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Time for clarity: Exploring the Evidence and Key Concepts of Human-Centered Design in Digital Healthcare - A Comprehensive Scoping Review

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Submitted to: JMIR Research Protocols
on: March 17, 2025

Preprint
JMIR Publications

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Abstract

Background: Methods such as Human Centered Design (HCD), Design Thinking (DT), User Centered Design (UCD) co-creation, and participatory design (PD) have been adopted to facilitate user and stakeholder involvement in the development of eHealth applications. However, there is frequent confusion around these methodologies leading to a fragmentation of the discourse and limiting integration opportunities. The absence of an empirically grounded framework for HCD limits research and theoretical consensus particularly in the highly regulated context of development of eHealth solutions.

Objective: This scoping review aims to explore and analyse the scope, definitions, key concepts, and motivations reported in peer-reviewed studies that have applied stakeholder engagement methods like HCD, PD or DT in developing eHealth applications.

Methods: The conduct of this scoping review follows the JBI methodology for scoping reviews and the guidelines for conducting systematic mapping studies in software engineering. The reporting of the results will be guided by the PRISMA-ScR extension. A single reviewer will conduct the initial screening and charting, with random quality checks by a second reviewer. Inclusion Criteria: This review will include only primary studies reporting on the experience, challenges and applicability of HCD for the design and development of eHealth applications, identified through PubMed, IEEE Xplore, and Web of Science, and limited to articles from the past 10 years.

Results: This review is expected to summarize the current understanding, terms, definitions and methods of HCD in the development of eHealth tools. We identify research gaps, and trends that will inform the current and future development of mHealth technologies to enhance mHealth adoption and sustainability with special focus on vulnerable populations. A preliminary search applying the search strategy resulted in 3181 records. The search was initiated in July 2024 and the results are expected in 2025.

Conclusions: This review will provide knowledge about what, how and why are HCD methods being applied in the development of eHealth tools. This knowledge will translate in consistency reducing confusion, facilitating collaboration and implementation of HCD methodologies. To our knowledge, this is the first scoping literature review aiming to shed light in how the HCD processes are specifically applied in complex and highly regulated environments such as digital healthcare. Furthermore, we aim to understand why the application of the HCD methodology within the eHealth sector is surprisingly limited, especially concerning solutions for vulnerable patient groups.

(JMIR Preprints 17/03/2025:74067)
DOI: https://doi.org/10.2196/preprints.74067

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This protocol follows JBI methodology for scoping reviews.

Original Paper

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Keywords: Patient Centric Healthcare, UX/UE, usability, mHealth, Human-Centered Design, Design Thinking, Scoping Review, Participatory Design

Introduction

According to a report by the Institute of Medicine (IOM), today's Health providers have access to more research findings and more technology than ever before. Yet, there are serious concerns about the inadequate quality of healthcare, driven by four key factors: i) the growing complexity of science and technology, ii) the increase in prevalence of chronic conditions as people live longer, iii) a decentralized, inefficient delivery system iv) challenges on leveraging information technology, as patients increasingly seek health-related information and advice online [1].

Patient-centricity, which emphasize Health care solutions that are that are humane and respectful of the needs and preferences of individuals, is one of six key factors to close this quality gap and in the new era of healthcare [1].

Adoption of eHealth solutions

When done right, eHealth applications can facilitate self-care promotion, enable informed decision-making, foster patient engagement, patient empowerment and ultimately improve patients' satisfaction and health outcomes [2,3]. eHealth solutions entail a variety of digital technologies for health management and care and may include telehealth applications, such as videoconferencing for medical consultations, electronic health records (EHRs) for storing, managing and accessing patient health information, and mobile health apps like medication reminders, diabetes self-management, mental health apps and Artificial Intelligence (AI) algorithms [4,5].

Despite their potential, the rapid and costly development of digital health technologies frequently leave no space for user involvement in the design process, leading to solutions that fail to address real-world needs[6,7]. Consequently, low adoption rates result in significant

technological waste[8–12].

Moreover, patient expectations for eHealth solutions are very high as users expect those applications to provide a similar user experience as their shopping, messaging or banking solutions. However, the low adoption rates demonstrate that eHealth applications still have a steep way ahead [11]. Similarly, healthcare professionals (HCPs) expect eHealth applications to integrate into their workflow easily, allowing for more time for patient care [12]. In reality, many HCPs spend large amounts of their time working with IT systems that do not add value to the quality of care [13,14].

Methods for stakeholder engagement: Design Thinking, Human Centered Design and Participatory Design

The importance of Human-centricity – placing patients, care givers and healthcare professionals (physicians, nurses and other medical staff) at the heart of the development process [15–17] to truly meet their needs and expectations – is acknowledged, but rarely applied to eHealth applications [18]. Methods such as HCD, DT, co-creation, and PD have been adopted in other industries to address this issue by helping software developers incorporating the needs, experiences and feedback of end users and stakeholders in the development process of digital applications in general. A recent systematic literature review by An et al. reported studies of eHealth applications comparing traditional interventions to HCD interventions, where the latter showed greater satisfaction, usability, and effectiveness [19].

Human Centered Design (HCD)

The term human-centered design has been defined in the international standard ISO 9241–220 as an approach to systems design and development that aims to make interactive systems more usable by focusing on the understanding of interactions among humans and other elements of a system in order to optimize human well-beign and overal system performance[20]. The term “human-centred design” goes beyond “user-centered design to foster involvement of other stakeholders, not only those typically considered as users throughout design and development activities[6,21].

Design Thinking (DT)

The DT methodology is an iterative, non-linear and human-centered method that helps to incorporate users’ needs and feedback throughout the development process. DT has been recognized as problem solving methodology and a driver of innovation and change [22–25]. According to Stanford d.school, the five phases of the process are: Empathy, Define, Ideate, Prototype and Test [26]

On a practical level, DT has been interpreted as a trilogy of interlinked modes: (1) a process with a sequence of steps, (2) a toolbox with a collection of methods, and (3) a mindset with a set of human-centered principles [27,28].

Over the last 40 years, researchers at Stanford University have studied this methodology, which has spread to other universities such as Aalto (Finland), Potsdam (Germany) and St. Gallen (Switzerland). It's been adopted in the private sector across many industries as business, fintech, hospitality, education and aviation to solve complex problems [22,29,30]. Examples of adopters are major companies such as Deutsche Bank, Proctor and Gamble, Google, Apple and

SAP [18]. More recently, it has emerged as a critical tool to drive innovation in health care [5,6,19,22,31–35], however when considering the scope of all ongoing research, development and innovation in healthcare, DT has been applied sparsely [12, 20].

Co-creation - Co-design

A core principle of DT is radical collaboration, also known as co-creation, which emphasizes trust-building within design teams and among stakeholders, ensuring that all participants actively contribute and learn from one another throughout the design process [37,38]. This principle relies on flexibility in thinking, creativity, and openness to new ideas and perspectives [39]

Participatory Design

Participatory Design has been defined as human centric approach to technology development guided by enhancement of the workplace democracy, mutual learning, and empowerment [12] and as toolbox for engaging users in order to deliver better products [24]. The principles of stakeholder participation are aligned with participatory ergonomics and other participatory design methods such as experience-based design [40].

A wicked problem

The DT method has been criticized as lacking theoretical and methodological rigor [24,41,42]. The literature often presents DT in general, as vague and sometimes ambiguous [43] or as “a practice rather than a precise science” [44]. While other descriptions and theoretical foundations provide a more specific definition as a methodology suited for use in broad and multidisciplinary settings [23,25,45,45–53]. Further, there is often confusion between DT, HCD, UCD, Patient Centered Design (PCD), Participatory Design (PD), gamification or Agile methods[30] which lead to a fragmentation of the discourse thus missing opportunities for integration. The absence of an empirically grounded framework for DT limits research and theoretical consensus particularly in the highly regulated context of development eHealth applications. [23,54].

Several studies report i) the lack of coherent evidence and theory driven methodologies that promote user and stakeholder involvement in the development process of eHealth applications [5, 21–24] and ii) the need for more co-creation between vendors and stakeholders in the development process of eHealth applications [57,58]. These two conditions are paramount factors for the adoption. They highlight the need to clarify the key concepts, key characteristics related to the methods promoting human centricity and stakeholder engagement.

HCD methodologies can be particularly valuable in the context of eHealth applications, and their use is expected to increase as they ensure that the software solutions are not only technically robust but also focusing on user needs and real-world contexts leading to more effective and widely adopted developments [19,22,34]. Conversely, the overall understanding and specific steps on how the HCD processes are applied in complex and highly regulated environments such as digital healthcare remains underexplored. Furthermore the empirical evidence on the application of the methods within the eHealth sector is surprisingly limited in comparison to other industries [5,59,60], especially concerning solutions for vulnerable patient groups [61]

For this scope review the term (HCD) will be used as an umbrella term, under which the terms

User-Centered Design, Patient Centered Design, co-creation, co-design, Participatory Design, and Design Thinking will be referred in this protocol.

The goal of this review

This scoping review, will act as a stepping stone in developing a methodological framework by i) characterizing the extent to which primary studies reported in peer-reviewed articles that are publicly available in the literature have adopted HCD for the development of eHealth applications; ii) mapping the quantitative and qualitative evidence to shed light on the methods, tools and principles that have been used in the context of HCD approaches to inform the development of eHealth applications.

Our goal with this review is to reduce ambiguity around the concepts of HCD Design in the context of software development of digital health applications and empowering researchers to develop solutions that place the needs of users and stakeholders in the forefront instead of being" lost in translation" in the confusion of the terms, while maintaining compliance.

Review Questions

Guided by the ultimate goal of creating a methodological framework, this review explores *what key concepts and instruments of HCD are available and how are those being applied in the context of software development of eHealth applications*. This high-level question is broken into five specific review questions (RQs).

Table 1. Review questions and sub questions

Review Questions	Sub-questions
RQ1 Concept: What is HCD?	RQ 1.1 Which theoretical frameworks of HCD and DT have been used in the studies?
	RQ1.2 Which terms and concepts are being used in connection with HCD in the reported studies?
RQ2 Process: How is HCD being used?	RQ2.1 Which HCD tools have been applied in the studies?
	RQ2.2 Which process, or lifecycle of HCD has been applied in the studies?
	RQ2.3 Which mindset elements have been used?
RQ3 Motivation: Why is HCD applied?	RQ3.1 Why do teams choose HCD methodologies over other methodologies?
RQ4 General: Where, when and who is applying the method?	RQ4.1 In which geographical locations based on author affiliation and in which year have the studies applying the method been published?
	RQ4.2 In which domains of healthcare is the method being applied?
	RQ4.3 Which stakeholders are being involved?
	RQ4.4 Which population are the reported applications being developed for?
	RQ4.5 What kind of technology is being developed with the HCD methods?
	RQ4.6 What type of research has been used?

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RQ5 Evaluation: How is the HCD method evaluated?	RQ5.1 Which approaches have been used to evaluate the application of HCD methods

Inclusion criteria

Population

There are no restrictions applied to participants in this scoping review.

Concept

The object of this scoping review is the exploration of HCD methodologies, with special focus on DT as a methodology to design, develop, describe, report or document experiences during the software development of eHealth applications. Articles will be included if two premises are fulfilled: i) the research paper had the main focus on conceptualizing on HCD methodologies, either through definition, descriptive methods, attributes or relationships and ii) the concepts were used in relation to the development of software applications in the area of eHealth, medical informatics and digital healthcare.

Context

The studies considered for this review include studies in all healthcare settings and areas of medicine in the private or public sector, as long as the eHealth applications are intended for medical purposes such as diagnosis, prevention, monitoring, therapy or rehabilitation. However, studies reporting on development of programs, education on the broader sense of healthcare will not be included in the review.

Types of evidence sources

This review will include all peer-reviewed primary research articles applying and reporting on the application of HCD and methods that have used HCD methodology for eHealth applications. The review will not include any peer-reviewed methodology papers, literature reviews, meta-analyses, guidelines or opinion papers reporting on HCD.
Furthermore, articles published between 2014 and 2024 in English, Spanish and German language will be included as the author is fluent in those languages.
All studies meeting the criteria will be included in this review. As the aim of a scoping review is to determine the state of the art of the literature on a specific domain therefore, in contrast to systematic reviews, exclusion based on critical appraisal of methodological quality is not required thus not performed within this review.
Table 2. Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Open Peer-reviewed papers including conference proceedings published in open access journals or journals accessible to the author	- No abstract available - No full text available - Language other than German, English, Spanish
Primary Studies, empirical studies reporting on experiences, challenges, applicability of HCD for the design and development of eHealth applications	- Literature reviews, methodological papers, opinion papers or theoretical papers, meta-analysis - Studies that have been already evaluated in one of the reviewed articles

	(duplicates)
	Any of the following: - HDC not mentioned in Title or Abstract - HCD not conceptualized - HCD not clearly operationalized - Not or limited theoretical underpinning - Not relevant to medical informatics or digital health
Written in English, Germany or Spanish language	
Published between 2014-2024	

Methods

The conduct of this scoping review follows the JBI methodology for scoping reviews [62] and the guidelines for conducting systematic mapping studies in software engineering [63]. The protocol consists of five stages: (a) defining the review question; (b) identifying relevant studies or search strategy; (c) Study screening and selection; (d) extracting and charting the data of studies included; (e) collating, summarizing, and reporting the data [14]

The reporting of the results will be guided by the referred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR).
Due to resource constraints, a single reviewer will be responsible for the initial screening and charting of the data. Random quality checks by a second independent reviewer will be implemented to reduce bias. The second reviewer (expert in medical informatics) will randomly select 10% of the included studies for independent review of the screening and charting process, ensuring consistency and reliability in data extraction. In case of disagreement the corresponding article will be reviewed by a third reviewer (expert in medical informatics) This approach, while resource-efficient, still maintains the integrity of the review.

Search Strategy

The studies will be identified initially through searches of three online data bases, PubMed, IEEE explore and the Web of Science core collection. Those databases were considered as they cover technical and clinical aspects of the literature. The identification of key concepts and domains was made based on a preliminary literature review of key papers known to the authors. The key words contained in the abstracts and titles led to several search terms that were clustered in two main themes following the concept and context as per in the inclusion criteria: i) HCD and ii) eHealth. The related key concepts to the two themes are presented in Table 3. These key terms will serve as basis for the search in each of the databases.

Due to time and resource limitations, articles will not be screened for additional studies (snowballing). The search will be limited to the last 10 years of publication.

Table 3. Search strategy and key terms

Domain / Context	Key Terms	Search strings
Human Centered Design Theme	Design Thinking, User Centered Design, Human Centered Design, Innovation, User Experience, Problem solving, Co-creation, Co-design,	“Design Thinking” OR “Service Design” OR “* centered design*” OR *innov* OR “design theory” OR “* experience” OR “problem solving” OR “co-creation” OR

	Participatory Design	“co-design, “participatory design”
Boolean	AND	
eHealth Theme	e-Health, telemedicine, mHealth, Health Informatics, Medical informatics, Remote Patient Monitoring, Med-Tech, digital technologies, patient, technology, Consumer Health Informatics, requirements, software, architecture, development	“e-health* OR *telemedi* OR "*mHealth*"OR "health informatics" OR "medical informat*" OR "med-tech*"OR "remote monitor*" OR *digit* OR *patient* OR *tech*, "Consumer Health Informat*"OR requirements, *software*, architectur*, development”

Study Screening and Selection

Based on the inclusion criteria Table 2, all retrieved articles will be organized in the bibliographic reference management software Zotero and any duplicates will be removed. Zotero will be used for the initial screening of titles and abstracts. Selected articles will be imported in the software for qualitative and mixed methods analysis MaxQDA[2] for full text analysis.

The screening will be performed by two reviewers on a pilot screening process. In this screening process, 10 randomly selected abstracts will be discussed between the two reviewers (both experts in medical informatics) to ensure consistency. The title and abstract screening of the remaining articles will be performed by one reviewer. In a second stage, six full text articles that met the inclusion criteria will be randomly reviewed by the second reviewer to pilot the screening process. Reasons for exclusion of the full text articles will be documented and reported in the scoping review in a PRISMA flow diagram. Any uncertainties or disagreements will be discussed with the second reviewer and discussed until consensus is reached. If a decision cannot be made a third reviewer will act as mediator.

Careful record keeping will be kept through a standardized screening table documenting reasons for rejection and will be utilized by all authors to minimize potential bias and allow for transparency. This table will be made publicly available as part of the results publication.

Data extraction and Charting

A data charting table including general study characteristics and variables related to the concept, context, review questions, key concepts will be included in the review as shown in Table 4. A pilot extraction process will be conducted for 10 of the selected articles to ensure completeness and accuracy. The data extracted and any uncertainties arising will be discussed with the second reviewer. If necessary, the data charting table will be adjusted accordingly.

Similarly to the screening phase, the charting phase will be done by one reviewer with random quality checks by the second reviewer, who will review 10 randomly selected articles and compare to the results obtained by the first reviewer to ensure consistency. Any uncertainties or disagreements will be discussed between the two reviewers and discussed until consensus is reached. If a decision cannot be made a third reviewer will act as mediator.

Based on the pre-reviewed literature and acknowledging the ambiguity surrounding HCD terminology, the authors will adopt a deductive approach, deriving sub-codes from the selected

[2] MAXQDA2022 , Release 2022.8 (September 12th, 2023)

studies and structuring them within a framework. Main codes are generated inductively, aligned with predefined review questions (see Appendix 1). Careful record keeping will be supported through the standardized charting table and will be utilized by all authors to minimize potential bias.

Table 4. example of the items to be included data charting table

	Data Item (CODES)	Value	Variable Type	Review Question
General	Study ID	Alfanumeric		
	Article Title	Name of Article		
	Author Name	Names of the authors		
	Year	Year of Publication	Quantitative	RQ4
	Country	Geographical location of Publication based on author affiliation	Quantitative	RQ4
	Journal	Source of publication		
	Area in Medicine	which medical area or specialty or health condition is addressed	Qualitative	RQ4
	Population	For what population are the reported applications being developed?	Quantitative	RQ4
	Stakeholders	What stakeholders are being involved	Quantitative	RQ4
	Type of technology	What kind of the Artifact was developed?	Quantitative	RQ4
	Research Type	It can be Qualitative, Quantitative or Mixed Methods	Quantitative	RQ4
Concept	Terms	Which terms and concepts are being used in connection with HCD in the reported studies?	Qualitative	RQ1
	Theories	Which theoretical frameworks of HCD have been used in the studies?	Qualitative	RQ1
Process	Tools	Which HCD tools have been applied in the studies?	Qualitative	RQ2
	Mindset	Which mindset elements has been used?	Qualitative	RQ2
	Phases	Which process or lifecycle of HCD has been applied in the studies?	Qualitative	RQ2
aMo	Why	Why do teams choose HCD	Qualitative	RQ3
Evaluation	Evaluation Method	Which practices have been used to evaluate the application of HCD methods	Qualitative	RQ5

Data collating, summarizing, and reporting

This review will follow a mixed methods approach. The data will be analyzed using descriptive

statistics for all quantitative data items referenced in the data extraction Table 4. The data items of qualitative nature will be analyzed using Qualitative Content Analysis [64]
The information for each extracted field will be tabulated and grouped by themes and sub-themes and visually illustrated. To create a compelling presentation of the findings, the data will be available in tabular accompanied by graphic visualizations in the form of evidence maps where possible and a narrative summary.

Results

The final results will be presented in a literature scoping review publication. This review is expected to summarize the current understanding, terms, definitions and methods of HCD in the development of eHealth tools. We identify research gaps, and trends that will inform the current and future development of mHealth technologies to enhance mHealth adoption and sustainability. A preliminary search applying the search strategy resulted in 3181 records. The search was initiated in July 2024 and the results are expected in 2025. The study is undertaken without any external funding.

Conclusions:

This review will provide knowledge about what, how and why are Human Centered Design methods being applied in the development of eHealth tools. This knowledge may translate in consistency reducing confusion, facilitating collaboration and implementation of HCD methodologies, hopefully increasing adoption of the technology and patient satisfaction. To our knowledge, this is the first scoping literature review aiming to shed light in how the HCD processes are specifically applied in complex and highly regulated environments such as Digital healthcare. Furthermore, we aim to understand why the application of the methods within the eHealth sector is surprisingly limited in comparison to other industries, especially concerning solutions for vulnerable patient groups

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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