

An integrative review of human-centered design and design thinking for the creation of health interventions

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Abstract

Background: In the United States, we have a healthcare system crisis with high rates of dissatisfaction among patients and providers. To transform health and healthcare, clinical providers must be proficient in the human-centered approach of design thinking (DT).

Objective: To synthesize the human-centered design (HCD) and DT literature for the creation of health interventions.

Methods: We performed an integrative literature review focused on how HCD and DT are used in the clinical healthcare setting. Four research databases were searched from inception through November 6, 2020. We analyzed the methodology used, who is using the frameworks, and the DT phases included.

Results: Twenty-four articles were included in the final analysis. Of the 24 manuscripts, 6 (25%) were nurse-led and 15 (63%) had interdisciplinary first and last authors (e.g., Nursing and Medicine). Overall, 10/24 (42%) included all DT method. When analyzing the articles by approach or methodology, 12 (50%) stated they were using the HCD approach, 5 (21%) the DT methodology, and 7 (29%) stated they were using both the HCD approach and DT methodology.

Conclusion: There are inconsistencies in who uses DT and the phases used to create healthcare interventions.

KEY WORDS

design thinking, healthcare innovation, healthcare interventions, human-centered design, nurse-led innovation, nursing innovation

1 | INTRODUCTION

1.1 | Healthcare quality chasm in the United States

The United States (US) health system is known for its complexities and inability to meet the needs of the populations including patients and providers.^{1–8} Instead, it is fragmented, with dismal outcomes in many diagnostic categories, particularly among those with a preventable chronic disease.^{5–14} Human-centered design (HCD) and design thinking (DT) approaches have the ability to solve some of our

most pressing health system challenges. When complemented by approaches to quality improvement (QI), the care processes can be improved with the end-user in mind, including healthcare providers seeking improved processes.

A report from the Institute of Medicine (IOM), entitled *Crossing the Quality Chasm: A New Health System for the 21st Century*, identified six reasons for what they believe is the “disconnect between an ideal system and what actually exists,” including:

“(1) poor design of systems and processes, (2) the system's inability to respond to changing patient demographics and related

requirements, (3) a failure to assimilate the rapidly growing and increasingly complex science and technology base, (4) slow adoption of information technology innovations needed to provide care, (5) little accommodation of patients' diverse demands and needs, and (6) personnel shortages and poor working conditions.^{6,15}

To perform the complex work needed to transform health and healthcare, healthcare agencies and funders agree that bold leadership that embraces risk-taking and creativity is required, nurses are fundamental to creating those transformational changes, and proficiency in the HCD thinking approach by nurses and other providers is essential.¹⁶⁻²⁰ The recent National Academies of Science, Engineering and Medicine (NAM) *Future of Nursing 2020-2030 (Future of Nursing)* report supports these assertions stating, "Changing the prevailing healthcare paradigm to address social determinants of health and advance health equity will require innovation" and "...knowledge and skill in innovation will be an important competency for nurses."¹⁹

1.2 | HCD and DT

1.2.1 | History of HCD and DT

HCD is a rigorous, innovative approach to solving problems and creating systems, products, and processes that center the needs of the people the design is aimed at.^{21,22} HCD dates back to the design methods movement and the participatory design movements of the 1960s and is now used in numerous fields outside of design, including business, engineering, and more recently, healthcare.²³ The core tenants of HCD is the need to understand the end-user's desires implicitly and explicitly which was framed in the early 1980s by the Disability Right's movement of "Nothing about us without us."²¹ HCD is a collaborative, creative, and iterative mindset (meaning that the designer understands the need to revisits phases continually throughout the process) rooted in empathy that engages with the end-users and stakeholders integral to understanding the problem and creating the solution. HCD leverages qualitative methods such as ethnographic interviews and observations to allow complete immersion to acquire deep, meaningful insights.²⁴

Incorporated within the HCD approach is the iterative process of DT. DT is distinguished from HCD in that, while HCD is a framework and mindset, DT is the methodology that guides the human-centered, innovative process.²⁵ The 5-step DT process includes the empathic discovery of the end-user's needs, defining the problem based on those insights, rapid ideation, prototyping of potential solutions, and finally testing the solutions.^{26,27} DT arose from an assortment of disciplines between the 1950s and 1980s to solve wicked problems, those problems that are considered highly complex and difficult to solve.²⁵ DT supports the need to "balance feasibility, viability, and desirability" while bearing in mind the human-centered needs of the end-users.²⁵ The DT methodology is a "learning by doing" process that incorporates data gathering, idea generation, creativity, and storytelling.^{17,24,25} Though the concepts of DT date back more than a

half of a century, the DT methodology has only recently become popularized within the last 15 years.^{28,29}

1.2.2 | Phases of DT

Empathy is the first phase of the DT methodology and is at the core of HCD. Empathy is defined as "the ability to be aware of, understanding of, and sensitive to another person's feelings and thoughts without having had the same experience."^{25,30} Though healthcare providers and caregivers tend toward empathy in their approach, in the context of DT, empathy is a deeper approach whereby designers immersing themselves in the experiences and environments of the end-user. The empathy phase centers on understanding how an end-user thinks, how they feel, and what they do, engaging fully with the end-user in the environment and situation where the problem is occurring in unprecedented ways.³¹ In this phase, the designers discern contextual cues through observation and interviewing to understand the problem and needs from the user's perspective. The designers put aside their suppositions of the problem or need and allow the end-user's experiences to provide insight and guide the process.

The way a problem is framed is a fundamental component of design and impacts the potential solutions.³² Therefore, the second phase of DT, the Define phase, gathers the insights from the Empathy phase to identify the salient problem by establishing themes that more accurately address the fundamental needs of the end-user.³³ Through Define activities, designers gain a deeper understanding of the problem by analyzing and synthesizing the data collected during the empathy phase to create an accurate problem statement for which ideas and solutions can be generated. At the end of the Define phase, a clear problem statement that encapsulates the end-user's point of view from which creative solutions are generated.

The third stage of DT is the Ideation phase, where multiple ideas are generated according to the problem statement developed in the Define phase.³³ The ideation process thrives on diverse experiences and ways of thinking. Brainstorming is a vital tenant of this phase to generate solutions that address the end-user's needs. In this phase, consideration is placed on creativity, and out-of-the-box thinking. All possible ideas are bundled together by topic and considered in the context of the problem statement. The idea(s) that most appropriately addresses the end-user's need will move to the prototype phase.

Prototyping is the fourth phase of DT.³³ During the prototype phase, designers transform their idea into a physical creation. Prototypes come in various forms, including physical, digital, paper, or any other form that best represents the solution; for example, process prototypes are sketched out on paper or digitally; they are also acted out in a skits that walk the end-user through the process being developed. A key feature of a prototype is that it must be a simple, low-cost, low-fidelity representation of the solution that the end-user can instinctually interact with to capture feedback for rapid iteration.

The final phase of DT is the Test phase.³³ During this implementation phase, the prototype is tested with end-users, preferably in the environment where the problem occurs, and the solution will be implemented. Feedback is solicited from the end-user and correlated into buckets, including what the end-user liked or did not like about the prototyped solution, what was missing, what should be removed, and what should be changed. This information is collected and used for quick refinement and revision of the prototype.

1.2.3 | Co-design

An essential component to HCD and DT is Co-design. Co-design is “a collaborative process that actively seeks knowledge and ideas from end-users” and “encourages stakeholders to be an active member in the process.”³³ (p. 24) Co-design should always be incorporated throughout the entirety of the HCD and DT process, allowing the end-users to be the co-creators of their solutions. Co-design relies on the involvement of stakeholders at the beginning of the DT process starting with the empathy phase, throughout all of the phases; co-designing with the stakeholders brings a depth of knowledge, resources and lived experience to the design process that otherwise would not be possible.

1.2.4 | HCD and DT in healthcare

HCD and DT in healthcare are relatively new, with most articles published in the 2010s.³⁴ As noted, there is a significant health and healthcare quality chasm formed by healthcare’s propensity to focus on symptoms resolution rather than problem resolution, or to misdiagnose the problem based on pre-existing biases. A survey of healthcare providers and leaders found that most respondents agreed that using DT in healthcare is beneficial.¹⁸ However, most acknowledged that DT was not generally widely adopted.¹⁸ One study found that the application of DT in healthcare varied but concluded that it is an acceptable and effective intervention for use, though more research is needed.³⁴

Conventional methods to solving healthcare problems most often place the healthcare provider as the “expert,” with those experiencing the problem on the outside, a power structure that places underserved populations in a position of vulnerability.¹⁸ Using HCD in healthcare moves away from the authoritarian approach of assuming healthcare providers know best to a co-collaborative environment where all experiences are centered equitably.³⁵ The *Future of Nursing* report supports this transition stating: “including co-designing innovations with individuals, and community representatives is a necessary component to developing, evaluating, and scaling evidence-based practice models.”¹⁹

1.2.5 | Innovation process and the nursing process

Nurses are the largest workforce in healthcare in the US, with close to 4 million registered nurses, most of whom work in a clinical

setting.³⁶ This places nurses in an ideal position to identify problems and create solutions they see in their practice.^{37–40} A recent report noted that to close the healthcare quality chasm and create the transformational change needed, it will take confident and unwavering leadership, and that leadership needs to come from nurses.³⁸ Nurses are critical to the health of patients and communities, and it will take their distinct set of skills, experiences, education, and knowledge to reduce health inequity and improve the quality of care.^{19,35,41–43}

A report on nurse-led innovation, which surveyed healthcare and business leaders, stated that to improve the care patients receive by 2025, nurses’ knowledge and competence in the innovative methodology of DT is vital.⁴³ Therefore, to create healthcare interventions that better address the needs of our end-users and stakeholders (e.g., patients, providers, the community), we need to embrace a more human-centered approach to the problems seen in healthcare. To do that, we must first understand how HCD and DT are being used in healthcare and by whom (e.g., nurses vs. physicians vs. designers) to better train and educate providers and researchers to use these methodologies in their practice. Thus, the study’s objective was to understand the landscape and utilization of HCD and DT within healthcare, specific to the creation of healthcare interventions.

We sought to analyze the characteristics of the articles reviewed, including the proportion of work performed by various disciplines (e.g., nurses vs. physicians), the methodologies used, and the phases of DT included, along with their associated activities. We also sought to examine the concordance of the methodology with the studies’ stated definitions.

2 | METHODS

We performed an integrative literature review using four research databases (PubMed, CINHAL, Embase, and Scopus), examining empirical literature on the application of HCD and DT for the creation of health interventions. An integrated review was used due to the nature of the evidence available and the conceptual scope of the area of inquiry. The articles reviewed were categorized as either “qualitative,” “quantitative,” or “multimethods.” Some of the literature was ambiguous and needed to be classified, so the term “multimethods” was assigned to articles that included both qualitative components (e.g., HCD workshops) and quantitative components (e.g., surveys). Examining a broad range of literature, including those that incorporated quantitative and qualitative methods, allowed us to gain a broader understanding of the landscape of use of HCD and DT in the peer-reviewed healthcare literature.

A trained medical librarian (RJ) searched each database from its inception through November 6, 2020. Combinations of search terms included: “design thinking,” “human-centered design,” “society centered design,” “equity centered design,” and “nursing OR nurses.” Articles were included in the review if written in the English language, published between January 1, 2016, through November 6, 2020, and focused on HCD or DT in healthcare. Articles were excluded if they

were not relevant to healthcare, did not include HCD or DT, were not focused on healthcare interventions, were not a published empirical article, and were older than 5 years. Additionally, to focus on a unified health system, any article that did not occur in the United States was also excluded (see the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram; Figure 1).⁴⁴

Data were extracted from the articles by the author and input into a shared spreadsheet (ML). The authors performed screening of articles, and any disagreement was discussed and adjudicated (ML, PZC). Initial screening of the articles comprised a review of titles and abstracts. Articles that did not meet the inclusion criteria were removed. A full review was performed on articles that could not be confirmed through the title and abstract review.

2.1 | Data synthesis

The abstracted data included: article characteristics (title, study year, design, aim, population, number of subjects), DT phases, characteristics (Co-design and definition), activities used, and lead author. The lead author was determined based on the degree and affiliation of the

first and last author of the article. Co-design was considered if the authors stated that they included the end-users, the people for whom the problem affected, in the design process.³¹ The 5 phases of DT were considered in the analysis if the authors stated the term specifically, or, for each respective phase, included terms such as:

- Empathy: understanding needs of end-users, patients, or stakeholders, interviewing, observing
- Define: synthesizing data or themes, analyze data, articulate the experience of, insights were used to identify challenges
- Ideate: Idea generation, brainstorming, conceptualizing solutions
- Prototype: creating solutions, create mock-ups or wireframes
- Test: implementing or evaluating outcomes

Elements, including whether the lead author was a nurse or other interdisciplinary professional, whether the article applied HCD, DT, or both, the phases of DT included, DT activities used, and whether the phases of DT in the article's identified definition were performed were classified as a binary variable (yes/no). Summary statistics (n, %) were performed to quantify which phases were used and the congruency between what the stated definition included and what DT phases were performed.

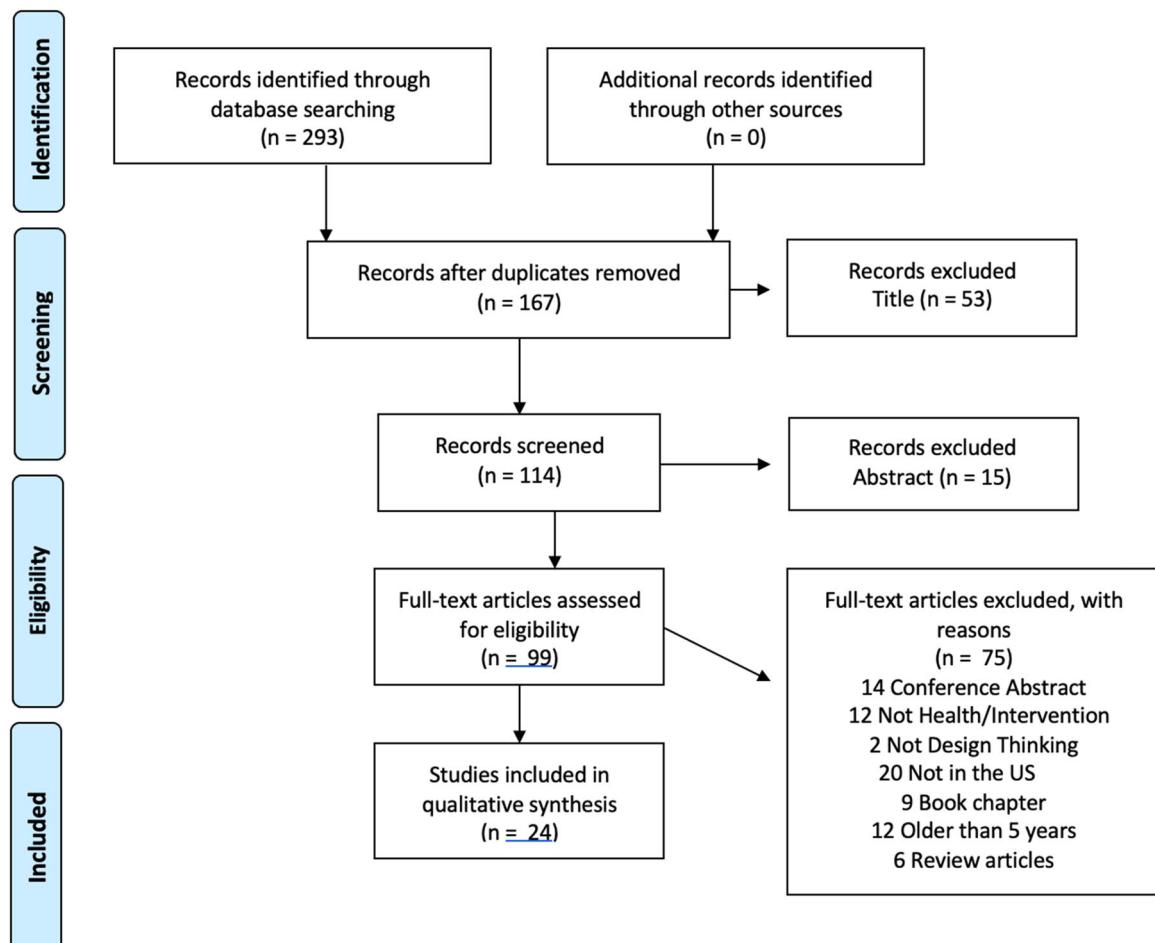


FIGURE 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses

2.2 | Article quality assessment

The Caldwell and colleagues framework for critiquing qualitative and quantitative research was used to evaluate the quality of the articles due to their heterogeneity and multimethod designs.⁴⁵ The Caldwell framework evaluates the main components of quantitative and qualitative studies, including the title, authors, abstract, and ethical considerations (Supporting Information: Appendix 1). This evaluation tool was chosen because HCD and DT projects are inherently qualitative, though often assessed using quantitative methods. After the critique was completed, the articles were classified as poor, fair, or good, depending on the total number of components from the framework performed. This assessment is a proxy to rate the quality of the articles but does not make assertions of the accuracy of the work.

3 | RESULTS

A total of 293 publications were retrieved from the database searches. After de-duplication review, 126 publications were removed, for a total of 167 unique manuscripts reviewed. Title and abstract review excluded 68 additional articles. After a review of the 99 full-text articles, 24 articles were included. Most articles were excluded because they were not intervention-related, did not occur in the United States, or were not peer-reviewed (Figure 1).

3.1 | Article characteristics

Of the 24 manuscripts, the majority were physician-led,¹⁵ (63%),^{20,22-24,29,46-55} whereas, 6 (25%) were nurse-led,^{28,51,56-59} see Tables 1 and 2.^{15,19,24,28,29,46-61} The articles included a mix of populations; patients were included in 11/24 (46%) of the articles,^{15,19,20,23,24,28,46,51,52,55,57} clinicians in 15 (63%),^{15,20,22-24,29,48-50,53-56,58,59} community members in 3 (13%),^{47,60,61} and others (e.g., parents, partners, or caregivers) in 7 (29%).^{15,20,22,28,46,51,56} Topics included Aging in Place, Infant Mortality, Childhood Asthma, COVID19, Pain Management and many others; there were no articles that focused on the same topic (Table 2).^{28,49,58,60,61} To accurately assess the literature using the Caldwell framework, the articles were categorized as either qualitative (15 [63%])^{15,23,24,28,29,46-48,55,56,58-60} or multimethods (9 [37%])^{19,49-54,57,61} if they included both a qualitative and quantitative component; no articles were identified solely as quantitative (Tables 1 and 2).

Of those that used qualitative methods, 5 (33%) were classified as fair quality,^{23,48,56,59,60} and 10 (67%) were classified as good quality^{15,20,22,24,28,29,46,47,55,58}; none were classified as poor quality. Of those that used multimethods, 3 (33%) were classified as fair quality^{19,49,57} and 6 (67%) were classified as good quality^{50-54,61}; none were classified as poor quality (Tables 1 and 2).

3.2 | DT phases included in the articles

Of the articles overall, 10/24 (42%) included all phases of the DT method^{23,24,28,46,47,53-55,58,59}; the Empathy phase was included in 20 (83%),^{19,20,22-24,26,28,29,46-48,52-59,61} 16 (67%) included the Define phase,^{15,20,22-24,28,46-49,52-55,58,59} 18 (75%) the Ideate phase,^{15,19,22-24,27-29,46-50,53,55,56,58-60} 22 (92%) the Prototype phase,^{15,19,20,23,24,28,29,46-59,61} and 15 (63%) the Test phase.^{23,24,28,46-50,53-59} Thirteen of the articles (54%) included a

TABLE 1 Overview of article characteristics

Articles included, n (%)	All articles 24 (100)	Nurse-led articles 6 (25)
First or last author, n (%)		
Nurse	6 (25)	6 (100)
Physician	15 (63)	—
Other	4 (17)	—
Article type, n (%)		
Qualitative	15 (63)	4 (67)
Quantitative	0 (0)	0 (0)
Multimethod	9 (37)	2 (33)
Quality of articles, n (%)		
Qualitative		
Poor	0 (0)	0 (0)
Fair	5 (33)	2 (50)
Good	10 (67)	2 (50)
Multimethod		
Poor	0 (0)	0 (0)
Fair	3 (33)	1 (50)
Good	6 (67)	1 (50)
Phases of DT used, n (%)		
All	10 (42)	3 (50)
Empathy	20 (83)	5 (83)
Define	16 (67)	3 (50)
Ideate	18 (75)	4 (67)
Prototype	22 (92)	6 (100)
Test	15 (63)	5 (83)
Stated methodology, n (%)		
HCD	12 (50)	3 (50)
DT	5 (21)	2 (33)
HCD + DT	7 (29)	1 (17)
Co-designed, n (%)	13 (54)	4 (67)
Compensation provided	6 (46)	4 (100)

Abbreviations: DT, design thinking; HCD, human-centered design.

TABLE 2 Characteristics by article

Authors	Aaronson and colleagues	Aifah and colleagues	Beaudry and colleagues	Becker and colleagues	Chan and colleagues	de Mooij and colleagues
Publication year	2020	2020	2019	2020	2020	2018
Type of study	Qualitative	Qualitative	Multimethod	Multimethod	Qualitative	Qualitative
Study quality	Fair	Good	Fair	Good	Good	Good
Nurse-led	No	No	No	No	No	No
First author affiliation	Medicine	Social work	Design	Fine arts	Medicine/public health	Design
Last author affiliation	Medicine	Medicine/public health	Design	Neuroscience	Medicine/public health	Medicine
Topics	ED overcrowding	CVD risk in people with HIV	Adolescents with chronic conditions transition to adult care	Aging in place	Hypospadias repair	Low risk pregnancy
Population	Patients and clinicians	Patients and clinicians	Patients	Community members	Patients and clinicians	Patients and partners
n	6278	20	60	15	27	20
Type	HCD + DT	HCD + DT	HCD	HCD + DT	HCD	HCD
Used All DT phases	Yes	Yes	No	No	No	Yes
DT phases included	Empathy, define, ideate, prototype, test	Empathy, define, ideate, prototype, test	Empathy, ideate, prototype	Empathy, prototype	Empathy, define, ideate, prototype	Empathy, define, ideate, prototype, test
Co-design	No	Yes	Yes	Yes	Yes	No
Compensation provided	Compensated but type not specified	Compensated but type not specified	\$25 intro workshop; \$50 postproject survey	Does not state if compensation provided	Compensated but type not specified	
Limitations	No primary interviews or observations with stakeholders					
Authors continue	Dwyer and colleagues	Foley and colleagues	Hopkins and colleagues	Lane and colleagues	Logsdon and colleagues	Michalec and colleagues
Publication Year	2020	2019	2016	2019	2020	2018
Type of study	Multimethod	Qualitative	Multimethod	Qualitative	Multimethod	Qualitative
Study quality	Good	Good	Good	Fair	Fair	Good
Nurse-led	Yes	No	No	Yes	Yes	No
First author affiliation	Nursing	Pharmacy	Medicine	Design	Nursing	Fine Arts

TABLE 2 (Continued)

Authors continue	Dwyer and colleagues	Foley and colleagues	Hopkins and colleagues	Lane and colleagues	Logsdon and colleagues	Michalec and colleagues
Last author affiliation	Medicine	Medicine	Medicine	Nursing	Public health/epidemiology & biostatistics	Neuroscience
Topics	Genetic testing	Women's health screening	Transitions of care	Home care for children with congenital heart disease	Postpartum	Anxiety in cancer care facilities
Population	Patients and parents	Community members	Clinicians	Parents and Clinicians	Patients	Patients, clinicians, and caregivers
<i>n</i>	103	21	8	Not stated	22	8
Type	HCD + DT	HCD	DT	DT	HCD	HCD + DT
Used All DT phases	No	Yes	No	No	No	No
DT phases included	Prototype	Empathy, define, ideate, prototype, test	Ideate, prototype, test	Empathy, ideate, prototype, test	Empathy, prototype, test	Empathy, define, ideate, prototype
Co-design	Yes	Yes	No	Yes	No	Yes
Compensation provided	Does not state if compensation provided	Staff time covered; community members received hourly stipend and childcare reimbursement		Does not state if compensation provided		Does not state if compensation provided
Limitations			No primary interviews or observations with stakeholders; did not specify the ideate, prototype and test activities performed			
Authors continue	Patel and colleagues	Philpot and colleagues	Pies and colleagues	Ragouzeos D and colleagues	Sammann and colleagues	Segall and colleagues
Publication Year	2020	2019	2016	2019	2020	2016
Type of study	Qualitative	Multimethod	Qualitative	Qualitative	Multimethod	Multimethod
Study quality	Good	Good	Fair	Good	Good	Good
Nurse-led	No	No	No	No	No	No
First author affiliation	Medicine	Public health	Public health/social work	Design	Medicine/public health	Engineering
Last author affiliation	Medicine	Medicine	Public health	Medicine	Medicine	Medicine
Topics	Hospital-based violence	Outpatient patient experience	Infant mortality	Rheumatoid arthritis	Trauma surgical rounds	Operating room-to-ICU patient handovers

(Continues)

TABLE 2 (Continued)

Authors continue	Patel and colleagues	Philpot and colleagues	Pies and colleagues	Ragouzeos D and colleagues	Sammann and colleagues	Segall and colleagues
Population	Patients, clinicians, and patients caregivers	Community members	Patients and clinicians	Clinicians	Clinicians	Clinicians
<i>n</i>	15	17141	Not stated	67	Not stated	32
Type	HCD	HCD	DT	HCD	HCD	HCD
Used All DT phases	No	No	No	Yes	Yes	No
DT phases included	Empathy, define, prototype	Empathy, define	Ideate	Empathy, define, ideate, prototype, test	Empathy, define ideate, prototype, test	Empathy, define, prototype, test
Co-design	Yes	No	No	Yes	No	No
Compensation provided	\$25 gift cards			Does not state if compensation provided		
Limitations	Did not include a definition of their HCD process		Did not specify the Ideate activities performed			
Authors continue	Shrier and colleagues	Song and colleagues	Sonney and colleagues	Stark and colleagues	Trail-Mahan and colleagues	Younger SJ
Publication year	2020	2020	2019	2020	2016	2020
Type of study	Qualitative	Qualitative	Qualitative	Multi-method	Qualitative	Qualitative
Study quality	Good	Fair	Good	Fair	Good	Fair
Nurse-led	No	No	Yes	No	Yes	Yes
First author affiliation	Medicine/public health	MBA/plastics medicine	Nursing	Medicine/MBA	Nursing	Nursing
Last author affiliation	Psychology	Medicine	Engineering	Medicine/Public Health	Fine Arts	N/A
Topics	Sexual and reproductive health in young women with depression	Wound care	Childhood asthma	COVID19	Pain management	Patient discharge planning
Population	Clinicians	Clinicians	Patients and parents	Clinicians	Clinicians	Clinicians
<i>n</i>	6	Not stated	14	7	50	284
Type	HCD + DT	DT	HCD	HCD + DT	HCD	DT
Used All DT phases	No	Yes	Yes	No	Yes	Yes
DT phases included	Empathy, ideate, prototype	Empathy, define ideate, prototype, test	Empathy, define ideate, prototype, test	Define, ideate, prototype, test	Empathy, define ideate, prototype, test	Empathy, define ideate, prototype, test
Co-design	Yes	No	Yes	No	No	Yes

TABLE 2 (Continued)

Authors continue	Shrier and colleagues	Song and colleagues	Sonney and colleagues	Stark and colleagues	Trail-Mahan and colleagues	Younger SJ
Compensation provided	Up to \$300 in gift cards and parking		Does not state if compensation provided		Does not state if compensation was provided	
Limitations		Did not specify the define and prototype activities performed		Did not include a definition of their HCD or DT process; did not specify the define activities performed	Did not specify the prototype activities performed	Did not specify the define and prototype activities performed

Abbreviations: DT, design thinking; HCD, human-centered design.

Co-design element^{15,19,20,22,24,28,29,47,51,55,56,59,61}; 6 (46%) provided compensation^{19,22,24,29,47,53} (Tables 1 and 2; Figure 2A).

When analyzing the articles by approach or methodology, 12 (50%) stated they were using the HCD approach,^{19,20,22,28,46,47,52–55,57,58} 5 (21%) the DT methodology,^{48,50,56,59,60} and 7 (29%) stated they were using both the HCD approach and DT methodology (HCD + DT; Tables 1 and 2).^{15,23,24,29,49,51,61} Of those specifically using the HCD approach, all included the Empathy phase 12/12 (100%),^{23–25,28,46,47,52–55,57,58} 10 (83%) included the Define phase,^{24,25,28,46,47,52–55,58} 8 (67%) the Ideate phase,^{23,25,28,46,47,53,55,58} 11 (92%) the Prototype phase,^{23–25,28,46,47,53–55,57,58} and 8 (67%) the Test phase (Tables 2 and 3; Figure 2B).^{28,46,47,53–55,57–59} Of the articles that used the DT methodology 3/5 (60%) included the Empathy phase,^{48,56,59} 2 (40%) the Define phase,^{48,59} 5 (100%) the Ideate phase,^{48,50,56,59,60} 4 (80%) the Prototype phase,^{48,50,56,59} and 4 (80%) the Test phase.^{48,50,56,59} In the articles that stated using HCD + DT, 5/7 (71%) included the Empathy phase,^{16,26,27,29,61} 4 (57%) the Define phase,^{16,26,27,49} 5 (71%) the Ideate phase,^{16,26,27,29,49} 7 (100%) the Prototype phase,^{16,26,27,29,49,51,61} and 3 (43%) the Test phase.^{26,27,49} Of the three cohorts, HCD 6/12 (50%),^{28,46,47,53,55,58} DT 2/5 (40%),^{48,59} and HCD + DT 2/7 (29%)^{23,34} included all phases of DT (Table 3; Figure 2B). Additionally, a co-design element was included 6/12 (50%) in the HCD cohort,^{23–25,28,47,55} 2/5 (40%) in DT,^{56,59} and 5/7 (71%) in HCD + DT.^{16,27,29,51,61}

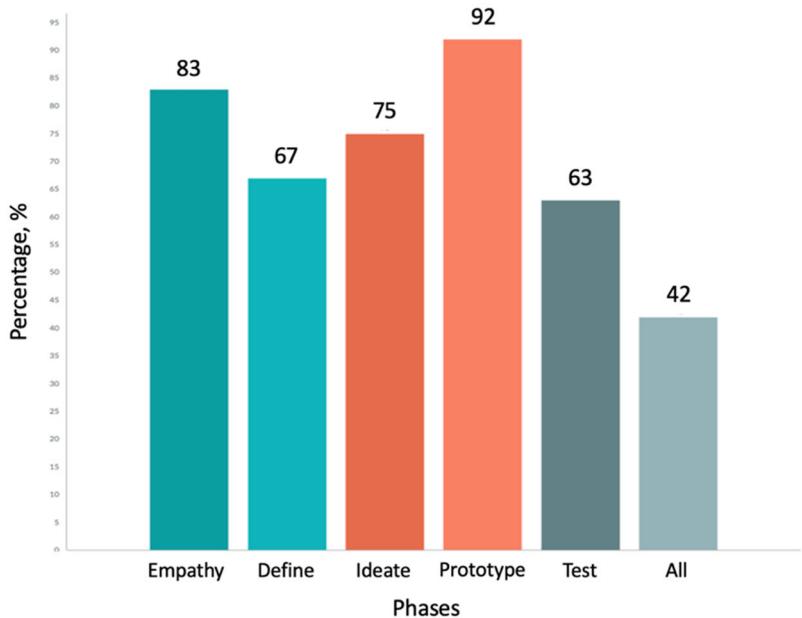
3.3 | DT activities used in each phase

Of the articles that included the Empathy phase, 14/20 (70%) included interviews,^{19,20,22,24,27–29,46,48,52–55,57,58} 9 (45%) observations,^{19,20,24,46,52–55,58}; other empathy activates were also performed, see Figure 3. Of the articles that included the Define phase the majority, 12/16 (75%) analyzed data for themes and insights.^{15,20,22–24,28,46,47,52,53,55,58} Of the articles that included the Ideate phase, 12/18 (67%) performed brainstorming or ideation sessions.^{19,23,24,28,46,47,49,53,56,59} Of the articles that included the Prototype phase, the majority 14/22 (64%) specified that they created or built prototypes.^{15,19,22,23,28,29,46,49,50,53,55–57,61} Of the articles that included the Test phase, most 12/15 (80%) specified examining their prototype during testing session.^{19,23,24,28,46,47,49,55–59} Finally, concordance of the DT phases used with their stated definitions were examined, see Figure 4.

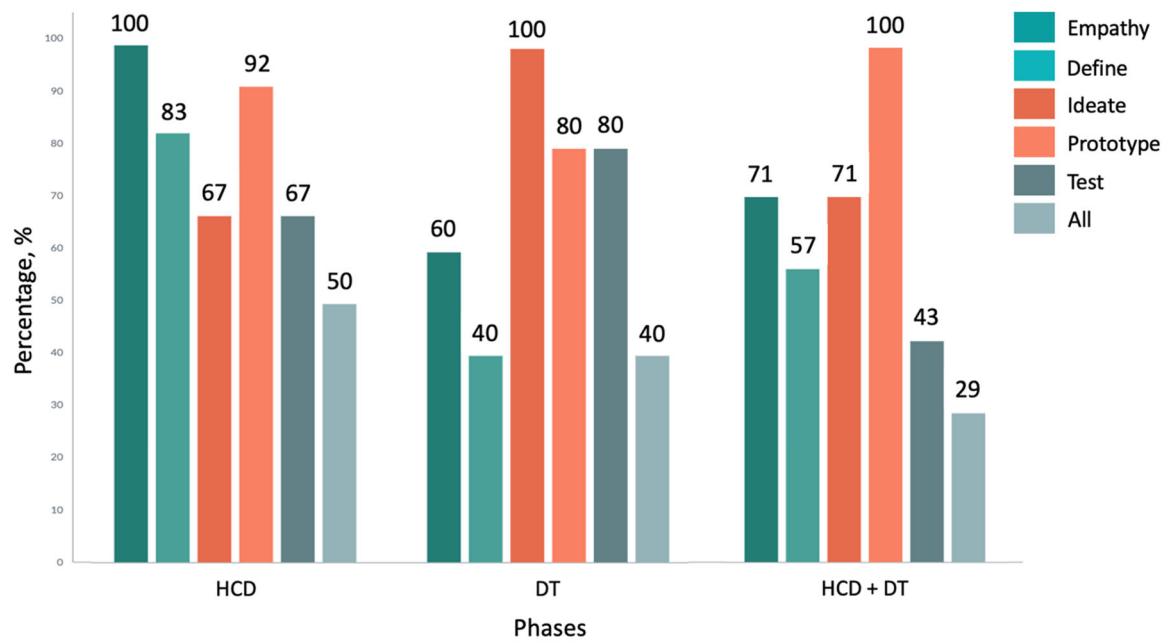
4 | DISCUSSION

The recent *Future of Nursing* report has stressed the need for nurses to embrace innovation to decrease the healthcare quality chasm and advance health equity.¹⁹ To do that, healthcare systems and providers must embrace a human-centered approach to creating solutions that meet the needs of our end-users, whether they are patients, clinicians, community members, or whomever the problem affects. Understanding how HCD and DT are used to create healthcare interventions, by whom, and the characteristics of use,

(A) Design Thinking Phases Included in All Articles



(B) Design Thinking Phases Used by Approach and Methodology



HCD, human-centered design; DT, design thinking

FIGURE 2 Design thinking phases (A) included in all articles; (B) included by methodology

is essential to creating interventions that increase patient adherence, patient and provider satisfaction, quality of care, and eventually outcomes.

HCD and DT provide a systematic approach to accelerating the creation and implementation of healthcare interventions, but with that acceleration must come a more rigorous method to assess their use and efficacy. Currently, there is no systematic approach to assessing the consistency and usefulness of HCD and DT in

healthcare. Whether fidelity of the application of each phase of DT is essential, or some variation of their use may be justified in the real-world setting, is unknown. As was found in this review, there was extensive heterogeneity in the use of HCD and DT in the studies analyzed, with less than half containing all phases of DT. The majority of the articles included the Empathy phase (83%), though far less included the Define phase (67%). While most of the articles made an effort to correctly understand the problem they were solving, fewer

TABLE 3 Design thinking phases included by article

Authors, primary	Type	Design thinking phases				
		Empathy	Define	Ideate	Prototype	Test
Aaronson and colleagues	HCD + DT	x	x	x	x	x
Aifah and colleagues	HCD + DT	x	x	x	x	x
Beaudry and colleagues	HCD	x		x	x	
Becker and colleagues	HCD + DT	x			x	
Chan and colleagues	HCD	x	x	x	x	
de Mooij and colleagues	HCD	x	x	x	x	x
Dwyer and colleagues	HCD + DT				x	
Foley and colleagues	HCD	x	x	x	x	x
Hopkins and colleagues	DT			x	x	x
Lane and colleagues	DT	x		x	x	x
Logsdon and colleagues	HCD	x			x	x
Michalec and colleagues	HCD + DT	x	x	x	x	
Patel and colleagues	HCD	x	x		x	
Philpot and colleagues	HCD	x	x			
Pies and colleagues	DT			x		
Ragouzeos and colleagues	HCD	x	x	x	x	x
Sammann and colleagues	HCD	x	x	x	x	x
Segall and colleagues	HCD	x	x		x	x
Shrier and colleagues	HCD + DT	x		x	x	
Song and colleagues	DT	x	x	x	x	x
Sonney and colleagues	HCD	x	x	x	x	x
Stark and colleagues	HCD + DT		x	x	x	x
Trail-Mahan and colleagues	HCD	x	x	x	x	x
Younger and colleagues	DT	x	x	x	x	x

Note: x denotes the phases included in each study.

Abbreviations: DT, design thinking; HCD, human-centered design.

took those insights and created an accurate problem statement, an essential component to creating the right solution. There is a disconnect between understanding the needs of the end-users and then accurately defining those needs. As was noted, up to 69% of medical hospitalizations occur because of poor adherence; if we continue to solve for inaccurately defined problems, we will continue to have patients and other end-users who do not "comply" with the care they require.^{6,7}

In the healthcare setting, QI is a framework used most often to systematically identify problems, collect and analyze data, and create solutions to improve systems, processes, and care; it is an integral part of nursing.⁶² QI is similar to DT though there are differences in their initial approach. While QI processes such as the Lean Six Sigma Improvement cycle generally begin with the Define phase (Define, Measure, Analyze, Improve, and Control), DT begins with the Empathy phase.⁶²⁻⁶⁸ These two processes should not be in contrast

to each other; DT can improve the processes created through QI by focusing on a deeper understanding of end-user needs and adding a human-centered component to the quality process that is currently missing. Moreover, as most of the articles included in this review that used DT did not include the Define phase in their process, integrating QI and DT could be useful in making sure that the problem is accurately defined before moving on to ideating a solution. To do this fully, we must define and categorize what we heard and saw in the empathy phase, expressing insights from the stakeholder's perspective as a defined statement of the problem and meaningfully incorporate co-design throughout the process. Only then will we create and solve the salient problem accurately.

Co-design acknowledges the lived experiences and history of the end-users and creates shared power throughout the process, leading to better-designed interventions, improved implementation, and more equitable outcomes.⁶³⁻⁶⁵ Therefore, every project that

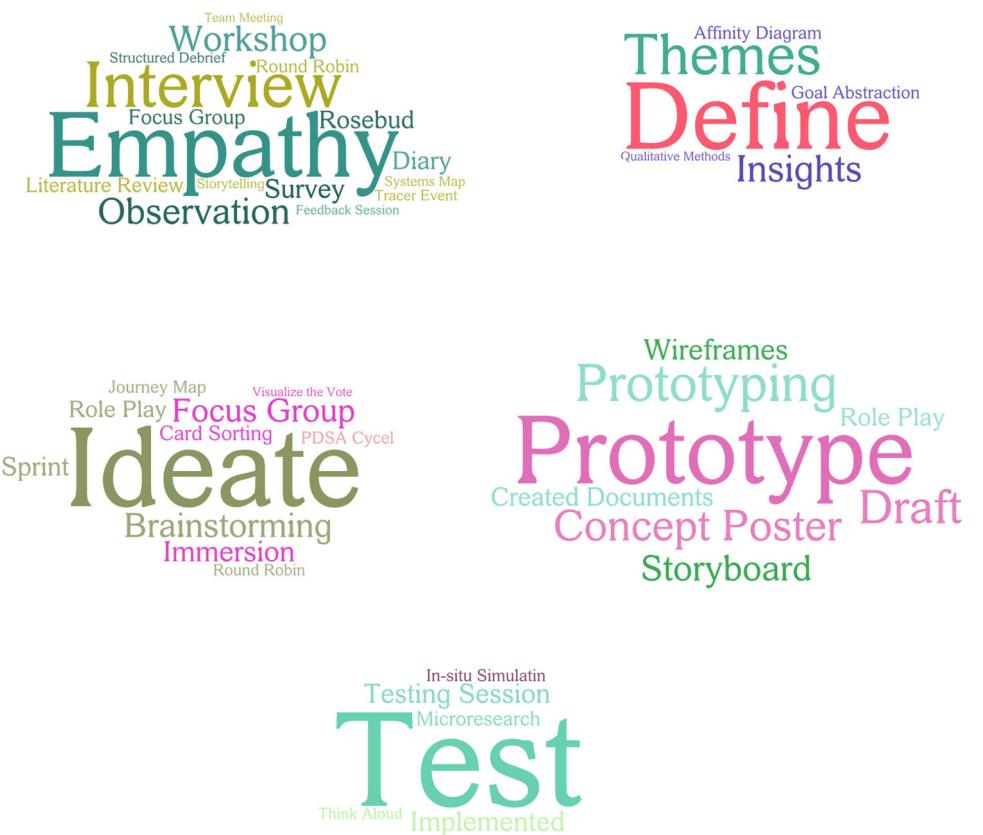


FIGURE 3 Word cloud representing the design thinking activities used in each phase. The larger the word the more frequently the activity was used.

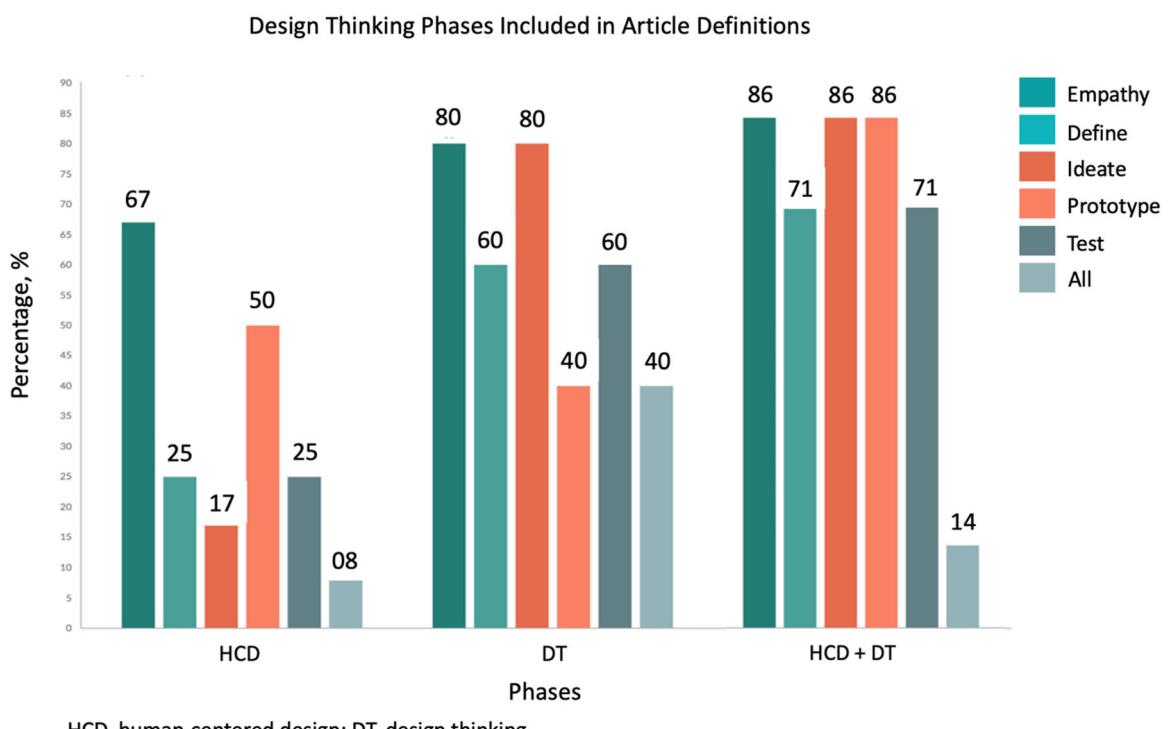


FIGURE 4 Design thinking phases included in the articles by definition

incorporates HCD and DT methodologies needs to include the end-users throughout the entirety of the process actively. In addition, we must take it a step further and apply a design justice lens, recognizing how design allocates burdens and advantages among different groups to "ensure a more equitable distribution of design's benefits and burdens; meaningful participation in design decisions; and recognition of community-based... traditions, knowledge, and practices."³² Of the articles analyzed, just over half (54%) included the end-users in the design process. As was found, of the 24 articles examining the use of HCD and DT were included in this review, just six (25%) were led by nurses. As in healthcare, HCD and DT is a team endeavor, requiring diverse skillsets, education, and experiences of all its members. Health systems must see nurses as leaders in the healthcare innovation space and allow them the time and space to include HCD and DT in their practice. As the *Future of Nursing* report stated, nurses have an opportunity to be innovators and should be encouraged by leadership to incorporate this behavior and mindset into their work.¹⁹ In the articles examined, an ideation session (75%) and prototyping (91%) were performed in most of the articles, though far fewer tested (63%) the potential solutions with their end-users; to accurately iterate a solution, end-user feedback is essential. Without testing of the solution in the context where the problem occurs, with the people for whom the problem affects, the uptake will be affected, as highlighted by the low patient adherence rates.^{6,7} Healthcare providers and health systems need to fully integrate end-users (patients, caregivers, providers) into the development of health interventions. Healthcare providers, researchers, and academics can no longer determine the best approach for patients, families, and communities without patients, families, and communities.

Interestingly, there were differences between the phases included in articles that identified using the HCD approach versus the DT method; those that stated they used HCD included the Empathy phase 100% of the time and the Define phase 83% of the time compared with just 60% and 40% for DT, respectively. As the name suggests, the human-centered approach focuses on understanding the needs of the people for whom you are designing a solution. Therefore, those who chose to use HCD may have had a bias toward critically understanding their population. In contrast, those identified using DT included the Ideate phase 100% of the time and the Test phase 80% of the time compared with 67% and 67%, respectively, for HCD. As DT is a methodological approach that encourages active learning (e.g., learning by doing), the authors who chose to use DT may have been biased toward creating and testing the solution, more so than understanding the problem. Articles that used either HCD or DT included the Prototype phase the majority of the time (92% and 80%, respectively). There was no discernable uniformity in the phases used in the HCD + DT articles, highlighting the phases' variability even when the authors purported to use both HCD and DT.

To fully integrate HCD and DT into healthcare intervention creation, we must include a systematic approach to designing with these tools. One option could be to create a comprehensive HCD and DT checklist or reporting guideline for healthcare intervention creation that practitioners

can use. Using a standardized reporting guideline and checklist for HCD and DT, similar to, for example, the Template for Intervention Description and Replication (TIDieR), which was created to "improve the completeness in reporting of interventions in research studies" could decrease variation in the process.⁶⁹

Only 42% of the articles reviewed included all five of the DT phases; even the articles that stated they used the DT methodology only used all of the DT phases 40% of the time. Checklists and reporting guidelines are an established, standardized way to improve adherence in healthcare settings. By incorporating this type of systematic approach to HCD and DT, the inclusion of all DT phases could be increased, and consistency could be improved.^{70,71} Though we argue for a more systemized approach to using HCD and DT, we must also understand the barriers a systemized approach brings, whom it includes and excludes, and the equity and power dynamic it produces.

There are several limitations to this study; firstly, related to the scope of the review, to compare similar healthcare systems, all articles included were performed within the United States and published in English, which could have omitted relevant articles. Whether there are differences in how HCD and DT are used in healthcare outside of the United States is unknown; future studies will be needed to examine this further. Due to the nature of the project aims, only healthcare/biomedical research databases were searched for the analysis. Additional articles may have been published in other fields, such as design, that were not accessible in those databases.

There is a potential for publication bias regarding these topics; for example, though nurses led only six of the articles reviewed, it is unknown how many nurses are leading HCD and DT projects in health systems that have not been published. Finally, whether publication bias also affects which phases of an HCD and DT project is published is unknown; articles describing the implementation phase may be submitted and accepted for publication more often than articles describing the define phase.

5 | CONCLUSION

The creation of health interventions that incorporate the needs of the people experiencing the problem can improve implementation, uptake, and hopefully outcomes. This analysis is a first step in deciphering how HCD and DT are being used in healthcare, which methodology or approach is being applied, and by whom. While HCD and DT are being used in healthcare, they are not uniformly used by all providers. Additionally, not all DT phases are used equally, leading to discrepancies in the creation of health interventions. Having a better understanding of the integration of these methodologies in healthcare will allow for a more rigorous integration of these frameworks in the future.

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CONFLICT OF INTEREST

M. L., is the PI of a grant focused on the use of human-centered design and design thinking. The remaining authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICAL STATEMENT

This material is the authors' own original work, which has not been previously published nor is it currently being considered for publication elsewhere. The paper reflects the authors' own research and analysis and all authors have contributed meaningful to the work.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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