



HAL
open science

Design as a quality improvement strategy: the case for design expertise

Guillaume Lamé, Alexander Komashie, Carol Sinnott, Tom Bashford, Mrcp Frca, Future Healthcare, Mrcp Frc, Guillaume Lamé, Mbiochem Phd

► To cite this version:

Guillaume Lamé, Alexander Komashie, Carol Sinnott, Tom Bashford, Mrcp Frca, et al.. Design as a quality improvement strategy: the case for design expertise. Future Healthcare Journal, In press, pp.100008. 10.1016/j.fhj.2024.100008 . hal-04484733v1

HAL Id: hal-04484733

<https://hal.science/hal-04484733v1>

Submitted on 29 Feb 2024 (v1), last revised 11 Apr 2024 (v2)

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.



Distributed under a Creative Commons Attribution - NonCommercial - NoDerivatives 4.0 International License

Journal Pre-proof

Design as a quality improvement strategy: the case for design expertise

Guillaume Lamé PhD , Alexander Komashie PhD ,
Carol Sinnott MB, BAO, BCh, MMedSci, PhD, MICGP, MRCPI ,
Tom Bashford MBBS MBiochem PhD MRCP FRCA

PII: S2514-6645(24)00006-7
DOI: <https://doi.org/10.1016/j.fhj.2024.100008>
Reference: FHJ 100008



To appear in: *Future Healthcare Journal*

Please cite this article as: Guillaume Lamé PhD , Alexander Komashie PhD ,
Carol Sinnott MB, BAO, BCh, MMedSci, PhD, MICGP, MRCPI , Tom Bashford MBBS MBiochem PhD MRCP FRCA
Design as a quality improvement strategy: the case for design expertise, *Future Healthcare Journal*
(2024), doi: <https://doi.org/10.1016/j.fhj.2024.100008>

This is a PDF file of an article that has undergone enhancements after acceptance, such as the addition of a cover page and metadata, and formatting for readability, but it is not yet the definitive version of record. This version will undergo additional copyediting, typesetting and review before it is published in its final form, but we are providing this version to give early visibility of the article. Please note that, during the production process, errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

© 2024 Published by Elsevier Ltd on behalf of Royal College of Physicians.
This is an open access article under the CC BY-NC-ND license
(<http://creativecommons.org/licenses/by-nc-nd/4.0/>)

Design as a quality improvement strategy: the case for design expertise

Design as a quality improvement strategy: the case for design expertise

Guillaume Lamé, PhD ^a

Alexander Komashie, PhD ^{b,c}

Carol Sinnott, MB, BAO, BCh, MMedSci, PhD, MICGP, MRCPI ^c

Tom Bashford, MBBS MBiochem PhD MRCP FRCA ^{b,d,e,f}

a Université Paris-Saclay, CentraleSupélec, Laboratoire Génie Industriel, Gif-sur-Yvette, France.

b Health Systems Design Group, Engineering Design Centre, Department of Engineering, University of Cambridge, Cambridge, UK

c The Healthcare Improvement Studies (THIS) Institute, University of Cambridge, Cambridge, UK

d Department Anaesthetics, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK

e NIHR Global Health Research Group on Acquired Brain and Spine Injury, University of Cambridge

f Technology and Systems Theme, Cambridge Public Health Interdisciplinary Research Centre, University of Cambridge

Correspondence to: Guillaume Lamé

Laboratoire de Génie Industriel, CentraleSupélec, 3 rue Joliot Curie, F-91192
Gif-sur-Yvette Cedex, France

guillaume.lame@centralesupelec.fr

+33 (0) 1.75.31.63.83

Word count: 2,366 words, excluding title, abstract, references, and figure captions

69 references

1 figure

Funding: AK and CS are funded by The Healthcare Improvement Studies (THIS) Institute, AK through a Postdoctoral Interdisciplinary Fellowship. THIS Institute is supported by The Health Foundation, an independent charity committed to bringing about better health and healthcare for people in the UK. TB is supported by the NIHR Global Health Research Group on Acquired Brain and Spine Injury using UK aid from the UK Government to support global health research. The views expressed in this publication are those of the author(s) and not necessarily those of the NIHR or the UK government.

Contributions: GL and TB conceived the idea of the piece. GL wrote the first draft. All authors revised and improved the manuscript.

Conflicts of interest: the authors declare no conflict of interest.

ABSTRACT: Bad design in safety-critical environments like healthcare can lead to users being frustrated, excluded, or injured. In contrast, good design can make it easier to use a service correctly, with impacts on both the safety and efficiency of healthcare delivery, as well as the experience of patients and staff. The participative dimension of design as an improvement strategy has recently gained traction in the healthcare quality improvement literature. However, the role of design expertise and professional design has been much less explored. Good design does not happen by accident: it takes expertise and the specific reasoning that expert designers develop through practical experience and training. Here, we define design, show why poor design can be disastrous and illustrate the benefits of good design. We argue for the recognition of distinctive design expertise and describe some of its characteristics. Finally, we discuss how design could be better promoted in healthcare improvement.

Introduction

Much has been written around the use of co-design in healthcare as a key approach to involving a range of stakeholders in healthcare science, delivery, and improvement. However, while the collective, participative dimension of this process has been emphasised, the discipline of design has been largely ignored, and the role of expert designers is thinly described in existing methods and publications.

Design is a fundamental determinant of the extent to which we appreciate, enjoy, and use products and services, as well as of their efficacy, efficiency, sustainability, and safety.¹ In this article, we define design, show why poor design can be a disaster, and illustrate the benefits of good design. We then argue for the recognition of distinctive design expertise and describe some of its characteristics. Finally, we discuss how design could be better promoted in healthcare improvement.

Design—beyond pleasing the eye

*Everyone designs who devises courses of action aimed at changing existing situations into preferred ones*²

In common parlance, design is often reduced to a matter of aesthetics: creating appealing products that can distinguish themselves from their competitors. Although this is important, good design is not just about being “eye-pleasing”. Good design is about improving our experiences of life by creating useful, intuitive artefacts that solve our problems while fitting seamlessly into our environment, our routines, and our value systems. Within this definition, artefacts are not limited to physical objects but also include services, organisations, spaces and buildings, and, at least as important, systems combining these into integrated wholes. Design is a school of thought and practice which draws on a range of different disciplines and professions, including industrial design, social sciences, ergonomics, as well as both materials and systems engineering. Design can act as a methodological bridge between the largely analytical corpus of medical knowledge, and the action of bringing about change in the world of healthcare delivery. This not only intersects with the emerging quality improvement literature, but also human factors, patient safety, and the design of interventions in clinical science.

To achieve their objectives, designers enact a structured process for understanding the needs of people and the wider social and regulatory landscape, then exploring a range of possible solutions to meet these needs, and iteratively selecting the best options for testing and refinement.³

Bad design can frustrate, exclude, hurt, and even kill

Bad design infects all areas of modern life, with various degrees of gravity. In its mildest form, bad design can be frustrating. Design expert Don Norman famously holds a grudge against doors that require more than one attempt to find the way to open them,⁴ but many of us have experienced frustration at poorly designed interfaces, impermeable phone lines or maze-like hospital corridor systems we lose ourselves into.

Although infuriating, frustration usually remains benign. Bad design becomes more concerning when it unwittingly excludes whole categories of users. In medicine, this ranges from respiratory protective equipment designed to best fit a caucasian male body shape to trauma care services and products built around the characteristics of adults without considering those of children.^{5,6} In the wider world, women, elderly people, ethnic minorities, or people living with disabilities are often overlooked in design decisions.

Even more sinister, bad design can hurt or kill. Confusing interfaces in prescribing software or radiotherapy equipment can lead to deadly doses being administered.⁷ In one example, the only green button on a defibrillator switched the device off, whereas the only red button was for shocking. In simulated emergency situations, it was no surprise that some participants pushed the green button and inadvertently switched the device off when intending to shock.⁸

Good design can make life easier and safer

*One of the most curious features of the modern world is the manner in which design has been widely transformed into something banal and inconsequential. In contrast, I want to argue that, if considered seriously and used responsibly, design should be the crucial anvil on which the human environment, in all its detail, is shaped and constructed for the betterment and delight of all.*¹

Poor design has been explicitly linked to impaired patient safety by the UK's Department of Health and Social Care, and the Health Services Safety Investigation Body.^{9,10} Yet, as surely as bad design can hurt, good design can make life easier and safer.

Good design accounts for all categories of users. As considerations of equality, diversity, and inclusion come more sharply into focus, an inclusive design approach can help better understand how processes and systems exert demands that exclude some users, e.g., how poor dexterity can challenge engagement with COPD treatment.¹¹ Inclusive design can lead to better systems, such as emergency departments that accommodate the needs of patients with dementia through noise reduction, altered lighting, orientation aids and fixed seating.¹²

Good design also makes it hard to do the wrong thing. Sometimes, design makes it physically impossible to misuse a product: there is only one way to plug a three-pin electric socket. Other times, design simply makes the right way the obvious way. In an experiment on adrenaline injectors, simple, inexpensive changes to the colour and signage on the product improved correct use from 22.6% to 65%.¹³

Good design is also about favouring and structuring creativity to find new ways to solve old problems, while avoiding fixation on the 'normal' way of doing things. The inspiration for the ODon device, a low cost, easy to use inflatable device to facilitate operative vaginal delivery, came from a trick to open corked bottles.¹⁴

Improvising only takes you so far: good design takes expertise

If good design can be so beneficial, why do we not see more of it, especially in healthcare? The answer is simple: good design is hard and takes expertise. Design is a specialist skill (or range of skills), requiring an understanding of theory married to practical experience. Evidence proves that the mundane issues that are familiar to designers as being important to safety (for example, proper needs analysis, anticipating practical implementation details or prototyping and piloting solutions) recur and risk harm when designers are absent from projects.^{15 16} This is because designers have developed their own ways of thinking about problems, which utilises concepts, processes and techniques to account for complexity and practical implementation (Fig. 1) (Tables 1 and 2).

Table 1. Examples of design concepts and models and processes.

Concepts	
Affordances	The actions that are possible with a product or system, as perceived by its users. ⁴
Abductive reasoning	A reasoning mode that stands at the heart of design, distinct from inductive and deductive reasoning, where designers start from a problem to be solved, and reason back to a concept, and a form. ¹⁷
Function-Behaviour-Structure model	A model of the design process as transitions and iterations between the three spaces of product functions, behaviour, (expected and observed), and structure. ¹⁸
Jobs-to-be-done	What customers hopes to accomplish in a situation, which the proposed solution should help them achieve. ¹⁹
Frames	Mental constructs that connect problem categories and solution categories, based on the designer's knowledge and experience. ²⁰
Models and processes	
Double-diamond model	A staged process of problem- and solution-definition, alternating divergent thinking (expanding the scope) and convergent thinking (focusing on selected options). ³ Example: co-design of a dementia caregivers telehealth peer support program. ²¹
Design thinking	A non-linear approach to understand users and their problems, and iteratively prototype and test solutions. ²² Example: design thinking as a large-scale innovation process across a healthcare provider. ²³
Experience-Based CoDesign	A participatory approach that draws upon design thinking to bring healthcare staff and patients together to improve the quality of care. ²⁴ Example: improving the care pathway for women who request Caesarean section. ²⁵
BioDesign	Innovation method for medical technology. ²⁶ Example: development of a disposable patch-based monitor to identify cardiac arrhythmias. ²⁷
Human-Centred Design	An approach to interactive systems that aims to make systems usable and useful by focusing on the users, their needs and requirements. ²⁸ Example: development of a clinical decision support system in an

	emergency department. ²⁹
--	-------------------------------------

Journal Pre-proof

Table 2. Examples of design tools and techniques.

Prototypes	<p>Artefacts that reproduce some aspects of the intended solution (e.g., through sketching, 3D printing or cardboard mock-ups) to help obtain feedback on this solution.</p> <p>Example: evaluating a prototype for an injection device for contraceptive implants.³⁰</p>
Storyboards	<p>Visual representation, akin to short comic strips, showing how users will interact with a solution and how this solution will fit in their environment.</p> <p>Example: developing concepts for technology-enabled support for caregivers of hematopoietic stem cell transplant recipients.³¹</p>
Journey maps	<p>Visual representation of the trajectory of patients in a healthcare system.</p> <p>Example: improving wayfinding in an emergency department.³²</p>
Persona	<p>A personalized fictional character that represents a category of users.</p> <p>Example: defining six personas of older adults with heart failure to support the development of eHealth solutions.³³</p>
Scenarios	<p>Descriptions of various possible interactions between users and a solution.</p> <p>Example: defining scenarios of work processes in shared homecare.³⁴</p>
Design ethnography	<p>An observation-based approach where the designer immerses themselves in a situation to identify needs and problems, and envisage possible solutions.</p> <p>Example: exploring cooperative home care work before proposing new IT support.³⁵</p>
Kansei design	<p>A method to better account for emotions, affects, and subjective perceptions during design.</p> <p>Example: exploration of the influence of color on users emotions in a lactation room.³⁶</p>
TRIZ – Theory of Inventive Problem Solving	<p>A methodology for identifying and resolving conflicting constraints in design.</p> <p>Example: exploring the development of a distant blood pressure monitoring service.³⁷</p>

People often jump to solutions without conducting a proper assessment of the causes and manifestations of the issues they face - this is akin to making a clinical diagnosis without taking a patient's history, doing a physical examination or conducting any investigations. As a result, they rarely solve the right problem, and can waste time and resources in the process. For designers, the generation of a 'solution-neutral problem statement' is key to understanding the fundamental problem at hand (the 'job-to-be-done'), rather than an easy proxy. They have multiple ways to explore situations and reframe issues to tackle the right problem.³⁸

Once the right problem has been identified, designers adopt a number of approaches to foster creativity in identifying possible solutions. These seek to avoid fixation (an overreliance on existing solutions and knowledge), while also remaining within the bounds of physical, regulatory, and ethical constraints. Mitigating fixation is difficult, and design expertise includes knowledge on how to best do it.³⁹

Finally, designers have ways of developing, visualising, sensing, testing and validating various concepts before deciding on a solution. Visual representation is at the heart of design, with imagery used to help users and designers understand complex concepts, combine quantitative and qualitative data, and explore potential solutions and their consequences. From cardboard mock-ups to 3D-printed prototypes through virtual reality, sketches, journey maps and storyboards, designers use a range of methods to share their insights and test them with users.⁴⁰ Crucially, a good designer does not need to be an accomplished artist, but rather they need to be able to consider the different visual abstractions required to explore a range of user needs, identify creative solutions, and manage risks.

Throughout this process (Fig 1), good design takes a systems perspective on situations, taking account of multiple competing factors and viewpoints. Good design incorporates an appreciation of risk, and the trade-offs required to create a sustainable solution.

Good design is also about pragmatic change, improvement and problem-solving. To produce acceptable solutions rather than idealistic concepts, good designers engage with everyone impacted by a problem. They integrate different types and sources of expertise and knowledge when framing the issue, looking for solutions and implementing them. Expert designers can support users in participative, rather than expert-led, projects: they can add greatest value at the interface of healthcare providers, researchers, patients, and the public.⁴¹

This process and these principles may seem simple enough to implement. Yet, studies of expert designers show how they build on accumulated experience to propose early solution concepts that help them explore both the problem they face and the range of possible solutions.⁴² Expertise cannot be reduced to rules or formulas, and expert designers have, through training and experience, accumulated a set of "frames" that allow them to look at a problems in a way that effectively encompasses the fundamental working mechanisms of a set of possible solutions.⁴³ Where novices can be trapped into analytic, rule-based reasoning, experts can trigger generative, pattern-based reasoning.

Any one designer is unlikely to be expert in all the skills listed above. Designing solutions to complex problems often requires the integration of different strands of design. Good design borrows from a range of other evaluative methodologies, both quantitative and qualitative, and brings these

together to solve a given problem. It sits alongside, rather than instead of, existing approaches to improvement.

In particular, design is a key feature of human factors/ergonomics.⁴⁴ Human factors/ergonomics is 'the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance'.⁴⁵ Ergonomics includes *physical* ergonomics (e.g., work-related musculoskeletal disorders or workplace layout), *cognitive* ergonomics (e.g., mental workload or human-computer interaction), and *organisational* ergonomics (e.g., design of working times or teamwork).

However, the reach of good design extends beyond the realm of human factors and ergonomics. Distinctive design expertise is also present in architecture, with increasing attention afforded to how the built environment affects care delivery as well as patient and professional experience.⁴⁶ Social and organisational sciences have also embraced design as a mode of action and developed methods to directly engage with problems and stakeholders to solve problems.^{24, 47} Finally, (industrial) design also stands as a discipline in its own right, with its training curricula, its subspecialties (Table 3), its professional bodies, and its approaches to engage with health services.^{1, 48} Human factors professionals regularly work alongside designers, engage this additional expertise as required, and frequently rely on many of the methods highlighted above.

Table 3. Examples of areas and sub-specialties of design.

Visual and information design	Conveying messages in the most effective (persuasive, simple, understandable) way. Example: redesign of Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) forms. ⁴⁹
Service design	Designing an arrangement of tasks, people, communications and systems to best meet service users' needs. Example: designing the Portuguese national electronic health record as a service. ⁵⁰
Product design	Designing physical products that meet users' needs. Example: needs analysis for medical device development. ⁵¹
Interaction and user-experience design	Shaping digital artifacts that optimise users' perception of utility and ease-of-use. Example: defining guidelines for smartphone applications for people with Parkinson's disease. ⁵²
Interior design	Enhancing buildings' inner spaces, to provide healthy and pleasing environments. Example: analysing nurses' experience of working in an

	evidence-based designed ICU patient room. ⁵³
--	---

Promoting design as a route to improvement by involving designers

Design has contributed to many great achievements in healthcare, from better drug labelling systems to point-of-care digital health records for community health workers, new business models in prescription drug delivery, or better newborn phototherapy devices.⁴⁰ Many design skills, like creativity, problem finding, co-production, or idea generation, have been found to be key habits of mind of good healthcare improvers.⁵⁴ Initiatives exist to promote design at institutional levels, e.g. through partnerships between healthcare and engineering or design institutions.⁵⁵ We can also learn from innovative healthcare providers.⁴⁰ However, some caution is warranted. Despite the enthusiasm around design in healthcare, this field is still victim to false assumptions and expectations, and its impact on health services remains limited. Design is further plagued by its fragmentation between different disciplines and institutions⁵⁶ and the rift of mindsets and worldview between designers and health services researchers.⁵⁷

So how can we make progress? Involving expert designers in improvement efforts is an obvious first step. Aside from project-based design consulting, embedding designers in health services is another possibility. Clinically-embedded designers could be a way to identify and solve issues where they arise,^{58 59} or support frontline workers' problem solving efforts. Exciting results have been seen with 'makerspaces', where professional designers support clinical staff to identify problems in their work environments and develop clinical innovations to solve them.^{60 61} Giving frontline staff material resources and expert design support has led to innovations that make their own jobs more efficient, safer or better, and are associated with significant cost-savings, for example limb-splinting devices that use plastic instead of plaster, dressings to improve wound coverage during showering, and structures that protect intravenous cannulas from disruption in paediatric patients.

The know-how of professionals already active in healthcare environments whose training includes elements of design could also be better leveraged. For example, the expertise of biomedical and clinical engineers who are often familiar with design principles and practices could be better harnessed by improvement efforts.⁶²⁻⁶⁵ Software engineering students are also increasingly exposed to design thinking concepts.^{66 67} Working with human factors specialists offers synergies to design-orientated improvement, especially those involved in occupational health/ergonomics programmes.⁶⁸ Consideration is also warranted on whether quality improvement specialists themselves could benefit from specific design training to help them integrate design into existing QI approaches⁶⁹ and build on the specific contributions of different types of design specialists.⁷⁰ Design in healthcare has an important role to play in the minimization of risk and should not be overlooked by quality improvement teams who seek to integrate existing expertise within healthcare. Design can act as a pragmatic expertise which can help coordinate the perspectives of different fields like human factors/ergonomics, behavioural psychology, quality improvement, or implementation science to better mitigate hazards and adapt systems.

We also need to better understand actual design practice in healthcare improvement. Many design-inspired improvement projects do not mention the contribution of designers, and often do not detail the minutiae of the design process: who drew what? Who facilitated which session? What prompts, advice, examples were provided to project participants? Even basic design input can sometimes go a long way in helping non-professional designers come up with more diverse and robust solutions, but this input is hardly ever recorded. We need better knowledge of what good healthcare design entails, beyond methods and frameworks and into practice.

Conclusion

Design has an established body of theory and practice which has a well-recognised, significant, role to play in improving healthcare provision. Evidence abounds on the positive impact expert designers can have in various areas, including healthcare (although perhaps not in the form usually expected in evidence-based medicine or epidemiology. Despite this, design is rarely discussed in the medical literature, and there remains a paucity of understanding of its value among clinicians and academics involved in improvement. This may be addressed through greater engagement between designers, health service users, and improvement academics both practically and methodologically. To start with, improvement researchers and practitioners need to consider design expertise as a fundamental part in improvement processes that will lead to safer, more inclusive healthcare. Design is not a 'nice to have' skill, it is seen as essential to all other safety critical industries, where it is integrated into developing safety as well as improvement of quality, performance and the reliability of the system. With its focus on creativity and user-centredness, design can help not only improve, but transform and reinvent our healthcare systems.

References

1. Heskett J. Design : a very short introduction. Oxford: Oxford University Press 2005.
2. Simon HA. The sciences of the artificial. 3rd ed. Cambridge, MA; London: MIT Press 1996.
3. The Design Council. What is the framework for innovation? Design Council's evolved Double Diamond: The Design Council; 2015 [updated 17 March 2015. Available from: <https://www.designcouncil.org.uk/news-opinion/design-process-what-double-diamond> accessed 12 June 2018.
4. Norman DA. The design of everyday things. Revised and expanded edition ed. New York, NY, USA: Basic Books 2013.
5. Carvalho CYM, Schumacher J, Greig PR, et al. Prospective observational study of gender and ethnicity biases in respiratory protective equipment for healthcare workers in the COVID-19 pandemic. *BMJ Open* 2021;11(5):e047716. doi: 10.1136/bmjopen-2020-047716

6. McCarthy A, Curtis K, Holland AJA. Paediatric trauma systems and their impact on the health outcomes of severely injured children: An integrative review. *Injury* 2016;47(3):574-85. doi: 10.1016/j.injury.2015.12.028
7. Shariat J, Savard Saucier C. Tragic Design: The Impact of Bad Product Design and How to Fix It: O'Reilly Media 2017.
8. Høyer CS, Christensen EF, Eika B. Adverse Design of Defibrillators: Turning Off the Machine When Trying to Shock. *Annals of Emergency Medicine* 2008;52(5):512-14. doi: 10.1016/j.annemergmed.2007.11.037
9. The Department of Health, The Design Council. Design for patient safety : a system-wide design-led approach to tackling patient safety in the NHS. London: Department of Health Publications 2003.
10. Healthcare Safety Investigation Branch. National learning report. A thematic analysis of HSIB's first 22 national investigations. Farnborough: Healthcare Safety Investigation Branch, 2021:23.
11. Liu Y, Dickerson T, Early F, et al. Understanding the Influences of COPD Patient's Capability on the Uptake of Pulmonary Rehabilitation in the UK Through an Inclusive Design Approach. *International Journal of Chronic Obstructive Pulmonary Disease* 2021;Volume 16:1717-40. doi: 10.2147/copd.s305145
12. Bracken-Scally M, Keogh B, Daly L, et al. Assessing the impact of dementia inclusive environmental adjustment in the emergency department. *Dementia* 2019;20(1):28-46. doi: 10.1177/1471301219862942
13. Bakirtas A, Arga M, Catal F, et al. Make-up of the epinephrine autoinjector: The effect on its use by untrained users. *Pediatric Allergy and Immunology* 2011;22(7):729-33. doi: 10.1111/j.1399-3038.2011.01195.x
14. Requejo JH, Belizán JM. Odon device: a promising tool to facilitate vaginal delivery and increase access to emergency care. *Reproductive health* 2013;10:42-42. doi: 10.1186/1742-4755-10-42
15. Kriznik NM, Lamé G, Dixon-Woods M. Challenges in making standardisation work in healthcare: lessons from a qualitative interview study of a line-labelling policy in a UK region. *BMJ Open* 2019;9(11):e031771. doi: 10.1136/bmjopen-2019-031771
16. Jun GT, Morrison C, Clarkson PJ. Articulating current service development practices: a qualitative analysis of eleven mental health projects. *BMC Health Services Research* 2014;14(1):20. doi: 10.1186/1472-6963-14-20
17. Kroll E, Koskela L. Explicating concepts in reasoning from function to form by two-step innovative abductions. *Artificial Intelligence for Engineering Design, Analysis and Manufacturing* 2016;30(2):125-37. doi: 10.1017/S0890060416000020 [published Online First: 2016/04/18]
18. Gero JS, Kannengiesser U. The situated function-behaviour-structure framework. *Design Studies* 2004;25(4):373-91. doi: 10.1016/j.destud.2003.10.010
19. Christensen CM, Hall T, Dillon K, et al. Know your customers' "jobs to be done". *Harvard Business Review* 2016;9:54-62.
20. Dorst K. Frame innovation : create new thinking by design. Cambridge, Massachusetts: The MIT Press 2015.
21. Banbury A, Pedell S, Parkinson L, et al. Using the Double Diamond model to co-design a dementia caregivers telehealth peer support program. *Journal of Telemedicine and Telecare* 2021;27(10):667-73. doi: 10.1177/1357633x211048980
22. Brown T, Katz B. Change by design: how design thinking transforms organizations and inspires innovation. 1st ed ed. New York: Harper Business 2009.
23. Carlgren L, Rauth I, Elmquist M. Framing Design Thinking: The Concept in Idea and Enactment. *Creativity and Innovation Management* 2016;25(1):38-57. doi: 10.1111/caim.12153
24. Donetto S, Pierrri P, Tsianakas V, et al. Experience-based Co-design and Healthcare Improvement: Realizing Participatory Design in the Public Sector. *The Design Journal* 2015;18(2):227-48. doi: 10.2752/175630615X14212498964312

25. Kenyon SL, Johns N, Duggal S, et al. Improving the care pathway for women who request Caesarean section: an experience-based co-design study. *BMC Pregnancy and Childbirth* 2016;16(1):348. doi: 10.1186/s12884-016-1134-2
26. Zenios S, Makower J, Yock P, et al. *Biodesign: The Process of Innovating Medical Technologies*: Cambridge University Press 2010.
27. Schwartz JG, Kumar UN, Azagury DE, et al. Needs-Based Innovation in Cardiovascular Medicine: The Stanford Biodesign Process. *JACC: Basic to Translational Science* 2016;1(6):541-47. doi: 10.1016/j.jacbts.2016.06.011
28. International Organization for Standardization. ISO 9241-210: Ergonomics of Human-system Interaction - Part: 210: Human-centred Design for Interactive Systems. Geneva: ISO, 2010.
29. Salwei ME, Hoonakker PLT, Pulia M, et al. Retrospective analysis of the human-centered design process used to develop a clinical decision support in the emergency department: PE Dx Study Part 2. *Human Factors in Healthcare* 2023;100055. doi: 10.1016/j.hfh.2023.100055
30. Mohedas I, Sabet Sarvestani A, Daly SR, et al. Applying design ethnography to product evaluation: A case example of a medical device in a low-resource setting. In: Weber C, Husung S, Cascini G, et al., eds. *International Conference on Engineering Design*. Milano: The Design Society, 2015:401-10.
31. Bangerter LR, Looze M, Barry B, et al. A hybrid method of healthcare delivery research and human-centered design to develop technology-enabled support for caregivers of hematopoietic stem cell transplant recipients. *Supportive Care in Cancer* 2022;30(1):227-35. doi: 10.1007/s00520-021-06347-x
32. Reay SD, Collier G, Douglas R, et al. Prototyping collaborative relationships between design and healthcare experts: mapping the patient journey. *Design for Health* 2017;1(1):65-79. doi: 10.1080/24735132.2017.1294845
33. Holden RJ, Kulanthaivel A, Purkayastha S, et al. Know thy eHealth user: Development of biopsychosocial personas from a study of older adults with heart failure. *International Journal of Medical Informatics* 2017;108:158-67. doi: 10.1016/j.ijmedinf.2017.10.006
34. Hägglund M, Scandurra I, Koch S. Scenarios to capture work processes in shared homecare— From analysis to application. *International Journal of Medical Informatics* 2010;79(6):e126-e34. doi: 10.1016/j.ijmedinf.2008.07.007
35. Bossen C, Christensen LR, Grönvall E, et al. CareCoor: Augmenting the coordination of cooperative home care work. *International Journal of Medical Informatics* 2013;82(5):e189-e99. doi: 10.1016/j.ijmedinf.2012.10.005
36. López-Tarruella J, Llinares Millán C, Serra Lluch J, et al. Influence of Color in a Lactation Room on Users' Affective Impressions and Preferences. *HERD: Health Environments Research & Design Journal* 2019;12(2):55-70. doi: 10.1177/1937586718796593
37. Yang H-L, Hsiao S-L. Mechanisms of developing innovative IT-enabled services: A case study of Taiwanese healthcare service. *Technovation* 2009;29(5):327-37. doi: 10.1016/j.technovation.2009.01.006
38. Studer JA, Daly SR, McKilligan S, et al. Evidence of problem exploration in creative designs. *Artificial Intelligence for Engineering Design, Analysis and Manufacturing* 2018;32(4):415-30. doi: 10.1017/S0890060418000124 [published Online First: 10/05]
39. Neroni MA, Crilly N. How to Guard Against Fixation? Demonstrating Individual Vulnerability is More Effective Than Warning of General Risk. *The Journal of Creative Behavior* 2021;55(2):447-63. doi: 10.1002/jocb.465
40. Ku B, Lupton E. *Health design thinking : creating products and services for better health*. Second edition. ed. Cambridge: The MIT Press 2022.
41. Manzini E. *Design, when everybody designs : an introduction to design for social innovation*. Cambridge, Massachusetts: The MIT Press 2015.
42. Cross N. Expertise in design: an overview. *Design Studies* 2004;25(5):427-41. doi: 10.1016/j.destud.2004.06.002

43. Dorst K. The core of 'design thinking' and its application. *Design Studies* 2011;32(6):521-32. doi: 10.1016/j.destud.2011.07.006
44. Russ AL, Fairbanks RJ, Karsh B-T, et al. The science of human factors: separating fact from fiction. *BMJ Quality & Safety* 2013 doi: 10.1136/bmjqs-2012-001450
45. International Ergonomics Association. What Is Ergonomics (HFE)? Geneva: International Ergonomics Association; [Available from: <https://iea.cc/about/what-is-ergonomics/> accessed 21 Nov 2023.
46. Joseph A, Henriksen K, Malone E. The Architecture Of Safety: An Emerging Priority For Improving Patient Safety. *Health Affairs* 2018;37(11):1884-91. doi: 10.1377/hlthaff.2018.0643
47. Groop J, Ketokivi M, Gupta M, et al. Improving home care: Knowledge creation through engagement and design. *Journal of Operations Management* 2017;53-56:9-22. doi: 10.1016/j.jom.2017.11.001
48. Reay S, Collier G, Kennedy-Good J, et al. Designing the future of healthcare together: prototyping a hospital co-design space. *CoDesign* 2017;13(4):227-44. doi: 10.1080/15710882.2016.1160127
49. Fritz Z, Fuld JP. Development of the Universal Form of Treatment Options (UFTO) as an alternative to Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) orders: a cross-disciplinary approach. *Journal of Evaluation in Clinical Practice* 2014;21(1):109-17. doi: 10.1111/jep.12256
50. Grenha Teixeira J, Pinho NFd, Patrício L. Bringing service design to the development of health information systems: The case of the Portuguese national electronic health record. *International Journal of Medical Informatics* 2019;132:103942. doi: 10.1016/j.ijmedinf.2019.08.002
51. Chaturvedi J, Logan A, Narayan G, et al. A structured process for unmet clinical need analysis for medical device innovation in India: early experiences. *BMJ Innovations* 2015;1(3):81-87. doi: 10.1136/bmjinnov-2014-000010
52. Nunes F, Silva PA, Cevada J, et al. User interface design guidelines for smartphone applications for people with Parkinson's disease. *Universal Access in the Information Society* 2016;15(4):659-79. doi: 10.1007/s10209-015-0440-1
53. Sundberg F, Olausson S, Fridh I, et al. Nursing staff's experiences of working in an evidence-based designed ICU patient room—An interview study. *Intensive and Critical Care Nursing* 2017;43:75-80. doi: 10.1016/j.iccn.2017.05.004
54. Lucas B. Getting the improvement habit. *BMJ Quality & Safety* 2016;25(6):400-03. doi: 10.1136/bmjqs-2015-005086
55. Clarkson PJ, Bogle D, Dean J, et al. Engineering Better Care. London: Royal Academy of Engineering, Academy of Medical Sciences & Royal College of Physicians, 2017:88.
56. McMahan CA. Reflections on diversity in design research. *Journal of Engineering Design* 2012;23(8):563-76. doi: 10.1080/09544828.2012.676634
57. Pagliari C. Design and Evaluation in eHealth: Challenges and Implications for an Interdisciplinary Field. *J Med Internet Res* 2007;9(2):e15. doi: 10.2196/jmir.9.2.e15 [published Online First: 27.5.2007]
58. Perry SJ, Catchpole K, Rivera AJ, et al. 'Strangers in a strange land': Understanding professional challenges for human factors/ergonomics and healthcare. *Applied Ergonomics* 2021;94:103040. doi: 10.1016/j.apergo.2019.103040
59. Robert G, Locock L, Williams O, et al. Co-Producing and Co-Designing. Cambridge: Cambridge University Press, 2022.
60. Svensson PO, Hartmann RK. Policies to promote user innovation: Makerspaces and clinician innovation in Swedish hospitals. *Research Policy* 2018;47(1):277-88. doi: 10.1016/j.respol.2017.11.006
61. Marshall DR, McGrew DA. Creativity and Innovation in Health Care: Opening a Hospital Makerspace. *Nurse Leader* 2017;15(1):56-58. doi: 10.1016/j.mnl.2016.10.002

62. Goldberg J. Senior design - biomedical engineering/industrial design collaboration in senior design projects. *IEEE Engineering in Medicine and Biology Magazine* 2007;26(3):75-76. doi: 10.1109/MEMB.2007.364935
63. Davies TC, Manzin J, Meraw M, et al. Understanding the Development of a Design Thinking Mindset During a Biomedical Engineering Third-Year Course. *Biomedical Engineering Education* 2023;3(2):123-32. doi: 10.1007/s43683-022-00093-0
64. Farrar EJ. Implementing a Design Thinking Project in a Biomedical Instrumentation Course. *IEEE Transactions on Education* 2020;63(4):240-45. doi: 10.1109/TE.2020.2975558
65. Hall A, Leff D, Wojdecka A, et al. Beyond the Healthcare Paradigm: Co-Creating a New Model for Collaborative Transdisciplinary Healthcare Design Education. In: Bohemia E, Kovacevic A, Buck LB, et al., eds. 21st International Conference on Engineering and Product Design Education (E&PDE 2019). Glasgow: The Design Society, 2019.
66. Infusing Design Thinking into a Software Engineering Capstone Course. 2017 IEEE 30th Conference on Software Engineering Education and Training (CSEE&T); 2017 7-9 Nov. 2017.
67. Souza AF, Ferreira B, Valentim N, et al. An experience report on teaching multiple design thinking techniques to software engineering students. Proceedings of the XXXII Brazilian Symposium on Software Engineering. Sao Carlos, Brazil: Association for Computing Machinery, 2018:220–29.
68. Hignett S, Carayon P, Buckle P, et al. State of science: human factors and ergonomics in healthcare. *Ergonomics* 2013;56(10):1491-503. doi: 10.1080/00140139.2013.822932
69. Crowe B, Gaulton JS, Minor N, et al. To improve quality, leverage design. *BMJ Quality & Safety* 2022;31(1):70-74. doi: 10.1136/bmjqs-2021-013605
70. Lamb G, Zimring C, Chuzi J, et al. Designing better healthcare environments: Interprofessional competencies in healthcare design. *Journal of Interprofessional Care* 2010;24(4):422-35. doi: 10.3109/13561820903520344

Legends for figures

Figure 1. A model of the design process. The "double diamond" structure depicts how designers alternate between phases of divergent and convergent thinking to move from an ill-defined initial challenge to the actual problem that needs tackling, to a solution ready for implementation.³ The "spiral" patterns highlight how design projects move between steps in an iterative, non-linear way.⁵⁵

Journal Pre-proof

Figures

Figure 1

