

Design thinking as an approach for innovation in healthcare: systematic review and research avenues

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► Supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/bmjinnov-2020-000428>).

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Received 13 February 2020
Revised 5 September 2020
Accepted 25 November 2020
Published Online First
14 December 2020

ABSTRACT

Design thinking has been increasingly adopted as an approach to support innovation in healthcare. Recent publications report design thinking application to various innovation projects, across medical specialties, including paediatrics, psychiatry, radiology, gastroenterology, oncology, orthopaedics and surgery, as well as to innovation in hospital operations and healthcare management. Current literature in the area typically focuses on single case descriptions. With the recent increase in the number of cases, there is an opportunity to assess multiple cases to identify patterns and avenues for further research. This study provides a systematic review of published design thinking projects in healthcare. The aim of the study is to provide an overview of how design thinking has been applied in the healthcare sector. Data collection was based on Institute of Scientific Information (ISI) Web of Science, PubMed and Scopus databases. The systematic review followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. A total of 32 original pieces of research was selected for analysis, being classified and assessed. The paper presents current status of research and practice from various perspectives, including the design thinking progression phase—inspiration, ideation, implementation—and the prevalence of design thinking tools. Avenues for further research include the need to increase focus on the inspiration phase, the opportunity for platforms for leveraging the integration of individuals in innovation projects, and the opportunity to enhance the role of lead users in healthcare innovation.

INTRODUCTION

Healthcare is increasingly applying design knowledge and competence to deal with challenges,¹ as design provides a frame for understanding and developing a subject or business and its related policies, products, resources and services.² As a matter

Summary box

What is already known?

- Design thinking has been adopted in healthcare innovation projects in several domains, with reports of positive outcomes.

What are the new findings?

- The research details the design thinking processes and tools applied in healthcare based on multiple case reports.
- Design thinking provides a frame for addressing the development of healthcare innovation by balancing contextual factors (eg, users, stakeholders, resources) and clinical evidence.
- Design thinking is an ally for democratising access to healthcare through innovative solutions in low-resource settings.
- Opportunities for further research include: (a) increased focus on the inspiration stage, (b) creation of platforms for leveraging the integration of individuals in health innovation projects, (c) e-health focused user research and (d) lead user involvement.

of fact, innovation is required to address the changing environments (eg, ageing of the population) and guarantee the financial sustainability of health services;³ this may be achieved by improving health outcomes at a good value, reducing cost for care or tracking health outcomes.⁴ In this scenario, design thinking emerges as an approach for incorporating innovation in medical practice in public and private sectors.⁵ Clinical outcomes of healthcare interventions that claim to have employed design thinking have proven to be positive.⁶ Design thinking application may potentially benefit the design of new health devices, products and processes, and the implementation of evidence-based practices.⁷



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To cite: Oliveira M, Zancul E, Fleury AL. *BMJ Innov* 2021;**7**:491–498.

Brown⁸ popularised the term design thinking and promoted a significant increase in its published research literature. Despite the increase in research, there is still a lack of standardisation regarding the definition and understanding of what is design thinking.^{9–11} In convergence with trends in the literature, we define design thinking as a human-centred approach for solving complex problems employing attributes such as creativity, user involvement, multidisciplinary teamwork, iteration, prototyping and user centredness.^{9–11} Many toolkits^{12 13} and practical guides¹⁴ presenting design thinking processes have been published; despite of using different terms to refer to the design thinking phases, they follow the same overall logic for problem-solving.^{9–11 15 16} Practically, design thinking may be portrayed in three iterative phases: inspiration, ideation and implementation.

Inspiration is the first phase and it is based on need-finding: understanding the core issue of the problem by empathising with the user and discovering their explicit and non-explicit needs. Users and stakeholders identification is critical for innovation success;^{17 18} in healthcare, this task has an increased complexity due to the various paying systems structures.⁴ Ethnographic research techniques, such as observation and interviewing, are recommended at the inspiration phase.¹⁶ After the need is defined, data analysis and solution conceptualisation start at the second phase, ideation; many strategies may be used to foster concept generation and free-of-judgement creativity at this second phase.¹⁰ Studies acknowledge the positive effects of a visually stimulating environment on problem-solving;¹⁹ low-fidelity prototyping is used as a source of ideas and a tool for concept validation;¹⁵ sensemaking tools, like mind-mapping, are used to support brainstorming.¹⁶ The aims of the third and final phase, implementation, are to refine and build the concept validated during the second phase and draw a marketing strategy for the final product. Prototyping is again required at this phase, but with higher fidelity as testing will also be required.¹⁶

Previous works have analysed the impacts of solutions developed using a design thinking approach on health outcomes both in broad¹ and deep⁶ accounts. However, rigorous evaluations on how design thinking is operationalised in the health sector from a process perspective remain an opportunity for further integrating design knowledge into health research.¹ This article aims to appraise the final results of solutions developed using design thinking in healthcare and the course of actions and tools that took place throughout development. As the enactment of the design thinking approach is context-dependent,^{10 20} the format of a systematic literature search and review are aligned with the aim of this research;^{21 22} an exhaustive search allows for an aggregate appreciation of the literature, and capturing several configurations in which design thinking is adopted.

We contribute to the literature by consolidating previous reports on how design thinking has been

applied in the healthcare sector and drawing conclusions from these reports. This article is also directed to practitioners as it presents tools used when applying design thinking. We will analyse articles reporting solutions ranging from the early stages of their development to solutions that are available to the market. By reviewing articles that report developing solutions, we aim to capture perspectives on every phase in the development process and avoid publication bias. We will review and tabulate aspects of each study, such as the nature of the innovation intervention, which design thinking tools were employed, team multidisciplinary and stakeholder involvement. Finally, we will discuss the contents of the studies analysed and possible avenues for research. We aim to provide an overview of the best practices on design thinking in healthcare.

METHOD

Data collection began with a search in Institute of Scientific Information (ISI) Web of Science, PubMed and Scopus databases without start date constraint (ie, from their inception) until October 2019; the earliest publication record found dated from February 2003. The three databases were chosen to provide a comprehensive search on journals focused on the disciplines of interest of this paper (eg, design, business, engineering, health sciences). The search strings used were “design think*” or “user-cent* design” or “user cent* design” or “human-cent* design” or “human cent* design” + “innovation” + “health*” or “medical*” included on title, abstract or keywords. In spite of subtle differences among the terms user-centred design, human-centred design and design thinking,¹ there is a conceptual overlap between these terms. In accordance with previous works, we will use them as synonyms.^{1 6}

The systematic review followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (see online supplemental file exhibit A1).²³ Only primary peer-reviewed studies were eligible for the study. Search was restricted to papers published in English. A total of 224 articles and reviews were identified in database search, of which 150 came to be non-duplicate documents. Scopus yielded 89 unique results to our search, the Web of Science (WoS) database yielded 32 non-duplicate results when compared with Scopus results, and the PubMed database yielded 29 non-duplicate results when compared with Scopus and WoS results.

An initial selection process was conducted aiming to filter documents that were not aligned with the research scope through title and abstract analysis, followed by a full-text review of the selected articles. Our research targets articles describing experiences, perceptions and assessment on the development of innovative health-related solutions, specifically on medical devices, products and processes following a design thinking approach. In this review, medical devices refer to hardware solutions, medical products refer to innovative

treatments or service offerings solutions (eg, mobile health (m-health) solutions), and processes refer to untangible routines, whether these routines are visible to the patients or not.^{24 25} Articles unrelated were discarded. Most articles discarded in title and abstract review regarded pharmaceutical solutions and health aids to be used by the patients without an interface to a health professional. In full-text review, the articles discarded included theoretical reports without an associated solution development, literature reviews, event descriptions, and articles that were not focused on the solution development (eg, design theory, design teaching, testing routines).

After title and abstract review, 65 articles were selected for full-text review. This sample was submitted to bibliometric analysis to identify the main references in their cocitation network, which resulted in the addition of eight references. Finally, following a full-text review, 32 references were selected for analysis. Selection process is made available (online supplemental file exhibit A2).

LITERATURE REVIEW RESULTS

The final 32 studies were reviewed and summarised (online supplemental file exhibits A3 and A4). As design thinking has no unique coded language,⁹ some of the objects of interest in this review were coded for analysis and comparison purposes (online supplemental file exhibit A5 presents our codes and their correspondance with each of the papers in our sample). A few codes (eg, prototyping) are present in more than one design thinking phase; when evaluating the papers, we took into consideration reports given by the authors to assess the maturity of the activities and whether these activities would fall into one phase or another (eg, cardboard prototypes were considered an ideation phase activity, while functional prototypes were considered implementation phase activities).

Solution status was classified according to what is reported in their studies; due to design thinking's iterative nature, it is possible that one intervention has performed an 'implementation' phase activity, but its status is still at the ideation stage. At the time of publishing, five of the solutions were at the inspiration stage of design thinking and had finalised their need assessments,^{26–29} or had study protocols established.³⁰ Eighteen of the 32 solutions were at the ideation stage, having either a visual prototype,³¹ a design concept^{32–35} or a functional prototype^{36–48} finalised. Regarding the implementation stage, out of eight solutions, one had a final product developed but not implemented,³ six were fully implemented,^{49–54} and one had been implemented and failed.⁵⁵ One solution was discontinued due to resource limitations.⁵⁶

Regarding medical specialty, of the 32 studies, 10 discussed initiatives to manage chronic disease,^{3 32 35 37 38 40 41 46 50 55} 4 brought solutions for hospital management,^{26 34 47 49} 4 on paediatrics,^{43 44 51 53}

3 on psychiatry,^{30 31 48} 2 on radiology,^{27 39} 2 on geriatrics,^{29 43} and single articles pulverised in multiple areas, such as addiction,³⁶ family health,²⁸ gastroenterology,⁵² general practice,⁴² oncology,⁵⁴ orthopaedics³³ and surgery.⁴⁵

A noteworthy theme across our sample is the creation and use of cloud-based multipurpose digital platforms.^{35 38 41 43 46} This type of intervention aims to provide an actionable use of information by patients, health professionals and providers while optimising resource allocation (eg, one of the papers presents two solutions for medication management targetting two different populations using a shared architecture for personal health record systems).⁴³

Four of the papers in our sample provide solutions that aim to address more than one target condition;^{28 31 50 51} these works elicited from both user and desk research that these conditions were intertwined and could benefit from being treated as a whole rather than as separate parts. For example, one of the solutions developed a clinical decision support for addressing tuberculosis prevention and treatment considering the high prevalence of HIV infection among the local population.⁵⁰

Another recurring theme is the systematisation of stakeholder involvement across various specialties and target conditions, such as orthopaedics,³³ surgical rounds²⁶ and pharmacy management.³⁴ One of the papers even reported an increase in its engagement metrics after the refinement of the intervention based on stakeholder feedback.⁴⁸

The vast majority of the papers in our sample report interventions in the form of software tools. Only six of the papers report the development of medical devices; we assume this happens due to resource constraints and a longer time to market of medical devices when compared with other types of interventions (eg, one of the papers reported a 48-month project duration).³⁹ Isolated papers report the creation of events (eg, creation of a seasonal community market to generate income aiming to address social determinants of health inequities),⁵³ timetables (eg, collaborative creation of a timetable balancing employees' preferences and nursing home needs),⁴⁹ toolkits and decision support systems. The following sections present the main elucidations resulting from the systematic review.

Tools employed

Each phase of the design thinking approach and their objectives is presented in [figure 1](#); for each phase, we listed the five most reported tools in our sample and their prevalence rate.

As for the tools employed in the inspiration stage by the authors in our sample, they emphasise the bystander roles of the researchers or individuals when first starting a new project applying design thinking. At this stage, the designer—or any professional acting as a designer—must put aside his/her convictions about

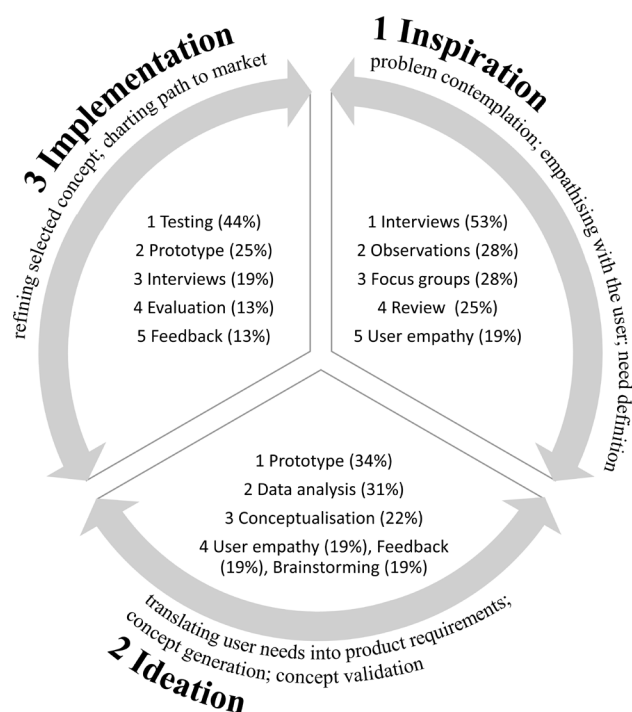


Figure 1 Three phases of the design thinking approach, objectives for each phase and main tools employed.

the problem addressed. Only then he/she is ready to effectively absorb relevant information regarding the context in which the solution is going to be developed. It is fundamental to consider this context as broadly as possible (considering time and resource limitations) to visualise the actors impacted, possible side problems that could interfere, previous documentation to improve the understanding of the situation, and any other relevant information.

Interview is the most employed tool in the inspiration stage. We assume this happens because an introductory interview is easy to perform, easy to gain access to, may have multiple formats (eg, by telephone,³³ semistructured,^{27 28 30 34 39 40} unstructured²⁶) and are greatly clarifying. Observations^{26 29 53} and reviews of various sorts (eg, clinical practice review,^{28 32 54} literature review^{30 51}) are also clarifying and, after the initial contact is made, require little effort from the user involved in the research. Focus groups^{31 36 56} and user empathy tools (eg, clinical immersion,⁵⁴ experience maps³¹) could bring substantial information to the project but have the downside of requiring significant time and effort from both the research team and possible users or stakeholders of the intervention. Tools that do not rely solely on spoken accounts of the users or stakeholders, such as observations, do have the advantage of allowing the research team to uncover opportunities for innovation that the users or stakeholders do not perceive as valuable or achievable; we refer to these opportunities as the user's unspoken needs.

The ideation phase gathers data collected at the immersion phase and makes sense of it by creating

inputs and specifications for the solution. In other words, the users' spoken and unspoken needs will be translated into the solution's technical requirements. However, this 'translation' and data analysis is not always obvious.^{34 39 50} To initialise the design of a solution, conceptualisation^{40 43 45} and correlated tools such as brainstorming^{27 33 49} are strongly recommended to keep the ideas as broad and fluid as possible. Other user empathy tools (eg, personas,^{29 36 45} experience maps^{33 47}) may be used to support this stage. After this initial wave of ideas, the most promising ones are selected for prototyping,^{36 37 40 48} which is used as a tool for concept visualisation. Design thinking postulates that prototyping helps the design team to perceive the strengths and weaknesses of their solution early in the design process and even get feedback^{3 34 37 40 42 43} from the users. Anchoring the conceptualisation activities in low-fidelity prototypes promotes a quick escalation in the attributes of the concept and smart allocation of resources in ideas that are worth pursuing.

The implementation phase, which aims to refine the ideated concept into a viable solution, was the least reported among our sample, as a significant portion of the articles did not report reaching this phase. Some of those who had reached it focused their reports on assessing the intervention and not describing their development process,^{51–53} and a couple of articles reported that they would not disclose these issues due to commercial confidentiality.^{27 39} Among the references that did report tools employed in the implementation stage, testing was the most mentioned tool (eg, user testing,^{37 42 44} requirements testing^{34 45}), followed by prototyping,^{31 34 36 38 40 45 47 53} interviews,^{33 36 42 50 54 55} solution evaluation,^{36 44 46 50} and solution feedback.^{3 34 38 44} It caught our attention that commercial analysis was reported by only three articles in our sample.^{33 53 54} If the solution is meant to be commercially viable, this aspect must be addressed in a diligent manner.

Disciplines and stakeholders involved

Although combining different competences and backgrounds is a best practice for design thinking,⁸ more than half of the articles in our sample did not report multidisciplinary in their design thinking teams. This is problematic as diverse teams are more likely to promote relevant innovative solutions.¹⁰ Among the literature that mentioned disciplines and areas involved in their teams, the most cited were health-related disciplines,^{3 27 30 32 37 38 49 50 54} design,^{30 33 38 49 53 54} Information Technology (IT),^{38 50 55 56} Research and Development (R&D)^{32 33 37 50} and engineering.^{27 32 54}

Besides congregating multiple areas of knowledge, it is necessary to gather different perspectives. Managing stakeholders in the healthcare sector is not trivial as healthcare users vary in their roles as device operators, patients or decision-makers.²⁹ Understanding who the stakeholders are and their roles is a key factor for

achieving relevant results and requires an understanding of the business model around the product.^{29 33} A solution development focused on technical issues and neglecting stakeholders' perspectives is susceptible to barriers in implementation.^{39 55} Stakeholder participation assessment tools⁵⁷ and frameworks for listening to the voices of the customer, business and technology³³ are strategies to promote effective stakeholder involvement.

Regulation

Developing medical devices and products must follow regulatory requirements. In the USA, the Food and Drug Administration (FDA) is the main body of regulation for medical devices.⁵⁸

Even though regulatory issues are inherently critical to the implementation of medical devices and products, only 12% of the articles in our sample mention the FDA or another regulator,^{27 33 54 56} with only one of them stating the class their devices were fitted in.³³ Our attempt to stratify the findings in our sample according to regulation status or classification was not successful, as we found that a number of our references did not address regulatory issues. This might indicate a lack of maturity of research—or even awareness—in this topic. Design thinking brings the possibility of everyone being a part of the design process on the table, but one individual must own the process and be accountable for design feasibility and regulatory issues. Additionally, two articles did not go into detail on their developments claiming commercial confidentiality.^{27 39}

DISCUSSION AND AVENUES FOR RESEARCH

Drawing attention to the inspiration stage

Regarding the reportings on the tools employed in the inspiration phase, it was noted that solutions that were in more advanced stages of development—ranging from having a functional prototype to being fully implemented and commercialised—often failed to report the tools employed in the inspiration stage (19% of the sample) or lacked detail about this stage. We believe that this bias is due to the fact that researchers often prioritise describing the intervention developed to the detriment of reporting the development process.

We perceive this 'setting aside' of the initial development stage as counterproductive for the replication of design thinking: the engagement and understanding of the final user which is acquired from the inspiration stage are essential for developing appropriate solutions, at the risk of developing solutions that relieve the symptoms of a problem without addressing its root causes.⁵⁹ In fact, it is more crucial for the direction of the intervention that users and stakeholders are involved in the early stages when compared with the late stages of the innovation process.^{18 60} If the body of literature on design thinking does not consider the relevance of this stage, there is a tendency that individuals learning from this body of literature will have the same perception. This may incur professionals

involved in projects employing the design thinking approach neglecting information collected in the inspiration stage, and realising that their solutions do not fulfil user needs.^{39 55} Although exhibits from the literature present a systematisation of how to incorporate the results of the inspiration phase and user-centred research throughout the development process,^{27 29} due to the variety of stakeholders, users and types of problems in healthcare, further studies seeking to formalise the incorporation of inspiration phase data throughout development would be beneficial to the theory and practice of health research involving design.

Research groups, networks and common platforms for healthcare innovation

One thing that caught our attention was the establishment of research groups and software platforms for improving synergy in the development of healthcare solutions. UK-based Multidisciplinary Assessment of Technology Centre for Healthcare—a publicly funded research group with close collaboration with medical device industries—presents substantial results on research regarding the role of the user in medical device development.⁶¹ Project HealthDesign was a sponsored multiyear, multisite project that gathered design teams across the USA to develop e-health applications using a common back-end platform.^{35 41 43} Tidepool is an open-access platform designed to host and integrate applications related to diabetes management, counting with open-source development to augment and sustain the platform.³⁸

How to make these fruitful connections happen? Norman *et al*⁶² propose the Complex Network Electronic Knowledge Translation Research (CoNEKTR) model for integrating individuals from distinct backgrounds by their common interest in promoting innovation in healthcare; we could not find evidence of CoNEKTR's applicability and performance outcomes. A proven effective model for leveraging the integration of individuals around healthcare innovation will certainly be a major contribution to this research field.

The future of e-health

Approximately 56% of the articles in our sample reported a healthcare solution using e-health, with the major amount of those discussing m-health. Regarding technology usage, a part of the papers in our sample reported the development of auxiliary technologies for telemedicine,^{52 56} and data-gathering technologies, such as personal health records,^{29 35 41 43 55} patient self-monitoring^{3 40 46} and patient motivation trackers.^{32 48}

Developing functional and usable e-health applications is not trivial, as there is a need to create an in-depth understanding of the user's needs, desires, limitations, preferences, attitudes and behaviours through a user model that will serve as a common point for the different individuals involved in the development process.²⁹ However, capturing these psychological and

psychosocial nuances is not possible with the 'traditional' application of user-centred methods like user profiles and personas, as they tend to rely on demographic data and shallow caricatures of user groups.²⁹ Not employing the rigour, time and collective sense of the importance of user research may doom user research to become an unactionable or overlooked work.^{39 55}

In-depth user research is necessary to address users' underlying cognitive and behavioural patterns, user subgroups and characteristics unique to different conditions (eg, knowledge about the disease, support network, comorbidities); capturing the amount of data necessary to build actionable user profiles and personas is resource consuming, but its benefits outweigh its costs.²⁹ Design thinking may provide a framework for aligning healthcare system needs, user needs and software requirements towards healthcare innovation.³⁴ There are numerous conceptual layers from which the development of successful e-health solutions can be studied: system integration, wearables, user heuristics and interface design are just a few of them.

User involvement

von Hippel⁶³ introduced the concept of lead users as composed of two main characteristics: the first is that lead users face needs that will be general in the market-place prior to the bulk of that market-place; the second is that they could benefit by obtaining a solution to their needs and thus are highly motivated to seek one. These users play an active role in the development process, beyond the passive role implied by expert-driven user-centred practices, such as interviews, personas and journey mapping. There is evidence of the potential benefits of involving lead users in the co-creation and development of solutions in healthcare.¹⁸ Involving these users could potentially increase development rates and expertise in pioneer technologies and boost commercial performance. Consequently, it could increase manufacturers' profits by reducing time to market and development costs.¹⁸ Even though there are generic suggestions in the literature of how to retain these lead users,⁶⁴ further research on identifying and contacting lead users in the healthcare sector may benefit future development projects.

Another discussion regarding user involvement in the healthcare industry is motivated by understanding who is the user of interest. While there are more obvious contexts where we can identify the main user (eg, a mobile app for patient self-monitoring^{3 29 30 46}), in other cases, such as a medical imaging device,^{27 39} it is not clear if the main user is the patient or the healthcare professional and it is not trivial to counterbalance their needs. On top of this, there is a third stakeholder—the payer—which could be either a provider or a healthcare organisation. Further discussion on whether and how design thinking is a suitable

approach to manage these user layers would be a contribution to the literature.

CONCLUSION

Design thinking is a flexible approach for innovation which is being used to develop healthcare solutions. Considering healthcare, our research shows evidence that design thinking is an approach to innovation in clinical and managerial settings, across a wide range of medical specialties. Our research findings endorse that design thinking provides a frame for addressing the development of innovation in healthcare by balancing contextual factors (eg, users, stakeholders, resources) and clinical evidence. Additionally, our sample shows that design thinking is an ally for democratising access to healthcare through innovative solutions in low-resource settings. Design thinking provides an arsenal of tools for problem-solving across the phases of inspiration, ideation and implementation.

With this review, we aimed to present a selection of practical applications of design thinking in healthcare, highlighting the most common practices among them. We present this selection of practice and tools as a guide, rather than as a toolset. The selection of 32 papers shows that design thinking is not a one-size-fits-all approach and that it may be adapted to different circumstances. To further advance this field, future research should follow more rigorous procedures for reporting health research involving design; this could be achieved by following structured guidelines.⁶⁵ Additionally, future research on emerging technologies in service of health should address user-centred design, providing replicable procedures on how to identify and address user needs. Finally, once a more consistent body of literature is consolidated, with standardised report procedures, a research agenda for quantitatively assessing the relationship between design choices and clinical outcomes may provide more assertive recommendations for the incorporation of design knowledge into health innovation.

Strengths and limitations

Despite our efforts to establish clear selection criteria, sample selection and subsequent codification were subjected to the authors' bias. The lack of standards in reporting health research involving design, and the variability of studies in our sample both in their objects of study and development stages refrained this review from assessing criteria such as design success rate, design success critical paths, optimal team composition for design success and types of intervention (eg, devices, products, processes) for which design thinking may be more suitable. This may be interpreted as a clash between design and health sciences underlying research traditions and epistemologies. To address this issue and enable further analysis in future literature reviews,

we recommend future works that report interventions on the intersection of design and health to consider following of systematic guidelines.⁶⁵

Contributors ALF and MO planned the study. MO conducted the data gathering and literature review analysis. ALF and EZ guided the research method and revised the manuscript.

Funding This study was financed by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES) – Finance Code 001 and by the Ocean R&D Programme.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplemental information. Data reuse is permitted.

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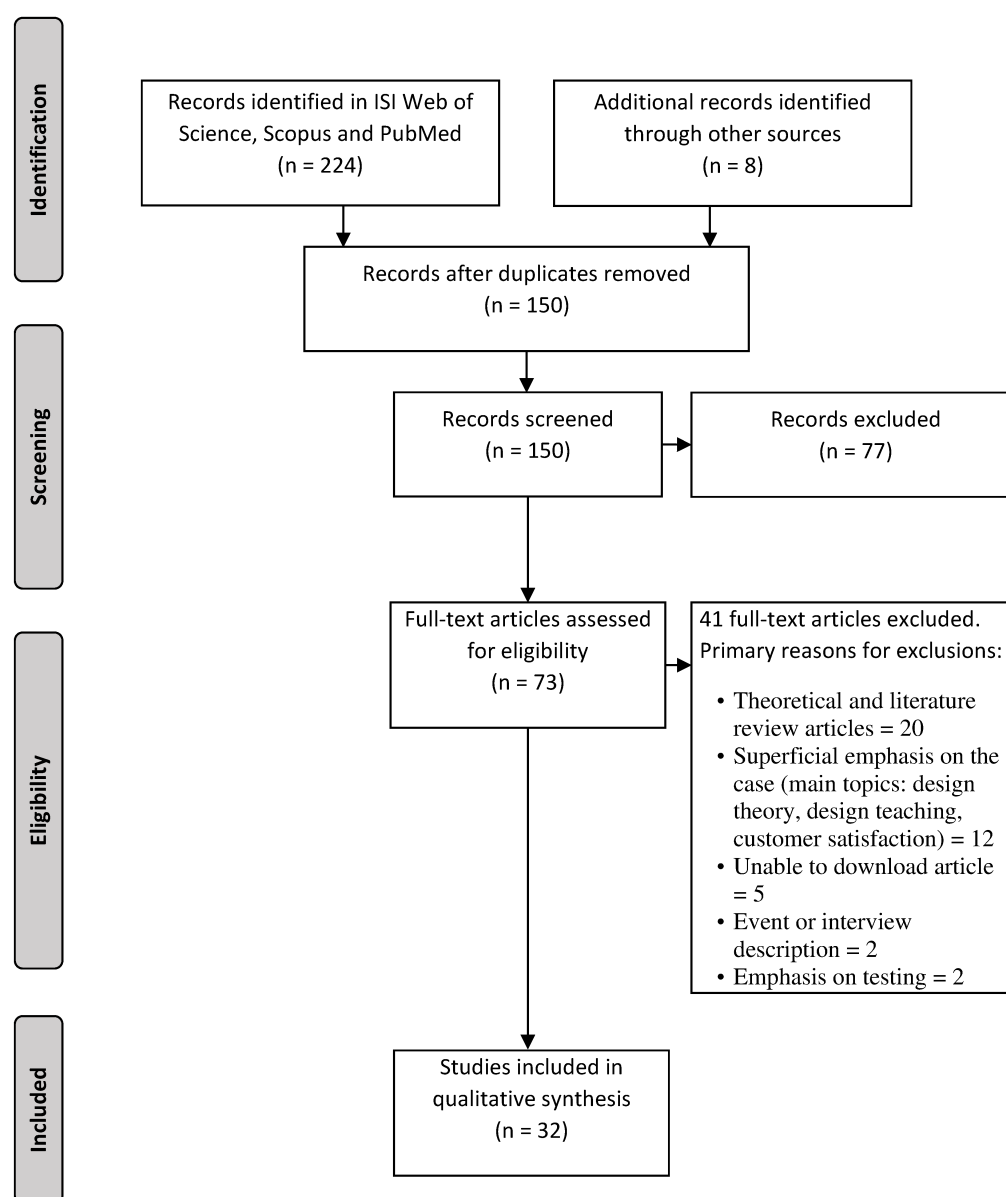
Supplementary files – Exhibit A1: PRISMA Guideline Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3-6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	NA
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	A3-A4
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	NA
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	NA

Supplementary files – Exhibit A1: PRISMA Guideline Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	6
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	A2
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	7-13;A3-A4
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	NA
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	NA
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	13-17
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	17
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	17-18
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	18

Supplementary files – Exhibit A2: PRISMA flowchart



Supplementary files – Exhibit A3: Data on study objectives, inclination, contribution, time-frame, funding, disciplines and stakeholders involved

Author, Year	Study objective	Inclination	Main contribution	Study time-frame	Funding	Multidisciplinarity codes	Stakeholders codes
Brennan et al, 2009	Envision how personal health records that promote healthy action can aid nurses in their practices	Design process	Insights about user-centered design focusing both on the patient and the nurse	18 months	Private (Foundation)	Mentions need for multidisciplinary but do not say which disciplines	Not mentioned
Brennan et al, 2010	Describes a program that promotes the development of a digital platform for using personal health records to aid multiple conditions	Design evaluation	Expanding the concept of personal health records to include observations of daily living and thus enhancing the provision of actionable health information	30 months	Private (Foundation)	Not mentioned	Not mentioned
Brooks et al, 2019	Co-develop and test the feasibility of a culturally-appropriate toolkit to promote mental health literacy and depression/anxiety focused self-management skills in young people, aged 11–15 years, in Java, Indonesia.	Product design	Detailed elaboration of research design	30 months	University-funded	Designers; education professionals; other health professionals	Carers; community; government; management; medical doctors; patients; others
Carroll and Richardson, 2016	Integration of healthcare needs and software requirements, focusing on improving connections between people, enhancing collaboration between stakeholders and establishing better communication	Design requirements	Presents and applies a framework for translating healthcare requirements into software requirements	Not mentioned	Funding agency	Not mentioned	Carers; medical doctors; patients; providers; others
Catalani et al, 2014	Create a clinical decision support system for aiding treatment prescription for HIV patients with tuberculosis	Design process	Detailed process from understanding of the problem to testing phases	12 months (estimated)	Funding agency	IT professionals; medical doctors; researchers	Community; medical doctors; patients
Cheung, 2012	Develop a solution for aiding spine surgery based on an analysis of social trends, economic forces, technological advances and cultural influences for need-finding	Design process	Detailed process for new product development coming from 80 new product opportunity gaps, funneling to 6 clusters of opportunities and combining those into 8 product opportunities	Not mentioned	Not mentioned	Not mentioned	Medical specialists
Coons et al, 2019	Describe the architecture, design, and early testing of a mobile application that facilitates the accurate sharing of medication lists among patients, pharmacy and doctors; the application has individual education resources regarding medicines	Design process	Description of design and evaluation of an app from the perspectives of both the community and the hospital	Not mentioned	National institute	Not mentioned	Medical doctors; patients; pharmacists
Cunningham et al, 2016	Performs a baseline study in four African countries to identify features of healthcare practices in rural clinics. Findings will serve as inputs for developing a mHealth solution for maternal and newborn care.	Design requirements	Identification of the state of the practice in healthcare clinics	Not mentioned	Public (European commission)	Not mentioned	Mentions stakeholder involvement as a step for future research
de Ana et al, 2013	Using a case study as a reference, proposes a process for balancing stakeholder voice in the front-end of medical device development	Design process	Creates a process for aligning solutions among multiple stakeholders	8 months	Not mentioned	Designers; management; marketing and business; researchers	Management; marketing, business and sales; medical doctors; patients; providers; researchers; others
Eines and Vatne, 2018	Assess the experiences of a nursing home on applying a design thinking approach to engage staff in innovation activities	Design process and evaluation	Correlation of design practices with organizational layers	Not mentioned	Public	Designers; management; nurses; others	Carers; management; nurses; patients
Greenhalgh et al, 2010	Evaluate the adoption of a personal electronic health record, avoiding the pro-innovation bias and addressing what went wrong in development	Design process and evaluation	Relates the design decisions to the success (or insuccess) of adoption of the innovation	36 months	NHS organizations	Implementation experts; IT professionals	Government; IT professionals; others; the author mentions that patients and physicians were under involved

Supplementary files – Exhibit A3: Data on study objectives, inclination, contribution, time-frame, funding, disciplines and stakeholders involved

Author, Year	Study objective	Inclination	Main contribution	Study time-frame	Funding	Multidisciplinarity codes	Stakeholders codes
Källander et al, 2015	Develop and evaluate approaches for increasing community health workers' supervision, motivation, performance, and retention. Assess the impact of these interventions on coverage of treatment for malaria, pneumonia and diarrhea in children	Design evaluation	Multiplatform approach for community health workers and vulnerable population	18 months	Private (Foundation)	Not mentioned	Mentions stakeholder involvement, but does not mention which stakeholders
Kumar, Uehira and Kay, 2009	Present a solution for improving patient experience in a hospital by providing on-demand directions and guidance	Design process	Detailed description of the design process and design tools employed	Not mentioned	Private (Enterprise)	Not mentioned	Not mentioned
Langell et al, 2019	Design a device for treating cervical cancer in resource-poor regions	Design process	Description of the entire design process, from need identification to market entry	24 months	University-funded	Designers; engineers; marketing and business; medical doctors	Mentions stakeholder involvement, but does not mention which stakeholders
LeRouge et al, 2013	Demonstrate patient involvement in the design and development of a consumer health technology; develop and employ user-profiles and personas as a tool to capture patients' mental model and apply these features to design and development decisions	Product design	Indication on how to effectively understand and model the patients' mental model through a revealing process and artifacts	Not mentioned	Private (Enterprise)	Not mentioned	Carers; management; medical doctors; patients; providers; others
Martin and Barnett, 2012	Drawing from what went wrong in a case of medical device development, establish a way to effectively collect, represent and employ user data in the medical device development process	Design process	Describes each aspect of the design process that contributed to the failure of the user-centered approach in this project	48 months	Private (Enterprise)	Not mentioned	Other healthcare professionals
Martin et al, 2012	Validate and refine the concept of a new device while investigating the process of involving users in early development phases	Design requirements	Demonstration of a rigorous user need validation research	Not mentioned	Public (national funds)	Engineers; medical specialists; nurses	Not mentioned
Mulvale et al, 2019	Apply and assess evidence-based co-design (EBCD) approach on design of three different services for youth with mental health issues	Design process	Method description and replicability	Service 1: 24m Service 2: 8m Service 3: 9m	Public (state and national funds)	Not mentioned	Carers; patients; other healthcare professionals; others
Neinstein et al, 2016	Create a cloud-based, device-agnostic, software platform that could download and integrate raw data from any diabetes device	Software design	Web-based cloud platform	18 months	Private philanthropists and Granting agencies	Designers; entrepreneurs; IT professionals; medical specialists	IT professionals; medical doctors; patients; researchers; others
Pham et al, 2018	Design, develop and assess an analytics platform to analyze data from a mHealth application	Design process	Detailed description of the indicators definition and verification processes	6 months	Not mentioned	Not mentioned	Not mentioned
Ramadas et al, 2015	Improve dietary habits in diabetic patients through a web-based intervention	Design evaluation	Detailed process evaluation of web-based intervention	Not mentioned	University-funded	Medical specialists; nutritionist; researchers; other health professionals	Not mentioned
Ross et al, 2011	Describing the use of a common platform for the development of two applications	Product design	Assessment of challenges in PHR development stages	18 months	Private (Foundation)	Not mentioned	Not mentioned
Rossos et al, 2015	Increase awareness to human factors engineering and user-centered elements of telecare, relating the previous aspects to the successful implementation of telehealth programs	Design evaluation	Correlation of the importance of both people and process in systems implementation	over 10 years	Not mentioned	Not mentioned	Not mentioned
Rudin et al, 2017	Develop a gamified intervention for implementing asthma symptom monitoring via mHealth “from the ground up”, starting with identifying the core components	Design process	Description of detailed requirements, decision points and stakeholder related issues	Not possible to infer full project length	Funding agency	Not mentioned	Medical doctors; patients; providers

Supplementary files – Exhibit A3: Data on study objectives, inclination, contribution, time-frame, funding, disciplines and stakeholders involved

Author, Year	Study objective	Inclination	Main contribution	Study time-frame	Funding	Multidisciplinarity codes	Stakeholders codes
Sammann et al, 2019	Identify needs and priorities from both the users (patients, clinicians, etc) and the system for daily trauma rounds at an academic hospital	Design process	Brings parallel between lean methodology and human-centered design approach; identifies valuable and non-valuable activities and the time spent in each of them during trauma rounds	Not mentioned	Did not receive any funding	Mentions need for multidisciplinarity but do not say which disciplines	Carers; management; medical doctors; nurses; patients; pharmacists; others
Schlosser et al, 2016	Evaluate feasibility, applicability and impact on patient outcomes of a mobile app treatment for schizophrenia on young patients	Design evaluation	Presents the increase in app acceptance after the first refinement iteration from engaging with stakeholders	4 months	Not mentioned	Not mentioned	Carers; patients; providers; researchers
Thaete et al, 2019	Create and evaluate a prototype for measurement of middle-upper arm circumference and determination of corresponding Z score	Design process	Description of the testing stage of a prototype	Not mentioned	Private (Foundation)	Not mentioned	Not mentioned
van der Weegen et al, 2013	Reports the user-centered design process applied for a monitoring and feedback tool to support the self-management of people with chronic disease to obtain an active lifestyle.	Product design	Establishes a process for requirements identification	Not mentioned	Funding agency	Engineers; implementation experts; medical doctors; researchers; others	Patients; other healthcare professionals
Vechakul, Shrimali and Sandhu, 2015	Describe and assess a human-centered approach to mitigate the root causes of health inequity in communities with high poverty rates	Design evaluation	Analysis of the entire design process from design definitions to outcomes	21 months (estimated)	Private (Foundation)	Designers; government and social development initiatives	Mentions community involvement, but does not refer to the term stakeholders
Vilardaga et al, 2018	Describe the rationale, ideation, prototyping, design, user research, and final feature set of a smoke cessation app for people with mental disorders	Design process	Explanation and application of the design process	Not mentioned	National institute	Not mentioned	Medical specialists; patients; others

Supplementary files – Exhibit A4: Data on design thinking tools and solution specification

Author, Year	Inspiration codes	Ideation codes	Implementation codes	Medical specialty	Target condition/ System	Solution modality	Solution objective	Status
Brennan et al, 2009	Not mentioned	Not mentioned	Not mentioned	Chronic disease	Children and teens with complex diseases (congestive heart failure; diabetes; chronic pain; cancer)	E-health (personal health records)	Collect observations of daily living and health monitoring data for clinical guidance	Design finalized
Brennan et al, 2010	Not mentioned	Not mentioned	Not mentioned	Chronic disease	Children and teens with complex diseases (congestive heart failure; diabetes; chronic pain; cancer)	E-health (personal health records)	Collect observations of daily living and health monitoring data for clinical guidance	Functional prototype finalized
Brooks et al, 2019	Focus groups; interviews; review; others	Collaboration groups; data analysis; focus groups	Focus groups; testing; others	Psychiatry	Mental health literacy; anxiety and depression self-management	Toolkit	Promote mental health literacy and depression and anxiety focused self-management skills in young people (11–15yo) in Indonesia	Not started (study protocol established)
Carroll and Richardson, 2016	Data analysis; interviews; observations; shadowing; user definition	Brainstorming; data analysis; feedback; prototype	Feedback; iteration; prototype; testing	Hospitalar management	Pharmacy management	Software	Promote connected health innovation through the improvement of pharmacy management	Design finalized
Catalani et al, 2014	Audio recordings; field notes; interviews; observations; others	Data analysis; prototype	Evaluation; interviews; survey; testing; others	Chronic disease	HIV and tuberculosis	Clinical Support Decision System (m-health)	Guarantee the appropriate treatment for HIV patients with tuberculosis	Implemented
Cheung, 2012	Ethnographic methods; interviews; lists; observations; review	Commercial analysis; conceptualization; field notes; interview; observations; product attributes definition; user empathy; others	Prototype; testing	Surgery	Spine surgery	Device (non-invasive patient tracker)	Minimize patient trauma in spine precise surgery	Functional prototype finalized Clinical feasibility tested
Coons et al, 2019	Need definition; survey	Feedback; sketching; testing	Focus groups; interviews; testing; others	General practice	Medicamentation misuse	E-health (m-health personal health records)	Accurately share medication lists among physicians, patients and pharmacy	Functional prototype finalized
Cunningham et al, 2016	Audio recordings; field notes; focus groups; interviews; need definition; review; user definition; user empathy; others	Not mentioned	Not mentioned	Family health	Maternal and newborn overall health	E-health (m-health)	Improve the quality of maternal and newborn healthcare delivery in rural clinics in Africa	Need assessment finalized
de Ana et al, 2013	Ethnographic methods; focus groups; interviews; need definition; observations; shadowing; surveys; user empathy; others	Brainstorming; focus groups; interview; prototype; user empathy; others	Conceptualization; interviews; marketing and commercial strategies; survey	Orthopedics	Fracture repair	FDA class III therapeutic device self-administrated at home	Enhance/accelerate fracture repair	Design finalized
Eines and Vatne, 2018	Observations; user empathy; workshops	Brainstorming; conceptualization	Testing	Hospitalar management	Meeting patients demands for service quality, economic sustainability and skilled health care professionals	Customized timetable	Determine roles and responsibilities for nursing team aligned with their personal abilities and nursing home needs	Implemented

Supplementary files – Exhibit A4: Data on design thinking tools and solution specification

Author, Year	Inspiration codes	Ideation codes	Implementation codes	Medical specialty	Target condition/ System	Solution modality	Solution objective	Status
Greenhalgh et al, 2010	Not mentioned	Not mentioned	Ethnographic methods; field notes; interviews; observations; shadowing; others	Chronic disease	Patient monitoring	E-health (personal health records)	Mitigate lack of integration across the NHS avoiding fragmentation of care, inefficiency, and risk	Implemented and failed
Källander et al, 2015	Consultations; lists; review	Not mentioned	Not mentioned	Pediatric	Children with diarrhea, pneumonia and malaria	Training of community health workers employing m-health	Improve health outcomes as result of increasing community health worker performance and motivation	Implemented Ongoing cluster randomized controlled trial
Kumar, Uehira and Kay, 2009	Interviews; workshops; others	Data analysis; data summarizing; interview; observations; user empathy	Prototype	Hospitalar management	Patient experience in a hospital	Direction and guidance system	Help patients that tend to get lost in the hospital	Functional prototype finalized Ongoing testing
Langell et al, 2019	Need definition; review; shadowing; user empathy; others	Data analysis; prototype; others	Interviews; iteration; marketing and commercial strategies; testing; others	Oncology	Cervical cancer	Thermal coagulation device	Allows for the treatment of precancerous cervical lesions at low cost	Implemented Commercialization
LeRouge et al, 2013	Audio recordings; focus groups; interviews; observations; review; others	Data analysis; user empathy	Not mentioned	Geriatrics	Diabetes	E-health (personal health records)	Improve self-monitoring of diet and exercise for elderly diabetics	Need assessment finalized
Martin and Barnett, 2012	Interviews; user definition	Data analysis	Ethnographic methods; shadowing; others	Radiology	Medical imaging	Imaging device	Provide an inexpensive, portable imaging device	Functional prototype finalized Route for commercialization being considered
Martin et al, 2012	Brainstorming; field notes; interviews; others; user definition	Brainstorming; data analysis; data summarizing	Not mentioned	Radiology	Medical imaging with an emphasis on phlebotomy applications	Imaging device	Provide an inexpensive, portable medical imaging device	Need assessment finalized
Mulvale et al, 2019	Audio recordings; focus groups; interviews; others; user empathy	Brainstorming; conceptualization; data analysis; prototype; others	Prototype	Psychiatry	Depression Anxiety Eating disorders Psychotic disorders	Not mentioned	Improving coordination of mental health care for youth, related supports, and transitions to adult care; improving employment supports for youth with mental health	Visual prototype finalized
Neinstein et al, 2016	Interviews	Not mentioned	Prototype; feedback	Chronic disease	Diabetes (Type 1)	E-health (m-health)	Create a cloud-based platform to integrate data from devices used to monitor diabetes	Functional prototype finalized Ongoing testing
Pham et al, 2018	Focus groups; review	Not mentioned	Evaluation; field notes; iteration; observations	Chronic disease	Chronic pain	E-health (m-health)	Pain self-management for youth and young adults from 12 to 25	Functional prototype finalized Full development hired

Supplementary files – Exhibit A4: Data on design thinking tools and solution specification

Author, Year	Inspiration codes	Ideation codes	Implementation codes	Medical specialty	Target condition/ System	Solution modality	Solution objective	Status
Ramadas et al, 2015	Prototype	Feedback; prototype	Testing	Chronic disease	Diabetes (Type 2)	Web-based education program	Improve population's dietary habits	Functional prototype finalized
Ross et al, 2011	Consultations; focus groups; interviews	Conceptualization; feedback; focus groups; prototype	Testing; others	Pediatrics and Geriatrics	Patients taking multiple medications	E-health (personal health records)	Manage drug self-administration to avoid adverse events	Functional prototype finalized (needs to meet data safety standards for release)
Rossos et al, 2015	Not mentioned	Not mentioned	Not mentioned	Gastroenterology	Bariatric surgery	E-health (remote telemedicine consultations)	Improve treatment follow up for people living far from the hospital	Implemented Over 300 consultations executed in the first 18 months
Rudin et al, 2017	Consultations; interviews; others	Conceptualization; feedback; prototype; user empathy	Conceptualization; prototype; testing; others	Chronic disease	Asthma	E-health (m-health)	Asthma monitoring in a way that data can be used by patients, physicians and EHR	Functional prototype finalized Tests finalized
Sammann et al, 2019	Interviews; observations	Not mentioned	Not mentioned	Hospitalar management	Trauma surgical rounds	Not mentioned	Improve efficiency on trauma rounds	Need assessment finalized
Schlosser et al, 2016	Interviews; workshops	Prototype; others	Not mentioned	Psychiatry	Youth with schizophrenia	E-health (m-health)	Improve motivated behavior in the early phases of the illness on young patients	Functional prototype finalized random control trials ongoing
Thaete et al, 2019	Not mentioned	Not mentioned	Evaluation; feedback; testing	Pediatric	Child nutritional status diagnosis	Analogical device (measurement ruler)	Provide both measurements of upper arm circumference and determination of corresponding Z score in a single step	Functional prototype finalized and tested Patent filed Next-generation of the prototype is redesigned
van der Weegen et al, 2013	Review	Collaboration groups; interviews; others	Not mentioned	Chronic disease	Chronic obstructive pulmonary disease or type 2 diabetes	E-health (m-health personal health records)	Stimulate physical activity in patients with chronic disease	Design finalized
Vechakul, Shrimali and Sandhu, 2015	Data analysis; observations; others	Brainstorming; conceptualization; data summarizing; prototype	Marketing and commercial strategies; prototype; testing	Pediatric	Infant mortality rate	Event	Addressing the roots of health inequities in infants mortality rate in poor communities	Implemented Served as an incentive for new initiatives
Vilardaga et al, 2018	Field notes; focus groups	Prototype; sketching; user empathy	Evaluation; interviews; prototype; testing	Addiction	Smoke addiction	E-health (m-health)	Engage smokers with mental health issues to quit smoking	Functional prototype finalized

Supplementary files – Exhibit A4: Data on design thinking tools and solution specification

Author, Year	Inspiration codes	Ideation codes	Implementation codes	Medical specialty	Target condition/ System	Solution modality	Solution objective	Status
Wilson et al, 2012	Ethnographic methods; focus groups; interviews; observations; surveys	Others	Survey	Geriatrics	Elderly care	E-health (hardware with supporting network and recording/monitoring software; a suite of telemedicine and telemonitoring devices; and an associated set of tele-accompany services)	Ease the life of older people in their home	Interrupted due to resource limitations
Woods et al, 2018	Brainstorming; field notes; user empathy; others	Conceptualization; data analysis; feedback; sketching	Feedback	Chronic disease	Heart failure	E-health (m-health)	Self-management of heart failure	Final product developed

Supplementary files – Exhibit A5: Codification of Design Thinking tools (references numbers according to the main document)

Inspiration tools codes	Inspiration tools as mentioned by authors
Audio recordings	audio recordings [50]; audio records [28]; audio-records [31]; recording [29]
Brainstorming	brainstorm [3]; brainstorming [27]
Consultations	consultations [51]; patient consultation [40]; visits [43]
Data analysis	data analysis [34]; synthesize insights [53]
Ethnographic methods	ethnography [56]; ethnographic methods [45]; ethnographic research [33]
Field notes	field notes [3,27,28,36,50]
Focus groups	expert panel [36]; focus groups [28–31,43,56]; group need assessment session [46]; panel of payers [33]; physician panels [33]
Interviews	Interview [31,33,38]; interviews [29,43,47,48,56]; key informant interview [50]; recorded interview [27]; semi-structured interviews [27,28,30,34,39,40]; telephone interviews [33]; unstructured interviews [26]; user interviews [45]
Lists	list of categories for opportunities [45]; list of product opportunity gaps [45]; list of social trends, economic forces, technological advances and cultural influences (SETC factors) [45]; list of potential innovations [51]
Need definition	core requirements identification [42]; draft of user needs [54]; uncovered pain points [33]; usability and user experience requirements [28]; validation of the clinical problem [54]
Not mentioned	not mentioned [35,41,44,52,55]
Observations	field observations [45]; field research observations [33]; in-context observations [26]; observation [29]; observation studies [34]; observations [49,56]; observe and inspire [53]; site observation sessions [50]
Others	clinical practice guidelines search [32]; definition of data elements to be captured [28]; feedback [54]; individual design sessions [40]; keyword collection [47]; photo-elicitation method [30]; photographs [3]; simulation testing [50]; specification of research objectives [27]; tell stories [53]; transcription [29,31]; trigger videos [31]; videotaping [33]; workflow and reporting requirements [28]
Prototypes	paper prototype
Review (literature, historical, best practices)	background research [54]; historical background review [51]; information about working practices [28]; literature research [32]; literature review [30,51]; review of previous documentation [29]; review of the therapeutic landscape [54]; scoping review [46]; task analysis [45]
Shadowing	procedural shadowing [54]; shadow [34]; shadowing [33]
Surveys	survey [56]; survey with potential users [42]; surveys [33]
User definition	analysis of end user profiles [28]; definition of a standard user [34]; user definition [27,39]
User empathy	clinical immersion [54]; concept preference testing [33]; environment examination [28]; experience maps [31]; individual summaries [3]; persona [3]; walkarounds [49]
Workshops	workshop [49]; workshops [47,48]

Supplementary files – Exhibit A5: Codification of Design Thinking tools (references numbers according to the main document)

Ideation tools codes	Ideation tools as mentioned by the authors
Prototype	digital prototype [54]; low fidelity mockups [40]; low fidelity models [33]; moch prototype website [37]; paper mockups [48]; paper prototyping [36]; physical device prototype [54]; pilot [43]; prototype [50,53]; prototyping [34,48]; rapid prototyping [33]; visual prototype [46]
Not mentioned	not applied [26,46]; not mentioned [28,35,38,41,44,51,52,55]
Data analysis	data analysis [3,27,29–31,34,39,47,50,54]; data translation [50]; verbalization analysis [27]
Others	audio recordings [45]; coding analysis [45]; computer screen captures [45]; data collection tools [33]; field notes [45]; photographs [45]; poker chip sort [33]; problem definition [31]; radiographic films [45]; simulations [48]; treatment modality selection [54]; user testing [42]; visualization tools [56]
Conceptualization	concept development [49]; create concepts [53]; holistic product definition [45]; individual design sessions [40]; storyboard [3,43]; theme clustering across participants [31]; wireframe [3]
User empathy	“before, during, after” experience tool [47]; experience maps [33]; persona tool [45,47]; personas [36]; scenario-based drama [29]; user persona [29]; user profile [29]; workflow diagrams [40]
Feedback	feedback [3,40,42,43]; feedback from experts [37]; prototype, test, and feedback from stakeholders [34]
Brainstorming	brainstorm [53]; brainstorming [27,33,34,49]; individual brainstorm [31]
Interview	audio-recorded interviews [45]; focus groups interviews [32]; in-depth interviews [47]; interviews [32,33]
Sketching	concept design [42]; sketches [3]; sketching [36]
Data summarizing	data synthesis [47]; executive summary [27]; main report summarizing data [27]; synthesize insights [53]
Focus groups	design workshops [30]; final review events [30]; focus groups [43]; panel discussions [33]
Observations	field observations [45]; observation research [47]
Collaboration groups	collaboration group [30]; expert meetings [32]; sustained group works [30]
Commercial analysis	stakeholder analysis [45]; value opportunity analysis (VOA) [45]
Product attributes definition	devised scenario [45]; product attributes [45]; weighted matrix [45]

Supplementary files – Exhibit A5: Codification of Design Thinking tools (references numbers according to the main document)

Implementation tools codes	Implementation tools as mentioned by the authors
Testing	beta test with patients [37]; identification of all variables tested in each prototype [34]; iterative testing [43]; multisite testing [30]; template for intervention description and replication [30]; test [49]; test and refine [53]; testing [36,44,49]; testing session [42]; usability testing [50]; user testing [40]; user validation testing [54]; validation with consulting surgeon [45]
Not mentioned	not applied[26,27]; not mentioned [28,29,32,35,41,48,51,52]
Others	audio recordings [50]; audiotapes [55]; data analysis [55]; evidence-based framework [30]; expert consultation [40]; heuristics analysis [40]; implementation [50]; informative flyer [42]; photos [39]; review of regulatory classification requirements [54]; socio-technical networks [55]; video records [43]
Prototype	creation of service and product ideas and prototypes [47]; functional prototype [45]; high fidelity prototype [40]; prototype [31,47,53]; prototyping [38]; software prototyping [36]; rapid prototyping [34]
Interviews	in depth interviews [50]; interview [33,36,54]; interviews [55]; semistrutured interviews [42]
Feedback	feedback [3,34,38,44]
Evaluation	evaluation [50]; measurement [50]; questionnaires [44]; rating [36]; usability and accessibility evaluation [46]
Iteration	iteration [34,43,46,54]
Survey	evaluation through surveys [56]; survey [50]; web survey [33]
Marketing and commercial strategies	business plan [54]; market penetration strategy [54]; marketing quantitative study [33]; “scale, spread and sustain” [53]
Shadowing	shadowing [39,55]
Observations	observation [55]; on-site observation [46]
Field notes	field notes [46,55]
Conceptualization	individual design sessions [40]; multiple concept creation [33]
Ethnographic methods	ethnographic methods [55]; ethnography [39]
Focus groups	focus group [42]; stakeholder consultation events [30]