology (study)	Android & IOS smart phones, MMS app now CareConvoy	Android smart phone, ActiGraph wGT3X-BT accelerometer	Smart phones, operating system NM				
Context (country, <i>study</i>)	USA, feasibility study (Ponder 2021), Higgs Boson Inc	USA, feasibility RCT (Allicock 2021), University of Texas	USA, RCT protocol (Yanez 2017), Northwestern University				

Identified from scoping review (Alidadi 2024). Text in italics is study related, e.g. comparator, outcomes. NA = not available, NM = not mentioned in publication. RCT = randomized-controlled trial.



PICOTS-ComTeC – Mobile Apps in Post-Surgical Breast Cancer Care in the US (page 2/2)								
	D. The-Optimal-Lymph-Flow (TOLF) system	E. Nuevo Amanecer (New Dawn)	F. imPROVE platform					
Population (study)	Breast cancer survivors	Spanish-speaking breast cancer patients at treatment end	Breast cancer post-surgery patients					
Intervention	TOLF mobile app, "self-care strategies for lymphedema symptom management"	New Dawn survivorship care planning program, printed materials, Spanish-language mobile app, activity tracker & coaching	imPROVE platform (improve adoption of PROs in breast cancer mobile app (5 components) & clinician dashboard					
Comparator (study control)	Web- and Mobile-based Arm Precaution program	None	None					
Outcomes (study)	Limb volume difference, pain, risk reduction behavior	General and disease-specific HRQoL/PROs (PROMIS)	Patient interviews, Advisory focus groups					
Timing (study)	3 months	2 months	NM					
S etting	Outpatient	Outpatient	Outpatient					
Com munication	NM	Weekly telephone coaching	NM					
Te chnology (study)	Web & mobile mHealth system, Infrared perometer (350S; Juzo)	Smart phone, operating system NM, trackC app & Fitbit Zip (now NA)	Android and IOS smart phones					
C ontext (country, <i>study</i>)	USA, RCT (Fu 2022, Fu 2016), Rutgers University	USA, acceptability and feasibility study (Napoles 2019), NIH	USA, app design & development, (Tsangaris 2022), Harvard University					

Identified from scoping review (Alidadi 2024). Text in italics is study related, e.g. comparator, outcomes. NA = not available, NM = not mentioned in publication. RCT = randomized-controlled trial.



Five Mobile Apps Selected for Audience Polling to Identify Comparators

- A. Manage My Surgery (MMS)
- B. Creating Healthy Actions Through Technology (CHAT)
- C. Mi Guía (My Guide)
- D. The-Optimal-Lymph-Flow (TOLF) system
- E. Nuevo Amanecer (New Dawn)
- F. imPROVE platform



It's Time for a Poll!

Which app(s) are for breast cancer post-op subpopulations?

A. Manage My Surgery (MMS)

- B. Creating Healthy Actions Through Technology (CHAT)
- C. Mi Guía (My Guide)
- D. The-Optimal-Lymph-Flow (TOLF) system
- E. Nuevo Amanecer (New Dawn)



Answer

Which app(s) are for breast cancer post-op subpopulations?

- A. Manage My Surgery (MMS)
- B. Creating Healthy Actions Through Technology (CHAT) African American
- C. Mi Guía (My Guide) Hispanic
- D. The-Optimal-Lymph-Flow (TOLF) system
- E. Nuevo Amanecer (New Dawn) Spanish-speaking



It's Time for a Poll!

Which app(s) are not specific to breast cancer?

- A. Manage My Surgery (MMS)
- B. Creating Healthy Actions Through Technology (CHAT)
- C. Mi Guía (My Guide)
- D. The-Optimal-Lymph-Flow (TOLF) system
- E. Nuevo Amanecer (New Dawn)



Answer

Which app(s) are not specific to breast cancer?

- A. Manage My Surgery (MMS) surgery not specific to breast cancer
- B. Creating Healthy Actions Through Technology (CHAT)
- C. Mi Guía (My Guide)
- D. The-Optimal-Lymph-Flow (TOLF) system
- E. Nuevo Amanecer (New Dawn)



It's Time for a Poll!

Which app(s) have the narrowest focus?

- A. Manage My Surgery (MMS)
- B. Creating Healthy Actions Through Technology (CHAT)
- C. Mi Guía (My Guide)
- D. The-Optimal-Lymph-Flow (TOLF) system
- E. Nuevo Amanecer (New Dawn)



Answer

Which app(s) have the narrowest focus?

- A. Manage My Surgery (MMS) surgical treatment
- B. Creating Healthy Actions Through Technology (CHAT)
- C. Mi Guía (My Guide)

D. The-Optimal-Lymph-Flow (TOLF) system lymphedema symptom management

E. Nuevo Amanecer (New Dawn)



It's Time for a Poll!

Which app(s) include two-way communication?

- A. Manage My Surgery (MMS)
- B. Creating Healthy Actions Through Technology (CHAT)
- C. Mi Guía (My Guide)
- D. The-Optimal-Lymph-Flow (TOLF) system
- E. Nuevo Amanecer (New Dawn)



Answer

Which app(s) include two-way communication?

- A. Manage My Surgery (MMS) communication with provider
- B. Creating Healthy Actions Through Technology (CHAT)
- C. Mi Guía (My Guide)
- D. The-Optimal-Lymph-Flow (TOLF) system

E. Nuevo Amanecer (New Dawn) - weekly telephone coaching



It's Time for a Poll!

Which apps are the most similar?

- A. Manage My Surgery (MMS)
- B. Creating Healthy Actions Through Technology (CHAT)
- C. Mi Guía (My Guide)
- D. The-Optimal-Lymph-Flow (TOLF) system
- E. Nuevo Amanecer (New Dawn)



Answer

Which apps are the most similar?

- A. Manage My Surgery (MMS)
- B. Creating Healthy Actions Through Technology (CHAT)
- C. Mi Guía (My Guide) Education and self-management program tailored for Hispanic breast cancer survivors
- D. The-Optimal-Lymph-Flow (TOLF) system
- E. Nuevo Amanecer (New Dawn) Planning, activity tracking & coaching for Spanish-speaking breast cancer patients at end of treatment



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Identification of Most Similar Apps – Potential Comparators for Long-Term Care of Hispanic Subpopulation

	Answers - Mobile Apps in Post-Surgical Breast Cancer Care in the US						
Polling questions	A. Manage My Surgery (MMS)	B. Creating Healthy Actions Through Technology (CHAT)	C. Mi Guía (My Guide)	D. The-Optimal- Lymph-Flow (TOLF) system	E. Nuevo Amanecer (New Dawn)	F. imPROVE platform	
1. Which app(s) are for breast cancer post-op subpopulations?		African American	Hispanic		Spanish-speaking		
2. Which app(s) are not specific to breast cancer?	Surgery not specific to breast cancer						
3. Which app(s) have the most narrow focus?	Surgical treatment			Lymphedema symptom management		Improve adoption of PROs	
4. Which app(s) include two-way communication?	Communication with provider				Weekly telephone coaching		
5. Which apps are the most similar?			Education and self- management program tailored for Hispanic breast cancer survivors		Planning, activity tracking & coaching program for Spanish-speaking breast cancer patients at end of treatment		



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Identification of Most Similar Apps, Alternative – Potential Comparators for Short-Term Postoperative Care

	Answers - Mobile Apps in Post-Surgical Breast Cancer Care in the US								
Polling questions	A. Manage My Surgery (MMS)	B. Creating Healthy Actions Through Technology (CHAT)	C. Mi Guía (My Guide)	D. The-Optimal- Lymph-Flow (TOLF) system	E. Nuevo Amanecer (New Dawn)	F. imPROVE platform			
1. Which app(s) are for breast cancer post-op subpopulations?		African American	Hispanic		Spanish-speaking				
2. Which app(s) are not specific to breast cancer?	Surgery not specific to breast cancer								
3. Which app(s) have the most narrow focus?	Surgical treatment			Lymphedema symptom management		Improve adoption of PROs			
4. Which app(s) include two-way communication?	Communication with provider				Weekly telephone coaching				
5. Which apps are the most similar?			Education and self- management program tailored for Hispanic breast cancer survivors		Planning, activity tracking & coaching program for Spanish-speaking breast cancer patients at end of treatment				

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Breast Cancer Use Case Conclusions

- Scoping review of mobile apps in breast cancer postoperative care US studies
 - Few relevant studies, despite proliferation of mobile applications
 - Lack of standardization in apps
 - Published studies contain limited descriptions of apps
 - No information about costs
 - Information about comparator, outcomes and timing from studies, not apps
 - Limited information about technology (ComTeC domains)
- Use of PICOTS-ComTeC to identify comparators using published studies
 - Prespecify criteria for selecting comparator(s)
 - Need to distinguish between the app and the study
 - May need additional research to characterize the app
- Benefits of using PICOTS-ComTeC framework
 - Better understand the app What does it do? How does it do it? What is the role of the provider?
 - Select most appropriate comparator(s)
 - Better understand differences in outcomes when comparing apps





How Does PICOTS-ComTeC Fit with Other Digital Health Intervention Frameworks?

- What items from PICOTS-ComTeC are present in other DHI frameworks?
- What does PICOTS-ComTeC add?
- How might PICOTS-ComTeC and other DHI frameworks be used together?

Independent DHI Frameworks



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Methods

Framework selection

- Published in English
- Selected by expert consensus
 - 15 DHI frameworks for standardizing evidence generation, reporting and assessment
 - One HEOR reporting framework (CHEERS)
- Representing diversity of organizations, objectives, geography, and healthcare systems

Mapping to PICOTS-ComTeC

- Pairs of reviewers extracted information from 16 frameworks
 - General information about the framework
 - Text that matched PICOTS-ComTeC items
 - Inclusive approach
- Third reviewer focused on consistency and missing data
- Descriptive analysis of results



Comparator frameworks grouped by purpose

Classification

WHO Classification of Digital Interventions, Services and Applications in Health (WHO CDISAH)

Development/Regulatory Approval

- ISO/TS 82304-2 Health software Part 2: Health and wellness apps—Quality and reliability (CEN-ISO/TS 82304-2)
- Mobile Application Rating Scale (MARS)*
- Target user, Evaluation focus, Connectedness and Health domain (TECH) systematic mHealth app reviews (TECH)*

Health Technology Assessment

- Assessment framework for mHealth apps. Australian Digital Health Agency (Australia DHA)
- · Mobile medical applications. National Institute for Health and Disability Insurance (RIZIV) Belgium (Belgium RIZIV)
- Fast-Track Process for Digital Health Applications (Finland Digi-HTA)
- Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care (France Haute Autorité de Santé (HAS))
- Fast-Track Process for Digital Health Applications (German DiGA)
- Evidence Standards Framework for digital health technologies (ECD7) (UK National Institute for Health and Care Excellence (NICE))

Adoption/Implementation/Reporting

- Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and onLine TeleHealth (CONSORT-EHEALTH)
- Evidence in Digital health for EFfectiveness of INterventions with Evaluative Depth (Evidence DEFINED)
- Guidelines and Checklist for the Reporting on Digital Health Implementations (iCHECK-DH)
- Consolidated Health Economic Evaluation Reporting Standards 2022 (ISPOR CHEERS)
- MARS*
- TECH*
- Value Framework to Assess Patient-Facing Digital Health Technologies That Aim to Improve Chronic Disease Management (VF-DHT)
- WHO Mobile Health Evidence Reporting and Assessment Checklist (WHO mERA)

* Two frameworks were listed twice



Domain Matching

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

Zsombor Zrubka¹, Annette Champion², Anke-Peggy Holtorf^{3,8}, Rossella Di Bidino⁴, Jagadeswara Rao Earla⁵, Artem T. Boltyenkov⁶, Masami Tabata-Kelly², Carl Asche⁸, Brian Seal⁹, Hoda Fotovvat¹⁰, Anne-Kilburg¹¹, Lisa Weiss ¹² Anita Burrell¹³

¹Obust University, Budgest, Hungany, Healthcare Research Insights, Inc. Lake Freest, LL USA, ¹Health Outcomes Strategies Ghield, Basel, Sattzedand, ¹Colutate School of Health Economics and Management (ALTEMS), Roma RM, Italy, ¹Merck & Co., Inc., Rahway, NJ, USA, ¹Semest Healthcare Dagnostics Inc., Heilertown, PA, USA, ¹Brandeis University Waltham, MA, USA, ¹University of Utah, Salt Lake City, UT, USA, ¹Organon, Jersey City, NJ, USA, ¹Evidera, Bethesda, MO, USA, ¹TikiburgDialogue, Basel, BS, Satterstrain, ¹DS: Transford College, New York, USA, ¹Neutrille Consulting LLC, Peimington, ULG A.

Objectives		Results									
Despite published guidelines and frameworks for			Р	- I	С	0	т	S	Com	Те	C
standardizing the reporting, evidence generation and	CONSORT EHEALTH	Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and onLine TeleHealth	0	0	0	0	0	0	0	0	0
assessment of digital health interventions (DHIs),	iCHECK - DH	Guidelines and Checklist for the Reporting on Digital Health Implementations	0	0	0	0		0	0	0	0
concerns persist about the quality of definitions used	MARS	Mobile Application Rating Scale	Õ	0					0	0	
definition domains of DHI assessment frameworks	mERA (WHO)	Mobile Health Evidence Reporting and Assessment Checklist	Õ	0		0	0	0	0	0	0
against those of the consensus-based PICOTS-	TECH	Target user, Evaluation focus, Connectedness and Health domain (TECH) systematic mHealth app reviews	Õ	0			-		0	0	
ComTeC (Population, Intervention, Comparator,	Evidence DEFINED	Evidence in Digital health for EFfectiveness of INterventions with Evaluative Depth	Õ						Õ	ŏ	0
Outcomes, Timing, Setting, Communication,	DHA (Australia)	Assessment framework for mHealth apps. Australian Digital Health	ŏ	0		ŏ			ŏ	ŏ	ē
framework for defining patient-facing DHIs for HEOR	RIZIV (Belgium)	Mobile medical applications. National Institute for Health and Disability Insurance (RIZIV) Releium.	ŏ	ŏ		ŏ		ŏ	ŏ	ŏ	6
Matheada	HAS (France)	Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care	ŏ	ŏ	-	ŏ	ŏ		ŏ	ŏ	
Wiethous	Digi-HTA (Finland)	Digi-HTA process for digital health technologies	ŏ	ă		ă			ŏ	ŏ	0
PICOTS-ComTeC was developed as a flexible tool for	DiGA (Germany)	Fast-Track Process for Digital Health Applications	ă	ŏ	ŏ	ŏ		ŏ	ŏ	ă	ē
Sixteen widely used frameworks were mapped to	NICE (UK)	Evidence Standards Framework for digital health technologies	ă	ŏ	ŏ	ŏ	ă	ŏ	ŏ	ŏ	ē
the 9 domains and 32 subcategories of PICOTS-	CDISAH (WHO)	Classification of Digital Interventions, Services and Applications in	ă	ă	ă	ă	ă	ă	ă	ă	ē
ComTeC. The CHEERS framework, although not	VF-DHT	Value Framework to Assess Patient-Facing Digital Health Technologier, That Alm to Improve Chronic Disease Management	ă			ă		-	ă	ă	č
specific to DHIs, was included because it establishes	CEN-ISO/TS 82304-2	Standard on labelling the quality and reliability of health and wollcore appr	3			3			3	3	7
standards for reporting health economic evaluations. Reviewer pairs manned an average of 2 frameworks	CHEERS 2022	Consolidated Health Economic Evaluation Reporting Standards	ă	ŏ		ŏ		ă	-	-	č
to PICOTS-ComTeC and agreed on a consensus		2022		<u> </u>	-	-	-	-			
mapping, which was then examined by a third		Conclusions				R	efere	ence	S		
reviewer, focusing on PICOTS-ComTeC domains that did not match. Descriptive statistics were used to characterize the overlap between these frameworks and PICOTS-ComTeC.	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.				Zrubka Z, mes Reser 022;25(9): Champion ng Digital alue Healt 0.1016/j.j	Champion arch? An I. 1469-147 h A, Holto Health Ini h. 2024;2 val.2024.0	n A, et al. / SPOR Spec 9. doi:10.1 orf A-P, et a tervention (7(4):383- 01.009.	How Use, ial Intere 016/J.jvz al. The PI s: An ISP 396.	ful Are Dig est Group I II.2022.04 COTS-Corr DR Special	ital Healt leport. Va 1730 TeC Fram Interest o	h Term ilue wwork Group

Zsombor Zrubka, Annette Champion, Anke-Peggy Holtorf et.al., MT22 Mapping Definitions of Patient-Facing Digital Health Intervention in Published Frameworks Against the PICOTS-ComTeC Minimum Information Framework. *Value in Health*, 27(6) Supplement, S285, June 2024.

- Five frameworks matched all 9 PICOTS-ComTeC domains: WHO CDISAH, Belgium RIZIV, Germany DiGA, UK NICE, and CONSORT-EHEALTH
- Two frameworks matched only 4
 domains: MARS and TECH
- Population domain present in all 16 frameworks, followed by Communication and Technology domains (both 15)
- Domains with fewest matches were Comparator (9) and Timing (8)



PICOTS-ComTeC Framework for Defining DHIs

Population Domain

- 1. Target population / diagnosis
- 2. Demographic Characteristics
- 3. Special User Characteristics

Intervention Domain

- 1. Key function / Intended use
- 2. Modality
- 3. Limits of intervention

Comparator Domain

- 1. Model of Care
- 2. Alternative DHIs
- 3. Usual Care Alternatives

Outcomes Domain

- 1. Health benefits
- 2. Improved care structure / processes
- 3. Social / Societal Benefits
- 4. Safety
- 5. Non-health related risks
- 6. Efficiency, convenience and economic benefits

Timing Domain

- 1. Timeliness
- 2. Frequeny and Duration of Intervention

Setting Domain

- 1. Care Setting
- 2. Patient Location
- 3. Geographic Scope

Communication Domain

- 1. User
- 2. Message
- 3. Interaction Pattern
- 4. User Experience

Technology Domain

- 1. Channel / medium
- 2. Device
- 3. Software
- 4. System
- 5. Data management

Context Domain

- 1. Regulatory status
- 2. Medical / legal liability
- 3. Financing

Each of the nine domains has supporting subcategories, ranging from 2 for the Timing Domain to 6 for the Outcomes Domain.



Subcategory Matching

- Subcategory matching was generally incomplete
- The most complete frameworks in terms of PICOTS-ComTeC matches were
 - WHO CDISAH (9 domains, 26/32 subcategories)
 - German DiGA (9 domains, 25/32 subcategories)

Mapping of WHO CDISAH to PICOTS-ComTeC Domains and Subcategories									
Domain/ Subcategories	1	2	3	4	5	6			
Population									
Intervention									
Comparator									
Outcomes									
Timing									
Setting									
Communication									
Technology									
Context									

Mapping of German DIGA to PICOTS-ComTeC Domains and Subcategories									
Domain/ Subcategories	1	2	3	4	5	6			
Population									
Intervention									
Comparator									
Outcomes									
Timing									
Setting									
Communication									
Technology									
Context									



Mapping Conclusions

- Comparison of 16 other frameworks to PICOTS-ComTeC revealed a great deal of commonality
 - PICOTS-ComTeC contributed items not uniformly present in the comparator frameworks
 - Some frameworks provided additional granularity for PICOTS-ComTeC items
- Suggests PICOTS-ComTeC represents a useful common ground for defining DHIs



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CHEERS-DHI Key Project





Audience Polling

- How familiar are you with the CHEERS framework for reporting health economic evaluations?
 - Attended previous ISPOR conference sessions
 - Read the *Value in Health* publication
 - Have used it in my work
 - Here to learn more



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Background

Introduction to CHEERS-DHI Project

Where we are now



Who We Are 2023/2024 KEY PROJECT

Co-Chairs

- Rossella Di Bidino
- Carl Asche

Coordination

Madeline Shipley

Advisory Board

- Don Husereau
- Zsombor Zrubka
- Anita Burrell
- Brian Seal
- Annette Champion

Working group

- 1. Rossella Di Bidino
- 2. Carl Asche
- 3. Farzana Malik
- 4. Katarzyna Kolasa
- 5. Steven McPhail
- 6. Don Husereau
- 7. Zsombor Zrubka
- 8. Anita Burrell
- 9. Brian Seal
- 10. Annette Champion



The ISPOR Digital Health Special Interest Group

2023

Completed scoping review of published definitions of umbrella and secondary digital health terms PICOTS-ComTeC framework for defining digital

health interventions (DHIs) developed from a Delphi consensus study



Mapped items in established DHI frameworks and guidelines (and CHEERS) with PICOTS-ComTeC domains and subcategories





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Introduction to CHEERS-DHI Project





CHEERS – DHI 2023/2024 KEY PROJECT

Consolidated Health Economic Evaluation Reporting Standards (CHEERS) for Digital Health Interventions

Background :

- ISPOR promotes the need to conduct health economic evaluations that are identifiable, interpretable, and useful for decision
 making.
- The original ISPOR Health Economic Publication Guidelines Good Reporting Practices Task Force's overall goal was to provide recommendations and a checklist to optimize the reporting of health economic evaluations in biomedical journals. This culminated in the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Statement that included a 24-item checklist.
- The CHEERS 2022 update has been published with the intention to be useful for all forms of evaluation (e.g., cost-benefit or cost-effectiveness) as well all underlying methods of measuring and valuing effects (e.g., network meta-analysis of epidemiological data, or methods to value consumption benefits of healthcare, such as discrete choice experiments).
- As with the original CHEERS statement, the CHEERS update also identified where other reporting standards should be used (e.g., PRISMA for Network Meta-Analyses (PRISMA-NMA)), ISPOR Conjoint Analysis Applications in Health Checklist.





Background

- The **ISPOR Digital Health SIG**, to capture the uniqueness of DHI, has proposed an extension of the PICOTS framework to include medical and technological aspects.
- The PICOTS-ComTeC also includes Communication (Com), Technology (Te), and Context (C) domains, as emerged from a scoping review and a Delphi panel.
- The PICOTS-ComTeC demonstrated the need to pay attention to issues such as the communication processes and channels, involved users and their roles, device and software on which the DHIs are based.





Open issues:

- Economic evaluations of digital health interventions (DHI) raise distinct challenges for economic evaluations compared with drugs and medical devices and pose a particular challenge for reporting because substantial information must be conveyed to allow the scrutiny of study findings.
- Should additional factors be considered when defining and conducting economic evaluations?



CHEERS – DHI 2023/2024 KEY PROJECT

Key Project: Objective

We aim to propose a specific reporting guideline named CHEERS for Digital Health Interventions.

The final goal it to propose a valuable tool in the reporting of economic evaluations of DHIs.

Research questions

- 1. When economic evaluations of DHIs are conducted, what is currently reported and what is not?
- 2. What is missing from current reporting guidelines for DHIs?



CHEERS – DHI

2023/2024 KEY PROJECT

Methods

Step 1

- To investigate the current applicability and limitations of CHEERS to DHI.
- Experts in the evaluation of DHIs will be involved.
- Online survey and semi-structured interviews will help to identify which topics of are considered when conducted economic evaluation of DHIs and if additional topics are included.
- Elements from the PICOTS-ComTeC that resulted from a Delphi survey of ISPOR Digital Health SIG members will be considered as a starting basis for discussion to identify specific topics requiring further elaboration.



Step 2

If s speci

If significant differences emerged, a specific list of issues to report in economic evaluations of DHIs will be defined.





Expected output

• At the end of the project, a specific health economic evaluation reporting guidelines able to capture the complexity, the peculiarities and the evolution of DHIs will be available.





Where we are now

2023/2024 KEY PROJECT

- Protocol & Information Consent Form
- Ethical approval
- Pilot Interviews
 - Responses will be blinded in published materials
- Experts to interview (n=20)
 - Names
 - Send invitation
 - Interviews

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Audience Q & A

ISPOR, the professional society for health economics and outcomes research (HEOR), is an international, multistakeholder, nonprofit dedicated to advancing HEOR excellence to improve decision making for health globally. The Society is the leading source for scientific conferences,

peer-reviewed and MEDLINE-indexed publications, good practices guidance, education, collaboration, and tools/resources in the field.

ISPOR's community of more than 20,000 individual and chapter members from 120+ countries includes a wide variety of healthcare stakeholders, including researchers, academicians, regulators and assessors, public and private payers, healthcare providers, industry, and patient representatives. The Society's leadership has served as an unbiased resource and catalyst for innovation in the field for more than 20 years.

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