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

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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, as design provides a frame for understanding and developing a subject or business and its related policies, products, resources and services. As a matter of fact, innovation is required to address the changing environments (eg, ageing of the population) and guarantee the financial sustainability of health services; this may be achieved by improving health outcomes at a good value, reducing cost for care or tracking health outcomes. In this scenario, design thinking emerges as an approach for incorporating innovation in medical practice in public and private sectors. Clinical outcomes of healthcare interventions that claim to have employed design thinking have proven to be positive. Design thinking application may potentially benefit the design of new health devices, products and processes, and the implementation of evidence-based practices.
Brown 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. 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. Many toolkits and practical guides 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. 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; in healthcare, this task has an increased complexity due to the various paying systems structures. Ethnographic research techniques, such as observation and interviewing, are recommended at the inspiration phase. 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. Studies acknowledge the positive effects of a visually stimulating environment on problem-solving; low-fidelity prototyping is used as a source of ideas and a tool for concept validation; sensemaking tools, like mind-mapping, are used to support brainstorming. 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.

Previous works have analysed the impacts of solutions developed using a design thinking approach on health outcomes both in broad and deep 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. 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, the format of a systematic literature search and review are aligned with the aim of this research; 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 multidisciplinarity 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, there is a conceptual overlap between these terms. In accordance with previous works, we will use them as synonyms.

The systematic review followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (see online supplemental file exhibit A1). 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 healthcare 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. 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, 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 correspondence 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, or had study protocols established. Eighteen of the 32 solutions were at the ideation stage, having either a visual prototype, a design concept or a functional prototype finalised. Regarding the implementation stage, out of eight solutions, one had a final product developed but not implemented, six were fully implemented and one had been implemented and failed. One solution was discontinued due to resource limitations.

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 pulsed in multiple areas, such as addiction, family health, gastroenterology, general practice, oncology, orthopaedics and surgery. A noteworthy theme across our sample is the creation and use of cloud-based multipurpose digital platforms. 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).

Four of the papers in our sample provide solutions that aim to address more than one target condition; 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.

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

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). 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), timetables (eg, collaborative creation of a timetable balancing employees’ preferences and nursing home needs), 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...
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. Observations36 29 31 and reviews of various sorts (eg, clinical practice review,28 32 54 literature review30 51) are also clarifying and, after the initial contact is made, require little effort from the user involved in the research. Focus groups31 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, conceptualisation30 40 43 45 and correlated tools such as brainstorming27 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 maps33 47) may be used to support this stage. After this initial wave of ideas, the most promising ones are selected for prototyping36 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,31–53 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,44 45 requirements testing,27 37 40 43 45 53 57 followed by prototyping36 37 40 42 50 54 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 multidisciplinarity 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 30 53 56 Research and Development (R&D)32 33 37 38 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. A solution development focused on technical issues and neglecting stakeholders’ perspectives is susceptible to barriers in implementation. Stakeholder participation assessment tools and frameworks for listening to the voices of the customer, business and technology 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.

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, with only one of them stating the class their devices were fitted in. 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 accountable for design feasibility and regulatory issues.

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. 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. 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. 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, 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. 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. 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.

How to make these fruitful connections happen? Norman et al 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 and data-gathering technologies, such as personal health records, patient self-monitoring and patient motivation trackers. 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. 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,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.  

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