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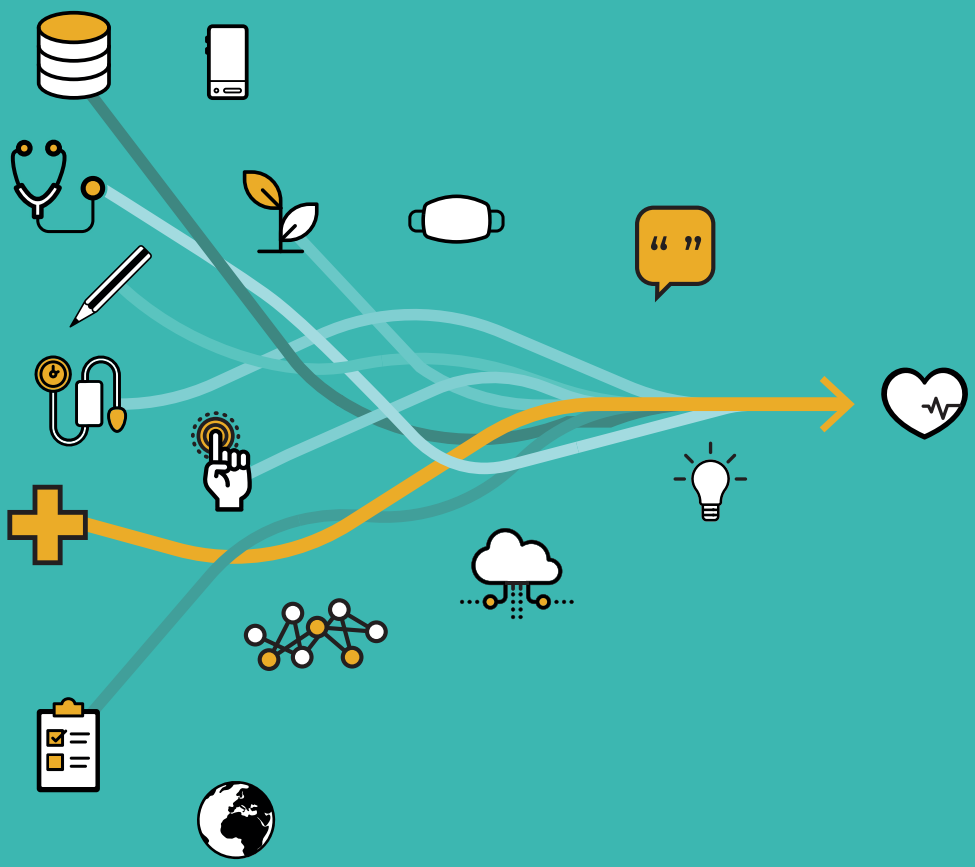
TOWARDS A **CONVERGENT** APPROACH TO THE USE OF **DATA** IN **DIGITAL HEALTH DESIGN**



VALERIA PANNUNZIO

Towards a convergent approach to the use of data in digital health design

Dissertation

for the purpose of obtaining the degree of doctor
at Delft University of Technology
by the authority of the Rector Magnificus prof.dr.ir. T.H.J.J. van der Hagen
Chair of the Board for Doctorates
to be defended publicly on
Thursday 22 June 2023 at 10:00 o'clock

by

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Keywords: Design for Health, Digital Health, E-health, Design Approaches, Design Methodologies, Data-enabled Design, Convergence
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Contents

Abbreviations

AI: Artificial Intelligence

BP: Blood Pressure

CA: Correspondence Analysis

DED: Data-Enabled Design

EMR: Electronic Medical Record

EPR: Electronic Patient Record

GP: General Practitioner

LUMC: Leiden University Medical Center

PD: Participatory Design

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

QoS: Quality of Service

RPM: Remote Patient Monitoring/ Remote Patient Management

RTD: Research Through Design

WHO: World Health Organization

UCD: User Centred Design

Foreword

Since the start of 2020, the covid-19 pandemic has confronted healthcare systems around the world with enormous challenges. The effects of this historical turn of events on public life and perception were deep: many of us were personally reminded of the prominent role of the healthcare realm in the shaping of our economy, our politics, and our life. This role, however, was always present, only less visible – much like the enormous challenges themselves. Scholars had already identified long-term demographic, epidemiologic, and socioeconomic trends that indicated a need for radical reconfiguration in the way healthcare is organised and delivered. Yet, the full weight of this need could not be appreciated before we were shown the unfolding of a global health crisis.

The work presented in this thesis was conducted across this moment of collective realisation. Almost exactly halfway through the doctoral journey, the unfolding of the global pandemic confronted key assumptions behind the ongoing research.

On one hand, previous characterizations of a systemic crisis affecting modern healthcare delivery were confirmed. Bottlenecks, imbalances, and structural sources of inefficiency were revealed even in the most advanced national health systems. WOn the other hand, previous assumptions on the opportunity to focus on certain classes of diseases over others in systemic health innovation - specifically, the non-infectious over the infectious - were sensationally disproven. Globally, non-infectious diseases kept causing a much higher proportion of directly attributable mortality and morbidity than infectious ones. However, the pandemic demonstrated how directly attributable mortality and morbidity alone do not represent the full extent of diseases' societal impact. In the case of covid-19, an additional pathway to widespread societal damage was revealed in the capacity of infectious diseases to damage health systems from within.

Furthermore, practical doctoral research activities conducted in clinical contexts were cast into a state of unpredictability. Collaborating hospitals became off-limits for anyone but essential staff, and ongoing projects were sidelined to focus on the development of covid-19 measures. At the same time, inspiring examples of agility and creativity emerged from healthcare stakeholders, both public and private. Real-life application of remote care was suddenly accelerated, together with novel forms of health data collection, analysis and use.

Altogether, it is important to recognise the impact that the advent of covid-19 had on the direction and spirit of this dissertation, which should be read in the light of this eventful temporal context.

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Summary

Digital health is a vibrant and dynamic field, encompassing subsets such as mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalised medicine. While digital health adoption has been markedly accelerated by the covid-19 pandemic (Inkster et al., 2020), an evolving body of research has focused on describing and addressing specific challenges related to the design and evaluation of digital health technologies (Pagliari, 2007; Murray et al., 2016; Blandford et al., 2018; Marvel et al., 2018). This research articulates a need for novel, interdisciplinary design approaches to digital health innovation, integrating disparate sets of requirements such as clinical soundness, user-centeredness, technical interoperability, and cost-effectiveness (Cornet et al., 2019). In this complex domain, design and health disciplines are called not only to collaborate with each other, but also to learn to work with digital data as the raw material fueling digital technologies.

This dissertation explores such challenges through a series of exploratory research efforts at the intersection of design, healthcare and digital data. These explorations are conducted within the context of the Cardiolab, a Delft Design Lab born out of a partnership between Philips Experience Design and Delft University of Technology. Throughout the dissertation, knowledge in this domain is gained through a mix of literature reviews and project-based action research (Somekh, 2005). In this way, the relevant scientific literature is connected and put in dialogue with real-life digital health design practice.

The first three studies included in the thesis are dedicated to explorations of data-relevant design practices in the digital health domain. In particular, **Chapter 2** is dedicated to a literature review on design research in digital health; **Chapter 3** is dedicated to a lead users study on blood pressure self-monitoring, and **Chapter 4** is dedicated to a data-enabled design study on behavioural change in bariatric care. As a result of these explorations, a first research question was formulated: What are existing and emerging approaches to the use of data for digital health design?

This question is answered in **Chapter 5**, which is dedicated to a definition and comparison of four existing and emerging approaches to the use of data for digital health design. The first, called the silent design approach, is conducted by individuals or groups who are not professional designers, and who as such do not explicitly perform data collection activities to inform a formal design process. The second, called the overt approach, is conducted by trained designers who explicitly perform data collection activities to inform their design processes.
The third, the data-enabled approach, is conducted by trained designers who go beyond linear data collection activities, and establish data collection loops directly from the context of application, to inform (re)design processes. Finally, the convergent is characterised as an approach in which continuous data collection from the context of application is employed both for (re)design purposes and for other kinds of data-driven processes, such as clinical evaluation, cost evaluation, policymaking, or algorithmic auditing.

The definition of the four approaches to the use of data for digital health design unlocked a new research opportunity, identified in the further formalisation and operationalization of the convergent approach. The Remote Patient Monitoring (RPM) domain was chosen as a relevant subset of digital health in which to investigate this research opportunity, as briefly illustrated in the **Intermission**. As a result, a second research question was formulated: How can the convergent approach to Remote Patient Monitoring design be formalized?

To answer this question, an effort was made to operationalize the convergent approach within the context of a real-life digital health design project, conducted in partnership with the Leiden University Medical Center (LUMC). This project revolved around a Remote Patient Monitoring (RPM) proposition for perioperative care, and included the integration of clinical and design data collection within a study protocol, in alignment with the principles of the convergent approach.

Through this project, two research results could be achieved. Firstly, the convergent approach could be further developed, and enriched with the concept of integrated data strategies as enablers of convergence. Second, new knowledge was produced on patient and staff experience in the Remote Patient Monitoring domain. Particularly, two literature studies were performed. One, described in Chapter 6, is a scoping review investigating the impact of perioperative Remote Patient Monitoring on clinical staff workflows.

The other, described in **Chapter 7**, is a systematic review of patient and staff experience constructs (e.g. Usability) and corresponding measuring instruments (e.g. System Usability Scale) used in contemporary RPM research.

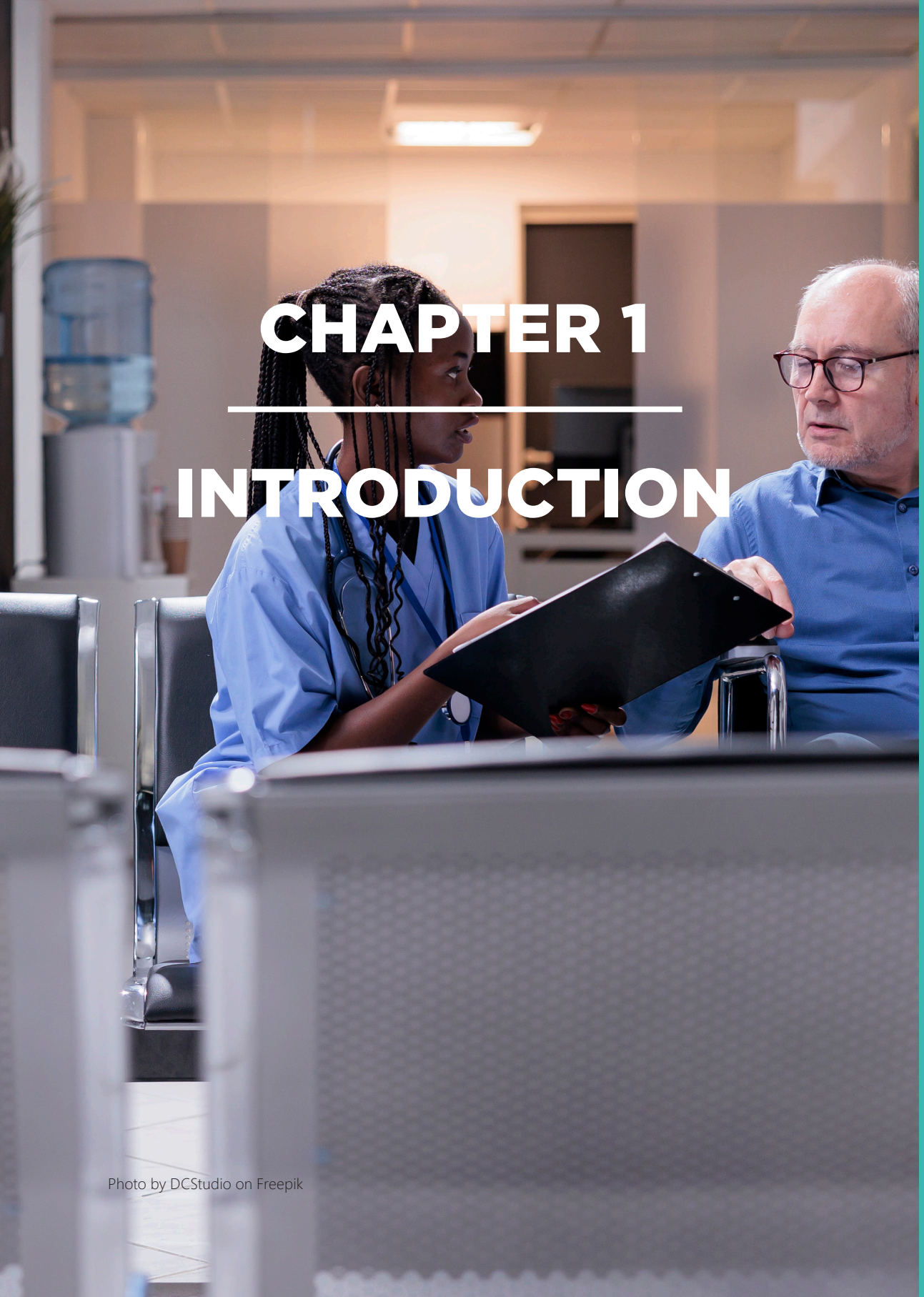
Finally, summative reflections and considerations were collected in **Chapter 8**.

Overall, this thesis is the account of a journey across data-related digital health design practices, touching on a series of key themes including digital health, patient and staff experiences, health systems transformation, and data strategies. This exploration was conducted through active involvement in real-world digital health innovation efforts, informed by the analysis, critique and revision of literature relevant to each step of the doctoral research.

The main research contributions of the presented work are to be found in the fields of design, medicine and human factors. Within the design domain, implications relevant to digital health design are provided in all included chapters, while implications relevant to health systems design are mainly provided in **Chapters 2, 5, 6** and **7** and implications relevant to digital service design are mainly provided in **Chapter 4**. Within the medical domain, implications relevant to digital medicine are mainly provided in **Chapters 6** and **7**, while implications relevant to perioperative care are provided in **Chapter 6**. Finally, implications relevant to human factors engineering are mainly provided in **Chapter 6**.

CHAPTER 1

INTRODUCTION



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"The practice of medicine is dominated by how we process information, how we record information, how we retrieve information, and how we communicate information"

Barnett, 1990

1.1 Digital health definitions, promises and issues

Ongoing demographic and epidemiological trends configure a situation of global health crisis. On one side, the progressive ageing of populations comes with an increase in the global burden of non-communicable (or noninfectious) diseases, posing a substantial and growing economic burden on health systems worldwide (Bloom et al., 2012). On the other side, increasing urbanisation and population density, proximity with animals, mass international travel, wars, natural disasters and climate change favour the occurrence of pandemics (Høiby, 2021), with their devastating effects on the functioning of health systems.

This double-faced crisis affecting health systems worldwide determines an unsustainable rise in global health spending, especially in high-income countries (Dieleman et al., 2019). In parallel, the crisis determines a global shortage of healthcare workforce, particularly nurses (Drennan & Ross, 2019). Radically new models of healthcare delivery become necessary in order to sustain the increasing global healthcare demand while relying on shrinking resources, both financial and human. In this context, digital health innovation is described as an opportunity for improving the effectiveness and efficiency of health systems worldwide (Labrique et al., 2018). While many definitions exist of digital health (Fatehi et al., 2020), this term is here employed in a broad sense to indicate "the field of knowledge and practice associated with the development and use of digital technologies to improve health", in accordance with the World Health Organization (WHO, 2023).

In itself, digital health is not new, and the current digital health landscape is the result of consecutive waves of innovation. These unfolded over several decades, from the introduction of "health telematics'' in the 1990s (WHO Group Consultation on Health Telematics, 1998), to the diffusion of the Internet and the Personal Computer in the 21st century (J. A. Powell et al., 2003), to the advent of mobile health technologies in the 2010s (Kao & Liebovitz, 2017). In the present days, a frontier of digital health innovation is represented by the application of Artificial Intelligence (AI) and 'smart' technologies in the health domain, comprehensively described by Rajpurkar et al. (2022)

As a result of these consecutive innovation waves, digital health has by now been adopted across health systems in a diverse range of applications, from diagnosis and treatment to patient engagement and adherence to administrative solutions (Davenport & Kalakota, 2019). Described benefits include relieving health workers from menial tasks, offering clinical decision support, predicting patient deterioration to allow for early intervention, optimising hospital resource management, and more. Overall, the promise of digital health to further automate healthcare processes, thus reducing the resources necessary for care provision, presents itself as a crucial strategic capability in the context of ongoing health systems transformation.

Yet, next to the described benefits, scholars have identified systemic issues arising from the increasing digitization of the healthcare domain. Birkland (2019) and Meskó et al. (2017), for instance, note that the shift to digital health determines major - and potentially risky - cultural transformations, especially in regard to the changing relationship between patients and care providers. More in general, the growing role of data within health delivery systems has been problematized by Ruckenstein & Schüll, (2017), who write of an increased "datafication" of health. Greenhalgh et al., (2009) point out the threats to the human side of medicine and nursing caused by the introduction of more data entry tasks, standardised protocols, and computerised records in clinical practice. They also detail how one of the largest systemic transformations brought about by the digital health revolution so far, namely the introduction of electronic patient records (EPRs), has been "plagued by delays, escalation of costs, scope creep, and technical glitches, including catastrophic system crashes".

Such issues are not confined to past digital health innovation efforts, but also pertain to the latest developments in the field. Notably, the contemporary frontier of digital health innovation, healthcare AI, is affected by what has been described as the "inconvenient truth", namely the fact that the algorithms that feature prominently in the research literature are not, for the most part, "executable at the frontlines of clinical practice" (Panch et al., 2019).

Overall, digital health innovation efforts often tend to fall short of delivering on their promises. In addition, digitising any aspect of care delivery comes with unique risks; unsupervised technical failure, systemic bias, and over-medicalization are only some of the system-level dangers that can turn digital health into another source of problems for healthcare systems, rather than a useful solution.

1.2 Research scope and methodology

In the described general context of digital health promises and challenges, an important role was recognized for digital health design, intended as the processes resulting in the (re)design of digital health interventions.
Cardiolab partners (from the Industrial Design Engineering faculty at TU Delft, from Philips Experience Design and from the Dutch Heart Foundation) recognized a challenge for designers facing data-related issues when designing digital health interventions. Particularly, the capacity of digital health technologies to generate vast amounts of data on their users and context was recognized as a design opportunity in this domain, but one that designers were not yet fully equipped to work with. This is because traditional design methodology tends to be focused on qualitative and relatively small-scale methods of user- and context research, making designers more used to working with qualitative contextual information rather than bytes, spreadsheets and live data dashboards.

To face these issues, new approaches to the use of data in digital health design have been developed and applied, including under the name of data-enabled design (Van Kollenburg & Bogers, 2019). Data-enabled design approaches are based on the use of digital data, continuously collected from the context of use through sensors and other digital agents (e.g. wearables, trackers, smart devices and chatbots), to remotely conceptualise and deploy new digital health interventions in real-time. In other words, data-enabled designers can rely on real-time data collected from the context of interest (e.g. participants' homes) to update the software components of the tested prototypes (e.g. health tracking apps), allowing for data-driven, contextual design iterations.

While data-enabled design approaches constitute a promise in the field of digital health design, it was unclear whether these approaches could be instrumental in tackling the large-scale digital health challenges outlined in 1.1. Furthermore, it was unclear whether other useful ways of using data for digital health design could be identified and developed. Therefore, I scoped the doctoral research towards exploring and developing new, desirable ways to use data in digital health design processes, building on recent relevant progress in the field.

Because the scope was to produce design knowledge applicable to real-life digital health innovation practice, I chose a mixed research approach, including project-based action research (Somekh, 2005) and structured analysis of relevant literature. In particular, the doctoral research journey was informed by best-practice, real-life case studies. These were conducted in collaboration with leading players in the Dutch digital health innovation landscape, including private partners, research hospitals, and other relevant organisations.

1.3 Thesis outline

An overview of the thesis structure, including the main Research Questions and Answers, is provided in Figure 1. The line between Chapters 2,3,4 and RQ1 is dotted as the research described in these chapters inspired - but did not directly lead to - the formulation of the first research question.

THESIS CHAPTERS

RESEARCH QUESTIONS & RESEARCH ANSWERS

CHAPTER 1
INTRODUCTION

PART A: **FOCUS ON DESIGN, DIGITAL HEALTH AND DATA**

CHAPTER 2
DESIGN RESEARCH IN DIGITAL HEALTH

CHAPTER 3
USING DATA IN AN EXPLORATORY DIGITAL HEALTH DESIGN STUDY WITH LEAD USERS

CHAPTER 4
THE SERVICE-SYSTEM PERSPECTIVE IN DATA-ENABLED DESIGN OF DIGITAL HEALTH

CHAPTER 5
FOUR APPROACHES TO USING DATA FOR DIGITAL HEALTH DESIGN

RESEARCH QUESTION 1
What are existing and emerging approaches to the use of data for digital health design?

ANSWER 1
The silent, the overt, the data-enabled and the convergent approach.

PART B: **FOCUS ON CONVERGENCE IN REMOTE PATIENT MONITOR-**

INTERMISSION

RESEARCH QUESTION 2
How can the convergent approach to Remote Patient Monitoring design be formalized?

CHAPTER 6
THE IMPACT OF PERIOPERATIVE REMOTE PATIENT MONITORING ON CLINICAL STAFF WORKFLOWS

CHAPTER 7
PATIENT AND STAFF EXPERIENCE EVALUATION IN REMOTE PATIENT MONITORING

ANSWER 2
Through the adoption of integrated data strategies.

CHAPTER 8
DISCUSSION AND CONCLUSION

Figure 1. Overview of thesis structure.

CHAPTER 2

DESIGN RESEARCH IN DIGITAL HEALTH

Photo by Alexander Grey on Unsplash

"Surely blood pressure can be taken more easily and more comfortably for anxiety-prone patients. Urinalysis can be a gamble. One commonly used device works like a hydrometer, but because the scale inside the tube is printed on a piece of paper that is not firmly fixed, such readings are completely meaningless. (...) The discomfort, pain, and puzzlement of a small baby that is teething is really pathetic. After experiencing 4.5 million years of this (according to Robert Ardrey), we have developed one toy: a plastic tube filled with water that can be frozen. It gives the baby comfort for about five minutes, by which time it has warmed up and is therefore no longer soothing. Surely we can do better than that."

Papanek, 1971

2.1 Contribution background

This chapter is dedicated to an initial literature study investigating the current role of design research in furthering the different elements of the Quadruple Aim (enhancing the individual experience of care, improving the work life of healthcare clinicians and staff, improving the health of populations, and reducing the per capita cost of care) across health systems through digital health innovation. This objective is relevant to the overall aim of the doctoral research as a way to gain a first understanding of the contemporary role of design within the set of disciplines involved in digital health innovation at large. As such, this contribution provides a foundation for later investigations.
In this contribution, examples of design research in the digital health domain are reviewed. Each is analysed to collect mentions of design objectives or achievements relating to one of the four goals of the Quadruple Aim. This analysis is used to operate the following observations:

1. Design researchers in digital health are largely focused on improving experiences of care, either patients' or health professionals'.
2. Design researchers' contribution on reducing per capita costs of care appears to be less pronounced, which is outlined as a point for improvement.
3. In a considerable amount of reviewed contributions, design researchers appear to be contributing to multiple 'aims' at once.

The latter observation leads to a reflection on the strategic role of design research in digital health, which is examined in the context of the non-communicable disease crisis. Relevant implications of this reflection for design researchers are identified in the opportunity to develop digital health-specific ways to orchestrate design integration. In this contribution, the notation 'eHealth' is used in place of digital health.

An adapted version of this article has been published in the IASDR 2019: International Association of Societies of Design Research Conference 2019. Please cite as:
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2.2 Contribution

Design research, eHealth, and the convergence revolution

Abstract

The Quadruple Aim is a framework which prioritizes four 'aims', or dimensions of performance, for innovating in the healthcare domain, respectively: 1) enhancing the individual experience of care; 2) improving the work life of health care clinicians and staff; 3) improving the health of populations; and 4) reducing the per capita cost of care. In this contribution, recent literature providing examples of design research in the eHealth domain is reviewed to answer the research question: 'in which measure has design research contributed to each of the 'four aims' of eHealth innovation in the past five years?'. The results of the review are presented and employed to draw three main observations: 1) design researchers in eHealth seem to be largely focused on improving experiences of care, either patients' or health professionals'; 2) design researchers' contribution on reducing per capita costs of care appears to be less pronounced, which is outlined as a point for improvement; and 3) in a considerable amount of reviewed contributions, design researchers appear to be contributing to multiple 'aims' at once. In this sub-group of reviewed contributions, several disciplinary areas and types of stakeholders interact and integrate through design research activities.
The latter observation leads to a reflection on the strategic role of design research in the contexts of the convergence revolution and of the non-communicable disease crisis. Implications of this reflection for design researchers are recognized in the opportunity and timeliness to develop eHealth-specific ways to orchestrate design integration. A direction for further research in this sense is identified in the use of sensory and self-monitored data as a boundary object for eHealth innovation. The prospective value of this direction is finally exemplified through the case of blood pressure.

2.2.1 Introduction

2.2.1.1 Design research in eHealth

eHealth is defined as the 'the application of information and communications technologies (ICT) across the whole range of functions that affect health' (Silber, 2003). In this paper, we set out to explore recent literature reporting design research case studies in the eHealth field, with the aim of understanding the specific effects and influences afforded by design researchers in this domain. Specifically, we collected eHealth-related examples of design research in the two acceptations of what Horváth (2007) calls Research in Design Context (RiDC) and Design-Inclusive Research (DIR), while discarding examples of Practice-Based Research (PBR) (ibid.). For instance, literature describing usability tests conducted on eHealth proposition for design purposes (RiDC) was included in this review, as well as literature providing accounts of eHealth-relevant findings obtained through design activities (DIR). Conversely, literature providing heuristics and guidelines for designing eHealth propositions (PBR) was excluded from the review. This was chosen because, in this stage, our interest lies in understanding effects and influences afforded by design research in eHealth, rather than in exploring the practical aspects of designing in the eHealth domain.

2.2.1.2 The Quadruple Aim framework

The framework here employed to distinguish between kinds of influences afforded by design research in eHealth is the 'Quadruple Aim', a widely adopted prioritization of four dimensions of performance for improving the quality of healthcare systems. The four dimensions are depicted in Figure 2.

The framework arises from a recognition of the intrinsic interconnectedness of the four dimensions; specifically, improving the health of populations is seen as the primary measure of performance of any part of a healthcare system, and the other three dimensions are seen as secondary measures of performance, all instrumental in the achievement of the former (Sikka et al., 2015). The framework is recognized as pertinent to the eHealth domain, and has been successfully employed to assess the impact of specific eHealth innovations (Liddy & Keely, 2018). Exploring the impact of design research processes on each of these four aims is intended to be an exercise which is deemed useful both to stimulate awareness and self-reflection for design research practitioners working in this domain, and to serve transdisciplinary eHealth teams, whose members might not always know which kind of value to expect from design research expertise.

The overall research question is formulated as; in which measure has design research contributed to each of the 'four aims' of eHealth innovation in the past five years?

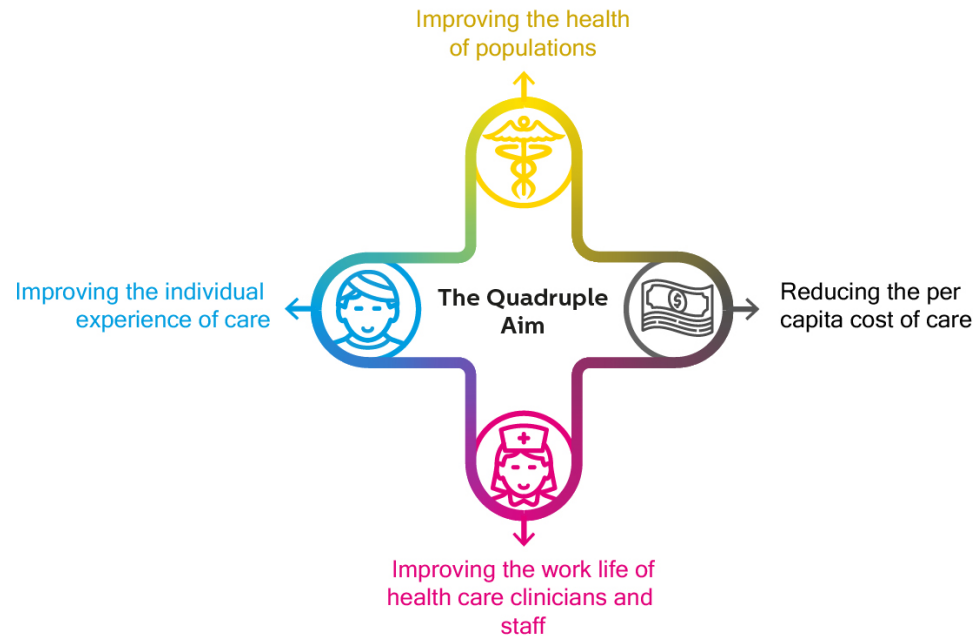

Figure 2. The Quadruple Aim framework (authors' own illustration).

2.2.2 Methods

The literature review is executed as follows;

- Step 1. Advanced searches were performed in three academic databases, namely IEEExplore Digital Library, Elsevier Science Direct, and ACM Digital Library, using a combination of keyword developed iteratively and reported in Table 1. This set of databases was chosen in reason of its coverage of multiple 'flavours' of eHealth literature, including the medical-oriented (represented by sources such as the International Journal of Medical Informatics) and the computer science-oriented ones (represented by sources such as or Pervasive and Mobile Computing). We focused on the past five years, so the search is performed on papers from 2014 onwards. This step resulted in a first selection of 785 papers.

Table 1. Keywords used for database searching.

EHEALTH KEYWORDS	DESIGN RESEARCH KEYWORDS
"e-health";"eHealth";"digital health"; "health IT"	"design research"; "user-centred design"; "patient centered design"; "user experience"; "user research"

- Step 2. We scanned the abstracts of the papers found in Step 1 in order to exclude contributions irrelevant to the research question.
- Step 3. The remaining contributions were read in full text and excluded if deemed by the authors that; a) the contribution does not describe a single case study; b) the contribution content is not to be regarded as an example of design research as defined in the introduction; c) none of the four goals of the Quadruple Aim framework are explicitly mentioned as an objective or as an achievement of the design intervention described in the contribution. Additionally, during the review and selection process, it was decided to exclude d) four contributions that were deemed to be only indirectly health-related (e.g. describing design projects aimed at designing a website accessible for user with disabilities), thus unfit to be scrutinized through the Quadruple Aim framework; and e) one contribution that was not fully written in English. An overview of the number of contributions excluded during each of these steps is provided in Figure 3.
- Step 4. The remaining 85 contributions were re-read and labelled depending on their mention of design objectives or achievements pertaining to one or more of the four dimensions of the Quadruple Aim framework. For instance, contributions mentioning 'improved patient satisfaction' as a goal or a result of an intervention supported by design research were labelled as pertaining to the first dimension, 'enhancing the individual experience of care'; contributions mentioning 'quantifiable improvements on the Healthy Eating Index' were labelled as pertaining to third dimension, 'improving the health of populations', and so on. Each contributions could be labelled on multiple dimensions. A table including the complete list of included contributions and the related mentions of objectives or achievements pertaining to one or more of the four dimensions of the Quadruple Aim is provided in Appendix I.

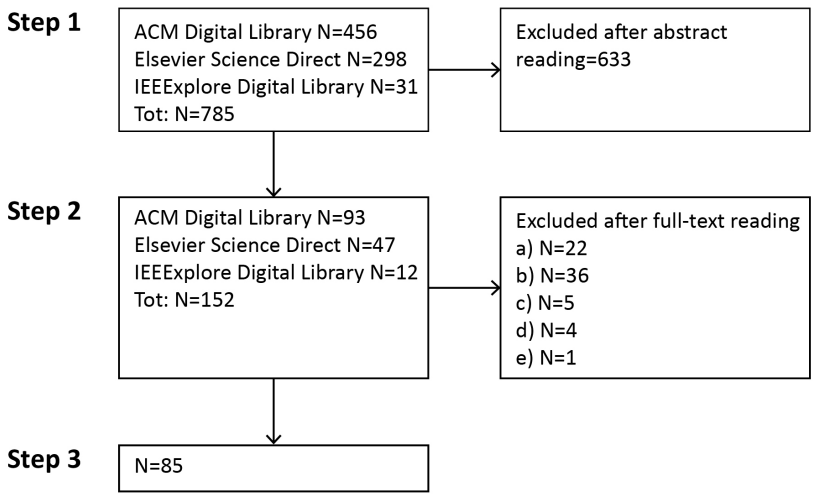

Figure 3. Diagram summarizing the first three steps of the literature review process.

2.2.3 Results

An overview of the raw results from the literature research is offered in Figure 4. To better understand the interconnectedness between the four aims, the contributions were also grouped based on their labels (Figure 5).

2.2.4 Discussion

Figures 4 and 5 collectively provide an impression of the kinds of benefits authors mention as related to design research in eHealth, and can lead us to a number of reflections.

2.2.4.1 Design research as the enabler for improved eHealth experience

Observing Figure 4, we can see how almost all reviewed contributions contain explicit mentions of the aim of enhancing the individual experience of care.
The few contributions not mentioning individual experience-related goals tend to be the ones that do mention improving the work life of health care clinicians and staff instead (as it is the case of contribution 5, 7, 20, 23, 27, 42, 53, 55, and 65). This effect of mutual exclusion is easily explained by looking at target users; some design research processes are simply situated in contexts in which healthcare staff members are intended to be the primary users of the innovation - see e.g. the case of Zarabzadeh et al. (2016), who investigates the utility of an electronic Clinical Prediction Rules (eCPR) amongst physicians.

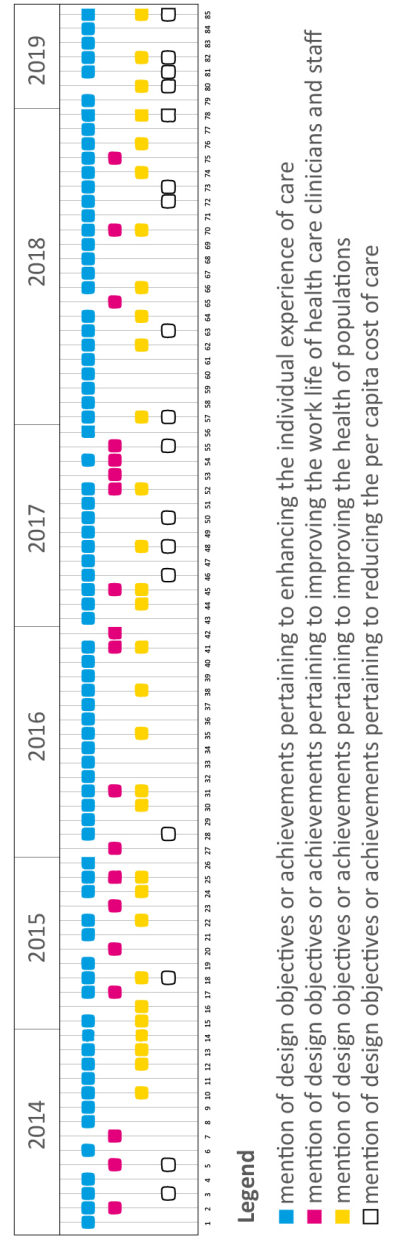

Figure 4. Each one of the 85 contributions, represented as a line, is labelled depending on the categories of aim mentioned as a design objective or achievement.

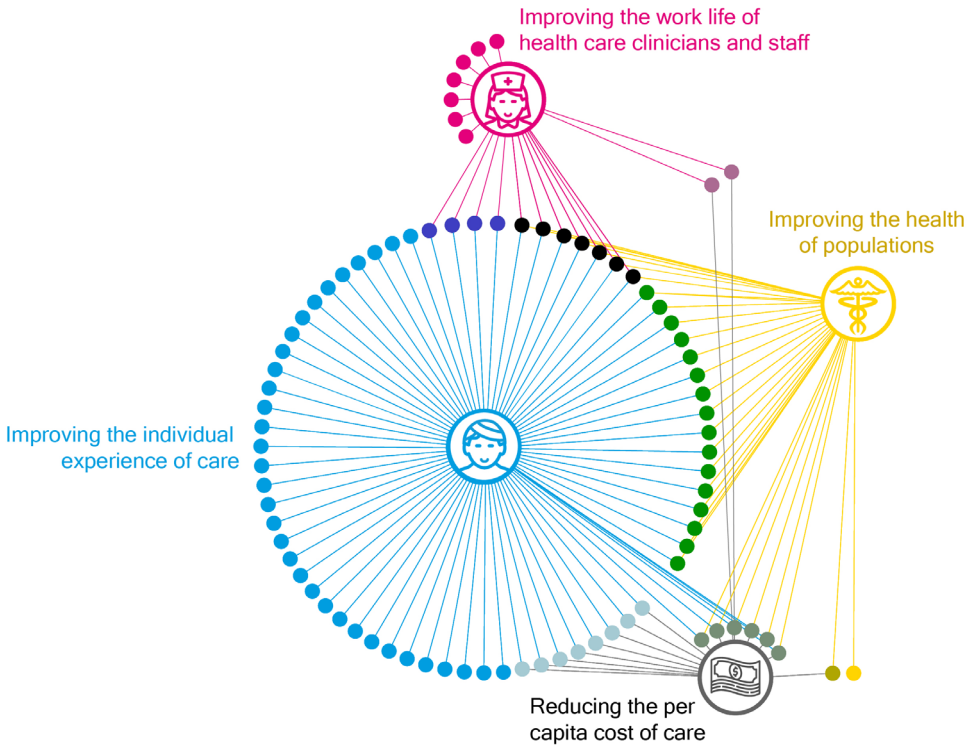

Figure 5. The 85 contributions, represented as a coloured dot, are linked to the relevant aims (each depicted by a coloured icon). Dots are coloured depending on their connections; contributions only mentioning improved individual experiences of care are coloured in blue, contributions only mentioning improved health of populations are coloured in yellow, contributions mentioning both are coloured in green, and so on. Authors' own illustration.

Altogether, thus, a first element that stands out from the overview is the strong focus on user experiences in eHealth design research literature, whether patients' or healthcare staff's.

The second most-often mentioned benefit of design research activities in the eHealth domain relates to improving the health of populations. A considerable number of contributions indicate specific improvements in term of health outcomes reached through or supported by design research activities. Crucially, these contributions almost never mention improved health outcomes as the only kind of benefit afforded, but rather as one that is coupled with improved experiences of care.

As we can see in Figure 5, green dots (contributions mentioning both improved individual experiences of care and improved health of populations) appear to be fairly common cases in the reviewed literature. Reading through these contributions, two main kinds of mechanisms emerge in the way design research connects improvements in individual experiences and improvements in care outcomes, respectively;

1. Design research activities that set out to promote individual experiences of care for existing eHealth propositions, and end up impacting on care outcomes in the process - see for instance the case reported by Bakker et al. (2018), in which the effort to develop an easy-to-use and engaging application resulted in a eHealth innovation which was, then, deemed to deserve its own Randomized Clinical Trial.
2. Design research activities that set out to promote improved individual experiences so that new, disruptive eHealth innovations that are already known to present health benefits become 'good enough' to be used - see for instance the case reported by Calvillo-Arbizu et al. (2019), in which a user-centered design process is followed so to 'maximize user acceptance' of an otherwise defined eHealth innovation.

The existence of both mechanisms, which we could refer to as 'experience-driven' and 'experience-enabled' care improvements, represent firstly a confirmation of the insights that lie at the very basis of the Quadruple Aim framework, such as the realization that care outcomes and experiences of care are inextricably linked; and secondly, a confirmation of the value of doing design research in the eHealth domain as a way to generate both 'pull' and 'push' care innovations. This last consideration aligns to theoretical models of design impact in healthcare systems, in which a distinction is drawn between a) design approaches in which design-generated knowledge is employed to develop a product or service, and b) design approaches in which design-generated knowledge is employed to develop a product or service and to trigger new health research (Pannunzio et al., 2019b).

2.2.4.2 Cost-awareness in eHealth design research: a point for improvement

Yet, the presented results should not only provide reassuring confirmations to design researchers working in the eHealth domain, but also raise puzzling concerns. The relative disinterest of design research practitioners in reducing per capita costs of care through eHealth innovations shown in Figure 4, if indeed representative of the larger eHealth scene, would be particularly alarming. In the current context of aging population and increasing prevalence of resource-intensive chronic diseases (Bloom et al., 2012), lack of cost-awareness would represent a regrettable missed opportunity for design researchers working in the eHealth domain - a field born with the very promise of providing cost-effective solutions to modern health

challenges (see e.g. Stroetmann et al., 2006). If eHealth becomes no more than another way to develop expensive care propositions, no matter how desirable and impactful in terms of care outcomes, the unsustainable economic burden put on modern health systems by current epidemiological trends stands few chances to be relieved.

2.2.4.3 Multiple-aim and multi-disciplinary design research: an ally for the convergence revolution

A conclusive reflection can be conducted on the overall landscape of design research in eHealth and its disciplinary implications. eHealth is, in fact, a realm described as inherently interdisciplinary (Pagliari, 2007; Van Velsen et al., 2013), in which diverse branches of knowledge - medicine, engineering, computer science, social sciences - come together and occasionally collide. Example of such 'collisions' are, for instance, the newborn fields of;

- infodemiology - described as ' the science of distribution and determinants of information in an electronic medium, specifically the Internet, or in a population, with the ultimate aim to inform public health and public policy' (Eysenbach, 2009), and
- synthetic biology, the field of study in which engineers and biologists come together to re-engineer living organisms (Khalil & Collins, 2010).

In the eHealth realm, design research can form different kinds of disciplinary bonds, some of which can be observed in the results of the literature research. Specifically, observing the overview provided in Figure 5, and keeping in mind our precedent observations, we can operate a division of the overall eHealth design research scene into three main 'zones' of transdisciplinary integration (Figure 6);

- Zone 1, in which eHealth challenges are tackled mainly from the user experience perspective (either patients', healthcare staff's, or both). Here, space for relevant transdisciplinary integration is identified between design research and disciplines such as Human Factors Engineering and Psychology.
- Zone 2, in which eHealth challenges are tackled in an integrated fashion. Here, space for relevant transdisciplinary integration is identified between design research and disparate disciplines, such as Health Service Research, Business Strategy, Industrial and System Engineering, and Computer Science.
- Zone 3, in which eHealth challenges are tackled mainly from the health outcomes perspective. Here, space for relevant transdisciplinary integration is identified between design research and medical disciplines.

This last snapshot of the eHealth design research scene is, possibly, the most intriguing one to look at to surmise upcoming developments in the field.

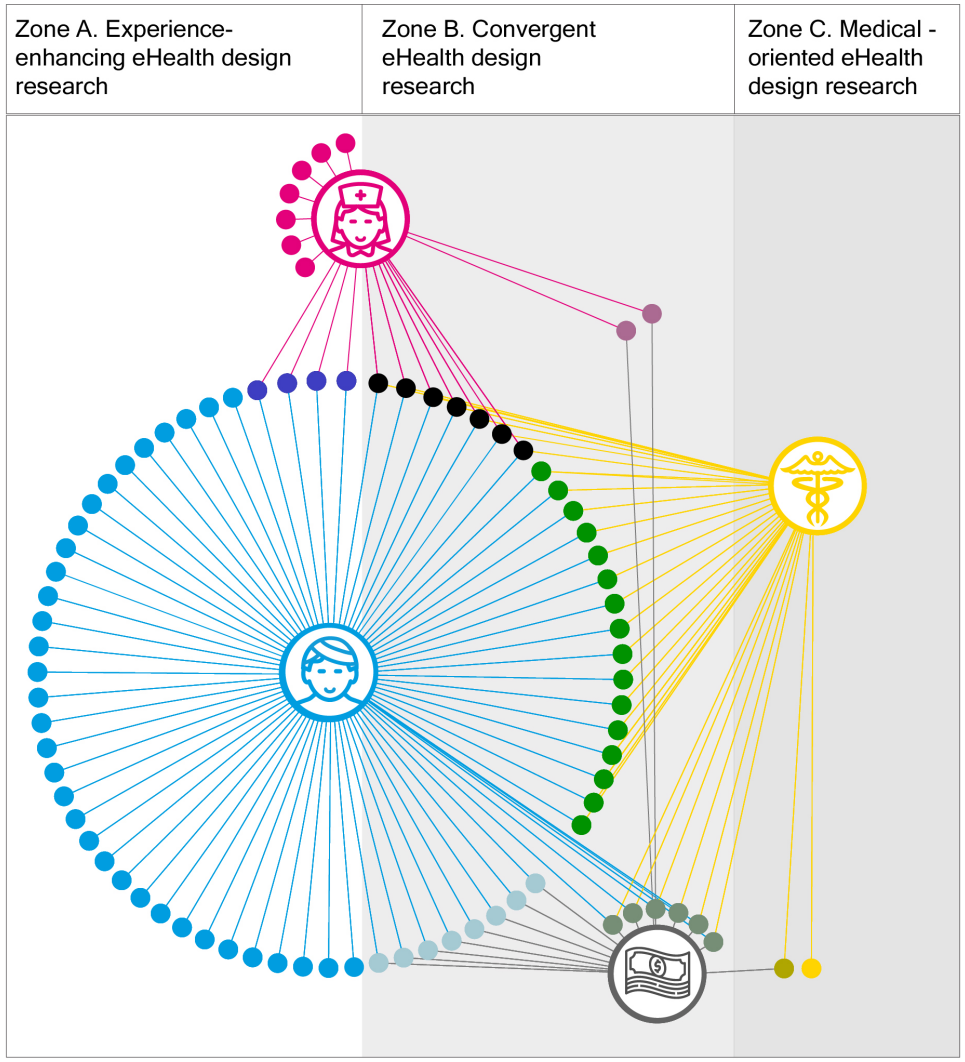

Figure 6. eHealth design research map, distinguishing three 'zones' of design research in the eHealth field. Authors' own illustration.

The existence in literature - and outside of it - of a number of examples in which design research is used to address diverse sets of care goals at the same time through the development of eHealth innovations, as we see happening in Zone 2, allows us to recognize the strategic relevance of design research in a future perspective of convergence.

Convergence, according to Hockfield et al. (2016), is the 'integration of historically distinct disciplines and technologies into a unified whole that creates fundamentally new opportunities for life science and medical practice'. Some scholars have written of the 'convergence revolution' as a third revolution in the health sciences after the discovery of DNA and the sequencing of the human genome (Khargonekar et al., 2017).
The Convergence Revolution, which is described as ongoing, is however not enabled by one breakthrough discovery, but rather arises from an integrated approach to the pursuit of health innovation.

2.2.4.4 Exploring the need for integrated approaches to health innovation: the non-communicable disease crisis

The value and timeliness of adopting an integrated approach on health innovation can be best understood by looking at large-scale healthcare modern challenges such as the non-communicable disease crisis. On a global level, non-infectious, or non-communicable diseases (NCDs) have been on the rise for decades, largely as a result of historical successes in the fight against infections (Figure 7).

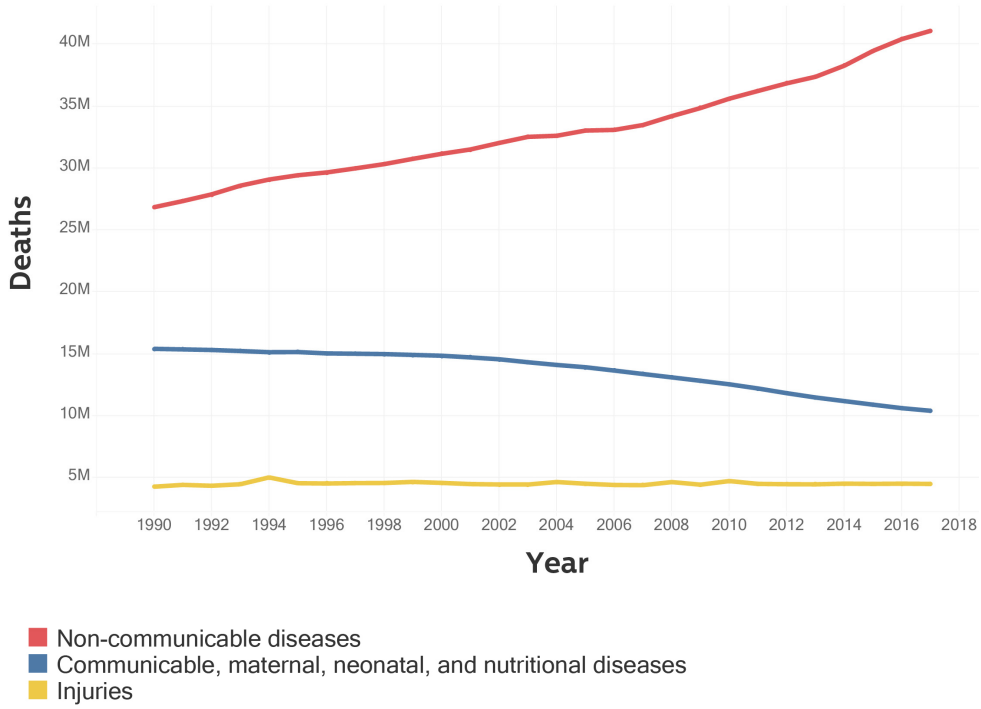

Figure 7. Causes of death globally from 1990 to 2017 (latest data available). Authors' own illustration. Data source; Institute for Health Metrics and Evaluation, 2019a.

Among these NCDs, four disease categories stand out (Figure 8); cardiovascular disease, cancer (and other neoplasms), diabetes, and chronic respiratory diseases.

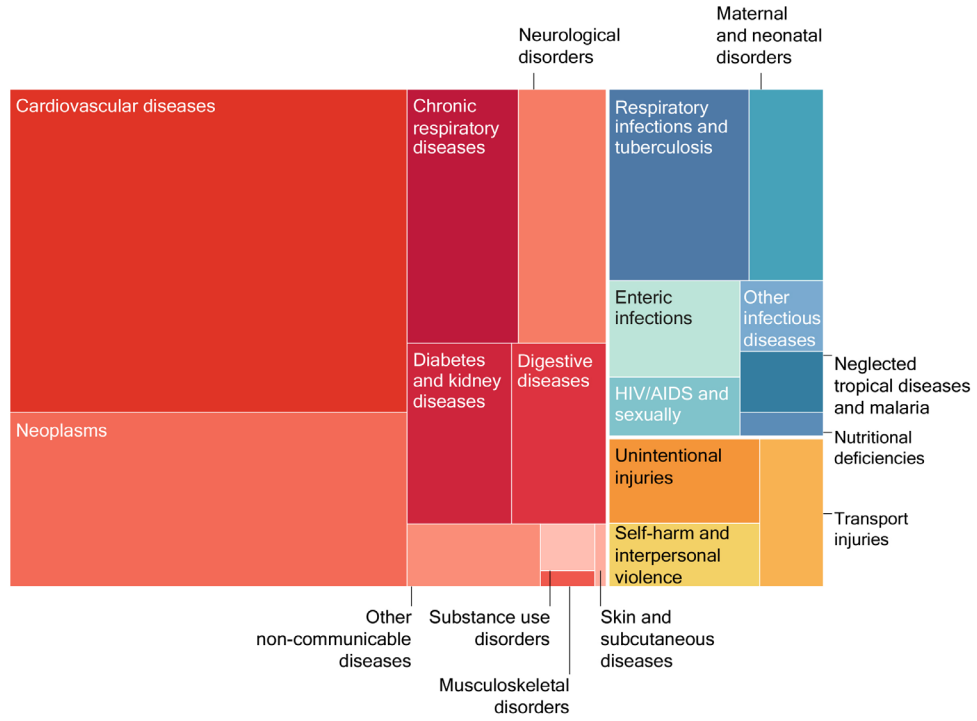

Figure 8. Causes of death globally in 2017 (latest data available) per disease category. Non-communicable diseases are depicted in shades of red; communicable, maternal neonatal and nutritional diseases are depicted in shades of blue; and injuries are depicted in shades of yellow. Authors' own illustration. Data source: Institute for Health Metrics and Evaluation, 2019b.

is forecasted that the total cost of these conditions between 2012 and 2022 will exceed 30 trillion US dollars, damaging global GDP growth and 'pushing millions on people below the poverty line' (Bloom et al., 2012). The rise of NCDs also determines an increased demand for social- and health-care which contributes to the global shortage of health workforce, projected to result in a potential deficit of 18 million health workers by 2030 (World Health Organization, 2016). In 2011, the United Nations acknowledged in a resolution adopted by the General Assembly that 'the global burden and threat of non-communicable diseases constitutes one of the major challenges for development in the twenty first century' (United Nations, 2011).

The same resolution states that prevention 'must be the cornerstone of the global response' to NCDs. Prevention is not only recognized as 'the only approach that will ensure future generations are not at risk of premature death' (Beaglehole et al., 2011), but also as the strategy with the greatest potential to alleviate NCDs unbearable costs and workforce toll - since 'once an NCD develops, the burden on health systems (...) is substantial' (Beaglehole, Bonita, Alleyne, et al., 2011). Following the UN high-level meeting in 2011, the World Health Assembly set a target of a 25 percent relative reduction in overall mortality from the four deadliest NCDs by 2025 (World Health Organization, 2013). However, the latest progress monitor, covering data up until 2017, reported that 'progress has been insufficient and highly uneven' (World Health Organization, 2017).

The insufficient progress should not surprise; preventing NCDs on a population level is a challenge that presents unprecedented difficulties for health systems. NCDs, in fact, tend to develop as results of a complex interplay of concurrent causes, or risk factors. As we can observe in Figure 9, typical risk factors for NCDs include dietary, physical activity or smoking behaviours.

Preventing NCDs through reduction of these kinds of risk factors means, in practice, getting individuals who do not have a disease to adopt healthier behaviours - for consistent amounts of time. Healthcare-specific capabilities find themselves ill-prepared to cope with a similar task; after all, both clinical disciplines and material systems of health practice evolved in rather different conditions and responding to the needs of sick individuals. Widespread, direct healthcare interventions towards non-sick individuals can be extremely efficient from a clinical point of view, but clash into problems that are beyond healthcare's disciplinary reach, and are more closely linked to historical, cultural, political and contextual factors. Worrisome, for instance, is the example of vaccination campaigns, one of the greatest achievements of public health, and yet among the interventions that generate the most long-lived controversies within subsets of the public (Dubé et al., 2015).

To cope with such 'externalized' health challenges, effective integration - of capabilities, contexts, and functions –is crucial. One good example of this principle can be found in the case of tobacco consumption: the reduction of smoking habits in a number of high- and middle-income countries is regarded as one the biggest successes so far in the control of NCDs risk factors (Ezzati & Riboli, 2013). Such result is deemed to have been driven by measures such as restrictive taxation, smoke-free policies in public spaces, warning labels, and bans on advertising promotion and sponsorship (Gravely et al., 2017). The implementation of these measures is described as a successful integration of achievements from different disciplines - production of clear scientific evidence regarding the harms tobacco consumption, execution of careful cost-effectiveness estimations, and innovative developments in legislation (Shibuya et al., 2003).

In other areas of NCD risk, examples of effective integration are yet to be found; the lack of effective measures for improving diet and exercise, in particular, led some to define overweight, obesity, and high blood glucose as the 'wild cards' of global NCD risks, and to call for 'bold, creative policies that address harmful alcohol consumption, improve diet, and increase physical activity' (Ezzati & Riboli, 2013). Others advocate the need for an "interdisciplinary social and behavioral approach, including the cultural aspects of nutrition" (Bousquet et al., 2011). Convergence, with its promise of integrating 'historically distinct disciplines and technologies', presents itself as an ideal approach for exploring 'what it means to be well, to function at the peak of our physical and mental capabilities, as well as to prevent or deal with illness' (Hockfield et al., 2016).

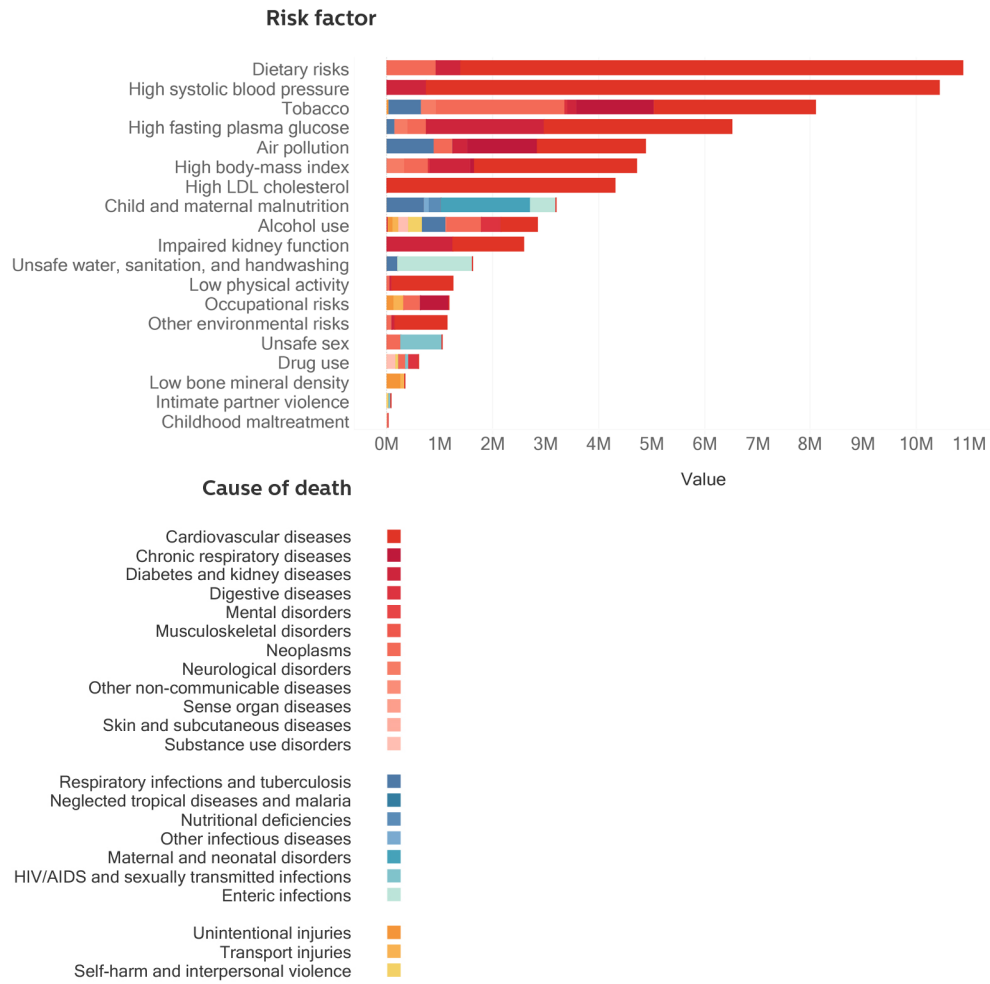

Figure 9. Risk factors linked to causes of death globally for 2017 (latest data available). Authors' own illustration. Data source: Institute for Health Metrics and Evaluation, 2019c.

2.2.5 Directions for further research

2.2.5.1 Design integration through digital data

The ability to integrate and connect different contexts and specialized disciplines is identified as a core design capability in design literature (Kleinsmann & Valkenburg, 2008). Buchanan (1992) elaborates on design as an integrative discipline, which connects knowledge from the arts and sciences in ways that are appropriate to the problems and purposes at hand. Dorst (1997) provides a detailed account of integration as a design activity, which he identifies as 'a reasoning process building up a network of decisions (part of the design problem or the design solution) while taking account of different contexts (distinct ways of looking at the problem or solution)'. Still recently, the integrative power of design and its specific value in the health domain has been examined by Romm & Vink (2019), who elaborate on the 'in-betweenness' of service design practitioners working in healthcare.

This integrative power appears to be especially necessary in a context of increasing convergence, in which health innovation is expected to arise from stakeholders afferent to different disciplines - each one with their own 'ways of looking'. We observe this design ability in action in the results of the present literature review, and specifically in the examples that populate 'Zone 2' (Figure 5).

Doing design research in convergent eHealth scenarios becomes, thus, not only a matter collecting and producing knowledge, but also a matter of reconciling different types of knowledge and orchestrating their contribution in the design process. Orchestrating service co-creation for the purpose of planning and carrying out knowledge integration activities was, indeed, recently recognized as a strategic design ability for integrated care innovation (Canales Durón et al., 2019).

A designerly way in which this orchestration can be managed is through the use of boundary objects, or artefacts that are 'both plastic enough to adapt to local needs and constraints of the several parties employing them, yet robust enough to maintain a common identity across sites' (Star, 1989). Carlile (2002) identifies three characteristics of 'effective' boundary objects in new product development, being;

1. (The boundary object) establishes a shared syntax or language
2. (The boundary object) provides a concrete means for individuals to specify and learn about their differences and dependencies across a given boundary
3. (The boundary object) facilitates a process where individuals can jointly transform their knowledge (p.451).

Boundary objects can be embodied in a wide array of formats, both material and immaterial. Mortier et al. (2014) elaborate on the use of digital data as a boundary object in ubiquitous computing settings, in reason of the capacity of these data to be 'open to multiple interpretations and the concern of many stakeholders'.

Indeed, in the eHealth domain, a unique opportunity of design-led integration is constituted by the possibility of using data (and especially sensory and patient-reported data) as a boundary object which satisfies each of the previously specified condition for effectiveness. Respectively;

1. Sensory and patient-reported data can be employed as a way to 'establish a shared syntax or language' in reason of their capacity to generate syntheses of complex, cross-contextual networks of meanings within eHealth design research. In one of the papers populating Zone 2. (Figure 6), for instance, we observe how 'data-driven' medical consultations are enabled by a eHealth intervention in which clinicians can prescribe '10,000 steps a day' to patients who wish to improve their physical activity levels (Kim et al., 2017). Here, a shared syntax for doctor-patient conversation is generated by collapsing the complexity of physical activity (both a clinician-understood health metric and a patient-understood everyday life behavior) into a quantified goal that can be easily recognized by both parties.
2. Sensory and patient-reported data can 'provide concrete means for individuals to specify about their differences and dependencies across a given boundary', in reason of their capacity to surface antitheses in stakeholders' needs and purposes regarding a eHealth proposition. In Van Kollenburg et al. (2018), for instance, we learn of an exploration of the value of parent-tracked baby data in interactions with healthcare professionals. Starting from parents-reported data, the design researchers could identify specific differences in how parents and health professionals envisioned a preferred care workflow (e.g. parents favoured richer data overviews while GPs preferred simpler data summaries).
3. Sensory and patient-reported data can 'facilitate a process where individuals can jointly transform their knowledge', in reason of their capacity to introduce changes in the knowledge bases themselves. For instance, the introduction of glucose self-monitoring devices for diabetic patients, which enabled more frequent measurements than previous technology, is described to have 'shifted the value' of the information about glucose levels, 'challenging the numerical standards for "normalcy"' (Mol & Law, 2004 as cited in Neff & Fiore-Gartland, 2015).

The use of sensory and patient-reported data as a boundary object in eHealth design research is identified as a promising strategy for design integration in a context of convergence. The entire field of medical-grade wearable sensors, specifically, which is recognized by Mertz (2016) to 'rely on' the convergence revolution, is a domain in which design researchers can effectively apply this strategy. Next, future opportunities for design research in this direction are illustrated through the case of blood pressure.

2.2.5.2 The blood pressure example

Unobtrusive wearable technologies for the self-monitoring of blood pressure, a crucial metric for cardiovascular health, are being developed and will become more and more common in the next decades. In January 2019, the first wristwatch able to take clinically accurate blood pressure readings was released in the American market (OMRON HeartGuide, 2019). According to the manufacturer's website, the product went almost immediately sold out, and to the moment in which this paper is written, aspiring customers can, at most, enrol in a waiting list.
This innovation opens new, uncharted eHealth scenarios: the early market success of the product indicates the existence of a robust demand for consumer-facing blood pressure wearable monitors, but does not help envisioning how will we, as consumers, use these wearables and the data they collect. How will this change our habits, routines and lifestyles? What opportunities will this technology afford us?
To investigate these questions, we intend to explore the use of self-monitored blood pressure data as a boundary object for the development of integrated services propositions for cardiovascular prevention. As observable in Figure 9, high blood pressure is a prominent risk factor for several NCDs, and in particular for cardiovascular diseases, the class of conditions responsible for most deaths worldwide. The development of measurable and cost-effective ways to control blood pressure in a large enough subset of the population would constitute a 'quadruple-aimed' innovation, able to;

1. Improve individual experiences of care by enabling personalized, meaningful ways of managing one's own cardiovascular health
2. Improve the work life of health care clinicians and staff by reducing chronic care workloads and promoting the availability of data useful for population health management
3. Reduce the per capita cost of care by preventing or delaying the development of chronic, non-communicable conditions
4. Improve the cardiovascular health of populations by reducing the incidence of hypertension, especially through the adoption of healthier behaviours such as a low-sodium diet and active lifestyle, which would have preventive effects on the other main NCDs as well.

Of course, this is easier said than done; in such a challenge lie numerous, multifaceted complexities, most of which are not for design researchers to solve. Yet, it is a challenge for design researchers to surface these complexities, so that the relevant disciplines and stakeholders may use them as a way to create shared understandings, to face misalignments, or to advance themselves.

2.2.6 Conclusions

In this contribution, recent examples of design research in the eHealth domain were reviewed to answer the research question: 'in which measure has design research contributed to each of the 'four aims' of eHealth innovation in the past five years?'. The research results provided a snapshot of the contemporary eHealth design research scene which led the authors to three main conclusions;

1. Design researchers in eHealth seem to be largely focused on improving experiences of care, either patients' or health professionals';
2. Design researchers' contribution on reducing per capita costs of care appears to be less pronounced;
3. In a considerable amount of reviewed contributions, design researchers appear to be contributing to multiple 'aims' at once. In this sub-group of reviewed contributions, several disciplinary areas and types of stakeholders interact and integrate through design research activities.

From these conclusions, key contributions to the field were identified, namely; 1) a solicitation for design research working in eHealth to reserve increased attention to cost-effectiveness aspects; and 2) a call for design researchers in eHealth to embrace their strategic role in the contexts of the convergence revolution, particularly by developing new, eHealth-specific ways to orchestrate design integration. A direction for further research in this regard was identified in the use of sensory and self-monitored data as a boundary object; finally, the prospective value of this direction was exemplified through the example of blood pressure.

CHAPTER 3

USING DATA IN AN EXPLORATORY DIGITAL HEALTH DESIGN STUDY WITH LEAD USERS

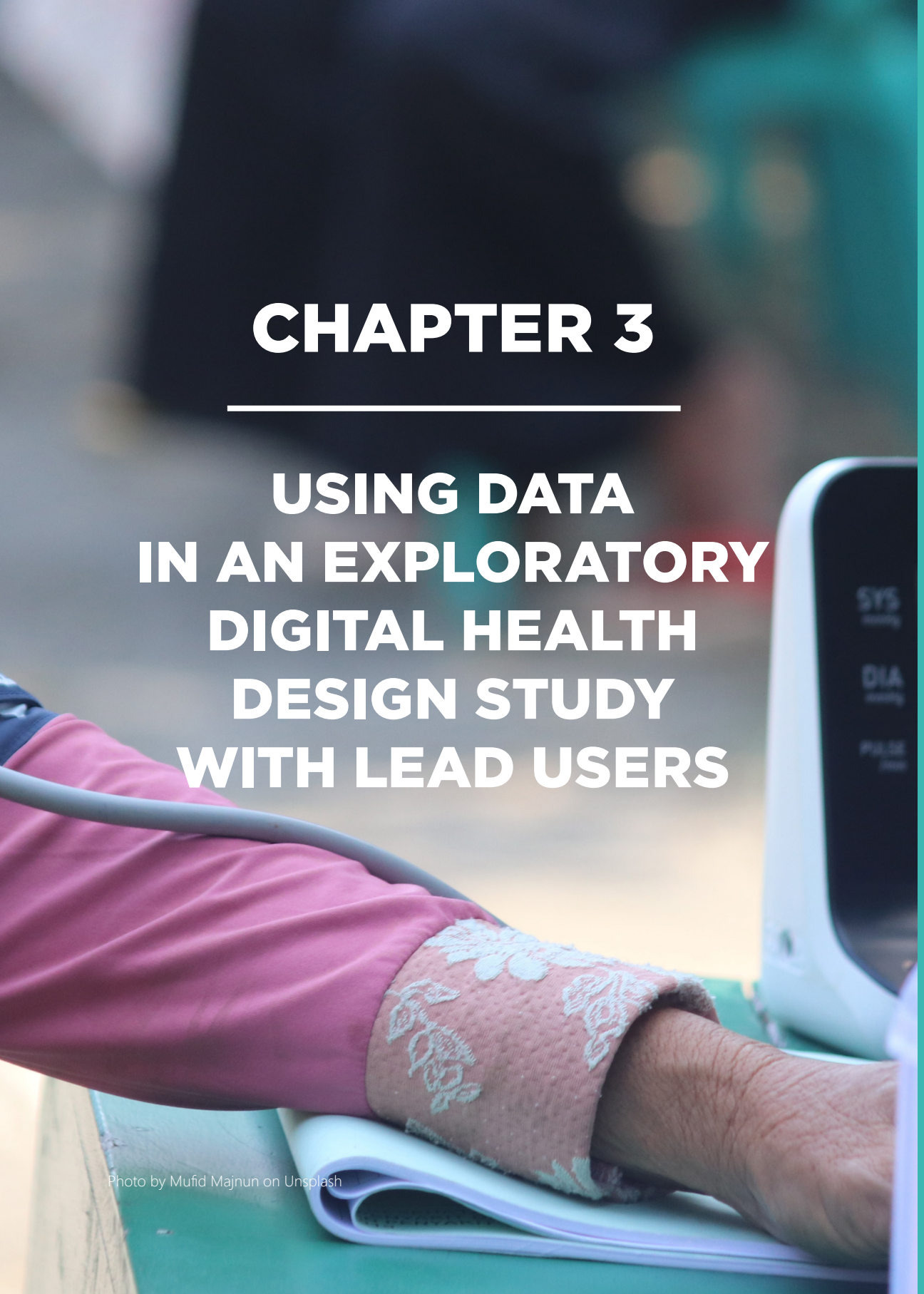

Photo by Mufid Majnun on Unsplash

"Patients possess a body of knowledge about themselves that we can never hope to master, and we have a body of knowledge about medicine that they can never hope to master. Our job is to bring these two groups together so we can serve each other well."

Wachter, 2017

3.1 Contribution background

The previous chapter contains a literature study on the role of design research in the digital health domain. This chapter is dedicated to an initial exploratory study with lead users of self-monitoring technologies and focuses specifically on blood pressure (BP) self-monitoring.
Lead user research (Von Hippel, 1986) is a traditional technique from Open Innovation literature in which ideas external to the firm are collected from the most advanced users.
In this study, lead users were identified as members of the Quantified Self community, a global community of users and makers of self-tracking tools. The study setup was remote: participants were shipped the relevant instrumentation and all interactions were conducted through webinars, chatrooms, or individual video calls. Participants self-monitored blood pressure and other data points deemed by the participants themselves to be potentially interesting.
In the active part of the study, which lasted for five months, observations and reflections on the self-monitoring activities were routinely shared within the group. These were collected, analysed and compared to similar research activities conducted with 'routine' users. Through this comparison, preliminary insights were drawn on the value of involving lead users in early-stage design research in the smart eHealth domain.

The main insights derived from the study are:

1. Lead users research can be useful for identifying both general and 'niche' needs in terms of functionalities of digital health platforms.
2. Lead user research can be useful not only for capturing digital health needs but also for specific solution characteristics.
3. Lead users present a high tolerance for study-related technical issues, which tend to be frequent in remote self-monitoring studies.

From these insights, a stage-based model was proposed integrating the collected results within a broader perspective on intelligent ecosystem design and management.

A research direction identified through this study is to pay more explicit attention to the service-system perspective in the use of data for digital health design. This direction is explored in the following chapter.

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3.2 Contribution

Finding the land, planting first seeds; lead user research in early-stage design for intelligent ecosystems

Abstract

This contribution explores the potential of lead user research for early-stage designing for intelligent ecosystems through a literature review and a single case study concerning a lead user research initiative on blood pressure monitoring. The results suggest advantages of executing lead user research in early-stage designing for intelligent ecosystems from the points of view envisioning broad initial ecosystem boundaries, developing first intelligence components, and overcoming research challenges related to technical issues.

3.2.1 Introduction

Designers who set out to develop complex digital ecosystems face a chicken-and-egg issue. On one hand, these kinds of propositions usually acquire their value by gaining a wide user base. On the other hand, it is problematic to attract a wide user base without offering tangible value. Hanseth & Lyytinen (2010) define this as the bootstrap problem of information infrastructures design, and examine the case study of the Internet itself to shed light on ways in which designers can deal with the issue.
They report how, unlike standard design processes, the development of what became later known as the Internet did not look like a problem solving activity; and quote Kahn, one of the initial developers of Internet protocols, reflecting:

'They (DoD) didn't have a problem. And that's why it's so hard for those kinds of things to actually get in motion. If you're saying, 'Can I imagine a problem that somebody might have at some unspecified point in the future?' Absolutely, that was what was driving it'.

Such reflections constitute a step further in our understanding of digital ecosystems design, but at the same time open puzzling questions.

Where to find future problems? How to proceed with building germinal prototypes of what can only later evolve into a meaningful and functional proposition? Which 'seeds' to plant, and 'where' to plant them, to let a flourishing digital 'garden' grow?

In this contribution, we examine the method of Lead User research (von Hippel, 1986) as a way for designers to navigate the uncertainties posed by early-stage digital ecosystem design. Next, a brief review is offered on both ecosystem design and lead user research literature.
Following, a single case study concerning a lead user research study in the context of smart blood pressure monitoring is presented. From it, key insights concerning the role of lead user research in early-stage design for intelligent ecosystems are illustrated and their relevance discussed. Finally, a three-phase model is proposed that integrates the insights offered in this contribution with a broader perspective on intelligent ecosystems design and management.

3.2.2 Literature review

3.2.2.1 Intelligent ecosystems and design

3.2.2.1.1 Defining ecosystems and their intelligence

The notion of 'ecosystem' in digital innovation literature is open to multiple interpretations and flavours. Among the main ones, we find the concepts of;

- Business ecosystems, intended as interconnected populations of organizations, be them 'small firms, large corporations, universities, research centres, public sector organizations and other parties which influence the system' (Peltoniemi & Vuori, 2004); and
- Digital or technological ecosystems, intended as 'solutions based on the composition of different software components and services that share a set of semantically defined data flows' (García-Peñalvo, 2018).

While these two characterizations describe different phenomena and arise from different disciplinary perspectives, they can meet in practice, since same entities can satisfy both sets of requirements (Figure 10). In the health and wellness domain, for instance, personal health apps such as Google Fit and Apple Health appear to be identifiable;

- As business ecosystems, since they constitute platforms which enable business interdependencies with and across digital products and services from other organizations; and
- As digital or technological ecosystems, since they are solutions which rely upon the interconnections with other software components and services, such as third party apps or connected devices.

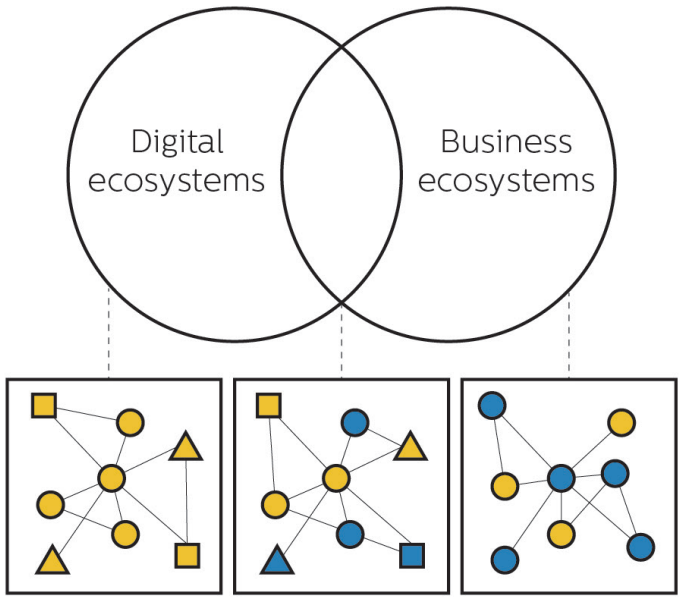


Figure 10. Digital ecosystems, business ecosystems, and their overlap

Both these ecosystem characterizations - and their overlap - appear to be relevant from a design perspective. As noted by Gardien et al. (2014), designers wanting to work in digital ecosystems scenarios need to 'anticipate and design for the complexity, openness, and growth of these ecosystems'; while business ecosystems characterized by a variety of organizational players open new scenarios for design as a discipline, which 'has a key role to play in bringing these parties together'.

The design perspective is, also, one from which it makes sense to consider both these aspects of 'eco systematicity' at the same time. This is because design practice is concerned with and driven by user experiences, which are impacted upon both by the technical and by the business interdependencies of the designed propositions. For instance, we can imagine that the experience of using Google Fit or Apple Health would be considerably different if these were an expression of stand-alone software, or only interoperable with other apps from the same brand.

Therefore, in this contribution, which aims at exploring design challenges and opportunities, we will adopt a broad definition of 'ecosystem', taking into consideration the digital characterization, the business one, and their overlap.

From a design perspective, it is also worth noting that in these kinds of ecosystems, as in many other digital domains, we can encounter the attribute of intelligence. Intelligence is, in fact, a feature achievable at an ecosystem level through the inclusion of AI components within the individual digital components of the ecosystem - or across their interconnections. In such conditions, ecosystems as a whole can acquire the capacity to evolve and adapt based on the inputs provided by their intelligent components, therefore achieving the status of intelligent ecosystem.
Incidentally, it must be observed that entities which can be recognized both as digital and as business ecosystems tend to constitute a fertile ground for intelligence. This is because, through their enabling of linkages between databases from different organizations, these entities can facilitate the aggregation of the large volumes of data usually necessary for the training of intelligent agents (K. Lee & Ha, 2018). Therefore, a focus will be maintained in this contribution on the aspect of intelligence within the ecosystems domain.

3.2.2.1.2 Designing for intelligent ecosystems

While intelligent ecosystems are relatively new in design literature, examples can be found of authors who explicitly addressed the theme. Hadzic et al. (2007), for instance, propose a bio-inspired method for the design of intelligent ecosystems, based on a five-step process which takes into account the design of every single digital component (or digital specie) in the ecosystem. The field of applicability of such a method appears, however, to be limited to situations in which the design of the ecosystems lies and is forecasted to lie in the hands of a single entity or organization.
Van Kollenburg and Bogers, on the other hand, propose an approach aimed at designing so to let intelligent ecosystems emerge, thus leaving space for further iterations and interpolations. They argue that 'the openness and complexity' associated with designing within the domain of intelligent ecosystems requires 'creative and generative approaches in which data can be used as a creative design material' (Van Kollenburg and Bogers, 2019). They propose a design research approach in which open-ended digital prototypes, situated in participants' everyday life, are used both to gain contextual, behavioural and experiential insights and to remotely conceptualize and deploy new design interventions. Through such continuous loop of in-situ iterations, first sprouts of intelligence can emerge, which the designers can then detail and expand.

3.2.2.2 Lead user research as a candidate method for ecosystem design

3.2.2.2.1 Defining lead users research

The 'lead user' construct was first introduced by von Hippel (1986) within a larger corpus of research on Open Innovation. Chesbrough (2006) defines Open Innovation as 'a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as they look to advance their technology'. Lead users research is one of the several techniques contemplated in Open Innovation literature as a way to source external ideas; specifically, the ideas coming from the most advanced users. Importantly, these users are defined as 'advanced' not in reason of their knowledge and skills, but in the sense that their needs in terms of products or services exceeds what is available to them in the market (Eisenberg, 2011). Because of this unsatisfied need, lead users have a stronger-than-average motivation and probability to come up with new ideas and solutions to fulfil that need.

Empirical research confirms that the more users display lead user characteristics, the more likely it is that they will develop commercially attractive innovations (Franke et al., 2006).
The lead user research technique, initially developed by von Hippel et al. (1986), is in many ways similar to routine market or user research. Eisenberg (2011) defines four main differences between lead user research and other kinds of user research, clarifying that lead user research projects:

1. 'Focus on the needs of leading-edge users, not routine users;
2. Seek not only needs data but innovations — user-developed solutions to leading-edge needs — from users;
3. Seek needs and solutions in adjacent markets and nonobvious, analogous markets, in addition to target markets;
4. Employ a cross-disciplinary team, bringing in perspectives from various parts of the organization.'

Lead users may not necessarily be identified as single individuals, but also as groups or companies (Eisenberg, 2011). Online or virtual communities, especially, have received attention in lead user research literature due to the opportunity of conducting participant recruiting through netnography techniques (Belz & Baumbach, 2010). Increasingly, lead user research is conducted through digital channels and with lead user communities who are 'naturally' aggregated online, through catalysts such as specialized websites, fora, chatrooms, and content platforms.

An important caveat in lead user research concerns the selection of the new product development stage at which to employ the technique. Gemser & Perks (2015) remark how lead user research may be more useful in the idea generation stage, to come up with the more radical ideas, while it may be more effective to involve 'traditional' users in ideas selecting and testing as they better represent the market. In the same way, Ebner et al. (2009) identify the main potential of conducting lead user research with virtual communities at the first stage of new product development (see Figure 11).

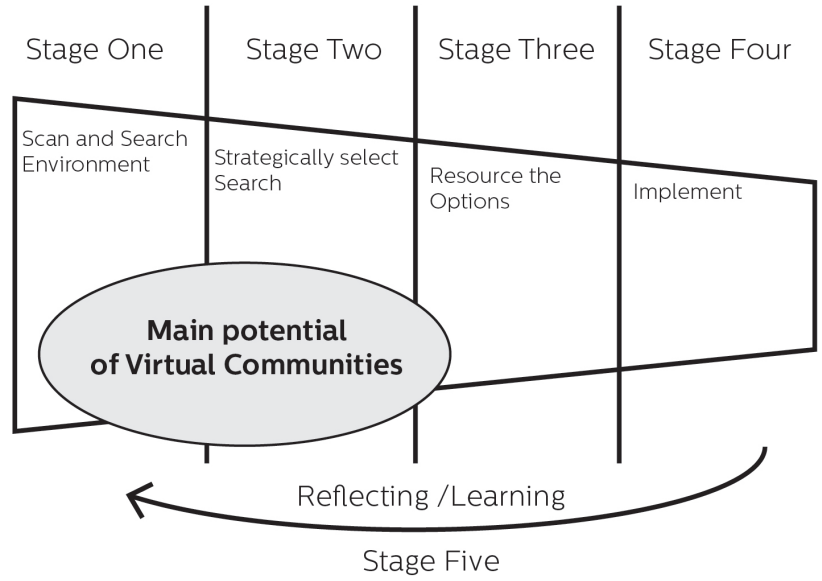


Figure 11. Process of innovation management and potential support of virtual communities (adapted from Ebner et al., 2009)

3.2.2.2.2 Leading into intelligence

The domain of intelligent ecosystem presents a few characteristics that can suggest potential advantages in employing lead user research techniques. These are;

- Low technological and market maturity.

According to Tidd & Bessant (2020), the usefulness of lead user involvement is maximized in circumstances of low technological and market maturity, when it is necessary for the technological and market aspects to co-evolve until the first viable solutions emerge.

Lead user research can then constitute a way to peek into the first indications of what the future could look like in a certain sector. Especially in their early stages, these circumstances apply to intelligent ecosystem propositions, which usually rely on advanced software and present the fast-growth patterns typical of unripe markets.

- Variety as a value.

Tsinopoulos & Al-Zu'bi (2012) highlight the positive impact of lead user research on the capacity of firms to increase the variety of their offerings. In an intelligent ecosystem scenario, offering variety is a crucial value driver, useful to consider both for innovating platform managers and complementors. For platform managers, lead user research may provide insights relevant to the management of the diversity of the platform modules, while for complementors lead user research may provide insights relevant to the discovery of areas of competitive advantage over fellow platform complementors.

- Quick-speed industry.

Dynamicity is identified as one of the key characteristics of the intelligent ecosystem domain. To innovate in such an environment, a forward-looking, trend-anticipating approach becomes a priority. Lead users, with their 'understanding of future needs' (Eisenberg, 2011), may therefore constitute an early source of knowledge for innovation. Moreover, Tsinopoulos and Al-Zu'bi (2012) report on positive effects of lead user involvement on new product development speed.

Finally, it is worth noting that lead user research is not new to the relatively young history of intelligent ecosystem design. An example can be found in the Philips Hue ecosystem, a smart home lighting solution which can interface with other domotics systems such as Google Home, supports connected bulbs from various brands, and even third-party apps. As reported in (Hilbolling et al., 2017), the development of Hue has been inspired by the creativity and emergent behaviour of amateur tinkerers and coders who had 'great and fantastic ideas' about things that could be done with smart illumination.
Yet, few studies to date have focused explicitly on the role and potential of executing lead user research in order to support designers navigate the uncertainties posed by early-stage intelligent ecosystem design. This topic is thus explored in the following case study, which sets out to answer the research question: how can lead user research support early-stage designing for intelligent ecosystems?

3.2.3 Case study: the Quantified Heart

The Quantified Heart study is a lead user research activity focusing on emerging blood pressure self monitoring practices among lead users of self-tracking technology adopters. Participants were recruited among expert users of self-tracking devices and systems, including members of the Quantified Self community, an international community of users and makers of self-tracking tools who share an interest in "self-knowledge through numbers" (see Lupton, 2016).
The Quantified Self community was, in the context of this study, identified as an existing Virtual Community (Ebner et al., 2009).
The Virtual Community paradigm was embraced and embedded in the study setup through the organization of a remote research setting: participants were shipped the self-monitoring instrumentation and the main research activities were conducted through webinars, chatrooms, and individual video calls. The study included 14 participants including the two researchers, who participated in the study in the first person. This group included participants from two continents (7 from Europe and 7 from North America), different ages (ranging from 21 to 64, for an average of 35.2) and genders (8 male, 5 female and 1 non-binary). All participants had experience in self-monitoring, and 10 had a professional background directly related to this topic (either in academic, industrial, or non-profit settings).
The setup included individual self-monitoring of blood pressure and other data points deemed complementary or potentially interesting by the participants. During the active part of the study, which lasted for five months, experiences on the self-monitoring activities were routinely shared among the group, together with data visualization and interpretation tools, relevant knowledge sources, observations, and ideas.
The research was performed according to the principles of the Helsinki Declaration and Nuremberg Code and was checked and reviewed by the human research ethics committee (HREC) of the Delft University of Technology. The participation in the research was voluntary, and the methods and data used were checked and approved by the HREC and the data steward of the Industrial Design Engineering faculty.
Raw data from the study, in the form of webinars and individual calls recordings, chatroom logs, and survey results (covering questions on preferred self-monitoring routines and modes of data exchange), was analysed through analysis on the wall (Sanders & Stappers, 2012) to distil relevant observations, needs, and ideas expressed by the participants. These, in turn, were compared with analogous material collected in a separate user research activity conducted on the same topic and through a comparable setup with 8 'routine' users. The two sets of results were compared and contrasted, until three main themes emerged. An overview of these findings is presented in the next section.

3.2.4 Findings

3.2.4.1 Core vs peripheral needs

The first difference in the sets of results from the two studies was individuated in the kind of user needs expressed by participants in relation to blood pressure monitoring.

These appeared to be at the same time more diverse and more specialized in the lead user study, compared to the study conducted with routine users. Routine users appeared to be mostly interested in 'core', relatively predictable ecosystem functionalities, such as the possibility to share blood pressure data with their general practitioners. On the other hand, among lead users, several examples could be found of envisioned ecosystem functionalities that could hardly be predicted in advance by the design researchers. Examples of wishes articulated by lead users included, for instance, the desire to gain insights into the relationships between blood pressure fluctuations and personally-relevant metrics such as tremor intensity, medication intake, or menstrual cycle. All in all, routine users appeared to mostly express general, widely applicable ecosystem needs and wishes, while lead users expressed both general and 'niche', peripheral, specialized ones. This effectiveness of lead user research in surfacing 'peripheral' needs can be interpreted as instrumental to early-stage ecosystem design, in the measure in which it did help design researchers to appraise the full range of an ecosystem possibilities. This suggests that lead user research can be employed for defining the 'extreme' boundaries of the intelligent ecosystem market space, which can then be strategically segmented through routine user research. In early-stage designing for intelligent ecosystems, realizing the potential width of an ecosystem appears to be relevant for designers who want to mitigate later risks of ecosystem lack of variety and flexibility, over-specialization, and premature aging.

3.2.4.2 Intelligence needs vs intelligence solutions

A second difference observed between the two studies concerned the fact that while routine users mostly expressed needs, wishes, concerns, and experiences, lead users articulated all of the former in addition to ideas and solutions. Importantly, these ideas and solutions concerned intelligence aspects too. Several conversations among lead user participants were spent speculating on possible ways to develop intelligent functionalities. These regarded, for instance, the possibility to predict measurement errors based on past personal results, to provide personalized feedback on the effects of physical exercise on blood pressure through interpolation of blood pressure data with activity data from a person's smartphone or fitness tracker, or to program automatic blood pressure data 'cleaning' through machine learning algorithms comparing blood pressure data with variables from other devices, such as such as heart rate, date-time, or temperature.
This insight, which represents a confirmation of general lead user theory, presents specific implications in the domain of intelligent ecosystems design, in which the technicalities related to intelligent components might be unfamiliar to designers themselves.
Especially, this insight indicates that employing lead users in data-enabled design projects may facilitate the emergence of first intelligence components, playing a crucial role in informing the design of 'minimum viable' ecosystems.

3.2.4.3 High vs low tolerance for technical issues

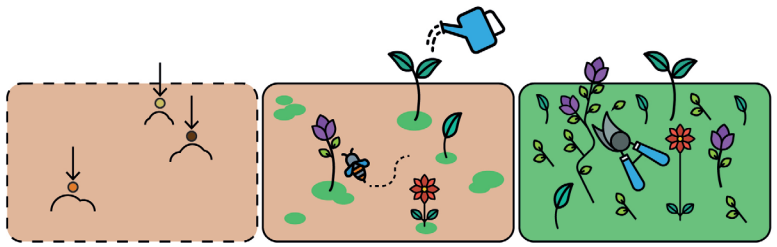
A final difference observed in the two groups concerned the attitude towards technical issues related to the data collection activities and the related self-monitoring devices. While the insurgence of such issue constituted in some cases a hard obstacle for conducting the research with routine users, lead users tended to be more tolerant towards these issues. In some cases, they even proactively found solutions design researchers were not aware of. An example in this sense concerns the Bluetooth pairing of the blood pressure monitors. Soon enough in the lead users study, it was discovered that participants based in other continents could not download the app used and suggested by the researchers; consequently, they could not retrieve blood pressure data from the monitoring devices. While the researchers were still looking for solutions, one of the participants found another app, compatible with the blood pressure device and downloadable irrespective of location. In this way, a fatal issue which would have severely compromised the viability of the study could be solved expeditiously. This highlights the convenience of conducting pilots with lead users before organizing data-enabled efforts with routine users as a way for design researchers to troubleshoot technical issues and be better prepared for unexpected occurrences.

3.2.5 Discussion

3.2.5.1 Findings relevance and positioning

The characterization of diverse, dynamic and self-evolving software platforms as 'ecosystems' builds on an analogy with the natural world. The 'ecosystem' metaphor builds on a set of analogies drawn between the main components of natural ecosystems (the organisms or biotic factors, the characteristics of their environment or abiotic factors, and the sets of relationships between organisms in the environment) and the main components of technological or software ecosystems (respectively, the stakeholders and software components, their business and digital environment, and the sets of relationships between components in the environment in the form of value exchanges or data flows).
Hillbolling et al. (2017) carry this natural ecosystem metaphor further, and compare the Hue light ecosystem to a garden populated by a thousand flowers (the third-party apps). In doing so, they build on the initial suggestion of Boudreau (2012) given to digital platform owners to attract an amount of complementors sufficient to 'let a thousand flowers bloom'.
The garden metaphor can be used to frame the findings of this contribution and connect them to a broader perspective on intelligent ecosystems design and management. The findings presented in section 3.2.4.1. can be seen as a way for designers in early-stage ecosystems design to 'find the land', or obtain an overview on the landscape of possibly relevant intelligent features.

Similarly, the findings presented in section 3.2.4.2. can be seen as a way for designers to collect first 'seeds', or potential self growing intelligence components that can be later enriched and evolved.
An overview of the relations between these insights and the previous contributions from Boudreau (2012) and Hillbolling et al. (2017) is offered in Figure 12.



Intelligent ecosystem stage	Birth	Growth	Maintenance
Design and governance strategy	Finding the land, planting first seeds	Letting flowers bloom (ensuring quantity)	Gardening (ensuring quality)
Source	Present contribution	Boudreau (2012)	Hillbolling et al. (2017)

Figure 12. The intelligent ecosystem stage-based model (authors' own illustration)

3.2.5.2 Limitations and opportunities for further research

The study presented in this contribution, and therefore the obtained results, presents definite limitations. The most important one concerns the fact that comparisons were drawn between two user studies of different size and duration. These limitations are highlighted as an opportunity for further research. Furthermore, to strengthen the reliability of the offered insight, further research in disparate ecosystem domains should be conducted comparing research activities following analogous setups.
Moreover, as already noted in section 3.2.2.2.2, it is relevant to remark that the presented advantages of employing lead user research are expected to be limited to cases of low technical and market maturity. While this currently applies to most products and services in the intelligent ecosystems domain, it is conceivable that in a near future the technical and market maturity of intelligent ecosystems will increase, thus diminishing the advantages of conducting lead user research in this domain.

Furthermore, it should be remarked that, both in lead user research and in data enabled design, special attention needs to be reserved to the ethics and transparency of research. Especially, existing Virtual Communities should not be exploited to generate data or ideas which will then be developed by separate, private institutions without their knowledge. Therefore, it is important to clarify research and design objectives upfront with all the involved participants, and to keep them informed about project developments even after the active phase of the study.
Relevant future research effort should further investigate on the complementarity of design research conducted with lead and routine users would and support the expansion and detailing of the stage based model drafted in this contribution. Finally, as already observed in Schreieck et al. (2016), the role of data as a boundary resource in intelligent ecosystems is identified as a fruitful object for further design research.

3.2.6 Conclusions

The present contribution explored the potential of lead user research for early-stage designing for intelligent ecosystems. Through a literature review and a single case study concerning a lead user research initiative in the context of blood pressure monitoring, three main advantages for designers in executing lead user research in early-stage designing for intelligent ecosystems were identified. These are formulated as:

1. Support in envisioning broad initial ecosystem boundaries;
2. Support in developing first intelligence components;
3. Support in overcoming research challenges related to technical issues.

From these results, a stage-based model was proposed that integrates the provided insights with a broader perspective on intelligent ecosystem design and management. Finally, limitations were recognized and characterized as opportunities for further research.

CHAPTER 4

THE SERVICE-SYSTEM PERSPECTIVE IN DATA-ENABLED DESIGN OF DIGITAL HEALTH

Photo by Koldunov Alexey on Shutterstock

"It is my thesis that the physical functioning of the living individual and the operation of some of the newer communication machines are precisely parallel in their analogous attempts to control entropy through feedback. Both of them have sensory receptors as one stage in their cycle of operation: that is, in both of them there exists a special apparatus for collecting information from the outer world at low energy levels, and for making it available in the operation of the individual or of the machine. In both cases these external messages are not taken neat, but through the internal transforming powers of the apparatus, whether it be alive or dead."

Wiener, 1988

4.1. Contribution background

The previous chapter focuses on an initial exploratory study with lead users of self-monitoring technologies. This chapter concerns the organisation of a study exploring the service-system perspective in data-enabled design.

In this chapter's contribution, the data-enabled method is applied in a clinical context with the aim of developing a digital health intervention for post-operative bariatric care, here named 'intelligent health ecosystem' in accordance with data-enabled design terminology. The intervention, fuelled by clinical, behavioural, experiential and contextual data, is meant to be able to provide tailored and personalised care and to connect patients, partners, and health professionals.

The disciplinary domain of service design (and specifically of the design of the service interface, in accordance with Secomandi & Snelders, 2011) is recognized as a relevant perspective in the project and in the data-enabled design methodology at large.
Because this perspective is, in digital health design, intimately linked to the functioning of the relevant digital system, we refer to it as a service-system perspective. In the contribution, we review opportunities and challenges related to such a perspective and we situate our insights within the larger context of digital health innovation.

Overall, this study contributed to the overall aim of this dissertation through the achievement of a deeper understanding of data-enabled approaches to using data for digital health design. Through this experience, a deeper definition of data-enabled approaches and of its difference and similarities with other possible approaches was reached, which is discussed in the next chapter.

An adapted version of this article has been published in the Proceedings of the 6th International Conference on Design4Health. Please cite as:
Pannunzio, V., Lovei, P., Neutelings, I., Deckers, E., Jansen, J. M., & Burghoorn, A. W. (2020). Exploring the service system perspective on designing intelligent health ecosystems: the co-responsibility study. In 6th International Conference on Design4Health2020/Online (pp. 469-477). Sheffield Hallam University.

4.2. Contribution

Exploring the service system perspective on designing intelligent health ecosystems: the Co-responsibility study

Abstract

Data-enabled design is an approach used when designing for intelligent ecosystems. It makes use of open-ended design probes situated in participants' everyday life. These probes are employed both to gain contextual, behavioural and experiential insights and to remotely conceptualize and deploy new design interventions. While the user-experience oriented perspective and the experimental, prototype-centric perspective on designing for intelligent ecosystems through a data-enabled design approach have been extensively described in previous literature, an examination of a service-system perspective is missing to date. In the present contribution, the latter perspective is explored through the lenses of a first-of-a-kind case study. The study was directed towards the development of an intelligent ecosystem for post-operative bariatric care, fuelled by clinical, behavioural, experiential and contextual data, able to provide tailored and personalized care and connecting patients, partners, and health professionals. Practical challenges and opportunities related to the adoption of a service-system perspective within the study were identified and connected to a reflection on the role of service design in contemporary eHealth innovation.

4.2.1 Introduction

Data-enabled design (DED) is an explorative and situated design approach in which both objective and subjective data, remotely collected from the users' everyday context, is used to design for intelligent ecosystems of products, services and people. Previous case studies showcase applications of this design approach in the health domain (van Kollenburg et al., 2018; Bogers et al., 2018)

DED is an inherently multidisciplinary design approach, in which the main relevant competences (design research, data design, software development, data science, domain experience) are represented by team members from different backgrounds. In previous literature (van Kollenburg and Bogers, 2019), two specific design roles have been presented as essential to the DED approach;
The role of the design researcher, adopting a user-experience oriented perspective rooted in qualitative and ethnographic research techniques;
The role of the data designer, adopting an experimental, prototype-centric perspective rooted in digital prototyping, software development, data analytics, and visualisation techniques.

In this contribution, we introduce service design capabilities as a third design skillset that can be relevant to a DED process. First, we provide brief theoretical considerations on these capabilities. Following, we present the results of the introduction of a service system perspective in DED through the Co-responsibility case study, review the encountered challenges, and propose relevant opportunities for further research. By doing so, we intend to enrich the DED approach with a novel and relevant perspective, and to stimulate a more general reflection on the role of service design in novel paradigms of value creation in digital health.

4.2.2 Service design for intelligent ecosystems

Service design is a branch of design knowledge and practice which is "concerned with systematically applying design methods and principles to the design of services" (Holmlid & Evenson, 2008). Secomandi and Snelders (2011) indicate service design to be concerned both with the service interface and with the service infrastructure, identified, respectively, as the sociotechnical resources involved on the 'front-end' and 'back-end' of the exchange relations between service providers and clients. They place emphasis on the service interface as the locus in which service-related exchange relations are materialized, to the point of suggesting that the design of the service interface constitutes the design of the service itself.
Such considerations can support us in identifying a role for service design capabilities within a DED process. In fact, DED processes aim at developing propositions that reach users through specific kinds of service interfaces: those of an intelligent ecosystem.

Van Kollenburg and Bogers (2019, p. XIII) characterize the intelligent ecosystem as: 'a collection of products and services, that can together gain a detailed and nuanced understanding of the user and context. This understanding allows the intelligent ecosystem to adapt, to deliver experiences at the moment and place where they matter most.'
If we adopt Gadrey (2000) definition of a service as the provision of a 'temporary right to use' a technical system, we see that, within intelligent ecosystems, service interfaces themselves need to be adaptive in order to ensure the timeliness of the service provision. Focusing on designing services that explicitly embed such timeliness and personalization at the level of the interface is deemed to constitute a relevant concern within DED, and one that we recognize to pertain to the disciplinary domain of service design. Because this aspect of service provision is intimately linked to the functioning of the intelligent ecosystem, we will refer to this as the service-system perspective.
Like the other roles within DED, the service designer cannot work in isolation. To design services that possess the aforementioned qualities, the service designer needs to obtain an understanding of the flow of information and knowledge through the ecosystem, and of its use in different touchpoints (in a certain context, at a certain moment). This understanding connects to both experiential and technical aspects of the ecosystem. In this sense, the role of the service designer in a DED process could be preliminarily identified as that of an *integrator* of:

- Experience-related insights, provided by the design researcher from a user-experience oriented perspective; and
- Infrastructure-related insights, provided by the data designer from an experimental, prototype-centric perspective at the level of the service interface.

Furthermore, the characteristics of services in intelligent ecosystems can be connected to a perspective that is specifically explored in traditional service design literature; the one of the facilitator of co-production. A central tenet of service design lies in fact in the difference between products and services, identified in the need for services to rely on a certain degree of participation from their users to become visible and tangible. Edvardsson & Olsson (1996) link service design to the responsibility of facilitating the engagement of customers in co-producing the outcome.
In intelligent ecosystems, the element of co-production is materialized not only in the user interacting with the services as intended, but also in the passive and active production of the contextual data fuelling the ecosystem. From a service system perspective, the user of the intelligent ecosystem is a continuous 'co-producer', whose actions and interactions, materialized in the form of data, sustain the ecosystem intelligence. An additional potential role for service design in a DED process is therefore recognized in the capacity to safeguard, prioritize and facilitate digitally mediated co-production in the intelligent ecosystem.

4.2.3 Case study

4.2.3.1 The Co-responsibility study

The 'Co-responsibility' study was a clinical trial following an explorative data-enabled approach. The study focused on the time following a bariatric or weight-loss surgery, in which keeping up with suggested lifestyle changes (e.g. regarding nutrition and physical activity) can prove challenging for patients.

Long-term success in maintaining optimal lifestyle appears to be significantly affected by the support provided by the healthcare professionals and the social circle surrounding the patient. Therefore, it was decided to investigate the potential value of an intelligent ecosystem designed for co-responsibility between patients, partners, and healthcare professionals. In line with Neutelings et al. (2017) we defined co-responsibility as the "responsibilities of people being intertwined, not in the sense that people share the same responsibilities, but in the sense that peoples' responsibilities are interdependent".
An intelligent ecosystem consisting of a communication platform (chatbot and mobile application), a Fitbit activity tracker, open-ended data trackers (flic button, rotary buttons) and event trackers (smart power sockets, motion sensors) was designed and deployed at the homes of six participating families. Using this system, we were able to explore the context and to develop and test design interventions involving the patient, partner and a team of healthcare professionals. Each family was recruited via the Obesitas Clinic of the Catharina hospital residing in the Eindhoven region of the Netherlands. The study was classified as a clinical trial and its setup was approved by the Philips internal ethical committee (ICBE), the medial ethical review board of Santeon Hospital group (MEC-U), and the local feasibility committee of Catharina Hospital.
The setup of the project, which was initiated by a team of design researchers and a data designer, is described in more detail in Lovei et al., 2020 and Jansen et al., 2020. By decision of the team, a service designer adopting a service-system perspective was then involved to support the project. This introduction surfaced both practical challenges and opportunities, which will be described in the next section.

4.2.3.2 Challenges and opportunities

Service designer as the integrator of the other data-enabled design perspectives

By the time the service designer had joined the team, extensive data-enabled explorations had already been performed. This resulted in the accumulation of rich insights both into experiential factors related to the post-surgical context, and into the technicalities related to the explorative ecosystem built for the study. Several ideas and intuitions related to possible (smart) functionalities and features of services in a future ecosystem had emerged.

Among these, we can mention;

- Ideas on how to provide the intelligent ecosystem with adaptive capacities (e.g. based on a user profile including medical history, baseline questionnaires, etc.);
- Ideas on how to surface and foster co-responsibility within the intelligent ecosystem;
- Ideas on how to provide health information previously delivered through non-digital media;

- Ideas on how to use specific probing devices (e.g. Fitbits, smart sockets, open data trackers) within the intelligent ecosystem.

From a service system perspective, each of these sets of ideas could provide valuable insights into desirable characteristics of service interfaces, and as such could be used as service design input.

Yet, early efforts to sketch the map of an integrated digital infrastructure that would permit the development of these ideas within an ecosystemic framework proved challenging. This is because each of the indicated interface-level features required the conceptualization of an automatized sub-process at the level of the infrastructure. For instance, the interface-level feature of 'adaptivity of service based on user profile' required, at the level of the service infrastructure, the conceptualization of a sub-system that would automatically manage options for personalization in a structured way, and would influence ecosystem interactions accordingly.

To this end, it is important to note that the conceptual complexity of the infrastructure behind an intelligent ecosystem tends to increase exponentially, rather than incrementally, with the addition of each element of 'smartness' perceivable at the level of the interface. This is because each newly added subsystem needs to interrelate to all other subsystems in a planned and rigorous way to ensure system coherency. Consequently, even simplified conceptual maps of an intelligent ecosystems' underlying infrastructure appeared overcomplicated and lacked capacity to show all of the relevant logical interdependencies (see Figure 13) From a service-system perspective, this challenge surfaced opportunities for future efforts to improve the integration of rich experiential and technical data-enabled insights through:
A strict prioritization of the features considered for service design, at least in early conceptualizations of the ecosystem;
A strong alignment between the service designer and the data designer in order to manage technical trade-offs;
A clear value proposition to guide interdisciplinary design choices.

Service designer as the facilitator of data-enabled co-production

Some of the most interesting service feature ideas emerging from the study relied on active user participation. For instance, the idea of embedding a way to track 'co-responsibility' trends between a patient and partner relied on both participants periodical filling of a fixed questionnaire, thus on their disciplined co-production of ecosystem-relevant data. From a service system perspective, this raised questions on the possibility and opportunity to impart designerly control over the behaviour of the users in the ecosystem setting.

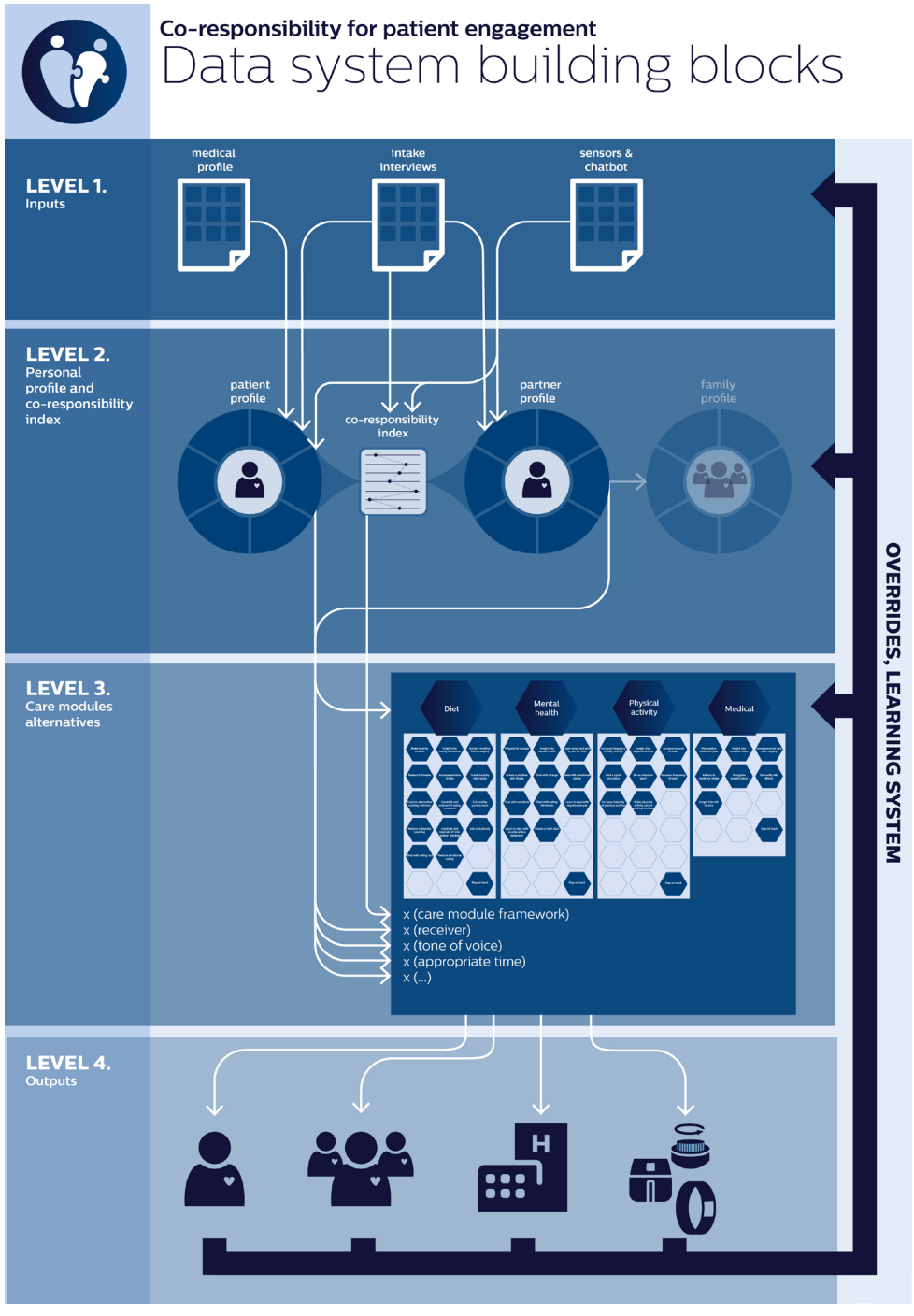


Figure 13. Early system map

In these terms, a challenge was identified in reaching an appropriate balance between the designerly control necessary to guarantee the intended functioning of the ecosystem, and the flexibility necessary to embrace and accommodate users' possible non-compliance or deviation from expected behaviour.

An opportunity to overcome this challenge could be found in Snelders et al. (2014), who can be credited with the notion of an appropriate balance of designerly control in service design, and who posit that 'the degree of control that designers possess should be contingent on the degree in which people in a service setting can accept the intervention of external parties to improve their social well-being'.
Their contribution suggests a connection between the levels of user tolerance for designerly control and the perceived utility of the service for the 'greater good' of improving social wellbeing. Similarly, in the Co-responsibility case, we can imagine that acceptance for designerly control would be conditional to the perceived utility of the service in supporting users' successful post-operative recovery. Future research could investigate the accuracy of this expectation, and further inform service design best practices when balancing between control and flexibility in digital health.

4.2.4 Discussion

4.2.4.1 Relationships between service designer and data designer

As previously specified, service designer capabilities can only be integrated within a DED project through close collaboration with the other capabilities involved in the project, mainly design research and data design. However, we would like to reserve special attention to the relation between service designer and data designer. In fact, we experienced the establishment of mutual understanding between these two roles to be possibly hard, but indispensable for successful collaboration. This is because the sketching of even just early service ideas within an intelligent ecosystem does require an iterative back-and-forth between a service-system and an experimental, prototype-centric perspective. During our project, we sometimes struggled to reconcile the two perspectives due to important differences in approach, knowledge, experience, and even vocabulary. However, we have found such struggles to be not only fruitful for the project, but also, ultimately, mutually enriching.

4.2.4.2 Implications for service design in eHealth

The considerations contained in this contribution can lead us to a more general reflection on the role of service design within the contemporary discourse in eHealth innovation. eHealth is in fact a domain in which both the integration of different disciplinary perspectives and the facilitation of digitally mediated service co-production appear to be recognized as largely unanswered needs.

Regarding the former aspect, Pagliari (2007) offers a compelling overview of the need for improved interdisciplinary integration in eHealth design and evaluation, while Romm & Vink (2019) reflect on the capacities of service designers in healthcare to act as 'catalysts' of the multiple relevant points of view.
Regarding the latter, Tummers et al. (2016) points out the opportunity to improve care co-production through enhanced use of Information and Communication Technologies (ICTs), and Boye (2012) provides an early theoretical framework for digitally mediated health co-production. In this sense, we believe our contribution's relevance to extend beyond the borders of DED, and to connect to the broader discourse at the intersection of service design and digital health.

4.2.4.3 Limitations

An important limitation of our work consists the uniqueness of the presented case study, a first-of-a-kind project under several points of view. Furthermore, we acknowledge that the dynamics we observed in the project might have very well been drastically influenced by independent circumstances, such as the team members' backgrounds, skills, and personalities. Accordingly, we see our preliminary considerations on the service-system perspective in DED to be project- and team-dependent. Finally, we believe our conclusions should not be interpreted in a way that constrains design professionals into too rigid roles and definitions. To this note, we point out that tasks that could be considered to be afferent to service design have been successfully executed in previous DED projects without the involvement of a formally trained service designer.

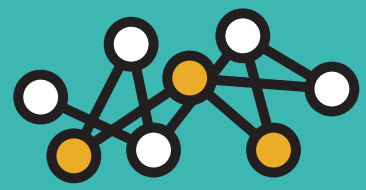
4.2.5 Conclusions

In this contribution we introduced the role of the service designer within the data-enabled design process. After touching on some theoretical considerations, we reviewed the challenges and opportunities related to such role as observed in a single case study. Finally, we briefly reflected on the relationship between the role of the service and the data designer and situated our contribution within the larger context of digital health innovation.

CHAPTER 5

FOUR APPROACHES TO USING DATA FOR DIGITAL HEALTH DESIGN

Photo by Sweet Life on Unsplash



"We can't impose our will on a system. We can listen to what the system tells us, and discover how its properties and our values can work together to bring forth something much better than could ever be produced by our will alone."

Meadows & Wright, 2008

5.1. Contribution background

The previous three chapters have touched on disparate ways to use data for digital health design. In this chapter, insights derived from these explorations (such as the interdisciplinary outlook of digital health design research described in Chapter 2, the opportunities of involving non-design experts in digital health innovation processes described in Chapter 3, and the definition of a service-system perspective in data-enabled design) are used to inspire an inquiry into the different approaches to the use of data for digital health design. In this chapter, these are described as the silent, the overt, the data-enabled, and the convergent approach. Each approach is characterised in terms of the use of data for design decision-making, and a real-life example of each is provided. The four approaches are then compared in terms of selected desirable characteristics of the design process, highlighting the relative advantages and disadvantages of each. Finally, a reflection is provided on the system-level relevance of the differentiation between the four approaches.

A major result achieved in this contribution in terms of the overall doctoral research aim is the definition of convergence as a distinct approach to digital health design, which had previously only been hypothesised. Furthermore, the contribution offers an example of the real-life application of convergent approaches in the collaborative development of the clinical trial protocol for the Perioperative Box, a digital health proposition for perioperative monitoring of major gastrointestinal surgery patients, which will be further discussed in the next chapters.

A version of this contribution is under a second round of review in a peer-reviewed journal.
Pannunzio, V., Kleinsmann, M., Snelders, D., Raijmakers, J. From digital health to learning health systems: four approaches to using data for digital health design.

5.2. Contribution

From digital health to learning health systems: four approaches to using data for digital health design

Abstract

Digital health technologies, powered by digital data, provide an opportunity to improve the efficacy and efficiency of health delivery processes, showing the potential for offering crucial contributions to the functioning of health systems at large. However, little is known about different approaches to the use of data for digital health design and their relations to system-level dynamics. In this contribution, we identify four existing approaches to the use of data for digital health design, namely the silent, the overt, the data-enabled, and the convergent. After characterizing each approach, we review and compare them in terms of the role of data within design decision-making processes, and provide a real-life example of each approach. Furthermore, we compare the four approaches in terms of selected desirable characteristics of the design process, highlighting relative advantages and disadvantages of each. Finally, we provide a reflection on the system-level relevance of the differentiation between the four approaches and outline related future research directions. Overall, the contribution provides researchers and practitioners in the field with a broad conceptual framework to examine data-related challenges and opportunities in the field of digital health design.

5.2.1 Introduction

Health systems worldwide face widespread challenges. Long-term demographic and epidemiological trends, combined with new, disruptive phenomena such as the covid-19 pandemic, result in a worrisome combination of systemic understaffing (Drennan & Ross, 2019) and increasing costs of care (Chang et al., 2019). One of the directions undertaken to relieve health systems from these pressing issues is the incremental adoption of digital technologies in the health domain, often referred to as the digital health revolution (see e.g. Powell & Arvanitis, 2015; Snyder & Zhou, 2019).

This revolution, which is described as ongoing, has undergone several phases; from the introduction of "health telematics" in the 1970s, to the diffusion of the Internet and the Personal Computer in the 21st century, to the advent of mobile health technologies in the 2010s (Manteghinejad & Javanmard, 2021). A contemporary frontier of the ongoing digital health revolution is represented by the growing use of AI and 'smart' technologies in the health domain, comprehensively described by Rajpurkar et al. (2022). In this contribution, we employ the term 'digital health' in a broad sense, encompassing categories such as mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine, in accordance with the characterization offered by the US Food and Drug Administration (2020).

Throughout the developments affecting the digital health domain, a common thread is represented by the increasing importance of data as the fuel of digital health transformation (Haggerty, 2017). Data access is, in fact, not only crucial for the continuous functioning of existing digital health interventions, but also for digital health innovation (Gopal et al., 2019). According to Hovenga & Grain (2022), increased availability of data can facilitate the development of new products and services in the digital health domain. Yet, while valuable research has been conducted on digital health design processes (Kowatsch et al., 2019) and multidisciplinary requirements (Van Velsen et al., 2013), little is known about possible ways to use data in digital health design processes. At the same time, while the impact of digitization and data-driven innovation have been described as a paradigmatic shift in the way artefacts are designed (Cantamessa et al., 2020), few contributions touch on the specific implications of this shift in the health domain.
In our pivotal stage of digital health innovation, increasingly moving towards AI-driven, smart solutions, it is worth to critically examine the role played by data within digital health design processes, intended as the processes through which new digital health artefacts are designed or existing ones are redesigned. Particularly, operating a first broad conceptual distinction among existing approaches to the use of data in digital health design can help practitioners and researchers in this domain to navigate the variegated and fragmented landscape of current digital health design practices, and to examine data-related challenges and opportunities. To do this, we employ design, digital innovation, and digital health literature, in an effort to achieve a well-rounded understanding of digital health data design practices and processes.

The paper is set up as follows. First, we make an initial distinction into four existing approaches to the use of data in digital health design. Furthermore, each approach is examined in terms of use of data for design decision-making and exemplified through a brief real-world case description. Finally, the four approaches are compared and contrasted, and future research directions are outlined on the basis of the provided reflections.

5.2.2 Four approaches to using data for digital health design

The concept of "data" is a broad one, rich of different interpretations and uses (Furner, 2016). Ways to use data within design processes could be described from a myriad of perspectives; in this contribution, we choose to proceed through increasingly professionalized and digital-specific approaches to the use of data in health design, in an effort to cover the spectrum of existing practices in an orderly, step-wise way. To do so, we start from the simplest possible form of data use for digital health design process and incrementally transition towards more complex, articulated courses of action, highlighting key developments and distinctions along the way.

Specifically, we distinguish between silent, overt, data-enabled, and convergent approaches to using data for digital health design, with the first two approaches applying to physical and digital health artefacts alike, and the last two applying exclusively to digital or hybrid health artefacts. Together, these approaches encompass a vast array of design practices and traditions, ranging from the most widely used to the most recently emerging.

The first approach we characterize, the silent, stems from a recognition that not all design activities in the digital health domain are explicitly recognized as design. Since our scope is to consider the broad landscape of digital health design practice and its impact, it is important for us to include design activities that might not be explicitly recognized as design while effectively fulfilling the design function. We are helped in this by traditional design literature, and in particular by Gorb & Dumas (1987), who first introduced the notion of silent design as "design by people who are not designers and are not aware that they are participating in design activity". Expressed in these terms, silent design appears to constitute a rather common occurrence in the history of healthcare, in which design activities have been conducted long before the formalisation and professionalization of design disciplines. To this day, countless new health solutions, including digital ones, keep on being developed without the involvement of professional designers. Often, the 'silent', non-professional health designers are individuals or groups who are invested in the context of the innovation, be it as healthcare professionals, as patients, or as patients' loved ones. Therefore, we borrow the term silent to describe an approach to digital health design which is conducted by individuals or groups who are not professional designers, and that as such do not follow a formal design process.
The seminal Gorb and Dumas paper from 1987 introducing the concept of silent design also offers a designation of its opposite: overt design, intended as design conducted by professionally trained designers who knowingly and purposefully engage in design activities. We thus borrow the term overt to describe a second approach to digital health design, in which design processes are formally conducted by trained designers through established design methods and tools.

In addition to silent and overt approaches, which are applicable, but not specific to the design of digital health artefacts, we note that unique characteristics of the digital health domain determine the emergence of novel, dedicated design approaches. In particular, two characteristics of digital health artefacts challenge traditional ways of designing. These are:

- The capacity of digital health artefacts to perform based on digital data, including data collected and analysed in real-time;
- The capacity of digital health artefacts to change and evolve over time, including while in use.

These characteristics are enabled by fundamental properties of digital technologies, namely data homogenization and re-programmability (Yoo et al., 2012). Data homogenization refers to the capacity of all digital data to be ultimately converted in binary numbers, while re-programmability refers to the capacity of digital devices to perform a wide array of functions through their flexible architecture.
Data-enabled design approaches explicitly deal with these specificities through the purposeful establishment of continuous loops of redesign informed by data collected directly by the digital health artefact in the context. In itself, this principle is currently applied in many non-health-related sectors, such as entertainment, transportation, or retail, in which usage data is routinely employed to gain inspiration for new service features, to develop them, to test them, to update them, and more. In the field of digital health, the possibility and usefulness of establishing closed loops of data (including data collected through the digital solution itself) continuously informing design processes have been demonstrated by van Kollenburg and Bogers (2019) through their data-enabled design explorations. An interesting implication of these developments for design theory is the changing role of the designed artefact itself, which becomes not only an output of the design process, but also a source of information, through the establishment of a dedicated data infrastructure. As a consequence, this data infrastructure has to be designed as part of the artefact itself. In consideration of such elements of novelty in the object of design processes following data-enabled approaches, we find it appropriate to differentiate these from overt approaches, even though data-enabled approaches do emerge from and build upon traditional, non-data-enabled design theories and methodologies.
The capacity of digital health artefacts to change and evolve over time determines the emergence of mechanisms of mutual adaptation between the artefact and its context of application, which includes multiple kinds of stakeholders including patients and medical professionals. Such mechanisms may lead their performance to change over time and across contexts, determining a need for continuous and contextual post-adoption evaluation.
In response to this need, continuous data collection becomes necessary to inform processes other than design-related ones: in the healthcare domain, which is heavily regulated, high levels of scrutiny and rigorous independent investigations are necessary in order for artefacts to be safely and successfully used in clinical practice. A concrete example of the need for continuous and contextual post-adoption evaluation in the field of digital health can be found in a recent study regarding a widely adopted proprietary sepsis prediction model, which unexpectedly revealed concerning underperformance at a large scale (Wong et al., 2021).
In this context, a fourth kind of approach to using data for digital health design emerges, in which shared data strategies are employed both for design purposes and for other kinds of data-driven processes, such as clinical evaluation, cost evaluation, policymaking, algorithmic auditing, or more.
We refer to these approaches as convergent, in association with the concept of digital convergence as intended by Yoo et al. (2010) and of convergence as the "integration of insights and approaches from historically distinct scientific and technological disciplines" in health innovation as intended by Hockfield et al. (2016). This is because the adoption of convergent approaches to the use of data for digital health design requires a relatively high degree of collaboration and mutual understanding between both non-professional (e.g. patients and loved ones) and professional actors afferent to disparate disciplines, such as design, engineering, medicine, computer science, and others. In this regard, we find it appropriate to differentiate convergent approaches from data-enabled ones, even though convergence is only made possible by previous advances in the field of data-enabled design.
Next, we will further examine the four approaches by focusing on design decision-making as a mechanism through which the design function affects the final characteristics of digital health artefacts. This characterization draws from Simon's seminal work on decision-making (1977), reflected both in traditional software design literature (including Freeman & Wasserman, 1983, who remark that "decision-making is what design is all about"), in engineering design literature (Badke-Schaub & Gehrlicher, 2003), and in related biomedical informatics literature (Jalote-Parmar et al., 2010). In particular, we will examine the way data is collected and used for design decision-making, intended as the broad variety of data used to gain inspiration, formulate hypotheses, test assumptions, or evaluate solutions as part of digital health design processes. Particularly, we will consider the way data is collected from (parts of) the health system, and the way data is used to make design decisions about digital health artefacts. Furthermore, we will offer a real-life example of each approach.

5.2.3 Silent approaches to digital health design

We have previously mentioned that silent approaches to the use of data for digital health design are often adopted by patients, health professionals, or other individuals or groups holding a direct stake in the context of application, who do not follow a formally structured design process. In particular, a step of formal design processes that tends to be skipped - or, perhaps more precisely, to be carried out implicitly - in silent approaches to digital health design is the collection

of data for design decision-making. This is because, due to the familiarity of silent designers with the context and the design problem at hand, design decision-making can happen naturally and intuitively: in a way, necessary data is already implicitly in possession of the silent designer, and as such does not need to be explicitly collected nor formally analysed. Figure 14. provides an overview of the characteristics of the use of data of silent approaches to digital health design depicted as a flowchart diagram.

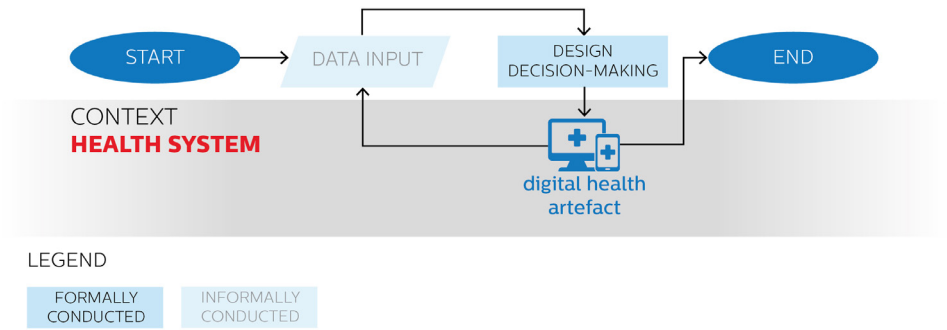


Figure 14. Use of data in silent approaches to digital health design depicted on a flowchart diagram

Example: the Do-It-Yourself Artificial Pancreas System (DIYAPS)

Dana Lewis, a person with diabetes "with no medical or technology background whatsoever" (Lewis, 2016) is a creator of the Do-It-Yourself Artificial Pancreas System, a widely adopted hybrid closed loop system to automate micro-adjustments of insulin delivery based on real-time glucose monitor data. Lewis describes the process leading up to the development of the system in detail in a dedicated blog (Lewis, 2016), from the initial frustration with existing medical devices, to the series of incremental self-experimentations and improvements eventually leading her to obtain a functioning closed-loop system, to the decision of sharing her knowledge publicly in an open-source format, enabling other patients to build their own systems. Today, thousands of individuals have reportedly implemented various kinds of DIY closed-loop solutions based on Lewis' work in their own everyday diabetes care routines (OpenAPS Outcomes, n.d.).
Lewis describes her design decision-making process to be intuitive and spontaneous: "at every stage, it was very easy to see what I wanted to do next and how to iterate, despite the fact that I am not a designer and I am not a traditional engineer"

(Lewis, 2016). It could be argued that, in her case, being a formally trained designer was simply not required, since she already possessed (through first-hand, real-life experience) the information necessary to conceptualise and define what would constitute a desirable digital health solution. Following its widespread adoption, the Do-It-Yourself Artificial Pancreas System has been evaluated in formal studies (Jennings & Hussain, 2020), reporting tangible benefits, including decreased HbA1c values and increased TIR (time in range). Currently, the system is being further developed and evaluated in the OPEN study, an initiative funded by the European Commission's Horizon 2020 Research and Innovation Program (O'Donnell et al., 2019).

5.2.4 Overt approaches to the use of data for digital health design

We have previously introduced the overt as a second approach to the use of data for digital health design, conducted by professional designers who do follow formal design processes – a relatively common occurrence in the modern health tech sector, in which the design function is increasingly professionalized. In overt approaches, design decision-making is formally conducted and informed by purposefully collected data. Figure 15 provides an overview of the characteristics of the use of data in overt approaches to digital health design depicted as a flowchart diagram.

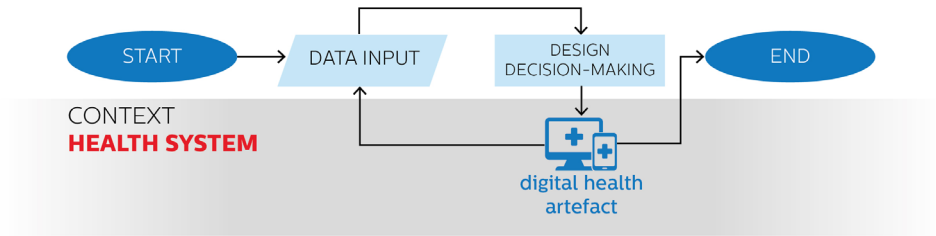


Figure 15. Use of data in overt approaches to digital health design depicted on a flowchart diagram

Example: the computerised AKI (acute kidney injury) decision support tool

Acute kidney injury (AKI), previously known as acute renal failure, is the clinical manifestation of a diverse set of disorders affecting the kidney acutely (Bellomo et al., 2012). Such clinical manifestation is particularly common among the critically ill, and it has been reported to occur in more than half of patients at some point of a critical care admission (Hoste et al., 2015). In 2016, a project was initiated as an internal collaboration between Philips Research North America and Philips Design, with the aim of improving early recognition and management of AKI in intensive care units through automated electronic alerts coupled with a clinical decision support

system (CDSS). Professionally trained designers worked on transforming this idea into an implementable service solution. As part of the design process, qualitative data was purposefully collected, through dedicated interviews and workshops, on aspects such as intensive care nurses' and clinicians' experiences and preferences with regard to clinical decision support systems. The design process resulted in a set of recommendations for the development of the service. A prototype system developed in co-creation with the clinical team at University Hospital Bristol was later tested in a prospective observational study, which reported a relation between the adoption of the system and a decrease in the proportion of patient worsening from stage 1 AKI, a decrease in the proportion of incorrect enoxaparin dosage, and a decrease in the overall prevalence of any AKI in the involved intensive care units (Bourdeaux et al., 2020).

5.2.5 Data-enabled approaches to digital health design

An opportunity enabled by the formalisation of design decision-making processes in the field of digital health is the establishment of continuous loops of redesign informed by data collected directly by the digital health artefact in the context. Data-enabled approaches seize this opportunity by purposefully designing built-in infrastructures for the continuous collection of contextual data as part of the digital health artefact itself. Figure 16 provides an overview of the characteristics of the use of data in data-enabled approaches to digital health design depicted as a flowchart diagram.

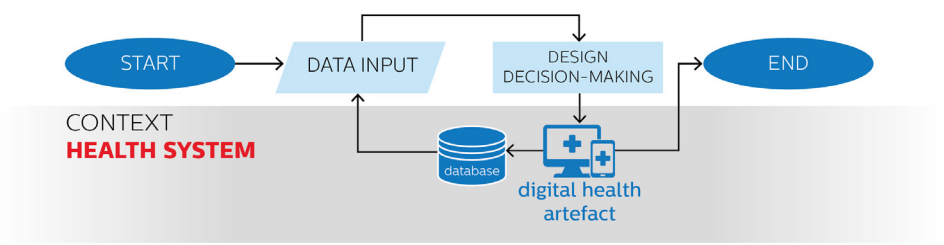


Figure 16. Use of data in data-enabled approaches to digital health design depicted on a flowchart diagram

Example: the Co-responsibility study

The Co-responsibility study is a recent research and design project following a data-enabled approach (Jansen et al., 2020). The project focuses on the design of an open system to support health behavioural change after bariatric surgery.

The system is meant to connect patients, partners, healthcare professionals, and involved researchers, and was devised to include data from different sources including medical records, self-reported data, and contextual data. Its functionalities were not pre-set, and could be modified remotely during the study itself.
The study participants themselves could reflect on the collected data and were actively engaged in the research. Through the study and its data, design-relevant use cases were found that could bring value to the system users, including ideas for new functionalities. Furthermore, the data-enabled nature of the study allowed the design team to reach a deeper, more nuanced understanding of the complex dynamics underlying the relationships between patients, their partners, their health professionals, and of how these dynamics contribute to shaping everyday life health behaviour.
The management of the collected data in the study was carefully orchestrated by a core design team, including design researchers, data designers, and service designers, who collectively shaped the system data infrastructure through the use of interactive dashboards (Lovei et al., 2020) and visual system maps (Pannunzio et al., 2020). In 2021, a concept called CoreCare, originated from the Co-responsibility study, was awarded a Red Dot Design Concept award (Red Dot Design Award: CoreCare, n.d.).

5.2.6 Convergent approaches to digital health design

The creation of infrastructures dedicated to collecting real-world data about the functioning of digital health solutions unlocks the chance to employ the continuously collected data for decision-making processes other than design-related ones, such as clinical evaluation, cost evaluation, policymaking, algorithmic auditing, or more. Convergent approaches seize this opportunity through the development of interdisciplinary data strategies devised to inform both design decision-making and other relevant data-driven processes such as clinical evaluation, cost evaluation, policymaking, algorithmic auditing, or more. Figure 17. provides a depiction of the characteristics of the use of data in convergent approaches to digital health design depicted on a flowchart diagram.

Example: the Perioperative Box

Major gastrointestinal surgeries are associated with a relatively high incidence of postoperative complications (Jakobson et al., 2014). In 2019, a multi-organization collaboration led by the Leiden University Medical Center in the Netherlands was initiated to develop and test a system for continuous remote monitoring and early diagnosis of complications following major gastrointestinal surgeries. The system, which is meant to include a machine learning algorithm generating alarms to flag patients at risk of developing complications, is a digital health artefact involving a complex set of interconnected monitoring devices, actors and interfaces.

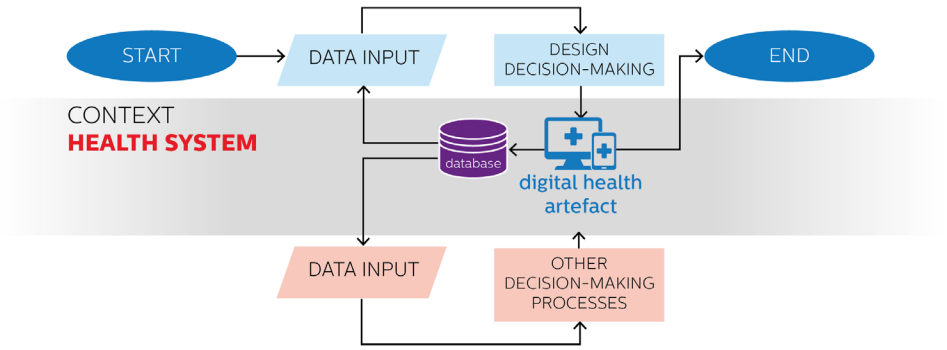


Figure 17. Use of data in convergent approaches to digital health design depicted on a flowchart diagram

Separate data collection activities have been carried out by the different actors involved in the design and evaluation of the system at different points; in addition, a research protocol for a pilot study to assess the feasibility of the intervention has been developed by an interdisciplinary team, including medical, technical and design experts. The protocol includes the collection of data necessary for the assessment of assumptions related to the design of the digital health proposition, and also the collection of data necessary for the assessment of clinically-relevant assumptions, such as the predictive value of the self-monitored data. Importantly, these two sets of data are not only collected from the same context, but also materially overlap. For instance, data on patients' compliance rates to the self-monitoring protocol (including the use of a blood pressure cuff, a smartwatch and a smart thermometer) is instrumental for reaching an understanding of the intervention's potential in terms of predictive capacity, but can also inform future redesigns of the suggested self-monitoring routine itself and of the informational material included as part of the intervention.

5.2.7 Comparing the four approaches

As demonstrated by the provided examples, each one of the described approaches can successfully result in the development of new, valuable digital health artefacts. While it is impossible at this stage to impart any value judgement on the overall merit of any approach over the other, we believe each to have unique advantages in terms of desirable characteristics of the design process.
In particular, we note how silent approaches possess, more than all others, the desirable characteristic of context embeddedness, intended as a deep understanding of the complex dynamics of the context of application of the new digital health artefact.

This is because this understanding is afforded, in the case of silent approaches, by a familiarity and understanding of the context pre-existing the design process itself. In non-silent design approaches, context embeddedness is aimed at, and often pursued explicitly through specific approaches such as context mapping (Visser et al., 2005) precisely because familiarity with the context is in these cases not a starting condition of the design process.

On the other hand, overt approaches possess the desirable characteristic of formalisation, since the professionalization of design practice confers an improved degree of accountability and communicability to the design function. The development of specialised knowledge dedicated to the disciplinary field of design undertaken across the past decades has detailed and expanded the formalisation of design practice, equipping professional designers with practical and theoretical resources to manage the design process without endangering the creativity of outputs from that process. Younger branches of design practice, such as data-enabled approaches, have more recently undertaken a process of formalisation noticeable in published literature (Bogers et al., 2016; Bogers, van Kollenburg, et al., 2016; Van Kollenburg et al., 2018; Van Kollenburg et al., 2018; Bogers, Van Kollenburg, Deckers et al., 2018; Lovei, Deckers et al., 2020; Jansen et al., 2020); while convergent approaches have only been conceptualised and applied in the past few years (Hockfield et al., 2016).

A consequence of the formalisation of design practice is the purposeful establishment of flows of information, collected through heterogeneous data sources, to support design processes. As design projects gain complexity, increase in sample sizes, and move into the digital realm, effective data management emerges as a desirable characteristic of design processes. In the most advanced examples of effective data management within design processes, such as data-enabled design projects, digital data becomes a creative material that can effectively fuel continuous loops of improvement.

Finally, as design practice becomes a continuous, data-driven process and as it expands in domains dominated by other data-driven sources of decision-making, the practical need emerges for design to interface with data-driven processes from other disciplines, most prominently through data sharing and multidisciplinary analysis. In the case of healthcare, crucial decision-making related to the adoption of new artefacts largely depends on evidence-based clinical research processes belonging to the well-established disciplinary realm of medical sciences. In these cases, data sharing becomes a desirable characteristic of design processes, at least in the measure in which the sharing of data between design and other decision-making processes facilitates successful adoption (and is, as such, beneficial for the larger innovation process).

At the same time, data-driven interdisciplinary collaboration can be instrumental in challenging, nuancing, enriching and complementing traditional clinical research methodologies, especially in areas in which these might be less effective in terms of accurately capturing and describing complex phenomena (such as heterogeneous pathophysiologies, context-dependent sociotechnical interventions, or multifarious outcome measures). Table 2. summarises and compares the unique strengths of each of the four approaches.

Table 2. Relative strengths of the four approaches to the use of data for digital health design on four desirable characteristics of the design process

	Silent approaches	Overt approaches	Data-enabled approaches	Convergent approaches
Context embeddedness	++	+	+	+
Formalisation	n/a	++	+	?
Data management	n/a	n/a	++	+
Data sharing	n/a	n/a	n/a	++

What can be noticed from this comparison is that each approach unlocks the possibility for the next one; for instance, without some level of formalisation in the design process, it would be impossible to conceptualise a systematic use of data for design purposes, and so on for each step. At the same time, it can be noticed that each novel approach constitutes an incremental improvement from the point of view of a specific desirable characteristic of the design process, but also that this improvement tends to come at the cost of reduced control on antecedent desirable characteristics. In this perspective, the four approaches might be described as a reflection of the growing sophistication of design as a field. While silent design might perfectly meet the needs of the single user or small group of users involved in the process, it may lack the wider stakeholder engagement that overt approaches support.
In turn, data-enabled approaches expand the multiple stakeholders perspective with contextual data accumulated as part of the design process, while convergent approaches allow for data-driven learning across and between different fields and perspectives.

These changes correspond to an evolution of the role of the professional designer, as a figure who draws from an increasingly wide range of data and perspectives to design generally better digital health interventions - which may then not be perfect for any one individual.

An open question remains on the possibility of successfully formalising convergent approaches. In this case, a core issue resides in the points of conflict between design-driven data management practices and data management practices adopted in other disciplines, particularly the ones afferent to clinical research. For instance, while an exploratory approach to data collection is adopted in data-enabled design (in which data is collected and later creatively analysed), clinical guidelines for data collection are based on apriori estimations of usefulness, which need to be formulated in advance (Noortman et al., 2022).
Furthermore, the need for integrating data created as part of the research project and data created as part of the normal care provided to patients might require the construction of complex, customised datasets and data infrastructures (Nepal et al., 2013).
As a result of these conflicts, methodological compromises become necessary in order for the joint data collection effort to proceed. The resolution of these interdisciplinary methodological conflicts appears to be crucial for the future of the digital health design field, in a context of increasing data-drivenness and need for continuous post-adoption evolution and re-evaluation of digital health systems, particularly the 'smart' ones. As such, we indicate the formalisation of convergent approaches to digital health design as a research challenge of crucial interest for the field.

5.2.8 The four approaches: system-level relevance

The description and comparison between the four approaches to the use of data for digital health design so far has dealt with differences in their internal decision-making processes. However, a different level of analysis can be proposed, focusing on the prevalence of any of these approaches in the overall health innovation landscape at any given point and on the possible effects of this prevalence on ongoing, system-level transitions.
Currently, this landscape appears to be in a state of flux. Silent approaches appear to be in relative decline, due to the professionalization of design activities and to the growing recognition of the importance of the design perspective in the (digital) health innovation arena (Tsekleves & Cooper, 2017). Conversely, overt approaches appear to be in a phase of relative maturity (Chamberlain & Craig, 2017), while data-enabled approaches keep on developing (Bogers, Frens et al., 2016; Bogers, Van Kollenburg et al., 2016; Van Kollenburg et al., 2018; Bogers, Van Kollenburg, Rutjes et al., 2018; Bogers, Van Kollenburg, Deckers et al., 2018; Lovei, Deckers et al., 2020; Jansen et al., 2020) and convergent approaches appear to be just emerging (see e.g. Hockfield et al., 2016; Alwashmi et al., 2019, Pannunzio et al., 2019).

Predicting the impact of these changes at the level of the health system at large appears impossible; however, we expect that different 'patterns of transformation' (Consoli & Mina, 2009) might emerge from the large-scale diffusion of one approach over the other, although the nature of such patterns appears arduous to predict at this stage.

Nonetheless, we must note that a common system-level dynamic of digital health innovation processes is a tendency to generate new problems in the way of solving others. Digital health innovation, especially, is not only prone to the emergence of unintended consequences typical of the field of health information technology (Wachter, 2017; Ash et al., 2004), but also to the paradoxical effects typical of automation efforts at large (Bainbridge, 1983; Strauch, 2018). While we cannot at this stage suggest any of the four approaches to digital health design to be preferable from this point of view, we can note that convergent approaches can in principle enable innovators to conduct iterative cycles of exploration and detection of possible unintended consequences through longitudinal, holistic system monitoring.

More at large, the diffusion of convergent approaches appears to be coherent with the ambition of the long-term vision of a learning health care system (Institute of Medicine US, 2011), at least in the measure in which it would facilitate the capturing of new, interdisciplinary knowledge 'as an integral by-product of the delivery experience' (Institute of Medicine US, 2013). Indeed, the challenge of convergent approaches lies in the development of effective healthcare data systems, able to continuously inform health actors from multiple disciplines using a wealth of heterogeneous, real-life data from the health system itself; this is, on a larger scale, the challenge of learning health systems (Budrionis & Bellika, 2016). In these terms, an opportunity exist for digital health design projects adopting a convergent approach to the use of data to constitute a small-scale, local testing ground for the larger-scale transition towards learning health systems. In the same perspective, we see an opportunity for future convergent methodologies to align with and provide input for the evolving regulatory framework in the field of digital health.

Next to these system-level considerations, we believe the distinction between the four approaches to the use of data for digital health design proposed in this paper to be of interest for practitioners in the field. In these terms, we intend this contribution to provide a first broad differentiation and characterization of the approaches available to digital health designers and design managers in terms of data management, decision-making processes, and their implications. In particular, we hypothesise that the conceptualization of convergent approaches may constitute a step towards the identification of effective design and adoption practices to overcome the current widespread difficulty in translating digital health innovation efforts into sustained real-world value, particularly in the healthcare AI domain (Panch et al., 2019). This hypothesis is characterised as an opportunity for further research.

INTERMISSION

Photo by DCStudio on Freepik

Towards formalising convergent approaches

In the previous chapter, which focused on the description of four approaches to the use of data in digital health design, a need was identified for further formalisation of convergent approaches in particular. This direction constitutes the focus of the second part of the doctoral research, which explores how to interface design data collection processes and evidence-based, clinical research processes.

This topic was explored through participation in the Perioperative Box, a project briefly introduced in the previous chapter. This project, conducted in partnership with the Leiden University Medical Center (LUMC) and Philips, revolved around the development and testing of a Remote Patient Monitoring (RPM) intervention for perioperative monitoring of patients undergoing major abdominal surgery. In this project, I mainly collaborated on service design tasks and on the definition of a monocenter investigational study on the Perioperative Box proposition. The study design consisted of two parts: part I, an observational study, and part II, an implementation study.

More specifically, I executed a workshop with an interdisciplinary set of project stakeholders to collectively discuss patient and staff experience metrics to include in the study protocol. The experience measures generated through the workshop were first clustered by content and de-duplicated. Following, two kinds of analysis were performed:

- Logical, in which measures of experience were organized in terms of their role in the causal chain determining the performance of the intervention as a whole.
- Chronological, in which measures of experience were organized in terms of their sequential order in patients' and staff's journey.

As a result of the workshop and analyses, detailed recommendations on patient and staff experience were provided in terms of intervention design and of pre-trial, in-trial, and post-trial research. A report illustrating the setup of the workshop, the analyses, and the list of recommendations is provided in Appendix II.

The Perioperative Box monocenter study was, in the end, not executed for reasons unrelated to my involvement. However, the collaborative definition of the study protocol led to new insights on ways to interface design data collection processes and clinical research processes.

First, the centrality of patient and staff experience data collection for design decision-making purposes, already noted in Chapter 2, was confirmed. Identifying design-relevant data with data on patient and staff experience allowed for increased interdisciplinary understanding, as it made it possible for non-design stakeholders to have a clear idea of the objective of design data collection, of its relevance for feasibility assessment purposes, and of its distinction from other forms of evaluation such as assessment of clinical effectiveness.

Furthermore, the activities connected to the Perioperative Box project led to the identification of two research gaps, each addressed through a new review study. The first research gap was represented by a lack of available information on the impact of RPM proposition on the workflow of perioperative staff. This gap is addressed through a scoping review in Chapter 6.
The second research gap was represented by the lack of a comprehensive overview of existing patient and staff experience measures available for use in RPM contexts at large. This gap was addressed in Chapter 7, which describes a systematic review on both patient and staff experience measures for RPM evaluation.

Focus on Remote Patient Monitoring

In addition to the shift in focus on convergent approaches, the second part of the dissertation sees a shift in focus from digital health at large to the sub-field of RPM.

RPM can be defined as a subset of digital health applications that aims at improving patient care through digitally transmitted, health-related patient data (Farias et al., 2020), usually collected through sensors used in the home environment.

The projects touched on in the first half of the dissertation, namely the Quantified Heart and the Co-responsibility study, are both related to the RPM domain; however, from this point on the focus on RPM becomes both explicit and exclusive.

The RPM domain is, in fact, a unique one in which to investigate patient and staff experience factors in addition to data flows. It is a unique domain in which to investigate patient and staff experience because the shift from in-person to remote care introduces radically novel circumstances for both patients and staff. This makes RPM particularly interesting from a design perspective, as understanding and optimizing user experience constitutes a central concern of design disciplines (see e.g. Desmet & Hekkert, 2007; and Secomandi and Snelders, 2013). On the other hand, RPM is a unique domain in which to investigate data flows because RPM is by its own nature centred around digital data collection. While the core collected data is usually health-relevant (e.g. vital signs, biomarkers, medication intake), the establishment of a digital interface between patients in their own environment and healthcare systems allows for the collection of other forms of digital data, including experiential, technical, and administrative data.

The uniqueness of the RPM domain is further elaborated upon in Chapters 6 and 7.

CHAPTER 6

THE IMPACT OF PERIOPERATIVE REMOTE PATIENT MONITORING ON CLINICAL STAFF WORKFLOWS

Photo by Jonathan Borba on Unsplash

"While someday the computerization of medicine will surely be that long-awaited "disruptive innovation," today it's often just plain disruptive: of the doctor-patient relationship, of clinicians' professional interactions and work flow, and of the way we measure and try to improve things"

Wachter, 2017

6.1. Contribution background

The previous Intermission has touched on a research gap represented by a lack of available information on experience factors for staff adopting Remote Patient Monitoring (RPM) propositions.

This chapter addresses this research gap through a scoping review performed in collaboration with Maria Alejandra Leon, a TU Delft master student who conducted a graduation research project on the Perioperative Box.

In this review, existing literature on the impact of RPM on staff workflows in perioperative care is collected and used to distil insights in the following categories: problems and challenges, benefits, risk-reduction strategies, and methods to measure and quantify the impact of RPM interventions on clinical staff.

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6.2. Contribution

The Impact of Perioperative Remote Patient Monitoring on Clinical Staff Workflows: Scoping Review

Abstract

Background Remote patient monitoring (RPM) interventions are being increasingly implemented in health care environments, given their benefits for different stakeholders. However, the effects of these interventions on the workflow of clinical staff are not always considered in RPM research and practice.
Objective This review explored how contemporary RPM interventions affect clinical staff and their workflows in perioperative settings.
Methods We conducted a scoping review of recent articles reporting the impact of RPM interventions implemented in perioperative settings on clinical staff and their workflow. The databases accessed were Embase and PubMed. A qualitative analysis was performed to identify the main problems and advantages that RPM brings to staff, in addition to the approaches taken to evaluate the impact of those interventions. Different themes were identified in terms of the challenges of RPM for clinical staff as well as in terms of benefits, risk-reduction strategies, and methods for measuring the impact of these interventions on the workflow of clinical staff.
Results A total of 1063 papers were found during the initial search, of which 21 (1.98%) met the inclusion criteria. Of the 21 included papers, 15 (71%) focused on evaluating new RPM systems, 4 (19%) focused on existing systems, and 2 (10%) were reviews.
Conclusions The reviewed literature shows that the impact on staff work experience is a crucial factor to consider when developing and implementing RPM interventions in perioperative settings. However, we noticed both underdevelopment and lack of standardisation in the methods for assessing the impact of these interventions on clinical staff and their workflow. On the basis of the reviewed literature, we recommend the development of more robust methods for evaluating the impact of RPM interventions on staff experience in perioperative care; the adoption of a stronger focus on transition management when introducing these interventions in clinical practice; and the inclusion of longer periods of assessment, including the evaluation of long-term goals.

6.2.1 Introduction

6.2.1.1 Background

Remote patient monitoring (RPM) interventions allow patients to be continuously monitored at a distance and beyond the physical borders of the hospital or health care institution (Farias et al., 2020). RPM interventions have been used to monitor patients within clinical settings (eg, in intensive care environments) or outside of care facilities (eg, in the patients' homes). Moreover, RPM has been used for delivering care for multiple health conditions, from heart failure (Seto, 2008) to diabetes (Koopman et al., 2014) and skin problems (van Os-Medendorp et al., 2012). RPM interventions can provide 24-hour care as they can collect data continuously and alert specialists when certain parameters are outside the standard thresholds (Ricci et al., 2008). This can enable real-time adjustments, timely decisions, and improved care. RPM as a field has also enjoyed an unprecedented acceleration as a consequence of the COVID-19 pandemic, which has stimulated the adoption of remote care to minimise face-to-face interactions between patients and staff (Bokolo Anthony Jnr., 2020). In the perioperative setting, RPM can be useful for assessing physical conditions preoperatively or monitoring patients' recovery after discharge. Although RPM applications in this domain are still relatively novel, encouraging results are driving an increased interest from researchers and practitioners.

An example of the application of RPM technologies to perioperative care was offered by (Atilgan et al., 2021), who evaluated a system comprising monitoring devices collecting several vital signs (including blood pressure, heart rate, oxygen saturation, body temperature, blood glucose, and electrocardiography) and a mobile app providing medication reminders, suggested daily life activities, diet and nutrition plans, and web-based visit capabilities. Vital parameters were measured in patients who had undergone cardiac surgery after discharge and automatically transferred to a telemedicine team for assessment. Overall, the authors reported the RPM intervention to have resulted in high patient satisfaction, prevention of incorrect medications and dosages, prevention of rehospitalization, and early detection of potentially life-threatening complications.

Much of the available research on RPM interventions in the perioperative domain focuses on the effects of RPM on patients (Belarmino et al., 2019; Dirnberger & Waisbren, 2020; Symer et al., 2017; van der Meij et al., 2018) and describes its advantages, especially in terms of clinical outcomes and efficiency gains (Baniasadi et al., 2020; Mehta et al., 2020; Shah et al., 2021). Some studies have also addressed the benefits for health care providers, such as hospitals, nursing homes, and other entities. These studies tend to focus on the economic benefits for providers, for instance through reductions in hospitalizations and thus, in the use of resources (Viers et al., 2015; Forbes et al., 2018). However, there is limited knowledge of the benefits and limitations of RPM for clinical staff.

6.2.1.2 Objectives

This research seeks to evaluate the impact of RPM interventions on the workflow of clinical staff in the context of perioperative care. To explain what we mean by workflow, we follow Carayon et al. (2011), who defined workflow as "the flow of people, equipment, information, and tasks, in different places, at different levels, at different timescales continuously and discontinuously, that are used or required to support the goals of the work domain." This means that we aimed to evaluate the impact of RPM-related tasks in combination with previously existing activities. In this paper, the words clinical staff will be used when referring to both nurses and specialists. To investigate the impact of RPM on the workflow of clinical staff, a human factor perspective was adopted in this review. As mentioned by Hignett et al. (2015), human factors help in understanding the interactions between humans and the elements of a system to optimize its performance and human well-being. This scoping review sought to answer the following overall research question: What is the impact of perioperative RPM interventions on the workflow of clinical staff?

To answer this main question, we developed the following subresearch questions:

1. What are the problems and challenges of perioperative RPM interventions for clinical staff from a workflow perspective?
2. What are the benefits of perioperative RPM interventions for clinical staff from a workflow perspective?
3. What strategies are implemented or proposed to overcome the problems that perioperative RPM interventions present to the workflow of clinical staff?
4. How is the impact of perioperative RPM interventions on the workflow of clinical staff evaluated and measured?

6.2.2. Methods

Overview

This scoping review followed the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist (Tricco et al., 2018). As the review focuses on collecting and comparing workflow-related insights from recent RPM literature rather than on drawing conclusions on specific outcomes, the risk of bias in the results of the included studies was not assessed. Conversely, the risk of bias in the synthesis of the literature review findings was considered. Specifically, the risk of bias owing to missing results was assessed by MAL and VP through the framework for assessing the risk of bias owing to missing results in a synthesis offered in the Cochrane Handbook for Systematic Reviews of Interventions (Page et al., 2019). The results of this assessment are discussed in the Limitations section.

Selection Criteria and Search Strategy

The databases used were PubMed and Embase. To define the inclusion criteria, key concepts were selected. For each of them, keywords were defined to guide the search strategy (Textbox 1). For the keywords of each concept, the logical operator OR was included to consider all the possibilities, whereas the logical operator AND was used between concepts. The full queries in both databases are presented in Appendix III. Finally, the search included articles that were written in English between January 2015 and March 2021. This was chosen to obtain a picture of contemporary RPM interventions as this review focuses on current challenges and opportunities. The search was conducted during the last week of March 2021.
The articles resulting from this search were screened based on the following inclusion criteria: (1) the inclusion of RPM interventions for perioperative care and (2) the mention of the impact on the workflow of clinical staff. The criteria were used for 2 iterations of screening: the first was based on the title and abstract of the articles, and the second was based on the full text.

Textbox 1. Concepts included in the literature search.

A keyword can have some variations (plural or singular form or simple or continuous verb form). An asterisk (*) is used for the search algorithm in the database to find all possible variations of a certain word.

- Remote patient monitoring: remote monitor*; telemedicine; telemonitoring; telehealth, remote follow-up; eHealth; remote consultation; remote sensing technology; self-monitor*
- Workflow: workflow; outcome and process assessment, health care; task performance and analysis; workflow; staffing; attitude of health personnel; alarm fatigue*; alert fatigue; professional burnout, workload; patient care management; nursing process*; clinical competence; caregiver burden; time and motion studies; work simplification; practice patterns, nurses; nursing audit
- Perioperative care: surgical procedures, operative; general surgery; perioperative; surgery; post-operative; post-discharge

Review Process and Analysis

Our main categories were established (Textbox 2) to analyze the studies, namely challenges and problems, benefits, risk-reduction strategies, and evaluation methods. These were based on the main goals of this research and the research questions.

Textbox 2. Categories used for data extraction

- Problems and challenges of remote patient monitoring (RPM) interventions for clinical staff: includes the problems shown regarding RPM interventions for clinical staff.
- Benefits of RPM interventions for clinical staff: includes the benefits concerning RPM interventions for clinical staff.
- Risk-reduction strategies regarding RPM interventions for clinical staff: includes solutions tested to tackle some of the problems brought by the introduction of RPM interventions and some of the proposals suggested.
- Methods to measure and quantify the impact of RPM interventions on clinical staff: includes the methods used to determine the impact of RPM interventions on clinical staff's tasks and workflow. It entails the variables and measures collected and analyzed.

The articles were reviewed by MAL, who was also responsible for data extraction. Subsequently, the first step of the analysis was performed by classifying the results into the chosen categories. The second step consisted of creating different themes per category. This step required several iterations to obtain the final set of themes.

6.2.3 Results

Overview

A total of 1063 articles were identified after searching both databases, of which 1007 (94.73%) were left after deduplication. Of these 1007 articles, 137 (13.6%) fulfilled the first round of selection, and 21 (2.09%) passed the final round of selection (Figure 18).
In general, the articles included in this review were experimental or observational studies. Of the 21 articles, 15 (71%) involved the evaluation of a design intervention (an RPM model, tool, or service), 4 (19%) consisted of an analysis of already implemented interventions, and the remaining 2 (10%) were reviews. The references and articles analyzed in these 2 reviews did not include any of the other selected articles in this scoping review.
The studies focused on a wide range of patient cohorts and surgical specialties, including orthopedic, bariatric, and oncological surgery. Most of these studies (20/21, 95%) focused on adult patients (aged >18 years). The described RPM interventions ranged from 1 to 45 months of duration.
In addition, the articles presented different types of RPM interventions, ranging from e-tools used only by the clinical staff to services and models that incorporated devices and platforms for both patients and specialists.

Moreover, most of the interventions contemplated nursing staff as the main actors responsible for remote care and included physicians for specific tasks or just in case a more detailed and in-depth analysis of the patient's data was needed.
Not all the included studies contained information on all the categories established. For example, the included reviews hardly mentioned the methodologies used to assess the impact of different RPM interventions on the workflow of the clinical staff.

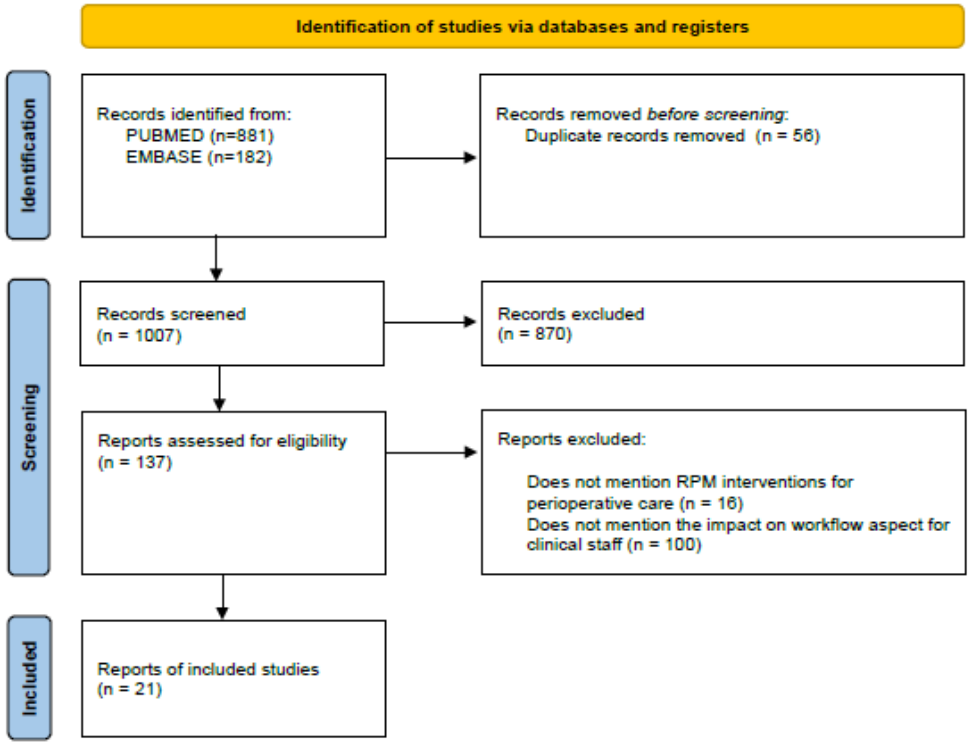


Figure 18. Flowchart of the scoping review process and the inclusion and exclusion criteria. RPM: remote patient monitoring.

Once the data were extracted from the articles, they were classified into the 4 categories. To better understand each category, different themes were defined (Figure 19) based on the similarity of the topics addressed in each of the articles. Figure 19 presents an overview of this classification, where each category is labeled with a different color. By means of a gradient in the color's intensity, it is possible to show the quantity of papers that touch on each of the proposed themes. In this case, more saturated colors represent more papers mentioning information relevant to a specific theme. The results for each category are discussed in detail in the following sections.

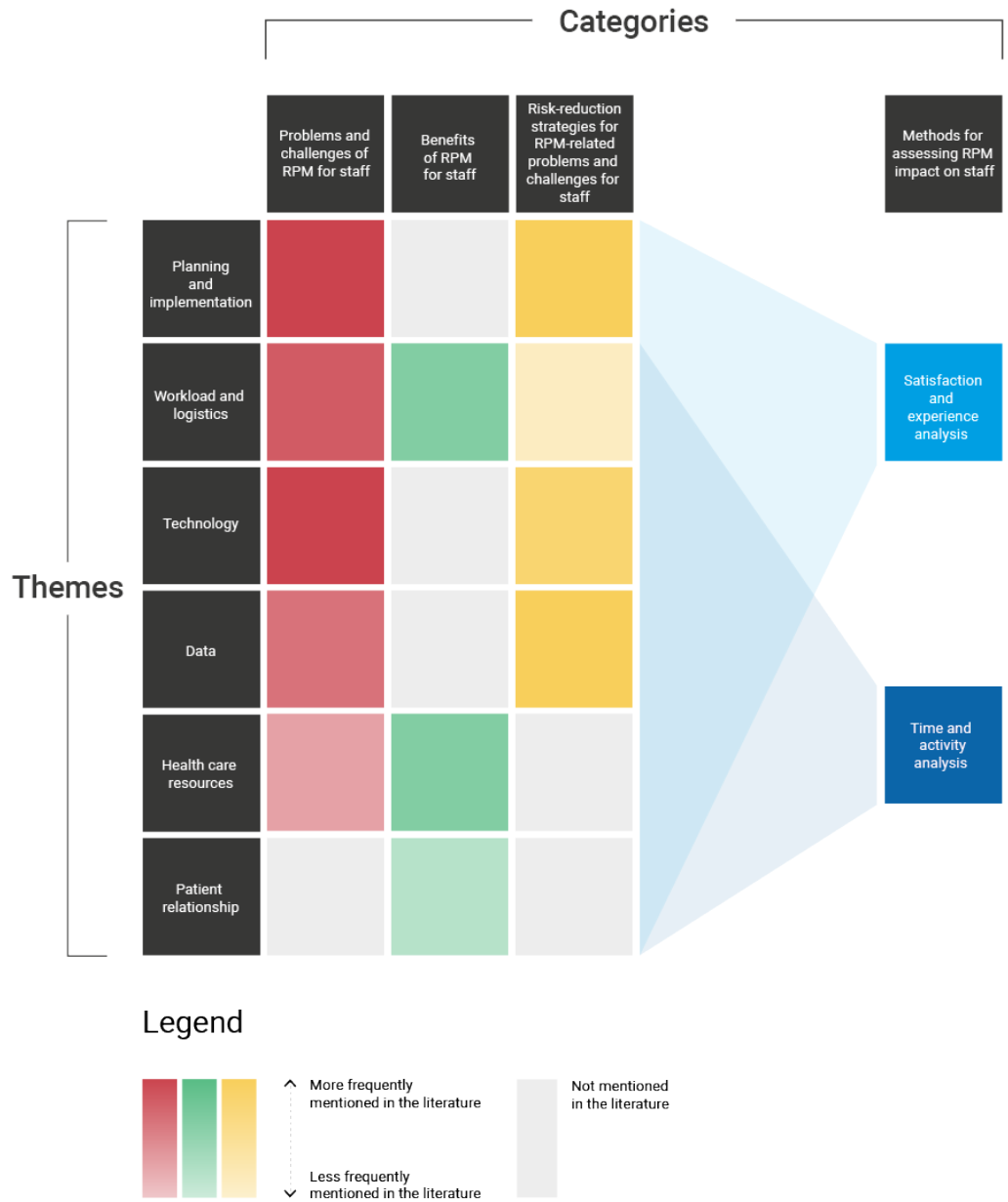


Figure 19. Heat map of the review results organized by categories (each corresponding to a research question) and themes (recurring topics touched on in the included studies). RPM: remote patient monitoring.

Category 1: Problems and Challenges of RPM for Clinical Staff

On the basis of the articles analyzed, 5 main themes regarding RPM challenges from the viewpoint of clinical staff were identified (Table 3).

The first theme was planning and implementation. Planning is a complex task in health care given the diversity of the stakeholders involved and their needs. RPM projects do not always involve or consider the complex context in which these interventions have to be implemented. This often leads to ambiguity in tasks and roles and, thus, to lack of clarity and structure in the workflow of the clinical staff.

The second theme was workload and logistics. Some staff members do not feel comfortable with the new behind-the-desk activities, which can result in unpredictable and emergent tasks when RPM systems register values outside the thresholds. Moreover, data analysis may require more than one specialist, making the workflow more complex. In addition, RPM is perceived as bringing more work, which adds to the existing schedule.

The third theme was technology. Systems might not be user-friendly, and different technical malfunctions may arise, which may require extra expertise from clinical staff.

The fourth theme was data, which can produce more informed decisions but also increase time and be burdensome to analyze. Moreover, it can be hard to keep all the data under 1 platform, so the staff may need to analyze multiple fragments of information to provide remote care.

The last theme was health care resources, intended as the new resources that RPM interventions require. Moreover, the aforementioned ambiguity in tasks determines a lack of clarity regarding reimbursement policies.

A detailed overview of the reported challenges for each category is provided in Table 3.

Table 3. Overview of problems and challenges of remote patient monitoring (RPM) interventions for clinical staff.

Theme	Description	Studies
Planning & Implementation	Lack of prior user testing	Harsha et al. 2019
	Lack of planning/inadequate planning • Lack of contemplation of changes in workflow (tasks/competences/ responsibilities/roles) • Emergence of uncontemplated tasks • No standardization in practices/no clear guidelines • Non-compatibility with current practices • No clear definition of time for tasks • No long-term care coordination • Services are implemented before all the resources are available/prepared	Das et al. 2015, Davoody & Hägglund, 2016, Harsha et al. 2019, Ke et al. 2019, Leppla et al. 2020, Sanger et al. 2016, Timmerman et al. 2017, Wiadji et al. 2021
	Lack of resource analysis ("readiness level") • No clear overview of required skills • No consideration of staff experience • No clarity on the resource accessibility (whether clinical staff is adequately equipped)	Ke et al. 2019, Parkes et al. 2019, Rothgangel et al. 2020, Wiadji et al. 2021
	Lack of multidisciplinary awareness • Uncontemplated users, non-users & other actors impacted	Harsha et al. 2019, Leppla et al. 2020, Makhni et al. 2020, Parkes et al. 2019, Wiadji et al. 2021

Planning & Implementation	• Limited or poor communication and coordination among users • Poor task planning (tasks overlapping, no consideration for the need of staff to attend one patient at a time) • Disregards for the specificities of different specialties and wards (cardiovascular, pediatric…)	
	Lack of compliance and engagement • Lack of involvement of stakeholders in planning • Fear of conflict of interest • Lack of promotion and motivation among staff • Decrease of use of systems over time • Resistance to change • (Specialists, rural hospitals…) feeling threatened to be replaced	Downey et al. 2018, Harsha et al. 2019, McMullen et al. 2018, Parkes et al. 2019, Rothgangel et al. 2020, Sharif et al. 2020, Timmerman et al. 2017, Wiadji et al. 2021
Workload & logistics	High workload • New tasks as an addition and not replacement • Telehealth tasks are perceived to be labor intensive (“More administrative work in arranging telehealth than meets the eyes”) • Tracking patients takes too much time (due to subtasks like setting up appointments, billing, mailing, analyzing, reviewing transmissions, documenting in the EMRa, and physician contact) • Online patients are not considered as part of “normal flow” (ignored for workload calculation)	Brophy, 2017, Das et al. 2015, Dunphy et al. 2017, Harsha et al. 2019, Ke et al. 2019, Leppla et al. 2020, Makhni et al. 2020, McMullen et al. 2018, Parkes et al. 2019, Sharif et al. 2020, Wiadji et al. 2021
Workload & logistics	• Potentially adding an unnecessary step when patient attention is needed (immediate patient check by GP instead of data follow-up by nurse) • Documentation is burdensome	
	Disruption in workflow • Unpredictable, emergent tasks • High memory load • Mistakes on interrupted activities • Unanswered/Unplanned calls	Das et al. 2015, Downey et al. 2018, Harsha et al. 2019, Sanger et al. 2016
	Non-urgent tasks emerge outside working hours	Ke et al. 2019
	Need of trustworthy professionals for data analysis • Nurses sometimes need to consult with physician	Leppla et al. 2020
	Fear of infringing on other providers’ patient care	Brophy, 2017
	Stress due to pressure for timely responses of multiple issues	Das et al. 2015, McMullen et al. 2018, Parkes et al. 2019
Technology	Difficulties in use of e-tools • Not user friendly • No experience/training	Brophy, 2017, Das et al. 2015, Davoody & Hägglund 2016, Parkes et al. 2019, Rothgangel et al. 2020, Sousa et al. 2016, Timmerman et al. 2017
	Technical problems • Troubleshooting/Malfunctions • Connection issues (congestion, no signal, delays) • Not compatible with current software	Augestad et al. 2020, Brophy, 2017, Harsha et al. 2019, Makhni et al. 2020, Timmerman et al. 2017

Technology	Deficient communication • Inappropriate means of communication • Hard to establish "personal connection" for communicating bad news or managing conflict with patients • New medical-legal situations (patients might misunderstand information, take it out of context) • RPM interventions might not be suitable to all the patients	Augestad et al. 2020, Dunphy et al. 2017, Ke et al. 2019, Leppla et al. 2020, Makhni et al. 2020, Parkes et al. 2019, Wiadji et al. 2021
	RPM does not offer monitoring to the same extent as in-hospital • No physical examination • Can't assess if patient does self-monitoring and prescribed activities correctly	Dunphy et al. 2017, Ke et al. 2019
Data	False/insignificant alarms or overreaction • Stress by constant sound • Turning devices off/not using them	Downey et al. 2018, Harsha et al. 2019, Richards et al. 2020
	Unclear data/meaning: • Require extensive analysis • Overabundance of data • No flag data • Missing connection among data	Das et al. 2015, Leppla et al. 2020, Sharif et al. 2020
	No clear "holistic" impression of patients • Lack of data integration with electronic medical record (EMR) and other existing platforms • Not all the reports generated by the system are consulted by physicians	Das et al. 2015, Semple et al. 2019, Sharif et al. 2020, Timmerman et al. 2017

Data	Low reliability of patient's monitoring • Incomplete data • Incorrect measurements	Leppla et al. 2020, Sharif et al. 2020
	Legal issues (privacy, firewall, licenses)	Brophy, 2017, Das et al. 2015, Ke et al. 2019, Makhni et al. 2020, Semple et al. 2019
Healthcare resources	Lack of funding • Higher costs than budget • Non-sustainable billing rates • No clinic income established • Higher payment for in-visits	Das et al. 2015, Brophy, 2017, Harsha et al. 2019, Makhni et al. 2020, Wiadji et al. 2021
	Demand new/more resources	Das et al. 2015, Makhni et al. 2020
	Difficult to quantify quality and effort	Wiadji et al. 2021
	Unclear compensation/ reimbursement policies • Telehealth can take up the same amount of time for significantly less remuneration	Brophy, 2017, Ke et al. 2019, Semple et al. 2019

Category 2: Benefits of RPM for Clinical Staff

For the benefits category, 3 main themes were identified as relevant (Table 4).

The first theme was the improvement that RPM brings regarding workload and logistics as it allows for the definition of guidelines for more consistent care pathways. This also includes improvements in data management and analysis, which produces timely detection and treatment of conditions.

The second theme was health care resources, which can be operated more effectively with the reduction of in-hospital visits and stays and the possibility of extending coverage of care.

Finally, patient relationship can be improved by increasing satisfaction and convenience of care.

Table 4. Overview of benefits of remote patient monitoring interventions for clinical staff.

Theme	Description	Studies
Workload & logistics	Care pathways are standardized • More systematic and consistent activities	Brophy, 2017, McMullen et al. 2018
	Reducing the incidence of duplicate documentation	Jansson et al. 2019
	Promote collaboration among healthcare specialists • New and appropriate means to hold clinical meetings • Patient's information can be made accessible to the caregivers involved	Sharif et al. 2020, Wiadji et al. 2021
	Reduce time to a clinical decision • Shortens face-to-face consultation time • Patients are better prepared to the appointment	Ke et al. 2019, Sharif et al. 2020
	Improve sense-making of data • Include more sources for analyzing patient's clinical condition (current state, feedback, patient's experience and feeling) • Reassuring system based on predefined algorithms for clinical support and suggestions • Increased detection of events • Real-time monitoring of symptoms over a prolonged period of time	Jansson et al. 2019, Ke et al. 2019, Leppla et al. 2020, Makhni et al. 2020, McMullen et al. 2018, Parkes et al. 2019, Richards et al. 2020, Sharif et al. 2020, Timmerman et al. 2017
Healthcare resources	Reduce manpower	Leppla et al. 2020, Parkes et al. 2019
	Can reduce costs • Prevents unnecessary visits & healthcare utilization • Reduce tests and investigations	Augestad et al. 2020, Makhni et al. 2020, Parkes et al. 2019, Sharif et al. 2020
	Increase accessibility • More patients can be attended • More hospitals (e.g., rural/remote) can track patients • Customizable service (awareness of unique individual challenges)	Augestad et al. 2020, Brophy, 2017, Das et al. 2015, Davoody & Hägglund 2016, McMullen et al. 2018, Timmerman et al. 2017
	Allow a new form of triage for better assessment of patients & resource allocation	Sharif et al. 2020, Wiadji et al. 2021
Patient relationship	Increase patient satisfaction & convenience	Augestad et al. 2020, Dunphy et al. 2017, Parkes et al. 2019, Sharif et al. 2020
	Increase awareness of patient's daily life	Das et al. 2015, Davoody & Hägglund 2016

Category 3: Risk-Reduction Strategies Regarding RPM for Clinical Staff

This category is about strategies to overcome and minimize the challenges that RPM interventions bring about to clinical staff (Table 5). For ease of reference, we refer to risk-reduction strategies related to the introduction of RPM interventions as strategies. First, we listed strategies regarding planning and implementation of RPM interventions. Most of the included studies (14/21, 67%) mentioned the value of involving the relevant stakeholders in these processes to understand their needs and the repercussions of the introduction of the RPM intervention on their workflow. Stakeholders'involvement and participatory approaches were also deemed useful to assess the resources necessary for RPM interventions, the possible risks associated with them, and the need for possible changes to the implementation plans.

Finally, training and establishment of protocols (regarding activities, communication, time, and resources) help in risk reduction during implementation and increase the chances of success and adoption.
Second, we listed strategies regarding workload and logistics. Several included studies (8/21, 38%) suggested the creation of new roles for nurses and teams for the remote care of patients, where specialists would be consulted only in special cases. Some strategies to avoid an increase in workload for nursing staff included facilitating collaboration between actors and helping them plan their tasks.
The third theme was technology, which should be user-friendly, interoperable with existing devices and systems, and allow for automatic data collection.
Finally, we identified the theme of data. To avoid the analysis of RPM data being burdensome for staff, smart systems based on customizable alerts were proposed to prevent resource overuse and the incidence of false alarms. These should include measurements from different devices or sources and be presented to the relevant staff in an actionable and understandable way to avoid extra time and burden.

Table 5. Overview of risk-reduction strategies regarding remote patient monitoring (RPM) interventions for clinical staff.

Theme	Description	Studies
Planning & implementation	Develop an integrated governance structure • Involve all actors concerned with patient management (co-design, participatory practices) • Set clear objectives, success metrics & methods to measure them	Das et al. 2015, Harsha et al. 2019, Ke et al. 2019, Leppla et al. 2020, McMullen et al. 2018, Parkes et al. 2019, Sanger et al. 2016, Semple et al. 2019, Timmerman et al. 2017
	Determine healthcare resources utilization, in terms of: • Clinical staff and skills • Tasks and their timing (to avoid invisible/additional work, time, roles/teams, alert response) • Awareness of the multidisciplinary environment • Plan for problem-solving and changes needed • Time for solving technical/ general problems • Devices and structure	Brophy, 2017, Das et al. 2015, Ke et al. 2019, Leppla et al. 2020, Parkes et al. 2019, Richards et al. 2020, Timmerman et al. 2017, Wiadji et al. 2021
	Define practice standards, policies & best practices, in terms of: • Workflow • Documentation • Communication pathways • Measurements • Types of data collected • Impact on the clinical staff's wellbeing (clinical staff's attitudes, performance, overall service satisfaction)	Augestad et al. 2020, Das et al. 2015, Harsha et al. 2019, Jansson et al. 2019, Ke et al. 2019, Leppla et al. 2020, Sanger et al. 2016, Semple et al. 2019, Timmerman et al. 2017, Wiadji et al. 2021
	Risk assessment • Perform adequate device testing • Contemplate technical/ general problems (extra time)	Brophy, 2017, Das et al. 2015, Leppla et al. 2020, Richards et al. 2020, Timmerman et al. 2017
	Consider current state and context • Plan according to resources, program, location, dynamics (within the hospital and among clinical staff), schedules (consider "less busy" and "very busy" times) • Customize interventions for integration with existing clinical dynamics and tools.	Brophy, 2017, Das et al. 2015, Davoody & Hägglund 2016, Jansson et al. 2019, McMullen et al. 2018, Richards et al. 2020, Sousa et al. 2016
	Definition of reimbursement policies • Automatically tracking time for standardization • Consider financial or non-financial options (awards, acknowledgments) • Automatically measure time to determine billing •Include billing functionalities in the intervention	Das et al. 2015, Wiadji et al. 2021

Planning & implementation	Training staff on tools and protocols • Promote enthusiasm/value/ importance among medical staff regarding RPM	Brophy, 2017, Das et al. 2015, Downey et al. 2018, Jansson et al. 2019, Leppla et al. 2020, Makhni et al. 2020, McMullen et al. 2018, Rothgangel et al. 2020, Semple et al. 2019, Sousa et al. 2016, Timmerman et al. 2017, Wiadji et al. 2021
Workload & logistcs	Devise a primary nursing-based model (physicians for emergencies and medical decisions)	Leppla et al. 2020
	Allow for easy collaboration between the different actors	Davoody & Hägglund 2016, Leppla et al. 2020
	Create dedicated teams for RPM interventions	Leppla et al. 2020
	Include planning tools for routines and tasks • Define goals for tasks to make progress clear	Davoody & Hägglund 2016
	Externalize tasks • Have specialized centers for data analysis & alarm reviews	Leppla et al. 2020
	Ensure accessibility to patients' contact details (to facilitate appointment scheduling and remote consultations)	Jansson et al. 2019, Ke et al. 2019
	Make e-tools available in different languages	Brophy, 2017
Technology	Provide appropriate support and access to software and technology for both patients and specialists • Ensure compatibility with different smartphones and tablets	Dunphy et al. 2017, Rothgangel et al. 2020, Wiadji et al. 2021

Technology	Ensure quality of Service (QoS) support	Harsha et al. 2019
	Integrate with current technologies • Interoperable and compatible with other/ existing devices and systems • Guarantee a seamless connection between RPM platform and staff's EMR system	Harsha et al. 2019, Leppla et al. 2020, McMullen et al. 2018, Rothgangel et al. 2020
	Ensure automatic measurements and documentation	Das et al. 2015, Ke et al. 2019, Sanger et al. 2016
	Develop user friendly tools for clinical staff and patients	Augestad et al. 2020, Brophy, 2017, Davoody & Hägglund 2016, Leppla et al. 2020, McMullen et al. 2018, Timmerman et al. 2017
Data	Alert-based follow-up protocol • Continuous data collection (24h data) but data analysis focused on alerts by patient prioritization & event-triggered assessment (Identify main events to follow) • Automatic event classification and suggestions for corrective actions • Providing memory aids to staff for interrupted task	Dunphy et al. 2017, Ke et al. 2019, McMullen et al. 2018, Richards et al. 2020, Sanger et al. 2016
	Customizable data collection • According to treatment, acuity, goal, progress, and diagnosis (Identify high-risk patients to determine extra measures needed)	Das et al. 2015, Davoody & Hägglund 2016, Downey et al. 2018, Jansson et al. 2019, Ke et al. 2019, McMullen et al. 2018, Rothgangel et al. 2020

Data	Present easy to interpret and actionable data • Filter data ("noise cancellation", false positives) • Provide comparison of individual scores with "standard values" of comparable patients.	Dunphy et al. 2017, Leppla et al. 2020, McMullen et al. 2018, Rothgangel et al. 2020, Sanger et al. 2016
	• Incorporate different kinds of measurements (from different physiological variables) • Include historical patients' data	Davoody & Hägglund 2016, Dunphy et al. 2017, Jansson et al. 2019, McMullen et al. 2018, Rothgangel et al. 2020, Sanger et al. 2016
	More effective use of patients' data • Use RPM data to guide future medical appointment • Use RPM data to assess eligibility for procedures, possible risks, and outcomes	Dunphy et al. 2017, Jansson et al. 2019, Parkes et al. 2019, Sharif et al. 2020, Wiadji et al. 2021
	Collect data on patients' and staffs' feedback on the intervention for improvement purposes	Jansson et al. 2019, Leppla et al. 2020
	Provide patients with tools to help assess, interpret, and act upon symptoms	Leppla et al. 2020

Category 4: Methods to Measure and Quantify the Impact of RPM on Clinical Staff

This category presents the methods used to identify the impact of RPM interventions on clinical staff tasks and workflows. In total, 2 main themes were established (Table 6) based on the kind of measures of the impact of RPM interventions on staff being collected and analyzed using different methods. The first theme was time and activity analysis, which includes methods for measuring clinical staff time expenditure and workload in relation to existing activities and RPM interventions. These methods allow for a comparative analysis between the standard of care and the RPM intervention. Other possible quantifiable measures found in this category are the number of times certain resources are accessed or the time spent on certain tasks.

The second theme was staff satisfaction and experience, which focuses on how RPM interventions are perceived by the staff and how the new tools and ways of working affect their behaviors. This theme includes subjective measures, such as those gathered through interviews and surveys, and more objective measures, such as measures of adherence to protocols or alert frequency.

Table 6. Overview of methods to measure and quantify the impact of remote patient monitoring (RPM) interventions on clinical staff.

Theme	Description	Studies
Time and activity analysis	Activities timing • Automatic recording of time spent on events & consultations • Duration of use of RPM tools • Cumulative time on activities • Cumulative time on platform • Frequency and quantity of alerts	Downey et al. 2018, Makhni et al. 2020, Rothgangel et al. 2020, Sousa et al. 2016, Timmerman et al. 2017, Wiadji et al. 2021
	Activities mapping • Current state mapping • Implementation assessment • Number of times telemonitoring tools were used • Number of transmissions and events • Selecting most busy times • Nurses tasks	Augestad et al. 2020, Leppla et al. 2020, Rothgangel et al. 2020, Sousa et al. 2016, Timmerman et al. 2017
	Comparative analysis with baseline (time in activities, number of in-hospital visits/ events)	Harsha et al. 2019, Sousa et al. 2016
	Hospital logistics • Number of in-hospital visits • Length of in-hospital visits • Type of complications • Type of resources • Accessibility to resources (quantity, quality)	Augestad et al. 2020, Downey et al. 2018, Rothgangel et al. 2020
	Costs savings based on time and resources used	Makhni et al. 2020

Satisfaction/ experience analysis	Surveys & questionnaires • Usability (e.g., System usability score) • Adherence to protocols • Utility and Efficiency of e-tools (frequency of incomplete data, effort and work needed for gathering extra data)	Downey et al. 2018, Leppla et al. 2020, McMullen et al. 2018, Parkes et al. 2019, Rothgangel et al. 2020, Timmerman et al. 2017, Wiadji et al. 2021
	Interviews & focus groups	Das et al. 2015, Davoody & Hägglund 2016, Downey et al. 2018, Dunphy et al. 2017, Jansson et al. 2019, Ke et al. 2019, Leppla et al. 2020, McMullen et al. 2018, Parkes et al. 2019, Sharif et al. 2020
	Ethnographic research • Observation • Journey mapping	Augestad et al. 2020, Das et al. 2015, Leppla et al. 2020, McMullen et al. 2018
	Co-design & co-creation sessions/workshops • Critical incident technique - think-aloud approach - mockups	Sanger et al. 2016, McMullen et al. 2018, Rothgangel et al. 2020
	Impact of alerts on performance and wellbeing	Downey et al. 2018

6.2.4 Discussion

Principal Findings

RPM is presented as a useful tool to help patients feel safer and more empowered in their self-care during the perioperative period. In addition, health care institutions benefit from it by increasing the efficiency in the use of their resources, both physical (such as beds and monitors) and human (clinical staff). In deciding on the adoption of RPM interventions, considering the impact on and perceptions of clinical staff is crucial as the success of these interventions is based on their cooperation and comprehension. As users and providers of remote perioperative care, clinical staff need to be comfortable and willing to adopt RPM interventions, which should not hinder their other tasks.

Overall, the main RPM-related problems found for clinical staff were related to undesirable changes in their workflow and lack of planning. In several included papers (11/21, 52%), the introduction of RPM led to a higher workload because of unforeseen tasks that emerged when the RPM intervention was implemented in the complex health care environment and not necessarily when the intervention was tested in controlled settings. In particular, tasks such as (remotely monitored) patient data analysis, remote alert response, and remote care reporting and billing were mentioned as sources of increased staff workload and disruptions in the usual care workflow. In addition, the time necessary for activities was often underestimated because of the lack of experience and knowledge of the clinical staff to perform some of the new tasks that RPM interventions created. Furthermore, problems were reported in relation to uncontemplated users as sometimes it was unclear who was in charge of these new tasks, the assigned actor was not the adequate one, or they depended on the assistance of a third party. Problems regarding the difficulty in use and functioning of RPM tools were also described. This was mainly due to lack of knowledge or training, technical malfunctions, or legal issues where the new services conflicted with the current systems. Although it is true that these problems might be temporary and limited to the initial introduction of RPM interventions, it is still important to assess and address them as they do have an impact on the workflow and might cause the intervention implementation to fail before familiarization and adaptation are even possible. Furthermore, it is important to consider initial workflow problems as adaptation strategies and coping mechanisms adopted by staff to overcome these problems might in themselves generate structural issues. For example, when new tasks are introduced by RPM interventions without a clear indication of who is responsible for them, the available actors will feel compelled to take over, adding to their daily workload.

Most of the reported benefits for clinical staff related to the improvement in monitoring and data analysis, resulting in better resource management and clinical outcomes. Even though most staff members agree on the advantages these interventions bring in terms of better follow-up of patients and resource allocation, they are still concerned about the extra workload they face.

Regarding best practices and risk-reduction strategies, most of the included studies (18/21, 86%) mentioned the need to strengthen the implementation process of RPM interventions through better planning and improved stakeholder involvement. This way, clinical staff can provide a better overview of their pre-existing work routines and needs so that the new interventions can be better integrated and adapted to their usual workflow rather than the other way around. Other strategies involved establishing protocols to guide the interventions' use and operations and providing the necessary training to avoid uncertainty and prepare staff.

Finally, several included studies (10/21, 48%) stressed the importance of interoperability and ensuring compatibility between the new RPM interventions and the existing tools and processes used by the staff to prevent double work or the emergence of conflicts in the recorded patient data.

Moreover, it is recommended that RPM-related interfaces be user-friendly and tested in the context to reduce time spent on training and possible technical problems. Enhancing staff's understanding of and familiarity with the tools can increase their willingness toward their adoption as technology will be perceived as an enhancer and not as an obstacle.

The included studies reported recommendations for best practices and risk-reduction strategies for most of the staff-related problems and challenges mentioned in connection with RPM interventions. It is important to note that these solutions address problems that represent major barriers to RPM implementation in the present. Therefore, adopting them more consistently in RPM research and practice represents a way to maximize the capability of RPM to deliver real-world results in health care services in the future.

Figure 19 shows the connections between themes and categories. Here, we can see how some of the identified themes were not present in all the categories. Notably, there are problems that lack specific recommendations in the literature, such as those related to health care resources. Reimbursement schemes prioritizing in-hospital care constitute a largely unaddressed challenge complicated by the complexity of the context and the different types of stakeholders involved. This affects the commitment and motivation of clinical staff toward RPM interventions as it is not always clear how the extra or new work will be reimbursed. In addition, there are currently few answers on how to increase funding for RPM interventions (Table 3). This is a big challenge, as RPM interventions may not clearly present benefits justifying their relatively high expenses, especially in the short term.
There is still room for improvement in ways to manage incoming alerts so that they do not create interruptions and annoyance among staff while ensuring timely responses. Another open challenge is related to providing a collaborative environment between the different staff members involved in patient care and defining clear roles so as to divide RPM-related tasks effectively and avoid confusion. In addition, there are opportunities to improve the devices and systems that collect, analyze, and communicate patient data. This includes the possibility of using data for more informed or automatized decisions that consider multiple data sources, thus avoiding biases, false positives, and incorrect inputs.

Most of the methods used to assess the impact of RPM interventions on staff-related workflows were qualitative and subjective, including interviews, questionnaires, and observations. Few reported studies (7/21, 33%) included the collection of quantitative measures such as tracking the time invested in using the interventions.

This is characterized as an opportunity for improvement in RPM-related research as quantitative impact measures would help assess resource use and, therefore, better evaluate the overall interventions. Furthermore, quantitative measures could unlock the possibility of meaningful comparisons across different interventions and contexts. Some of these more quantitative or objective measures could be anxiety levels using existing scales, as proposed by Jukic et al. (2020).
However, there is still not enough research on methods to track RPM-related workload quantitatively. Examples of RPM interventions in fields other than perioperative care can be useful in this regard. For example, in tele–intensive care units and the remote monitoring of cardiovascular implantable electronic devices, diverse methods have been deployed to measure staff workload (Cady et al., 2010; Papavasileiou et al., 2013; Ricci et al., 2014; Ricci et al., 2013) by, for example, time-motion studies (Tang et al., 2006; Tang et al., 2007). In these interventions, systems automatically record use time while an observer also tracks the nurses and annotates the duration of RPM-related activities. This has reportedly helped researchers identify the most time-consuming aspects of RPM-related workflow and find bottlenecks and weaknesses to improve designs and implementation plans. These tele–intensive care unit and cardiovascular implantable electronic device remote monitoring research methods could be profitably translated to perioperative care. In general, research on RPM interventions (Makhni et al., 2020; Brophy, 2017) helps in understanding possible outcomes and identifying barriers, facilitators, and recommendations (Rothgangel et al., 2022), which can guide the design and implementation stages of these interventions.
Further research should be dedicated to the quantification of resource use in RPM interventions—to standardize reimbursement policies—and the evaluation of the implementation of these strategies in different settings. Moreover, the time horizon of these studies should be extended to cover longer periods, as many relevant effects of RPM interventions cannot be observed in the short term - partly because of factors such as the staff learning curve.

6.2.5 Limitations

This scoping review has several limitations. The first is the diversity of RPM interventions examined as they might have different objectives, leading to variable results and problems.
In addition, the results will be influenced by the initial state and environment in which the RPM intervention was introduced. As mentioned by Herdman [49], intervention benefits depend on the baseline, whereby an initial higher performance may lead to a comparatively smaller advantage. Moreover, these interventions were executed under different circumstances and environments, which might change the dynamics among the clinical staff. Additional limitations are derived from the differences in the methodology used in the included studies as the target variables and outcomes might not be comparable.

Finally, most of the included studies (13/21, 62%) only considered short- and midterm impacts, whereas RPM interventions can have long-term effects that are decisive to assess their overall performance.

This review was also susceptible to risk of bias because of missing results. This risk is increased by our exclusive focus on articles in English, our use of 2 databases (PubMed and Embase), and our focus on a limited time frame (January 2015 to March 2021). Nonreporting bias risk is also likely to apply to this review as we noticed that only a small fraction of papers in the RPM domain reported any insight at all on the impact of the introduction of new interventions on staff workflow. Overall, in light of the aforementioned limitations and risks of bias, we recommend interpreting and using our contribution as an initial description of the types of workflow-related implications of RPM described in the current literature and not as an exhaustive overview.

6.2.6 Conclusions

Every day there are more studies that show the impact of RPM interventions given their increasing use in clinical practice and in perioperative care in particular. Most of these studies focus on the patient's perspective and on clinical outcomes. In our scoping review, we presented an overview of the recent knowledge regarding clinical staff's perspective, which reveals the possible problems and benefits that remote monitoring can bring. Further research regarding policy making and protocol standardization should be conducted to establish a more trustworthy analysis of RPM interventions.

Studies concerning the impact of RPM strategies on clinical staff workflows and dynamics should be clear about the study objective, the design, and the methods used to test the intervention. This will help future readers in assessing the overall performance of RPM interventions. Moreover, this can enable better comparative research and promote the establishment of valuable benchmarking and auditing systems.

CHAPTER 7

PATIENT AND STAFF EXPERIENCE EVALUATION IN REMOTE PATIENT MONITORING

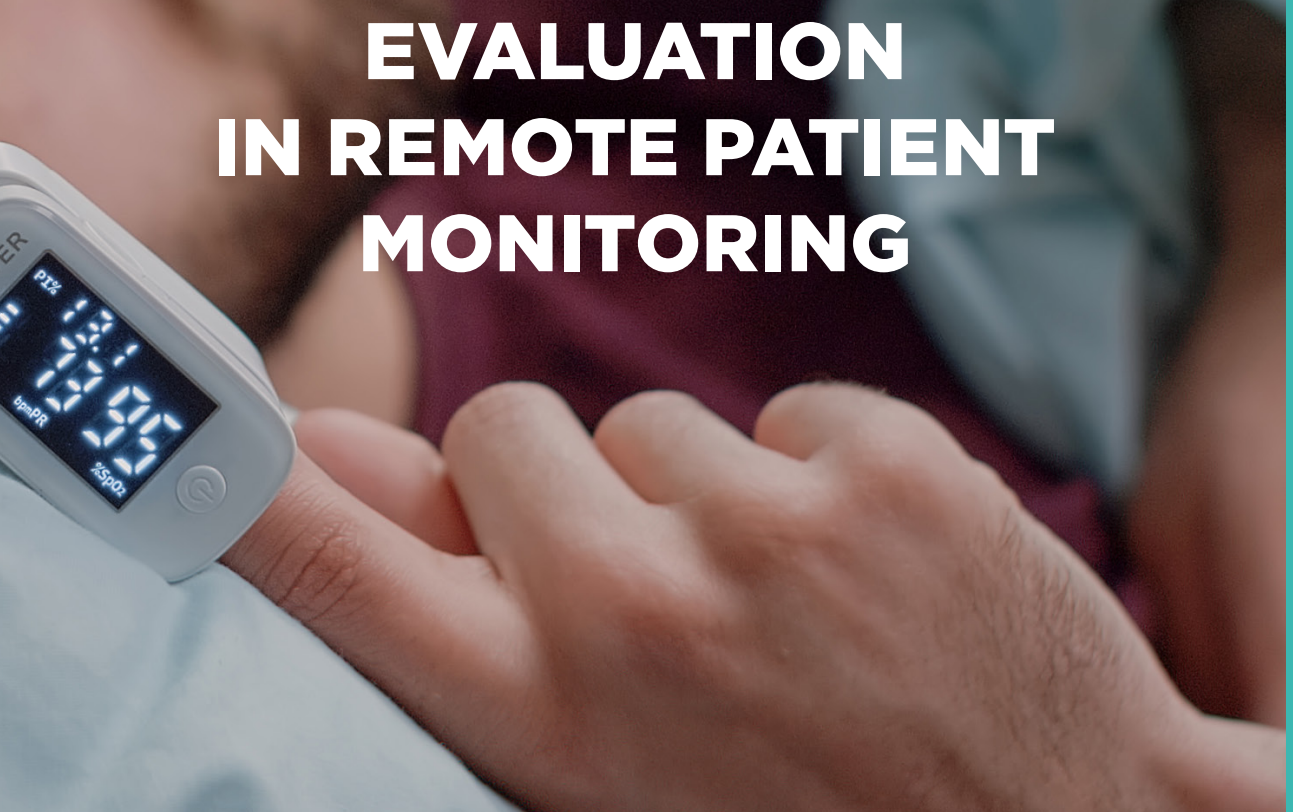


Photo by DCStudio on Freepik

"Absent modern medical telemetry, researchers enlisted the families of epileptic patients to record information about seizures on what they called "fits sheets," or printed forms, which had checklists of symptoms, timing, and other data. Family members, poor and afflicted as they all were, tried desperately to comply in the data col lection effort. The forms they filled out are moving documents revealing the relations of class and medicine in late nineteenth-century England, penciled in, misspelled, and assiduously brought to the doctor's files. And they tell another story as well: all around the edges of the documents are scribbled messages to the doctor that do not fit the actual form. "Had too much hot soup yesterday." "Exposed to night air." "Rode alone in carriage." A whole folk medicine exists in the side comments alongside the filled-in forms. However, this wealth of information was discarded as unimportant - lost in the files - even though in a sense the patients were acting as research assistants to the clinicians. This anomaly drew my attention to the problem of collecting, disciplining, and coordinating distributed knowledge. How does delegated work - what Julius Roth called "hired hand research" affect data quality? How do forms shape and squeeze out what can be known and collected? (...) The current Web-based patient information exchange groups face conceptually similar problems of group memory, language differences, and what fits on the forms of traditional medicine versus what the patients really know in their lives. I went on to analyze this problem with Bowker in our model of the management of data collection in the international classification of diseases, and the tensions between traditional systems of medical knowledge and the forms distributed by the WHO (...), and later, with Martha Lampland, in an analysis of standardization. I began to think of standards and boundary objects as inextricably related, especially over time"

Leigh Star, 2010

7.1. Contribution background

In the previous chapter, a scoping review was provided on the impact of Remote Patient Monitoring (RPM) on the workflows of perioperative staff.

In this chapter, a systematic review is offered on the broader topic of patient and staff experience evaluation in RPM at large. After performing a structured, comprehensive inventory of the constructs and instruments used to evaluate patient and staff experience in recent remote monitoring literature, we propose a set of recommendations for standardising patient and staff experience measuring in this domain.

A version of this contribution is under review in a peer-reviewed journal.
Pannunzio, V., Morales Ornelas, H.C., van Kooten, R.T., Gurung, P., van Os, H. J. A., Wouters, M.W.J., Tollenaar, R.A.E.M., Kleinsmann, M., Snelders, D., Atsma, D.E. Patient and staff experience evaluation in Remote Patient Monitoring; what to measure and how? A systematic review

7.2. Contribution

Patient and staff experience evaluation in Remote Patient Monitoring; what to measure and how? A systematic review

Abstract

Patient and staff experience are vital factors to consider in the evaluation of Remote Patient Monitoring (RPM) interventions. However, the current landscape of patient and staff experience evaluation in RPM suffers from a lack of methodological standardization, affecting the quality of both primary and secondary research in this domain. This contribution sets off by providing a brief recapitulation of the role of patient and staff experience of RPM within the broader system of care. Following, a systematic review is performed to obtain a comprehensive set of experience constructs and corresponding instrument used in contemporary RPM research. Within this corpus of results, four main experience clusters are identified, namely usage and adherence-related experience constructs, service-system-related experience constructs, care-related experience constructs and health outcomes-related experience constructs. On the basis of the collected results, a set of recommendations are provided for improving standardization in the evaluation of patient and staff experience in RPM.

7.2.1 Introduction

Remote Patient Monitoring or Remote Patient Management (RPM) is a subset of digital health applications that aim at improving patient care through digitally transmitted, health-related patient data (Farias et al., 2020). Typically, RPM interventions include the use of one or more sensors (including monitoring devices, wearables, or implants), which collect patient data either in or out of hospital to be used for remote clinical decision making. Partly due to an acceleration during the COVID-19 pandemic (Taiwo & Ezugwu, 2020; Fagherazzi et al., 2020; (Peek et al., 2020), the RPM domain has by now expanded to reach a broad range of medical specialities, sensing technologies and clinical contexts (Farias et al., 2020; Vegesna et al., 2017; Noah et al., 2018).

RPM is presented as a strategy for enabling healthcare systems worldwide to face the pressing challenges posed by ageing populations (Majumder et al., 2017; Coye et al., 2009; Schütz et al., 2022), including dwindling availability of health care workers (Drennan & Ross, 2019) and rising health care costs (Chang et al., 2019). This is because deploying effective RPM solutions across health systems holds the potential to reduce healthcare resources utilization while maintaining or even improving care quality. However, evidence regarding RPM effectiveness at scale is mixed (Mecklai et al., 2021). Few large-scale trials have been conducted so far demonstrating meaningful clinical impact of RPM, and more research is urgently needed clarifying and addressing determinants of RPM effectiveness (Noah et al., 2018).

Among these determinants we find the experience of patients and staff using RPM systems. This is because RPM introduces radical changes in the interactions between patients, clinical staff and the broader system of care. From a patient's perspective, the shift from in-person care to RPM ushers considerable novelty: patients might be asked to download and install software, pair, charge, and wear monitoring devices, submit personal data, or attend alerts or calls, all in the midst of everyday life contexts and activities. Similarly, RPM introduces radical workflow changes for clinical and especially nursing staff, who might be asked to carry out data analysis, administrative work, and maintain remote contact with patients - often without a clear definition of roles and responsibilities and in addition to usual tasks (León et al., 2022).

Because of these radical changes, patient and staff experiences constitute crucial aspects to consider when evaluating RPM interventions. Next to qualitative methods of experience evaluation, mixed and quantitative methods are also fundamental, especially to capture information from large pool of users. However, the current RPM experience measuring landscape suffers from a lack of methodological standardization, reflected both in what is measured and how it is measured. Regarding what is measured, it has been observed that a large number of constructs are employed in literature, often without a clear specification of their significance. This can be noticed even regarding popular constructs such as satisfaction: Mair (2000), for instance, observe how the meaning of the satisfaction construct is seldom defined in patient surveys, leaving readers "unable to discern whether the participants said they were satisfied because telemedicine didn't kill them, or that it was 'OK,' or that it was a wonderful experience". Regarding how measures are used, previous work registers a broad diversity in the instruments employed to measure a specific construct. For instance, in their review of RPM applications for heart failure, (Kraai et al., 2011) report that none of the articles they examined used the same survey to measure patient satisfaction, and only one was assessed on validity and reliability.

In this proliferation of constructs and instruments, no comprehensive overview exists of their application to measuring patient and staff experience in RPM settings. The lack of such an overview negatively affects research in this domain in at least two ways. At the level of primary research, RPM practitioners and researchers have little guidance on how to include experience measuring in their study designs. At the level of secondary research, the lack of consistently used measures makes it hard to compare results between different studies and RPM solutions. Altogether, the lack of standardization in experience measuring constitutes a research gap that needs to be bridged in order for RPM to fully deliver on its promises.

In this contribution, this gap is addressed through an effort to provide a structured overview of patient and staff experience constructs and instruments in RPM. First, we position the role of RPM-related patient and staff experience within the broader system of care using the Quadruple Aim framework. Following, we perform a systematic review on patient and staff experience-relevant constructs and instruments used in contemporary research aimed at evaluating RPM interventions. In this way, we obtain a comprehensive overview of what is measured in this domain and of how it is measured. Finally, we propose a set of guidelines for RPM experience evaluators and indicate directions for further research

7.2.2 The role of patient and staff experience in RPM

Many characterizations exist of patient and staff experience (Wolf et al., 2014; Lavela & Gallan, 2014; Wang et al., 2022), some of which distinguish between determinants of experience and experience manifestations (Zakkar, 2019). For the purpose of our review, we maintain this distinction, as we aim to focus on the broad spectrum of factors affecting and affected by patient and staff experience. To do so, we adopt the general conceptualization of patient and staff experience as characterized in the Quadruple Aim, a widely used framework for health systems optimization centred around four overarching goals - improving the individual experience of care, improving the experience of providing care, improving the health of populations, and reducing the per capita cost of healthcare (Sikka et al., 2015). Adopting a Quadruple Aim perspective allows health systems researchers and innovators to recognize not only the importance of patient and staff experience in the healthcare domain, but also the inextricable relations of these two goals to the other dimensions of health systems performance (Pannunzio et al., 2019a). In order to clarify the nature of these relations in the RPM domain, a schematic overview of the relations between patient and staff experience of RPM and other components of the Quadruple Aim framework is provided in Figure 20.

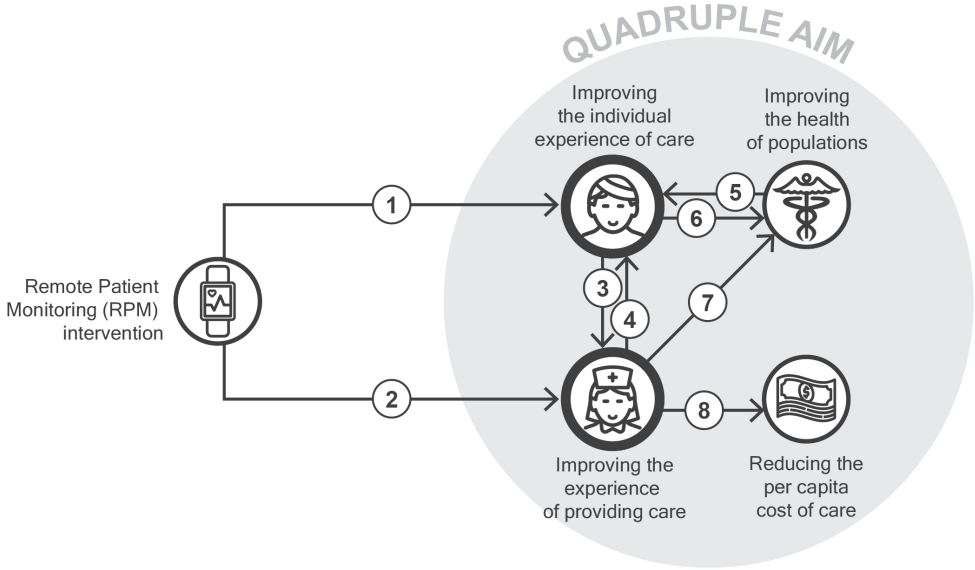


Figure 20. Schematic overview of the relations between patient and staff experience of RPM and the other components of the Quadruple Aim framework. Each arrow symbolizes a relation.

Following, we will touch on prominent relations between patient and staff experience of RPM within the Quadruple Aim framework, and provide examples of experience constructs relevant to each relation.

(1) (2) The characteristics of specific RPM interventions directly affect the experience of patients and staff. Examples of experience constructs related to this mechanism are expressed in terms of Usability or Wearability, which are attributes of systems or products contributing to the care experience of patients and work experience of staff.
(3) (4) Patient and staff experience relate to each other through care delivery. Human connections, especially in the form of carer-patient relationships, represent a major factor in both patient and staff experience. An example of experience construct related to this mechanism is expressed in terms of Quality of Relationship.
(5) (6) A major determinant of patient experience is represented by the health outcomes achieved as a result of the received care. An example of a measure of quality related to this mechanism is expressed in terms of Quality of Life, which is an attribute of patient experience directly affected by a patient's health status.
On the other hand, patient experience itself is a determinant of clinical effectiveness of RPM interventions. For example, the patient experience afforded by a given intervention is a determinant of both Adoption and Adherence to that intervention, ultimately affecting its real-world impact. In a recent review, low patient adherence was identified as the main factor associated with ineffective RPM services (Thomas et al., 2021).

(7) Similarly, staff experience is a determinant of clinical effectiveness. Issues such as Alarm Fatigue, for instance, contribute to medical errors and lower the quality of care delivery (Sendelbach & Funk, 2013).
(8) Staff experience can, also, impact on costs of care. For example, Time Effort required by the use of a given intervention constitutes a source of extra costs. More indirectly, low staff Satisfaction and excessive Workload can increase healthcare staff turnover, resulting in additional expenses at the level of the health system.

Overall, the overview in Figure 20. can help us grasp the nuances of the role of patient and staff experience in the overall impact of RPM interventions, and the importance of measuring experience factors not only in isolation, but also in relation to other dimensions of quality. Therefore, we will cover a broad range of experience-relevant factors in the review, including both experiential determinants (e.g. usability) and manifestations (e.g. adherence).

7.2.3 Methods

The study protocol was registered in the PROSPERO database (CRD42021250707). This systematic review adheres to the Preferred Reporting Items for Systematic Reviews guidelines. The PRISMA checklist is provided in Appendix IV.

Criteria for Study Eligibility

Our study population consisted of adult (≥18 years) patients and staff members involved as participants in reported RPM research. Full-text articles written in English were considered for eligibility. To collect a coherent and unified corpus of results, we developed a set of criteria we could use to determine which kinds of interventions would fall under the definition of RPM and of patient or staff experience measuring- as this was not always explicitly addressed in the contributions themselves. The full set of criteria we used to assess whether contributions would be relevant for the scope of this review is provided in Appendix V.

Search method

To identify relevant publications, the following electronic databases were searched: (I) Medline (PubMed) and (II) EMBASE. Search terms included controlled terms from MeSH in PubMed and Emtree in EMBASE, as well as free text terms. Query terms selection and structuring were performed collaboratively by VP, HCMO, PG who is a clinical librarian at the Leiden University Medical Center. The full search strategies are reported in Appendix VI. Because the aim of the review is to paint a contemporary picture of experience measures used in RPM, only studies published starting from the 1st of January 2011 (10 years before query execution) were included.

Study Selection

Study selection was performed by VP and HCMO. The initial screening was based on title and abstract; full texts of relevant articles were then retrieved and screened independently by VP and HCMO using Rayyan. Discrepancies were solved by discussion. A flowchart of study selection is depicted in Figure 21.

Quality appraisal

The objective of this review is to provide a comprehensive overview of the relevant literature, rather than a synthesis of specific intervention outcomes. Therefore, no papers were excluded based on quality appraisal, in alignment with similar studies (White et al., 2022).

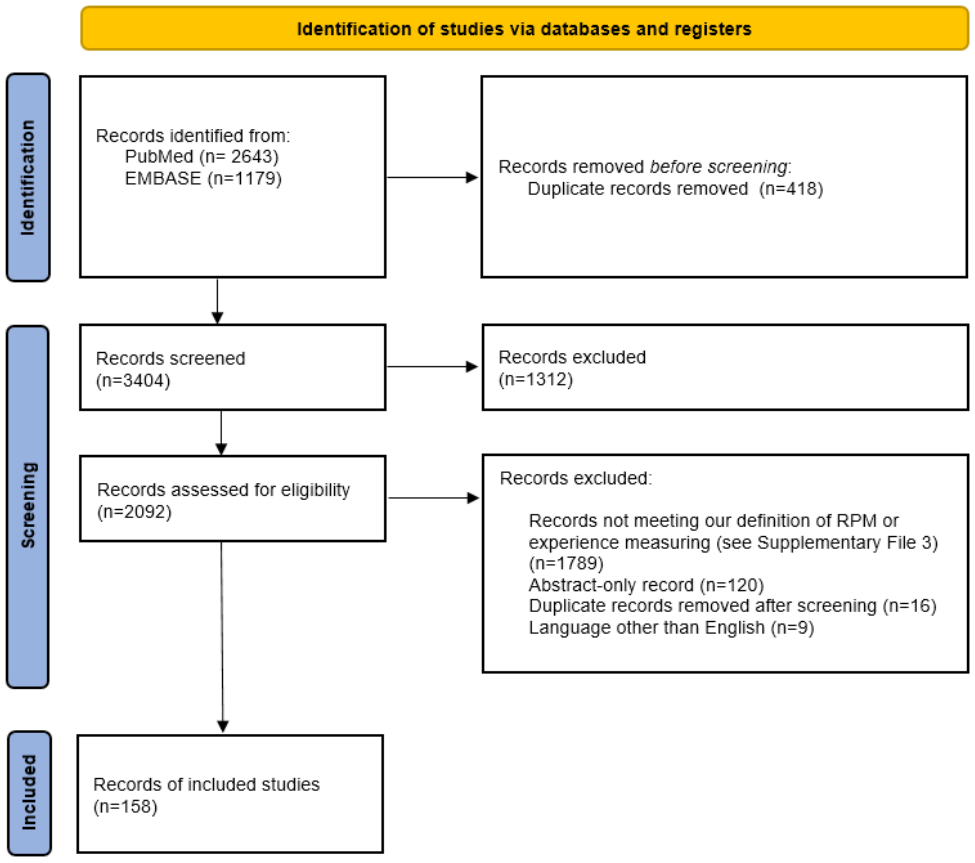


Figure 21. Flowchart diagram of the systematic review selection process

Data Extraction and Management

Data extraction was performed by VP and HCMO. The data extraction was performed in a predefined Excel sheet, designed by VP and HCMO. The sheet was piloted in at least one included study. Discrepancies were resolved by discussion. The following data were extracted: (1) General study information – authors, title, year of publication, type of study, country or countries (2) target disease(s), intervention and/or clinical specialty (3) used patient or staff experience evaluation instrument and measured experience construct (4) evidence base if indicated (5) number of involved staff or patient participants. By 'construct', we refer to the "abstract idea, underlying theme, or subject matter that one wishes to measure using survey questions" (Lavrakas, 2008). To identify the measured experience construct, we used the definition provided in the source contribution whenever available.

Data Analysis

First, we analysed the collected data through building general overviews depicting the kind of target participants (patients or staff) of the used experience measures and their utilization over time. To organize the diverse set of results collected through the systematic review, we then performed a correspondence analysis (CA, Greenacre, 1999), a multivariate statistical technique used for exploring and displaying relationships between categorical data. CA transforms a two-way table of frequencies between a row and column variable into a visual representation of relatedness between the variables. This relatedness is expressed in terms of inertia, which represents 'a measure of deviation from independence' (Sourial et al., 2010). In other words, the model's inertia describes the amassed evidence base for dependence between the row and column variables. CA breaks down the inertia of the model by identifying mutually independent (orthogonal) dimensions representing deviations from independence. Each successive dimension explains less and less of the total inertia of the model. On each dimension, relatedness is expressed in terms of the relative closeness of rows to each other, as well as the relative closeness of columns to each other. CA has been previously used to find patterns in systematic review data in the healthcare domain (Franceschi et al., 2021).

In our case, a two-way table of frequencies was built based on how often any given instrument (e.g. "System Usability Scale") was used to measure any given construct (e.g. "usability") in the included literature. To do this, the data extracted from the systematic review underwent a round of cleaning, in which the formulation of similar constructs was made more homogeneous: for instance, "Time to review", "Time to response" and "Time for task" were merged under one label ("Time effort"). An overview of the merged construct formulations is provided in Appendix VII.

The result of the CA was a model where two dimensions contributed to more than 80% of the model's inertia (respectively explaining 44,8% and 35.7%), and where none of the remaining 59 dimensions contributed more than 7,3% to the remaining inertia. This gap suggests the first two dimensions to express relations that are not purely based on random variation, and a two-dimensional solution will thus be presented.

7.2.4 Results

A total of 158 studies reporting at least one instance of patient or staff experience measuring in RPM were included in the review. These included studies covered a broad range of RPM applications, most prominently diabetes care (18%), implanted devices (7%), and Chronic obstructive pulmonary disease or COPD (6%). From these studies, we reported 546 instances of experience measuring in RPM, covering the use of 160 unique experience measuring instruments employed to measure 120 unique experience constructs.

Our results include four kinds of 'versatile' (intended as non-specific) experience measuring instruments, namely the custom survey, the log files analysis, the protocol database analysis, and the task analysis, all of which can be used for measuring disparate kinds of constructs.

- By custom survey, we refer to survey instruments created to evaluate patient and/or staff experience in connection to one specific RPM study, and only used for that study.
- By log file analysis (Huerta et al., 2019), we refer to the set of experience assessment methods based on the automatic collection of data through the RPM digital infrastructures themselves; examples are clicks, uploads, views, or other forms of interactions between users and the RPM digital system. This set of methods is typically used to estimate experience-relevant constructs such as adherence and compliance.
- By protocol database analysis, we refer to the set of experience assessment methods based on the manual collection of data performed by RPM researchers within a specific research protocol; typical examples are enrolment and drop-out rates.
- By task analysis, we refer to the set of experience assessment methods based on the real-life observation of users interacting with the (RPM) system (Diaper & Stanton, 2003).

Besides these four, our results include a large number of specific instruments – such as standard indexes, surveys and questionnaires. Overall, the most frequently reported instrument was by far the custom survey (reported in 155 instances), while the most frequently reported experience construct was Satisfaction (85), closely followed by Quality of Life (71).

Target participants and timeline

We found large differences in the amount of RPM-relevant experience constructs and instruments used for patients and for staff (see Figure 22). We also found instruments used for both patients and staff. These were either broadly used instruments (e.g. the System Usability Scale, or SUS) that were administered to both patients and staff within the same study, or measures of interactions between patients and staff (e.g. log files analysis instruments) recording the number of remote contacts between patients and nursing assistants.
Expectedly, RPM research appears to focus much more on patient experience than on staff experience, which is investigated in only 12% of the included papers. Even in the contributions which do investigate staff experience, we notice that the number of participant staff members involved in the reported research is only reported in a minority of cases (36%).

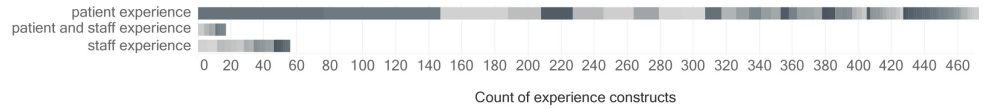


Figure 22. Count of mentioned instances of experience constructs organized by target participant: patient, staff or both. Different shades of grey indicate different constructs.

Furthermore, a time-based overview of the collected results (Figure 23) gives us an impression of the expansion of the field in the timeframe of interest for both patient and staff measures.

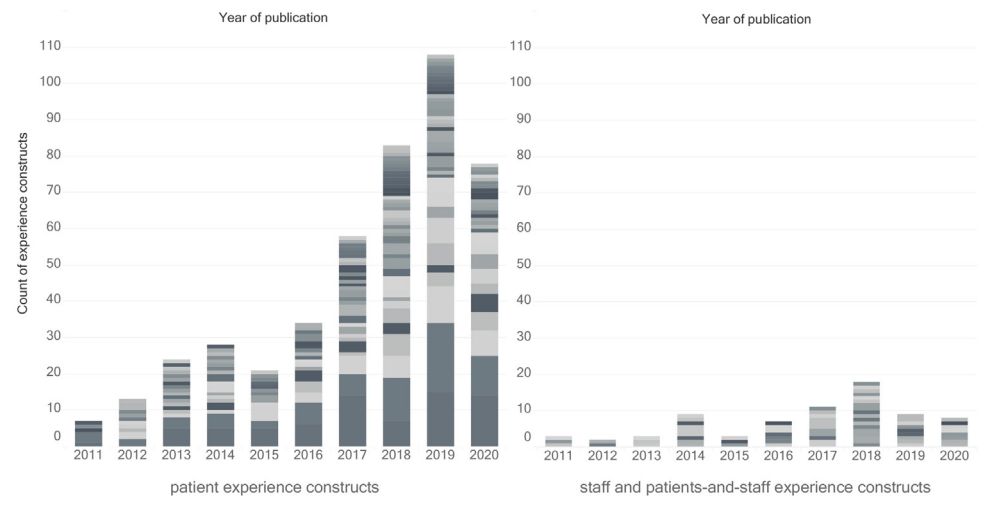


Figure 23. Count of mentioned instances of experience constructs for patients (left) or staff and patients-and-staff (right) in the included literature for each year of publication. Different shades of grey indicate different constructs.

Correspondence analysis

The plotted results of the CA for experience constructs are shown in Figure 24. Following, we discuss the outlook and interpretation of each dimension.

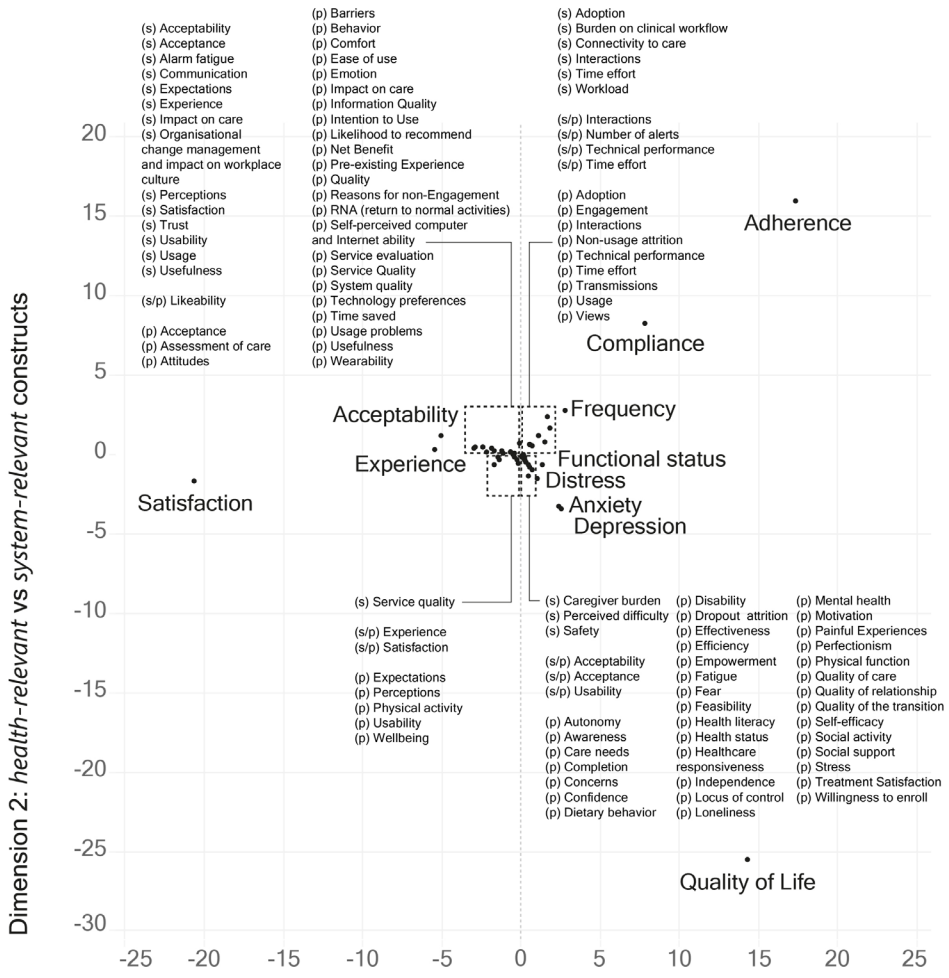


Figure 24 Graphical display of the results of the correspondence analysis, visualized on the coordinates of dimensions 1 and 2. The labels (s), (p) and (s/p) refer to experience constructs used for patients, staff, and both.

The first dimension explains more than 44% of the model's inertia. The contributions of this dimension show which constructs had the most impact in determining the orientation of this dimension: Satisfaction (36%) and to a lesser extent Adherence (26%) and Quality of Life (17%). On the negative (left) side of this dimension, we find constructs such as Satisfaction, Perceptions and Acceptability, which are associated with subjective measures of patient and staff experience and relate to how people feel or think in relation to RPM interventions. On the positive (right) side of this dimension, we find constructs such as Adherence, Compliance and Quality of Life, which are associated with objectified variables of patients and staff experience. Adherence and Compliance, particularly, are often measured through passive collection of system data (such as log file analysis), which reflect objective measures of the way patients or staff interact with RPM systems. On the other hand, measures of Quality of Life may not reflect properly objective measures, especially for what concerns self-reported outcomes. Yet, these measures are objectified in the sense that even self-reported measures of Quality of Life are meant to be treated as concrete indications of patient status. In this sense, we attribute a distinction between how people feel vs what happens experience constructs to this first dimension. We note that a similar distinction (between subjective vs objective measures of engagement in remote measurement studies) has been previously proposed as a meaningful differentiation to structure 'a field impeded by incoherent measures' (White et al., 2022).

The second dimension explains 35% of the model's inertia. The contributions of this dimension show which constructs had the most impact in determining the orientation of this dimension: Quality of Life (62%) and Adherence (24%).
On the negative (bottom) side of this dimension, we find constructs such as Quality of Life, Depression, and Anxiety, which are often used as experiential descriptors of health outcomes. On the positive (top) side of this dimension, we find Adherence, Compliance, and Frequency, which are often used as descriptions of the interactions of patients or staff with a specific (RPM) system. Thus, we attribute a distinction between health-relevant vs system-relevant experience constructs to this second dimension.

Based on the results of the correspondence analysis, we propose a categorization of constructs of patient and staff experience in RPM literature into four, partly overlapping clusters. Coherent with the offered explanation of the two dimensions and in consideration of the constructs found in each area, we label these: service-system-related experience measures; care-related experience measures; usage and adherence-related experience measures; and health outcomes-related experience measures. In Figure 25, we display the results of the correspondence analysis labelled through this categorization. In this second visualization, we present the results on a logarithmic scale, to improve the visibility of constructs close to the centre of the axes.

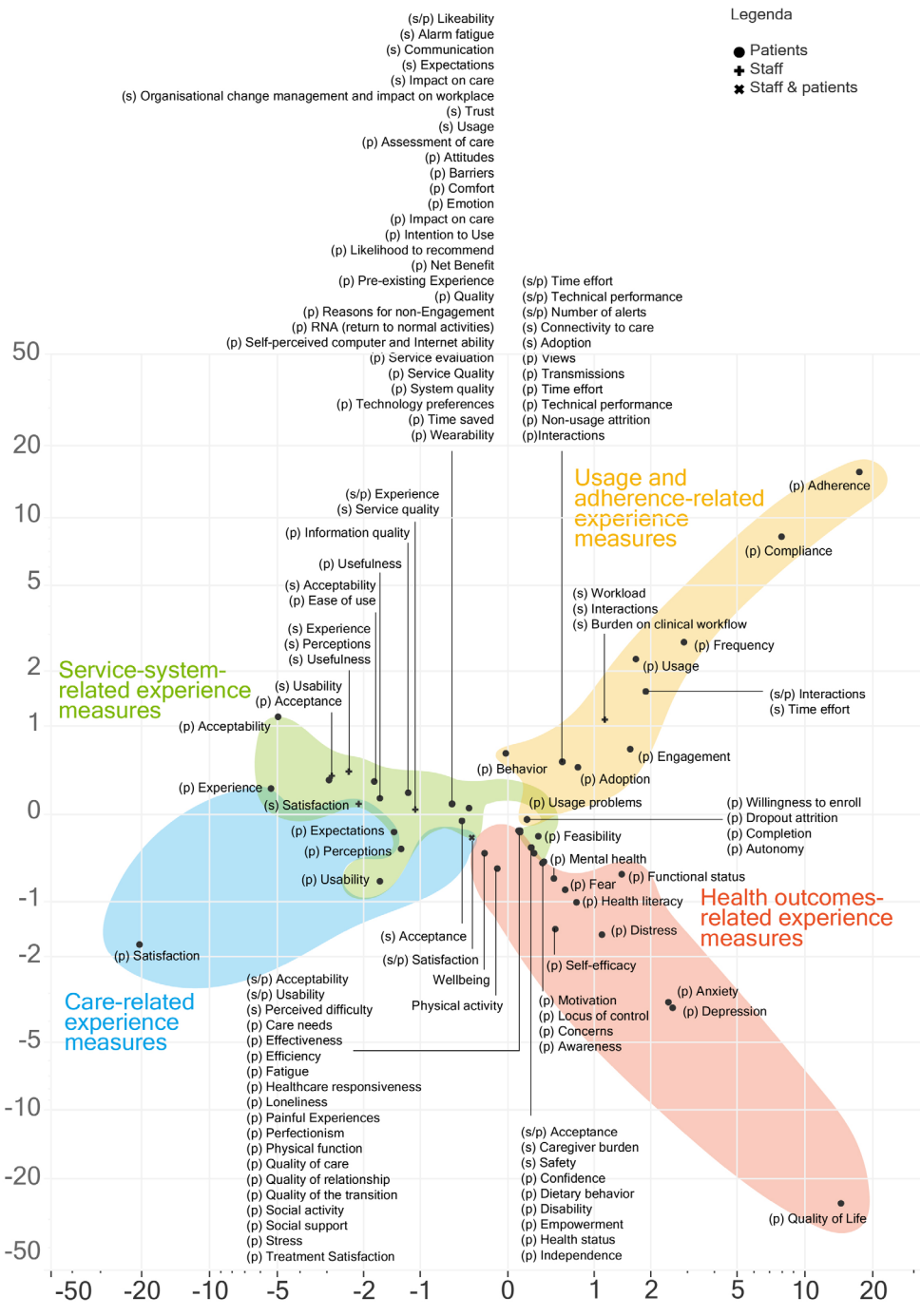
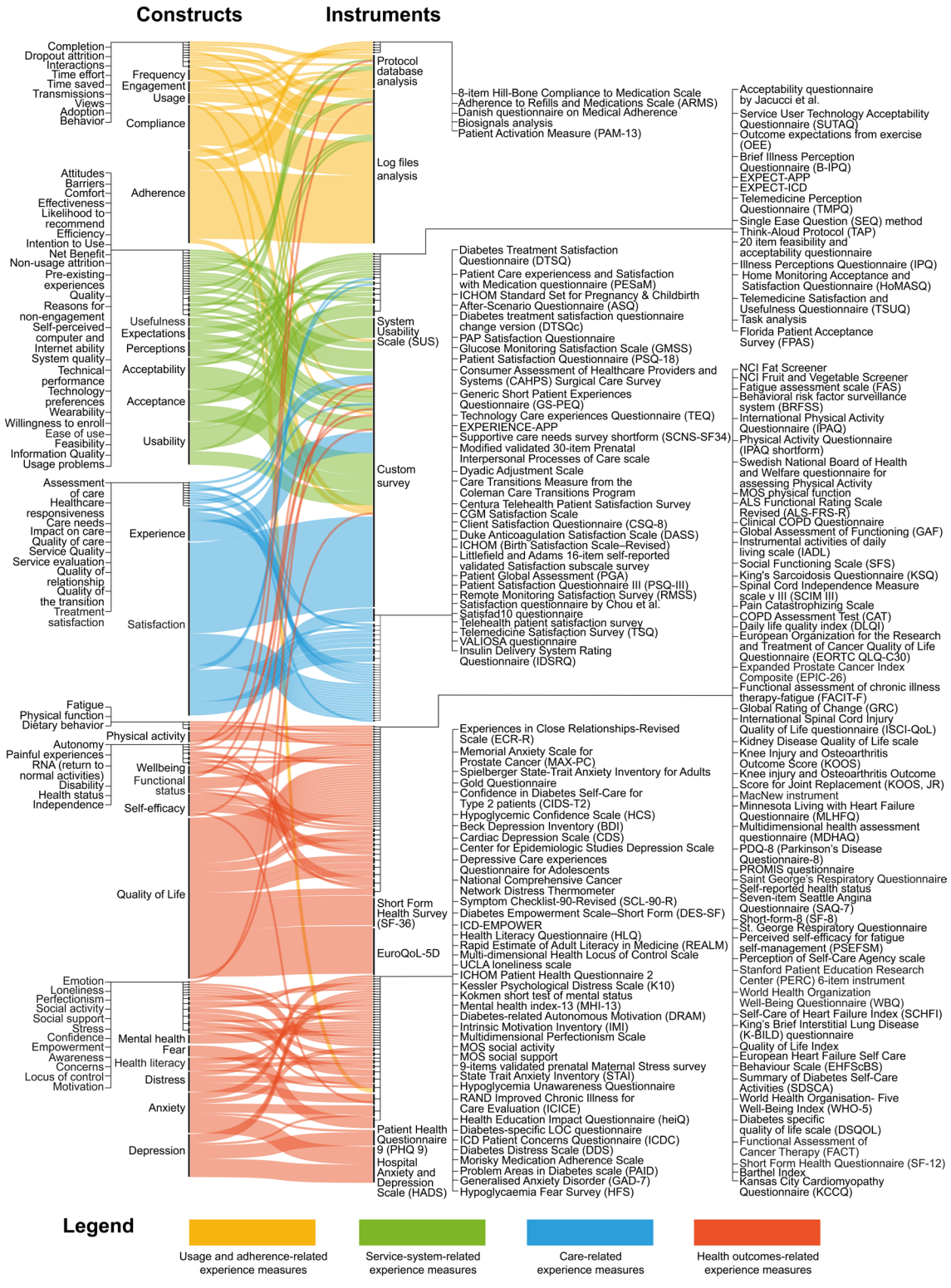


Figure 25. Clustered results of the correspondence analysis (displayed on a logarithmic scale).

Overall, this categorization of patient and staff experience constructs used in RPM literature paints a landscape of the contemporary research in this field, which shows a mix of influences from clinical disciplines, health psychology, human factors engineering, service design, user research, systems engineering, computer science, and their overlaps.



An overall visualization of the reported patient experience constructs and related measuring instruments, organized by the categories identified in the correspondence analysis, is available in Figure 26. In this figure, we can note the limited crossovers between constructs belonging to different categories, with the exception of versatile instruments such as custom survey and log file analysis.

Figure 26 (previous page) . Reported patient experience constructs (left) and associated measuring instruments (right). The thickness of each line refers to the number of instances each construct was used in the included literature.

7.2.4 Discussion

This review aimed at building a structured overview of patient and staff experience measures used in contemporary RPM research. From this effort, it was found that the research landscape has seen a sizeable growth in the past ten years, that it is affected by a relative lack of focus on staff experience, and that the overall corpus of collected measures can be organized in four main categories (service-system-related experience measures; care-related experience measures; usage and adherence-related experience measures; and health outcomes-related experience measures). Furthermore, it was found that while a large number of studies mention experience measuring, little to no consensus or standardization was found in the adopted methods. These results align with and expand on recent contributions in the field, with particular regard to the work of White et al. (2022).

We acknowledge both strengths and limitations of the chosen methodologies. The main strength of this review is its extensive focus, covering a large number of experience measures and RPM interventions. However, a limitation introduced by such a broad scope is the lack of differentiation by targeted condition, clinical specialty, RPM intervention characteristics, geographical area or other relevant distinctions. Furthermore, limitations are introduced by choices such as focusing exclusively on contributions in English and on non-primary care and non-paediatric RPM interventions.

In the light of the collected findings, we provide a set of recommendations to RPM patient and staff experience evaluators, both in terms of what to measure and of how to measure it (Figure 27). While these recommendations are functional to strengthen the quality of individual research protocols, they are also meant to stimulate increased standardization in the field.

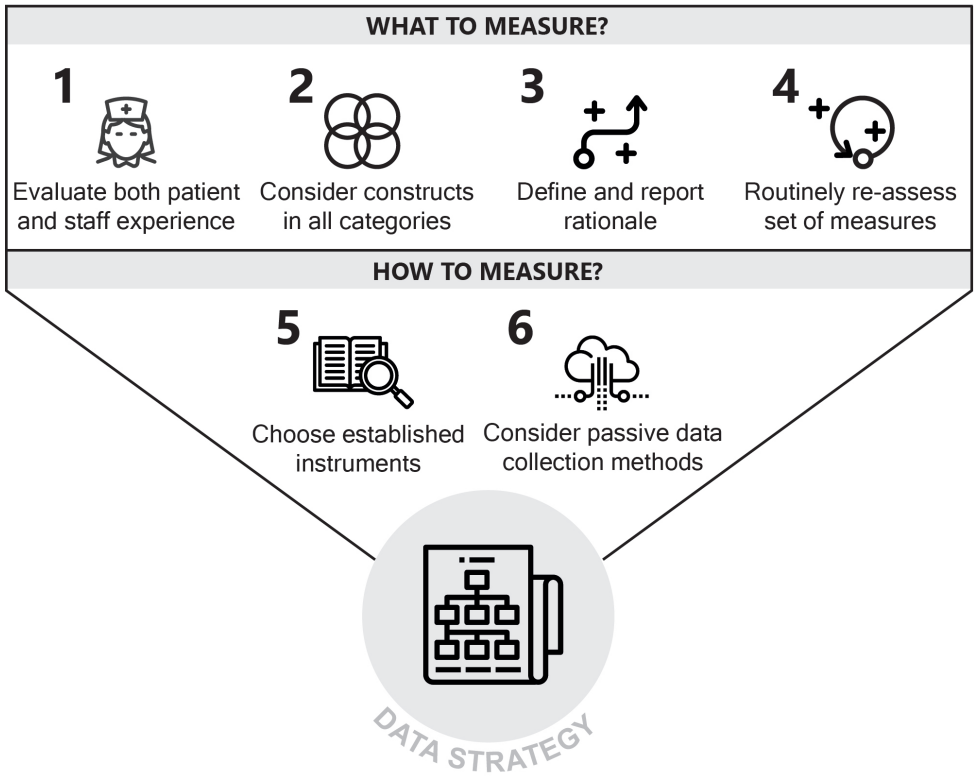


Figure 27. Recommendations for patient and staff experience evaluation in the Remote Patient Monitoring domain.

When it comes to determining what to measure, four main recommendations are provided.

The first is to conduct structured evaluations of staff experience next to patient experience. Failing to evaluate staff experience leads to risks such as undetected staff non-adherence, misuse, and overworking. While new competencies need to be developed in order for staff to unlock the untapped potential of RPM (Hilty et al., 2021), seamless integration with existing clinical workflows should always be pursued and monitored.
The second recommendation is to consider experience constructs in all four clusters indicated in Figure 25, as these represent complementary facets of an overall experiential ensemble. Failing to do so exposes RPM evaluators to the risk of obtaining partial information on patient and staff experience, e.g. only shedding light on how people feel but not on what happens in terms of patient and staff experience, or vice versa.

The third recommendation is to explicitly define and report a clear rationale regarding which aspects of patient and staff experience to prioritize in evaluations, depending on the goals and specificities of the RPM intervention. This rationale should ideally be informed by preliminary qualitative research, and by a collaborative mapping of the expected relations between patient and staff experience and other components of the Quadruple Aim for the RPM intervention at hand. Failing to follow this recommendation exposes RPM evaluators to the risk of obtaining results that are logically detached from each other, and as such cannot inform organic improvement efforts.A virtuous example of reporting a clear rationale is provided by den Bakker et al. (2019), in which a detailed logic model of the problem and contextual digital intervention is used to guide the selection of the used measures. Several existing frameworks and methods can be used to map such relations, including the NASSS framework (Greenhalgh et al., 2017) and the logical framework (Dey et al., 2006). A relatively lightweight method to achieve such overview can also be represented by the use of Figure 20 as a checklist to inventory possible Quadruple Aim relations for a specific RPM intervention.
The fourth recommendation is to routinely re-assess the chosen set of experience measures after each iteration of the RPM intervention design. Initial assumptions regarding relations between experience factors and other dimensions of intervention quality should be verified once the relevant data is available, and new ones formulated if necessary. If the RPM intervention transitions from research stages to implementation as standard of care, it is recommended to keep on collecting at least some basic experience measures for system quality monitoring and continuous improvement. Failing to update the set of collected measures as the RPM intervention progresses through successive development stages exposes RPM evaluators to the risk of collecting outdated information, hindering iterative improvement processes.

When it comes to determining how to measure RPM patient and staff experience, two main recommendations are provided.

The first is to work with existing, validated and widely used instruments as much as possible, and only create new instruments after a convincing critique against current ones. Figure 25 and 26 can be used as a way to find existing instruments measuring a broad range of experience-relevant constructs, so to reduce the need to create new ones. Failing to follow this recommendation exposes RPM researchers to the risk of obtaining results that cannot be compared to meaningful benchmarks, to other RPM interventions, or be included in meta-analyses.
The second recommendation is to consider adopting automatic, 'passive' methods of experience data collection, such as the ones we have referred to in this review as log files analysis, so as to obtain actionable estimates of user behaviour with a reduced need for patients and staff to fill tedious surveys (de Koning et al., 2021), or otherwise provide active input.

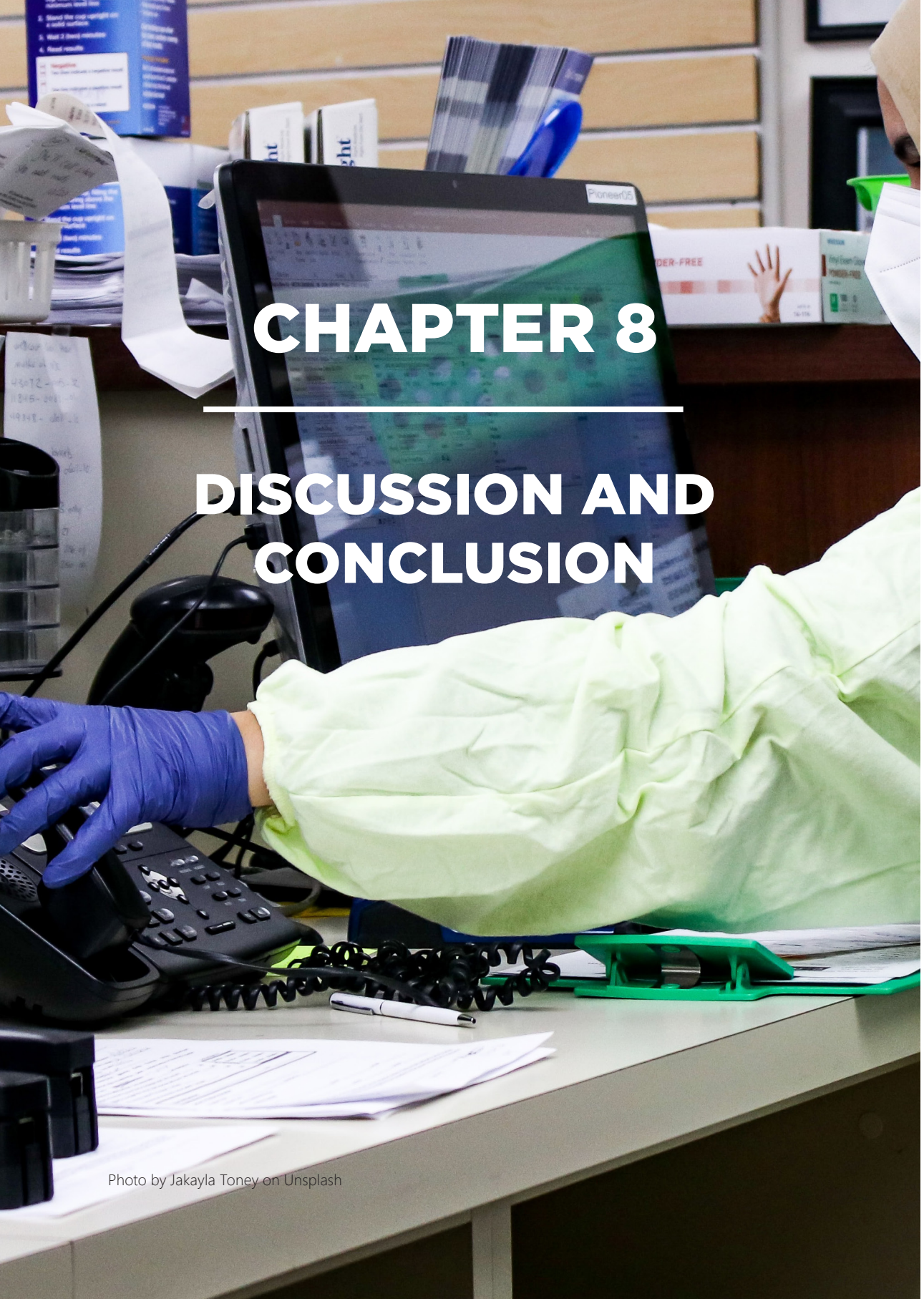
Failing to consider automatically collected log files data on patient and staff experiences constitutes a missed opportunity both in terms of quality and cost of evaluation data. We recognize such nascent data innovations as promising (Miriovsky et al., 2012) but also in need of methodological definition, particularly in terms of an ethical evaluation of data privacy and access (Fernández-Alemán et al., 2013; Martínez-Pérez et al., 2014) to avoid exploitative forms of prosumption (Lupton, 2014)

Ultimately, a structured overview of patient and staff experience measures will allow for the establishment of integrated data strategies for RPM, intended as the processes and rules that define how to manage, analyse, and act upon RPM data, including continuously collected experience data, and clinical, technical and administrative data. Data strategies can represent a way to operationalise a systems approach to healthcare innovation, described by Komashie et al. (2021) as "a way of addressing health delivery challenges that recognises the multiplicity of elements interacting to impact an outcome of interest and implements processes or tools in a holistic way." As complex, adaptive and partly automated systems, RPM interventions require sophisticated data strategies in order to function and improve (Abdolkhani et al., 2019); continuous loops of system feedback need to be established and analysed in order to monitor the impact of RPM systems and optimize their performance over time while respecting patients' and staff's privacy. This is especially true in the case of RPM systems including artificial intelligence (AI) components, which require continuous monitoring and updating of algorithms (Feng et al., 2022; Gerke et al., 2020; de Hond et al., 2022).

We characterize the development of integrated, interdisciplinary data strategies as a paramount challenge in contemporary RPM research, and hope to have provided a small contribution to this overall goal through our effort to structure the current landscape of RPM patient and staff experience evaluation.

Data availability

The datasets generated and analysed during this review study are available in the 4TU.ResearchData repository at https://doi.org/10.4121/21930783.v1



CHAPTER 8

DISCUSSION AND CONCLUSION

Photo by Jakayla Toney on Unsplash

8.1 Summary and review of findings

As described in **Chapter 1**, the doctoral research started out with a series of explorative studies on the topics of design, data and digital health.

The objective of my first study (**Chapter 2**) was to investigate the role of design in the health domain at large, to better understand the positioning of my research and its potential impact. I did this by applying the Quadruple Aim (Sikka et al., 2015), a well-known framework of healthcare improvement based on four pillars: improving health outcomes, reducing costs, improving the experience of patients, or improving the experience of clinical staff. By reviewing recent papers in the digital health design domain, I found that digital health designers almost always worked on improving the experience of patients and staff, rarely focused on cost-effectiveness, and only sometimes considered multiple aims at once. This last category of design research examples particularly interested me, as I suspected that improving experiences alone - without consideration for the other aims - may be insufficient for responding to the needs of the healthcare domain. Through a brief analysis of global epidemiological trends, I sketched a profile of the situation of crisis affecting health systems worldwide, and argued that such a crisis needed to be addressed by considering human, technical and clinical factors in an integrated way within design processes. Closer collaboration across designers and stakeholders from other perspectives and disciplines, possibly facilitated by the collaborative use of data, was suggested as a way to facilitate such integration. Blood pressure data was used as an example of a possible health-related data point to explore through collaborative design research.

Chapter 3 further explored the topic of collaborative design research with the use of blood pressure data through a lead user study. The study was based on the collaborative exploration of self-tracked blood pressure (BP) data with participants belonging to the Quantified Self, an online community of users and makers of self-tracking tools who share an interest in "self-knowledge through numbers" (see Lupton, 2016). These participants were chosen as they were expected to be more interested in their own health data compared to the general population, in addition to being more knowledgeable and creative about self-tracking devices and data transfer. Through the collaborative exploration of emerging BP data collection and analysis practices in this group, early ideas for data-driven functionalities for personal digital health interventions could be collected.

Examples of these functionalities included the capacity to observe relations between BP fluctuations and personally-relevant metrics such as tremor intensity, medication intake, or menstrual cycle. Such ideas were recognized to be especially relevant for the early-stage design of complex digital health interventions (relying on different users, devices, software components and organisations).

In **Chapter 4**, I explored and expanded an existing design approach called data-enabled design (van Kollenburg & Bogers, 2019). This approach is based on the use of continuously collected data to conceptualise and deploy new digital health design interventions directly in a remote context. Designers involved in data-enabled studies can learn from sensor data collected from the context (e.g. through wearables, trackers, and smart devices in the house of participants) and directly code updates, new features, or new interactions into the digital intervention being tested. To deepen my practical knowledge of the data-enabled design method, I participated in a project directed at the development of a digital health intervention for post-operative bariatric care. This intervention was fuelled by clinical, behavioural, experiential and contextual data, and was meant to provide tailored care and connect patients, partners, and health professionals. The project was used as a case study to explore a potential role for service designers within data-enabled projects, in addition to the previously defined roles of design researchers (adopting a user-experience oriented perspective) and data designers (adopting an experimental, prototype-centric perspective). The role of service designers within data-enabled design was preliminarily defined through the identification of two functions, namely the integration of other perspectives and the facilitation of data-enabled co-production.

The explorations conducted in the previous three chapters represented a way to delve into the existing research and practice landscape in digital health design, surfacing relevant themes such as patient and staff experience, interdisciplinary integration, and digital data. Yet, the collected insights were so far mosty from within the design domain, and stemming from a designer perspective on digital health. However, I was also interested in understanding the impact of different approaches to the use of data in digital health design on broader, system-level dynamics in the health domain. In this sense, an overview of existing and emerging approaches to the use of data for digital health design was found to be missing. This was identified as a knowledge gap preventing researchers from navigating the variegated and fragmented landscape of current digital health design practices, and from critically examining data-related challenges and opportunities. Therefore, a first research question was formulated: 'what are existing and emerging approaches to the use of data for digital health design?'

In **Chapter 5**, I provided an answer to this question through a contribution in which four approaches were identified and described: the silent, the overt, the data-enabled and the convergent.

In this contribution, four approaches were identified and described: the silent, the overt, the data-enabled and the convergent. The silent was characterised as a design approach to digital health conducted by individuals or groups who are not professional designers, and who do not explicitly perform data collection activities to inform a formal design process. The overt was characterised as an approach conducted by trained designers who explicitly perform data collection activities to inform their design processes. The data-enabled was characterised as an approach in which trained designers go beyond linear data collection activities, and establish data collection loops directly from the context of use to inform design processes. Finally, the convergent was characterised as an approach in which continuous data collection from the context of application is employed both for design purposes and for other kinds of data-driven processes, such as clinical evaluation, cost evaluation, policymaking, algorithmic auditing, or more.

This latter approach was recognized to be functional to the goal (initially identified as desirable in Chapter 2) of improving collaboration across designers and stakeholders from other perspectives and disciplines through data. In addition, the establishment of shared data infrastructures informing both continuous (re) design and other kinds of continuous data-driven processes was recognized as a challenge for convergent approaches. This challenge was linked to the vision of the learning health system, defined as 'one that is designed to generate and apply the best evidence for the collaborative healthcare choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care' (Medicine & America, 2013). Particularly, an opportunity was recognized for digital health design processes following a convergent approach to represent a small-scale, local testing ground for the larger-scale transition towards learning health systems. As such, the convergent approach was recognized as a direction for desirable methodological development in the digital health design domain.

The definition of the four approaches to the use of data for digital health design represented the conclusion of a first research cycle and the start of a second one. In this second cycle, the research focus was narrowed down to one of the four approaches described in the previous study, namely the convergent. Furthermore, the Remote Patient Monitoring (or Remote Patient Management, RPM) domain was chosen as an ideal subset of digital health in which to investigate convergence, as elaborated upon in the **Intermission**. Therefore, a new question was formulated: How can the convergent approach to Remote Patient Monitoring design be formalised?
To answer this question, a new activity was undertaken, aimed at applying the principles of convergent approaches as defined in Chapter 5 to a real-life RPM study protocol. This activity, described in Appendix II, concerned a project called the Perioperative Box, a digital health intervention for remote monitoring of major gastrointestinal surgery patients.

The objective of the Perioperative Box project was to monitor patients before and after the surgery, with the objective of spotting early signs of post-surgical deterioration and preventing postoperative complications. Within the context of this project, a study protocol was defined in collaboration with clinical and technical partners. This protocol was devised to allow for the collection of data relevant to design purposes (e.g. patient and staff experience evaluation) as well as data relevant to other processes (e.g. assessment of the predictive value of the data collected through the Box).
While the study itself was eventually not carried out for independent reasons, the effort to reconcile different data collection purposes within a single study design surfaced the need for methodological compromise, revealing practical implications of the convergent approach as defined in Chapter 5. For instance, from a design point of view, it would have been ideal to collect information on the care experiences of patients using the Perioperative Box as well as the experiences of patients receiving the standard of care, so as to obtain a patient experience baseline. However, this option proved impossible to implement in the study protocol, as the expected benefits from including an experience control group were overall not deemed to justify the connected costs and inconveniences to patients.
Furthermore, the choice of experience measures to include in the protocol was adapted to fit into a clinical research paradigm. Particularly, the use of standard, validated experience measures was preferred to the use of custom-made, intervention-tailored ones which might have been chosen in a mono-disciplinary design study. This is because the use of standardised and validated measures improves the chances of experiential insights to be trusted by health professionals, and allows for the establishment of links between experiential and clinical insights. The need to select existing patient and staff experience measures to include in the Perioperative Box pilot protocol prompted the execution of two more review studies.

Chapter 6 is dedicated to a scoping review of the main problems and advantages that RPM interventions bring to staff experience in perioperative care, and to the approaches taken to evaluate the impact of those interventions. Insights from the review were organised by categories (RPM problems and challenges, benefits, risk reduction strategies, and methods for assessing impact) and themes (planning and implementation, workload and logistics, technology, data, health care resources, and patient relationship).
The main RPM-related problems for clinical staff were found to be related to undesirable workflow changes. On the other hand, the main reported benefits of RPM for clinical staff pertained to improvements in patient monitoring and data analysis, resulting in improved resource management and clinical outcomes. Reported risk reduction strategies included the adoption of participatory approaches, the establishment of clear roles and responsibilities, user-friendly technology, and 'smart' monitored data analysis.

Regarding methods for assessing the impact of RPM interventions on clinical staff, two main types were identified, namely time and activity-focused, and satisfaction and experience-focused analyses.

In **Chapter 7**, I performed a systematic review of patient and staff experience constructs (e.g. usability) and corresponding measuring instruments (e.g. System Usability Scale) used in contemporary RPM research. The results included 173 unique experience measuring instruments employed to measure 121 unique experience constructs in recent papers evaluating RPM interventions. Within this corpus of results, a correspondence analysis (CA) was performed to identify four main clusters, namely usage and adherence-related experience constructs, service-system-related experience constructs, care-related experience constructs and health outcomes-related experience constructs. On the basis of the collected results, a set of recommendations was provided to improve the selection of patient and staff experience constructs and instruments to be used in RPM evaluation. Altogether, these recommendations are meant to improve the quality of individual research protocols on one side and stimulate an increased standardisation in the field as a whole on the other side. In this way, patient and staff experience data can become part of integrated data strategies - intended as the processes and rules that define how to manage, analyse, and act upon RPM data, be it experience data or clinical, technical and administrative data. The concept of integrated data strategies for RPM is recognized as a direction for further research.

A recapitulation of the overall structure of the doctoral research and of its main results is offered in Table 7.

Table 7. Recapitulation of doctoral research contributions, main results and main intended audiences.

Ch.	Contribution	Main results	Intended audience
2	Pannunzio, V., Kleinsmann, M. S., & Snelders, D. (2019). Design research, eHealth, and the convergence revolution. In IASDR 2019: International Association of Societies of Design Research Conference 2019.	• Recognition of digital health designers as enablers of improved patient and staff experiences. • Articulation of the need for designers to connect their focus on experiences to other dimensions of care improvement, particularly health outcomes and cost-effectiveness, in order to better support the tackling of contemporary health challenges.	Design (particularly digital health design and health systems design).
3	Pannunzio, V., Kleinsmann, M., Duarte, C., & Snelders, D. (2020, May). Finding the land, planting first seeds; lead user research in early stage design for intelligent ecosystems. In Proceedings of the Design Society: DESIGN Conference (Vol. 1, pp. 2099-2108). Cambridge University Press.	• Example of the potential for designers and (lead) users to collaboratively explore new digital health functionalities through the use of self-tracked health data. • Recognition of lead user research as a valuable source of insights for digital design, and in particular for the early-stage design of complex digital health systems.	Design (particularly digital health design)
4	Pannunzio, V., Lovei, P., Neutelings, I., Deckers, E., Jansen, J. M., & Burghoorn, A. W. (2020). Exploring the service system perspective on designing intelligent health ecosystems: the co-responsibility study. In 6th International Conference on Design4Health2020/ Online (pp. 469-477). Sheffield Hallam University.	• Definition of a role for service designers within data-enabled design, adding to the previously described roles of design researchers and data designers.	Design (particularly digital health design and digital service design)
5	This contribution is under a second round of review in a peer-reviewed journal.	• Structured overview of existing and emerging approaches to the use of data in digital health design.	Design (particularly health systems design and digital health design)
6	León, M. A., Pannunzio, V., & Kleinsmann, M. (2022). The Impact of Perioperative Remote Patient Monitoring on Clinical Staff Workflows: Scoping Review. JMIR Human Factors, 9(2), e37204.	• Overview of the challenges and benefits of perioperative RPM for clinical staff, of relevant risk reduction strategies, and of available methods for assessing RPM's impact on clinical workflow.	Design (particularly health systems design and digital health design) Human factors engineering Medicine (particularly digital medicine and perioperative care)
7	This contribution has been submitted to a peer-reviewed journal.	• Comprehensive, structured overview of patient and staff experience constructs and measuring instruments employed in RPM evaluation. • Set of practical recommendations to improve experience measuring in RPM evaluation within a broader context of integrated RPM data strategies.	Design (particularly health systems design and digital health design) Medicine (particularly digital medicine)

8.2 Summative reflections and opportunities for future research

A closing general reflection can be offered to review the overall doctoral research trajectory. This reflection concerns a gradual expansion, observable through the overall research pathway, of the factors and stakeholders considered as part of digital health design. This expansion can be noticed, for instance, in the kinds of data I considered as part of design processes in different chapters. Gradually, my focus shifted from self-managed, self-monitored vital signs alone (in the Quantified Heart study in Chapter 3), to patient profiles and data from various sensors and chatbots (in the Co-responsibility study in Chapter 4), to an even broader – but not anymore only design-managed – set, including medical records, sensors data, measures of interactions, and standardised experience questionnaires (in the Perioperative Box project in Chapters 6 and 7).

The reasons for this progressive broadening of scope are to be found in a change in my implicit assumptions behind the research. In the initial phases, I implicitly assumed that the inclusion of different perspectives in data-driven design could, in itself, help tackle large-scale challenges in the digital health domain (Chapter 2). This rather naive perspective was soon challenged by practice, as it quickly became evident that increased interdisciplinarity and collaboration would not, on their own, translate into better real-life outcomes. Interesting projects could be conducted, promising concepts could be drafted, and insights about digital health design could be collected (Chapters 3 and 4): yet, none of the above would likely result in bringing effective digital health innovations past experimental stages, and towards implementation at scale.

This realisation was related to the well-known issue of 'pilotitis', intended as the tendency for digital health projects to never advance from the pilot stage to implementation at scale (see e.g. Egermark et al., 2022). To overcome pilotitis, increased attention needs to be devoted to the larger system of care, and in particular to governance, including the relevant financial, organisational and regulatory frameworks. Therefore, different approaches to digital health design started to be examined from a system perspective rather than in isolation, and functions such as clinical evaluation, cost evaluation, policymaking, and algorithmic auditing started to be considered as relevant influences on digital health design (Chapter 5).

Following, the experience of the Perioperative Box project allowed for a closer look at the phenomenon of pilotitis and at the numerous challenges that affect collective efforts to develop and test digital health interventions. Technical and organisational problems, difficulties in obtaining medical ethical approval, and changes in system-level circumstances (including the advent of the covid-19 pandemic) contributed to deferring the initial project plan by several years.

Facing these challenges allowed for a deeper understanding of the complex set of factors affecting real-world success in digital health research and (large-scale) implementation. As a result, good patient and staff experience started to be understood as only one of the many system-level components necessary for effective digital health implementation and scaling. Consequently, increased attention started to be paid to the relations between patient and staff experience and other measures of quality. Particularly, the need was recognized for experience evaluation to be integrated with existing clinical evaluation practices and general health system governance (Chapter 6 and 7).

In addition, the Perioperative Box experience allowed for examining practical implications of the convergent approach to digital health design as defined in Chapter 5. Particularly, the need to integrate design data collection within an interdisciplinary study protocol resulted in both design pitfalls and design opportunities. By design pitfalls, we refer to choices that might have been preferable from a design point of view, but proved impossible to integrate within the collaborative study. For instance, the absence of an experience control group in the Perioperative Box study protocol constituted a necessary compromise for the practical application of the convergent approach. By design opportunities, we refer to choices that were motivated by the application of the convergent approach and resulted in advantages from a design point of view. For instance, the effort to standardise patient and staff experience evaluation measures for RPM resulted in an improved capacity for design-relevant (intended as experiential) insights to be embedded in interdisciplinary data strategies, expanding the capacity for design to inform interdisciplinary decision-making in a structured, integrated way.

Interestingly, both design pitfalls and design opportunities brought about by the application of the convergent approach in the Perioperative Box study relate to the issue of comparative evaluation. Specifically, the absence of an experience control group endangered the buildup of 'hard' evidence on patient and staff experience - intended as evidence based on a comparative evaluation between the experience of patients and staff using the standard of care, and the experience of patients and staff using the new digital health intervention. On the other hand, improved standardisation of patient and staff experience measures is a prerequisite for the buildup of 'hard' evidence - in this case, evidence that is based on the comparative evaluation of the experience of patients and staff between different digital health interventions.

Ideally, the integration of continuous, interdisciplinary data strategies within healthcare systems at large (an embodiment of the vision of the learning health system) would overcome the mentioned design pitfalls and fully reaps the benefits of the mentioned design opportunities.

Overall, it is proposed that both the identification of four approaches to the use of data for digital health design (RA1) and the offered set of recommendations for embedding experience measuring in RPM evaluation through integration in interdisciplinary data strategies (RA2) can constitute steps towards overcoming pilotitis. Particularly, these contributions support a closer integration of design and clinical perspectives on digital health innovation, as they provide an initial framework for multidisciplinary teams wanting to consider design-relevant factors, clinically-relevant factors and the relations between the two when developing and evaluating new digital health interventions. This, in turn, is expected to allow digital health innovators and researchers to achieve a richer understanding of the real-world effectiveness of digital health interventions, ultimately supporting the development and selection of better solutions.

Yet, many unanswered questions remain, including the feasibility of large-scale adoption of convergent approaches and the kind of organisational restructuring that would be required to achieve such a goal. Currently, governance structures carefully protect patient and staff data, and few forms of collaboration allow for the kind of longitudinal, interdisciplinary data sharing necessary for convergent design approaches. More stable forms of organisational integration might be necessary between digital health designers and digital health providers to achieve convergence at scale, and enable a digital health data ecosystem that is conducive to innovation, respectful of patients' and providers' privacy, compliant with relevant rules and regulations, and capable of performing continuous algorithmic monitoring and improvement. The aspect of organization design was not explicitly addressed in this doctoral research, but it constitutes an interesting opportunity for future investigation.

Future research opportunities are identified in the possibility of further developing practical knowledge on convergent digital health design through the application of integrated, dynamic data strategies. In particular, it will be valuable to apply data strategies in the scaling up of digital health interventions (in particular RPM) beyond the pilot stage, a next research step for which funding has been secured during the last year of the doctoral research (CLICKNL, n.d.).

Furthermore, collaboratively developing, applying and refining data strategies in interdisciplinary digital health innovation constitutes a chance to develop knowledge on designing for system change, since digital health innovation constitutes a form of sociotechnical transition with complex, multifaceted and hard-to-predict implications.

In part, this complexity derives from the fact that digital health systems are themselves part of larger, pre-existing systems of healthcare service delivery, in which they need to be effectively integrated in order to avoid redundancy, increased pressure on an already burdened workforce, and loss of overall quality of care. A stimulating direction in this sense is represented by the opportunity to conduct research on data strategies from a systems approach, exploring the use of interdisciplinary, longitudinal sets of measures at a system level.

In addition to the previously indicated opportunities for further research, we indicate the need for a re-examination of the premises behind the scope of the doctoral research itself. Particularly, the covid-19 pandemic and the growing threat of climate change have surfaced new priorities for global health systems, which no longer just need to be "learning", but also resilient. Modern health systems and their digital infrastructures need to be able to adapt to incremental, long-term trends but also to unexpected health emergencies, all while maintaining a sustainable utilisation of their financial and human resources. This need raises new questions regarding digital health transformation in general and convergent approaches to digital health design in particular. How to develop data strategies that allow not only for interdisciplinarity and continuous improvement, but also for rapid rearrangement? How to build digital health data systems that can be repurposed for the rapid development of new interventions in case of sudden crises? While stimulating research has been conducted on this topic (see e.g. Haldane et al., 2021; Fridell et al., 2019; Masko, 2011) further efforts are necessary to support a transition towards health systems that are both learning and resilient, which is to say adaptive at different scales.

8.3 Strengths and limitations

In my view, the main strength of this doctoral research can be attributed to an extensive entanglement of real-life practice with relevant scientific literature. On one side, practice-based activities were conducted in diverse settings and with different partners. On the other side, the reviewed literature spanned fields such as digital health design, human factors engineering, and clinical research. These two combined efforts, taken together, strengthened the capacity of the presented research to point to new standards for digital health design, building upon up-to-date, relevant knowledge from a broad, collaborative (research) community. This community includes several of the most advanced digital health innovation players in the Dutch context, strengthening the capacity for the presented research to constitute an up-to-date exploration of current, best-practice digital health design in the Netherlands and Europe, hopefully inspiring digital health practices worldwide.

At the same time, the research also presents a number of limitations.First, the relative advantages and disadvantages of the convergent approach compared to traditional digital health design practices could never be demonstrated through rigorous comparison, but are derived from the analysis of a series of case studies. As such, no hard conclusion can be drawn from this thesis regarding the capacity of the convergent approach in itself to improve any comparative measure of quality of digital health design outputs. This is however in line with convergence literature, which describes a need for convergence on a system level, rather than at the level of individual initiatives (Hockfield et al., 2016).

Second, this thesis has an explorative nature, and develops on the verge of a nascent field for design, namely data-enabled design methods in digital health. The consecutive explorations and iterations on the research focus have affected the linearity and consistency of the doctoral research outcomes: for instance, the technical sub-speciality of interest across the performed studies was recognized first as “eHealth”, then as “intelligent health ecosystem”, and finally as “digital health“, further limited to the context of “Remote Patient Monitoring”. Similarly, the notion of convergence changed throughout the doctoral journey from a broad, ongoing revolution in digital health innovation (Chapter 2), to a more specific approach to the use and sharing of data in digital health design (Chapter 5).

Third, a limitation is identified in the short timespan of the included projects, none of which covers a longitudinal, scaled-up digital health intervention. While this limitation proved impossible to overcome within the time of the doctoral research, it constrains the strength of the obtained results and their relevance for real-life practice.

Overall, I invite readers to consider this research as a practice and literature-informed exploration of current topics in data-driven digital health. By reporting on this exploration, I hope to have provided inspiration and support to other design and health researchers and practitioners wishing to participate in the urgent societal challenge to improve healthcare with the help of digital technology.

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APPENDICES

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Appendix I

Table 8. Included contributions and Quadruple Aim objectives or achievements

#	Reference	Year	Design research approach	Mention of improved patient experience	Mention of improved health staff experience	Mention of improved clinical outcomes	Mention of reduced cost
1	(Vandermaesen et al., 2014)	2014	UCD	'Therapists stated that the prototypes provided a challenging physical training on skill components. Our games also reduced the focus of the repetitive character of physical therapy, which made our training more motivating'			
2	(Lindberg et al., 2014)	2014	UCD, PD	'Social support'			
3	(Hernandez et al., 2014)	2014	UCD	'We show that networked video games can provide a venue for social interaction from the home'			
4	(Cornelius & Priyadarsini, 2014)	2014	UCD		'Superior user/ customer Experience was the foundational principle'		'Bring business benefits to the customers of the product'
5	(Jalil et al., 2014)	2014	'Clinical User-Experience Evaluation (CUE)'		'Touchscreens are fast to learn and enjoyable by patients (...) The use of familiar metaphors such as windows are helpful'		
6	(Sakata et al., 2014)	2014	UCD	'We expect users to continue to use the application and become more motivated to actively improve their mental health'			'Beam is a cost-effective solution'
7	(S. T.-Y. Huang et al., 2014)	2014	Contextual research, usability testing	'Can be helpful to better understand and deal with the emotions'		'Can be helpful for treating symptoms of bipolar disorder'	
8	(Gao et al., 2014)	2014	UCD	'Helping expectant parents to have better experiences during pregnancy'			

9	(Albiol-Pérez et al., 2014)	2014	UCD
10	(Threatt et al., 2014)	2014	UCD, PD
11	(Nørregaard et al., 2014)	2014	UCD
12	(Wärnestål et al., 2014)	2014	UCD
13	(Irani et al., 2014)	2014	User satisfaction (COBRA framework)
14	(Devine et al., 2014)	2014	Heuristic evaluation
15	(Klemets & De Moor, 2015)	2015	UCD

'The results that we are currently obtaining are based on the patients' feedback and their high level of satisfaction'		'Improve the effectiveness of upper-limb rehabilitation'; 'high levels of functionality related to muscle tone, pronation/ supination, flexion/ extension, and adduction/ abduction of the wrist'
'The research team sought to understand clinician and perceived patient usability issues associated with our development of an assistive robotic table'	'Allows the therapist to do much more in a [rehabilitation] setting than we were able to do'	
'Patients' expectations were mostly met'		'Overview over symptoms is improved while at the same time providing the opportunity to catch a recurring depression earlier'
'Facilitate health-promoting social connectedness to other children with similar experiences'		
'The qualitative feedback obtained from the participants can be used to further improve the PPC website functionality, user support, and increase citizens' trust and and awareness'		
'Usability evaluation results suggest that participants considered PGx information important for improving prescribing decisions; and that they would incorporate PGx-CDS when information is presented in relevant and useful ways'		'Usability evaluation results suggest that participants considered PGx information important for improving prescribing decisions; and that they would incorporate PGx-CDS when information is presented in relevant and useful ways'
	'The system could support and improve the communication among nurses and reduce the number of unwanted interruptions'	

16	(Park et al., 2015)	2015	UCD
17	(Georgiou et al., 2015)	2015	Blended user-centered approach
18	(Jain & Yammiyavar, 2015)	2015	UCD
19	(Chen et al., 2015)	2015	RTD
20	(Schaefbauer et al., 2015)	2015	UCD
21	(Kaziunas et al., 2015)	2015	UCD
22	(Claes et al., 2015)	2015	Research[x]Design
23	(Latulipe et al., 2015)	2015	UCD

‘Teens and providers can use the information to adjust medications or increase closer monitoring during stressful times'			‘Teens and providers can use the information to adjust medications or increase closer monitoring during stressful times'
			‘Restoring mobility and rehabilitation of gait'
‘Leverage the support of fellow adolescent girls in rural Assam to tackle problems of puberty and learn from each other’s experiences'			
‘A qualitative study is currently being carried out to investigate user experiences of engaging in the mindful walking activity supported by this app'			‘Enhancing mental health, for example, reducing physical symptoms and anxiety associated with minor stress'
‘More work needs to be done comparing the acceptability and effectiveness of different design approaches intended to bridge'			‘Family-level sociotechnical interventions for healthy snacking'
Supporting the processes of bringing people more comfortably into adopting very new life circumstances'			
‘We evaluated the user experience and its impact on a lay user’s insight generation process'			
‘Our findings point to some ways to make patient portals more palatable to low-income, elderly patients and caregivers'		‘Potential to actually see (...) health care benefits'	‘Potential to actually see economic (...) benefits'

23	(Latulipe et al., 2015)	2015	UCD			'Our findings point to some ways to make patient portals more palatable to low-income, elderly patients and caregivers'		'Potential to actually see (...) health care benefits'	'Potential to actually see economic (...) benefits'
24	(Jezewski et al., 2015)	2015	UCD			It should also increase their psychological and social comfort'	'Semi automatic realisation of medical procedures and workflows by the monitoring system should be enabled, as well as increased interoperability of all involved medical devices'	'Ensure effective medical care to all women from the group of high-risk pregnancy (diabetes, pregnancy induced hypertension, post term pregnancy)'	
25	(Yildirim Yayilgan et al., 2015)	2015	UCD			'Improve skiing experience'	'Improve the information chain to the medical staff from the ski resort'		
26	(Smaradottir et al., 2015)	2015	UCD				'Improve the information flow between the members of an inter-municipal dementia team'		
27	(Fronemann et al., 2016)	2016	UCD			'First results show that most positive experiences revolve around other people (family & friends). In total, twelve experience categories were identified which can be grouped into the three experience themes "connecting with people", "expressing oneself" and "meeting a challenge"'			
28	(Cila et al., 2016)	2016	UCD			'Measure its impact on participant motivation, health awareness, and neighborhood ownership'			
29	(Solomon et al., 2016)	2016	UCD			'We undertook an iterative, user-centered design process to explore ways to design meaningful representations of test results'			

30	(Katusiime & Pinkwart, 2016)	2016	UCD
31	(Rodolfo, 2016)	2016	UCD
32	(Branco et al., 2016)	2016	co-design, participatory design
33	(Geurts et al., 2016)	2016	UCD
34	(dos Santos et al., 2016)	2016	UCD
35	(Schäfer, 2016)	2016	UCD

'Moreover, the system saves time and saves the women from unnecessary travels to and from the health facilities to access maternal health information'	'To some extent, the system also reduces the workload of the health workers by sending information to the women's mobile phones instead of having face to face health education talks with the women'	'Results indicate that the implementation may be a feasible way (...) to reduce maternal mortality in the long run'		
We expect to promote the senior's awareness about their health status and empower them on making meaningful life care choices, through self-monitoring and provider's communication support'				
'Promote meaningful and adequate leisure moments for people with dementia and their social circle'				
'All participants marked in the pre-test questionnaire that they perceive cycling as an enjoyable activity'		'We move on to a larger field test (intervention study or randomized controlled trial) to evaluate the clinical / rehabilitation effects'		
Better familiarization'; 'intuitive commands and easy visualization'				
'The second level are the qualitative measures of sustainable application usage. Those are defined as follows: -Durability of usage by dropout rate -Frequency of usage -Frequency of data input -Acceptance of recommendations'			'The results of the interventions will be measures on a quantifiable medical level; Healthy Eating Index (...) Body Mass Index (...) Nutrients (...) Blood Values: Triglycerides, Cholesterol, Iron,	

36	(Hagood et al., 2016)	2016	UCD
37	(Putnam et al., 2016)	2016	User centered approach
38	(Rennick-Egglestone et al., 2016)	2016	Future workshop
39	(Risso et al., 2016)	2016	UCD

'To address "confusion" in user experience, we are now developing a player dashboard more integrated in the game world and game narrative'		'Since 1980 the adolescent obesity rate has tripled, growing from 5% to 18% (...). Youth need access to information and resources to live healthier lives'	
	'Helped therapists use games with more confidence'		
'We have presented specific findings that complement prior work on user experiences of engagement with mental health technologies'			
'Initial research conducted on patients and caregivers shows promise for a smooth adoption of the CMS and evidences the impact of RTs in family quality of life'			'The CMS can potentially replace the pulse oximetry devices currently used at home, bringing economic benefits. (...) Furthermore, the CMS could potentially have an important impact on public health and healthcare costs through the implementation of specific disease prevention programs and through improved disease management programs'

40	(Neubeck et al., 2016)	2016	UCD
41	(Herselman et al., 2016)	2016	Design Science Research Process
42	(Zarabzadeh et al., 2016)	2016	Design Science Research Process
43	(Stütz et al., 2017)	2017	co-creation, UCD
44	(Yang et al., 2017)	2017	UCD
45	(Herrlich et al., 2017)	2017	UCD
46	(Poetri et al., 2017)	2017	user experience design me
47	(Al-Masslawi et al., 2017)	2017	UCD
48	(Martí Carrillo et al., 2017)	2017	co-design, In-Situ Design
49	(Andersen et al., 2017)	2017	PD

'Effective in strengthening relevance and usability of technology-based tools both for patients (...) and clinicians'	'Effective in strengthening relevance and usability of technology-based tools both for patients (...) and clinicians'	'Follow-up at 18-months has been inbuilt to the CONNECT randomised, controlled trial to provide useful insight into the lasting benefits of an e-health system'	
'Improve the quality of life of ordinary citizens.'			
	'Facilitate and support the wider adoption of CPRs amongst physicians'		
'The patients satisfaction using the app was very high'		'Exercise correctness was nearly perfect'	
'The functional prototype enabled us to implement different interaction strategies to elicit corresponding values'			
'Our results show that the concept was received well, as evidenced by excellent quantitative usability ratings and very positive qualitative feedback.'			
'By using the SUS, seven out of ten respondents deemed that the mock-up website is 'acceptable' or fit to be launched and used.'			
	'Improving ease of use and usefulness'		
'Increasing patient motivation to comply with prescribed exercises'			
'This study empirically explores what patient experience is in cardiac remote monitoring and considers the implications for user experience'			

50	(Kim et al., 2017)	2017	UCD
51	(Hochstenbach et al., 2017)	2017	UCD, co-creation
52	(Johnson et al., 2017)	2017	UCD
53	(Lambert et al., 2017)	2017	Human-centered design
54	(Miah et al., 2017)	2017	DSR (design science resear
end users to evaluate the system, process, reliability and satisfaction'			'Simple, flexible and lowcos to healthcare support' 'Sys helpful for time saving'
55	(Deighan et al., 2017)	2017	User centered approach
56	(Carr et al., 2017)	2017	UCD, PD
57	(Carabali & Solano, 2018)	2018	UCD

'The doctor–patient relationship is enriched through increased eye contact and depth of conversation'	'The doctor–patient relationship is enriched through increased eye contact and depth of conversation'	'Patient-generated data could offer supporting evidence for diagnoses'	
'The integration of patient self-management and professional care by means of healthcare technology facilitates partnership with shared responsibilities'	'The integration of patient self-management and professional care by means of healthcare technology facilitates partnership with shared responsibilities'	'The integration of patient self-management and professional care by means of healthcare technology (...) offers valuable insights that complement usual care and accommodates subsequent consultations or referrals.'	
'We validated our interface design decisions through a smallscale usability study'			
'eMotion aims to offer person-centred support through optimising engagement in web-based support'		'eMotion is a web-based intervention designed to treat depression and simultaneously promote physical activity'	'Can be
'Daily living practice has changed using the system' 'The main objective of the field study was to collect data from			
'The Digital Heart Manual is user friendly and accessible to patients and health professionals'	'The Digital Heart Manual is user friendly and accessible to patients and health professionals'		
	'We identified specific design recommendations that will increase the likelihood of user acceptability and uptake of the user-interface and underlying decision support tool in practice'		
'The application (...) allows communication (sic) between families and medical care centers'	'The application (...) allows communication (sic) between families and medical care centers'	'The application contributes to the monitoring of cancer treatments ...'	

58	(Duval et al., 2018)	2018	UCD	‘We expect there are many benefits to using a mobile speech therapy game, including the ability to practice anywhere, collect fine-grained speech data, track the frequency and time individuals spend practicing, track performance over time (...)'		‘Mobile speech therapy games could help people practice articulation anywhere (...) which may potentially expedite their speech therapy progress', 'We expect there are many benefits to using a mobile speech therapy game, including (...) and create dynamic, custom therapies to each individual.'
59	(Z. Huang et al., 2018)	2018	UCD	‘Support decision making, and increase situational awareness'		'Provide early warning'
60	(Wang, Huang, et al., 2018)	2018	scenario research	‘Could effectively (...) relieve patient anxiety to some extent'	‘Could effectively shorten inquiries time'	
61	(Marcu et al., 2018)	2018	co-design	‘In a preliminary evaluation, participants found the application engaging and useful'		
62	(Lee et al., 2018)	2018	wizard of oz prototyping, user interview			Help patients relieve panic disorder symptoms'
63	(Graf et al., 2018)	2018	UCD	‘Comfortable and easy to use'		
64	(Kytö et al., 2018)	2018	UCD	‘Motivate and support stroke survivors in rehabilitating bimanual movement'		‘Support both the effective execution of existing bimanual ADL exercises and support interaction with everyday devices'
65	(Herrera et al., 2018)	2018	UCD, RTD	‘Explore and assess strategies to support people as active providers and consumers of information about their health'		

66	(Lindahl et al., 2018)	2018	Human-centered computing	'We found patient acceptance levels of performing self-measurements using interactive and context-aware guidance, without staff participation, to be an overall positive experience'			'An automated blood pressure self-measurement procedure could save sparse staff resources'
67	(Monteiro & Lopes, 2018)	2018	Human-centered computing, Usability tests	'Empowers the patients, easing their daily health tasks and self-care ability'			
68	(Vandenberghe et al., 2018)	2018	Human-centered design	'We focused on patients' expectations towards the system and its implementation, perceptions of the platform, and potential barriers related to these expectations and perceptions'		Self-management technologies can be successful in the aim for better care'	It could help save resources as patients are less dependent on the availability of caregivers'
69	(Nägele et al., 2018)	2018	PDFi: Participatory Design Fiction	'The experience can be emotionally challenging'			'The accumulation of associated doctor's visits and hospitalizations, costly'
70	(Marent et al., 2018)	2018	Co-design	'Having these multiple dimensions of ambivalence available may offer a more nuanced framework to the widely studied phenomena of 'resistance to' or 'acceptance of' digital health technologies'			
71	(Citrin et al., 2018)	2018	UCD	'Can effectively integrate the people-centered care work of CHWs, while safeguarding the privacy and dignity of communities'			'Enable an appropriate and affordable shift from systems organized around acute problems to those able to address longitudinal care needs'

72	(Bakker et al., 2018)	2018	UCD
73	(Rathnayake et al., 2019)	2018	Co-design, UCD
74	(Hides et al., 2018)	2018	co-design, PD
75	(Nichols et al., 2018)	2018	PCD (patient-centered design)
76	(Pel-Littel et al., 2018)	2018	co-design
77	(Keikhosrokiani et al., 2018)	2018	Patient-Centered Design

'Preliminary testing revealed that MoodMission was rated superior to other health apps in terms of entertainment, aesthetics, and information'		'At the time of writing, MoodMission has one RCT in progress investigating its efficacy in improving mental health, positive well-being, emotional self-awareness, mental health literacy, and coping self-efficacy.'
	'An mHealth application for carers to address the needs related to functional disability care'	
'The Ray app provides a youth-friendly and easily-accessible way of increasing young people's alcohol knowledge'		'Both groups achieved significant reductions in the typical number of drinks on a drinking occasion over time. A reduction in maximum drinks consumed was also found at 1 month.'
'Motion graphics and close-up demonstrations are employed to provide clear, user-friendly instructions regarding all steps involved in the process of insulin injection'		
'Older patients might benefit more when they are able to exercise health care conversations with health professionals in a safe and inviting digital environment'		
'The results indicate that the patient-centric healthcare system such as iHeart must have usability, communicability, data processing and time response for its success and attracting the users'		

78	(Wang, Zhang, et al., 2018)	2018	UCD	‘The survey result shows that the new smart mobile system has achieved high level user satisfaction and proven its effectiveness in clinical practice'	‘This system provides a practical solution to address the major challenges in general wound care processes, which include precise wound measurement, wound healing monitoring, standard and comprehensive wound assessment and integrated wound case management in the existing clinical information system context of general hospitals'	‘It is clear that the efficiency of the task operation and the performance of the care were significantly improved by cutting the time of each task in the normal workflow.'
79	(Merlo et al., 2019)	2019	Human-centered design		‘Improve drug catching by reducing the risk to forget it'	‘To improve monitoring without a nurse by saving and/or sending in real time information about the events associated to the pill'
80	(Tsvyatkova & Storni, 2019)	2019	PD, co-design	‘We identified requirements for the users and their learning experience, the language and perspective that are favoured in communicating the educational contents, and the level of interactivity offered by the educational resources'		
81	(Morita et al., 2019)	2019	UCD	‘Improved quality of life for patients'		‘Benefits of home dialysis with respect to cost savings'
82	(Holden et al., 2020)	2019	UCD	‘Consumer-facing technology can be a low-cost, scalable intervention to improve older adults’ medication safety, by informing and empowering patients'	‘Consumer-facing technology can be a low-cost, scalable intervention to improve older adults’ medication safety, by informing and empowering patients'	‘Consumer-facing technology can be a low-cost, scalable intervention to improve older adults’ medication safety, by informing and empowering patients'

83	(Wray et al., 2019)	2019	UCD
84	(Calvillo-Arbizu et al., 2019)	2019	UCD
85	(Rohani Ghahari et al., 2018)	2019	Patient-Centered Design

'Understand the app's intended users to assist in planning and constructing a product that helps users accomplish their goals in a desirable way'		
'Raising user acceptance of the final product'		
'Incorporating these design implications may also enhance an individual's experience with their CIED and remote monitoring'	'Therefore, one possible benefit of sharing transmitted data with patients is a shorter time interval between deterioration of LV pacing and related adjustments in CRT-CIED'	'Prior research suggests that use of remote monitoring of CIED data has reduced mortality and healthcare expenditures of patients with CHF'

Appendix II

Document introduction

This appendix is an internal document summarizing the results of a workshop conducted within the Peri-operative Box project, aimed at the development and testing of a Remote Patient Monitoring (RPM) proposition in the perioperative domain. The objective of the workshop was to collectively discuss priorities in terms of experience metrics to focus on in an upcoming feasibility study. Following, the results of the workshop are analysed in order to provide specific recommendations.

The document is structured as follows: first, the rationale for the selection of measures of experience is briefly outlined. Secondly, the body of proposed experience measures that emerged in the workshop is clustered and analysed both from a logical and a chronological point of view. Selected recommendations are mentioned as a result of these analyses. Thirdly, relevant experience constructs indicated as useful for the trial are connected to existing research instruments, found through the systematic review described in Chapter 7.

Measuring experiences of the Perioperative Box: rationale

Telehealth (or telemedicine) can be defined as the use of medical information that is exchanged from one site to another through electronic communication (e.g., Bluetooth, 4G) to improve a patient's health (Tuckson et al., 2017). While telehealth has received growing interest in medical research and practice for decades (Wosik et al., 2020), the covid-19 pandemic has determined an unprecedented acceleration in the adoption of telehealth interventions (McLean et al., 2013; Monaghesh & Hajizadeh, 2020; I. Lee et al., 2020). Among these, a large category of interventions falls under the definition of RPM, a subset of telehealth applications that concerns the use of electronic communication for the specific purpose of monitoring patients at a distance (Meystre, 2005). The introduction of RPM interventions in hospital settings changes care paths and workflows, affecting both patient and staff experience (Andersen et al., 2011).

By patient and staff experience, we here refer to the broad set of human factors that influence the interactions of patients and healthcare professionals with the RPM interventions, affecting not only the adoption and effectiveness of the interventions themselves, but also patients' satisfaction of care and healthcare personnel's work satisfaction. Popular models of healthcare evaluation and improvement, such as the Quadruple Aim, stress the importance of these latter two factors, and note their inextricable connection to aspects such as clinical outcomes and cost-effectiveness (Bodenheimer & Sinsky, 2014). Large-scale qualitative studies in the RPM domain have reported common patterns in patient and staff experience, for instance linking specific characteristics of RPM interventions with both positive and negative consequences on adoption (Hanley et al., 2018).

When conceptualizing, developing, implementing, testing, scaling and improving RPM interventions, aspects related to patient and staff experience need to be carefully considered. In particular, rigorously observing and measuring the impact of these interventions on aspects of patient and staff experience allows for fruitful primary and secondary research.

The main principles used for the selection of experience measures to be included in the Peri-operative box trial are indicated as:

- Completeness and relevance: the selected set of measures should cover the main and most important aspects of both patients' and staff's experience.
- Unobtrusiveness: the selected set of measures should require as minimal need for active input from patients and staff as possible.
- 'Mixedness': Qualitative and quantitative measures should be complementary in supporting a balanced understanding of patient experience, staff experience, and their implications for the assessment of the overall feasibility of the Peri-operative Box system.

Furthermore, specific attention in terms of patient and staff experience should be reserved to the main elements of novelty in the study, namely the machine learning algorithm and the use of the Healthdot R Philips monitoring patch, a wearable device collecting heart rate, respiratory rate, activity, and posture data.

Workshop setting

An online workshop was conducted with a total of 8 participants, including two researchers from the Leiden University Medical Centre, two senior scientists, a biomedical engineer, and a senior director of design innovation from Philips, and two design researchers from the Delft University of Technology including the workshop organizer. All participants were involved or interested in the Peri-operative Box project.

During the workshop, participants worked in teams to map key assumptions related to the experience of patients using the Peri-operative Box in terms of activities and outcomes. The generated assumptions were then translated by the participants into measures (both quantitative and qualitative). Following, participants 'voted' (through the use of digital 'stickers') on the most important measures to collect before, during and after the trial. In addition, the most voted measures were organized on an intervention journey map. Finally, the same exercise was performed on staff experience measures. Screenshots of the digital boards used for the workshop are provided in Figure 28.

Figure 28. Screenshots of the digital boards used for the workshop on patient and staff experience measuring in the Perioperative Box project

Analysis

Around 200 digital post-its containing suggestions for experience measures were produced during the workshop.

These were first clustered by content and de-duplicated. Following, two kinds of analysis were performed:
Logical, in which measures of experience were organized in terms of their role in the causal chain determining the performance of the intervention as a whole.
Chronological, in which in which measures of experience were organized in terms of their sequential order in patients' and staff's journey

Logical analysis

Fault tree analysis is one of the most widely used techniques for system reliability and safety studies (Xing & Amari, 2008). An initial structure for a fault tree analysis of the Perioperative Box intervention was built by listing the main possible courses of actions within the study leading to either reaching or missing the target results (Figure 29).

Secondly, measures of experience prominently mentioned during the workshop were clustered and grouped depending on their potential to uncover the reasons behind possible system pitfalls and inefficiencies (Figure 30).

Some measures, such as the ones regarding possible unintended consequences of the system on patients' overall satisfaction of care or on staffs' overall work satisfaction, were not connected to the main fault tree, as they are not directly related to any specific system component or node, and instead affect the broader context in which the intervention is implemented.

The main recommendations resulting from the fault tree analysis are listed hereafter.

Design

Patient booklet/information brochure and patient-facing app:

- Include instructions on how to use the devices, when and how to take the measurements (including the ECG in case of palpitations), and information about when and how to get in contact with the care provider.
- Include a way to get in touch with the helpdesk in order to obtain technical support, and ideally a FAQ section.

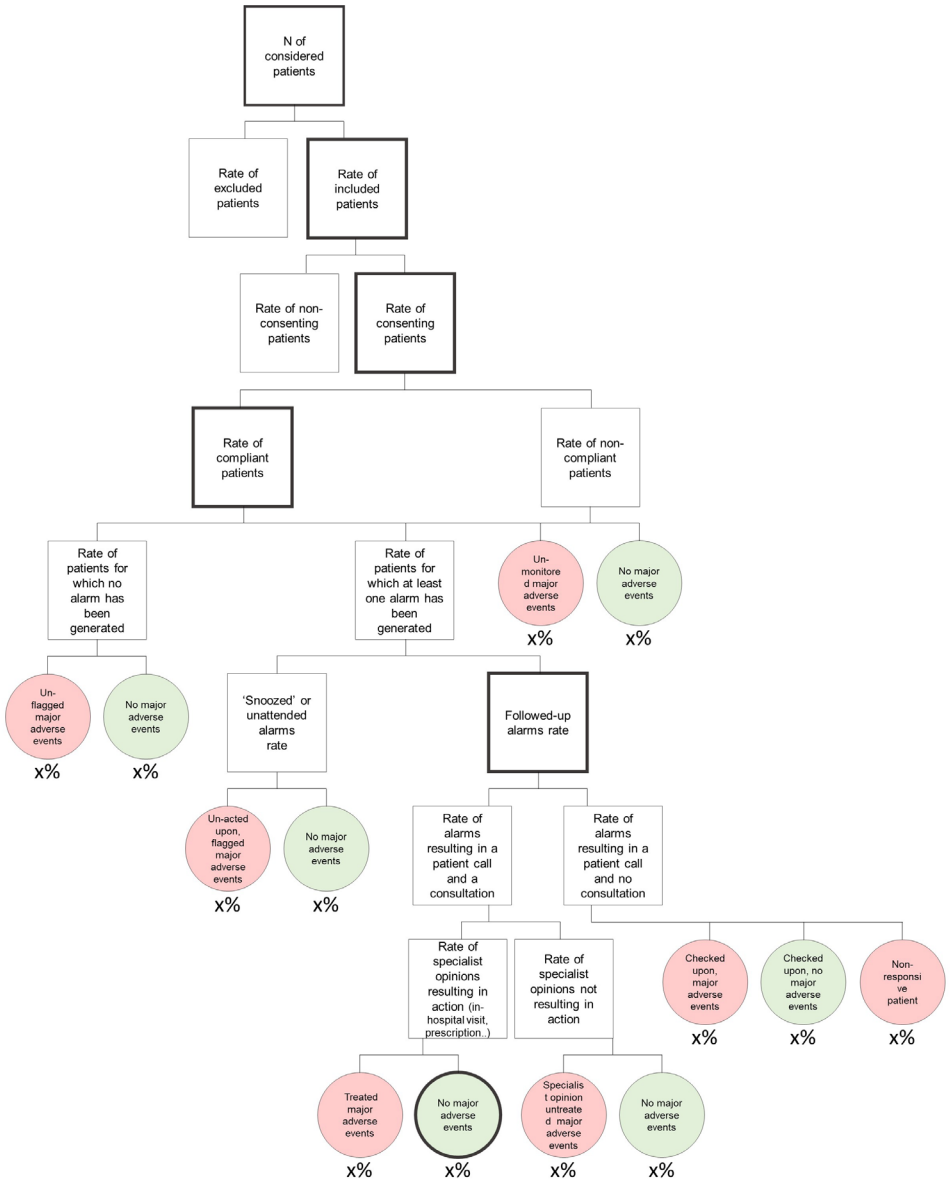

Figure 29. Fault tree analysis of the Perioperative Box

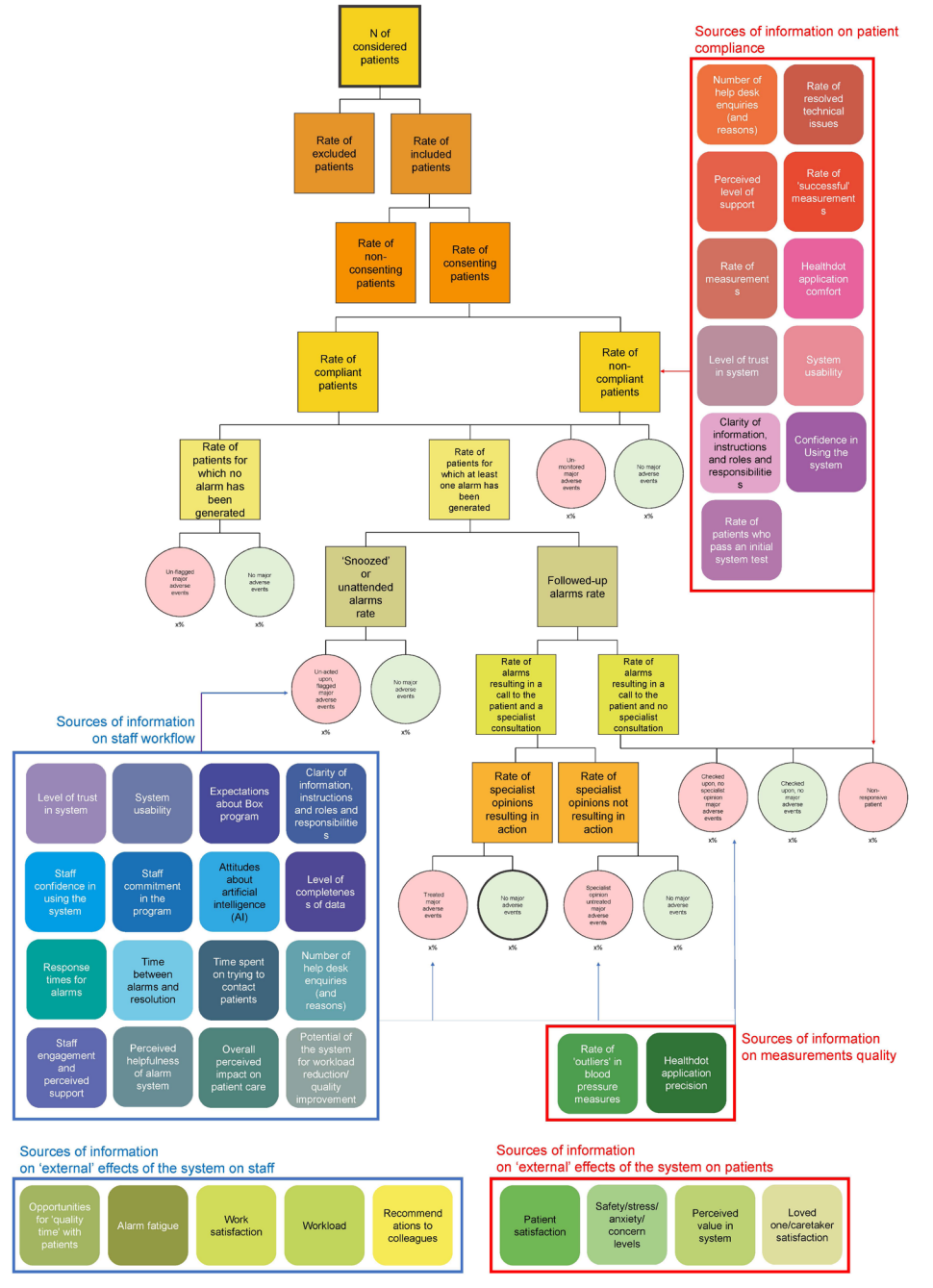

Figure 30. Patient and staff experience measures in relation to the fault tree analysis of the Perioperative Box

Pre-trial research

Pilot the Healthdot application protocol on a small number of volunteers to roughly assess precision of self-application at home.

In-trial research

Include the following measures if feasible (Tables 9-13):

Table 9. Experience measures by components of the fault tree

	Measure	Qual/ quant	Source
1.	N of considered patients	Quant	Research log (?) data
2.	N of included vs excluded patients	Quant	Research log (?) data
3.	Rate of consenting vs non-consenting patients	Quant	Research log (?) data
4.	Rate of compliant vs non-compliant patients	Quant	CWM and EMR data
5.	Rate of patients for which no alarm has been generated vs patients for which at least one alarm has been generated	Quant	CWM and EMR data
6.	Rate of 'snoozed' or unattended alarms vs followed-up alarms	Quant	CWM and EMR data (?)
7.	Rate of alarms resulting in a call to the patient and a specialist consultation vs alarms resulting in a call to the patient and no specialist consultation	Quant	CWM and EMR data (?)
8.	Rate of specialist opinions resulting in action (e.g. in-hospital visit, prescription..) vs specialist opinions not resulting in action	Quant	CWM and EMR data (?)

Table 10. Sources of information on patient compliance

	Measure	Qual/quant	Source
1.	Number of help desk enquiries (and reasons)	Both	Helpdesk log
2.	Rate of resolved technical issues	Quant	Helpdesk log
3.	Rate of 'successful' measurements	Quant	Engage (?)
4.	Rate of measurements	Quant	Engage (?)
5.	Perceived level of support	Qual	Engage (?)
6.	Healthdot application comfort	Qual	Engage (?)
7.	Level of trust in the system	Qual	Castor
8.	System usability score	Quant	Castor
9.	Confidence in using the system	Qual	Castor
10.	Clarity of information, instructions and roles and responsibilities	Qual	Castor
11.	Rate of patients who pass an initial system test	Quant	Engage (?)

Table 11. Sources of information on measurements quality

	Measure	Qual/quant	Source
1.	Rate of 'outliers' in blood pressure measures	Quant	EMR data (?)
2.	Healthdot application precision	Qual	Research log (?)

Table 12. Sources of information on staff workflow

	Measure	Qual/quant	Source
1.	Level of trust in the system	Qual	Castor
2.	System usability score	Quant	Castor
3.	Expectations about the Box program	Qual	Castor
4.	Clarity of information, instructions and roles and responsibilities	Qual	Castor
5.	Staff confidence in using the system	Qual	Castor
6.	Staff commitment in the program	Qual	Castor
7.	Attitudes about artificial intelligence (AI)	Qual	Castor
8.	Level of completeness of data (is it enough to assess status? What else could be needed?)	Qual	Castor
9.	Response time for alarms	Quant	CWM and EMR data (?)
10.	Time spent between alarms and resolution	Quant	CWM and EMR data (?)
11.	Time spent on trying to contact patients	Quant	CWM and EMR data (?)
12.	Number of help desk enquiries (and reasons)	Both	Helpdesk log
13.	Staff engagement and perceived support	Qual	Castor
14.	Perceived helpfulness of alarm system	Qual	Castor
15.	Overall perceived impact on patient care	Qual	Castor
16.	Perceived potential of the system for workload reduction/quality improvement	Qual	Castor

Table 13. Sources of information on 'external' effects of the system on patients

	Measure	Qual/quant	Source
1.	Patient satisfaction	Qual	Castor
2.	Safety/stress/anxiety/concern levels	Qual	Castor (daily questionnaire)
3.	Perceived value in system	Qual	Castor
4.	Loved one/caretaker satisfaction	Qual	Castor

Table 14. Sources of information on 'external' effects of the system on staff

	Measure	Qual/quant	Source
1.	Opportunities for 'quality time' with patients	Qual	Castor
2.	Alarm fatigue	Qual	Castor
3.	Work satisfaction	Qual	Castor
4.	Workload	Qual	Castor
5.	Recommendations to colleagues	Qual	Castor

Recommendations on analysis of trial results:

- Assess the relative usefulness of all 'secondary' experience measures in relation to the components of the fault tree. It can be expected that certain measures will be more useful than others in explaining the reasons behind 'primary' performance indicators (such as patients' compliance to the self-monitoring protocol). Therefore, it is expected that it will be possible to narrow down the (now relatively extensive) list of experience measures to collect in a possible next version of the system.
- Explore retrospective data on Box devices (e.g. differences in compliance rates depending on device) to spot opportunities for improved devices selection and patient communication.

- Explore retrospective data on the relative predictive power of different combinations of vital signs to spot opportunities for improved devices selection.
- Explore retrospective data on blood pressure (outliers, relations with continuous Healthdot measurements..) to spot opportunities for improved data collection.

Post-trial research

- During the workshop, it was suggested to include questions on the 'experience of delivering tailored care' for the staff. For now, this aspect does not appear to be relevant as the current opportunities for delivering tailored care through the Perioperative Box are limited. However, this aspect should be kept into consideration for future versions of the system.

Chronological analysis

A summarized overview of the main touchpoints within the perioperative journey for the main stakeholders involved was visualized, and the time of collection of the previously defined measures of experience was mapped (Figure 31).

The most relevant observations regarding the chronological aspects of the Perioperative Box experience measures concern the 'time-sensitive' actions performed within the system, and particularly the chain of actions that are triggered after the generation of alarms.
As one of the main expected advantages of the Perioperative Box system lies in the early detection of post-operative deteriorations, timeliness in the reaction to alarms is expected to constitute an important determinant of the effectiveness of the overall intervention.

This chain of events can be broken down into several steps, including: the time between the generation of an alarm and its acknowledgement, the time between the alarm acknowledgement and the decision towards a course of action, (possibly) the time necessary to successfully execute a remote consultation with the patient, (possibly) the time necessary to escalate to a specialist, and (possibly) the time necessary to organize follow-up actions such as an in-hospital consultation or a rehospitalisation.

Collecting detailed log data about time expenditure for each of these steps would provide a rich source of information for system redesign and optimization. However, the feasibility of collecting some of these measures directly through the digital system used by the nursing staff is still unclear, and the option to rely on manual entry for this data would appear to constitute an excessive burden on staff. This aspects is characterized as one of the main remaining open issues for what concerns the collection of measures of experience in the study.

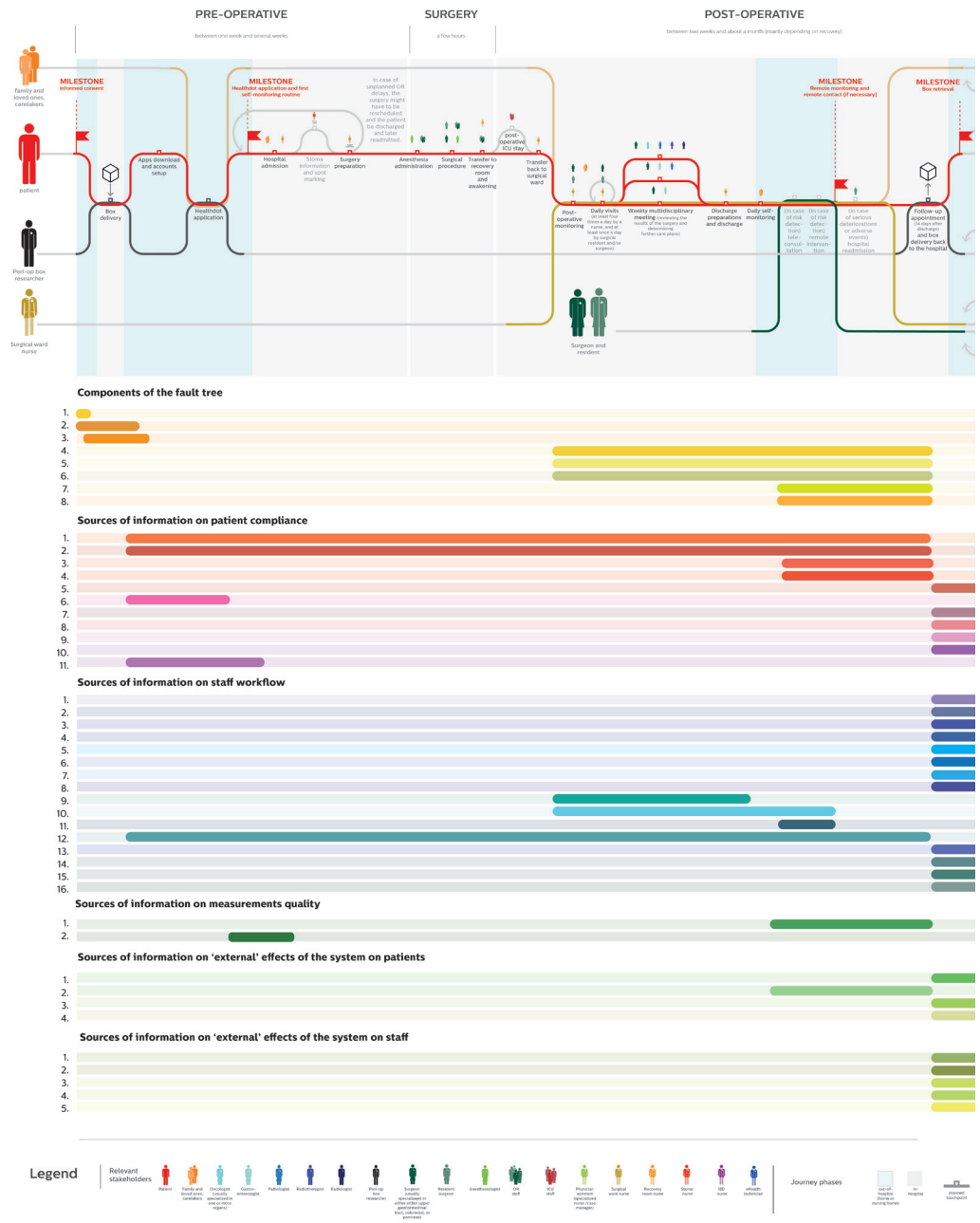

Figure 31. Experience measures across the perioperative journey for the main stakeholders

Similarly, it is recommended to collect certain measures of patient experience throughout the journey, as opposed to during the final questionnaire. It is especially recommended (if feasible) to introduce a brief 'test' of the home self-monitoring protocol to be proposed to patients in the pre-operative stage, ideally right after the delivery of the box, not only to assess the quality and actionability of the information given to patients, but also for troubleshooting possible issues and uncertainties before the crucial stage of post-operative monitoring. Finally, it is recommended to obtain feedback about patient comfort and ease of application of the Healthdot right after the action.

These and other recommendations related to the chronological analysis are listed hereafter.

Design

Patient-facing app:
- Include a 'perform a test measurement' reminder on the day the box is delivered and collect data on success rate.
- Prompt a brief questionnaire on the Healthdot application comfort and clarity in Engage after the out-of-hospital application procedure.

Pre-trial research

- Organize a small pilot testing the quality of the initial information and instruction about the self-monitoring protocol on a small number of volunteers to roughly assess clarity.
- Define a meaningful definition of 'self-monitoring compliance' for the Peri-operative Box system. Consider defining several categories for compliance (depending on possible patterns of self-monitoring behaviour shown by time series data) as opposed to a binary division between compliant and non-compliant patients.

In-trial research

Recommendations on analysis trial results:
- Explore changes in measures of experience for staff over time (especially over the phases of the study).

Post-trial research

- Explore (technical) opportunities for the collection of real-time experience measures (as opposed to relying heavily on the final questionnaire) to spread the burden on patients and staff and obtain more ecologically valid information.

Existing experience measurement tools

Several construct for aspects of patient and staff experience have emerged from the workshop as potentially relevant for investigation within the upcoming Peri-operative Box trial.

When possible, it is important to connect these constructs to existing theory, in particular by identifying validated measuring tools to include in the study. Following, a list of key constructs will be discussed in the light of relevant existing measuring tools. Such measuring tools were identified by navigating a database of 3403 papers obtained through a systematic review on experience measures used in RPM research (Prospero registration number CRD42021250707).

Usability
Both patients and staff

Usability is one of the most well-known and widely used experience metrics in health technology assessment, both for patient and staff. Broekhuis et al. (2019) compare several methods for assessing usability in eHealth, and recommend to combine the System Usability Score (SUS), a 10-item questionnaire, with intervention-specific task metrics, especially on task completion. This recommendation appears to fit within the scope of the Perioperative Box, especially since the System Usability Score includes concepts identified as relevant for the study (particularly, confidence and informational needs). Therefore, it is recommended to include the SUS questionnaire as part of the final survey for both patients and staff (thus covering measure 8 in the source of information on patient compliance and measure 2 in the sources of information on staff workflow), while also collecting metrics on key tasks expected to be accomplished through the system (particularly measures 4,6,7,and 8 in the components of the fault tree).

Anxiety/stress/concern
Patients

In the current protocol, the 'anxiety' construct is already included in the daily questionnaire submitted to patients as part of their self-monitoring, which includes the question:

9) Voelde u zich in de afgelopen 24uur angstig?
Antwoord opties: Heel angstig, angstig, neutraal, niet, helemaal niet
9) Have you felt anxious in the past 24 hours?
Answer options: Very anxious, anxious, neutral, not, not at all.

As such, no additional anxiety measurement tool will be considered to avoid excessive patient burden.

It is important to mention that during the workshop this construct was mentioned as a possible form of unintended consequence brought about by the Perioperative Box implementation - the rationale being that the introduction of post-operative home monitoring might make patients more anxious about their own physical state in comparison with patients who are not monitored post discharge. This particular hypothesis will not be investigated in the upcoming trial, which will not include a patients control group for experience measures.

However, the daily measurements on patients' anxiety levels from the daily questionnaires are deemed to be useful not only for clinical decision making within the system, but also for retrospective investigation (e.g. focused on possible relations between patients anxiety levels and compliance rates, number of phone calls from patients to hospitals, or overall clinical outcomes).

Trust
Both patients and staff

The construct of trust appears to be mentioned in different ways in recent RPM literature. For what concerns patients' trust, this can happen in the form of trust in internet-based health information (Sillence et al., 2019), trust in health technology (Montague, 2010), or trust in care providers (e.g. trust in clinicians, see Barkai et al., 2021, or trust in GP, see Roettl et al., 2016). This latter form of trust has also been associated with adherence to self-monitoring protocols (Vaeth, 2011).

For what concerns staff, the concept of trust has been used to investigate teamwork dynamics (Lazzara et al., 2015). In this case, trust was examined as trust in colleagues and their utilization of the RPM system rather than trust in the system itself.

Unfortunately, regardless of these many variations, it appears that not many options exist regarding validated measuring tools for assessing trust in the field of RPM or health technologies in general. A notable exception is constituted by the trust in medical technology instrument (TMT) (Montague & Asan, 2012), a validated 31-items questionnaire. While the value of the instrument appears to be robust, including the full questionnaire in the final survey for both patients and staff would appear too cumbersome for research participants. Therefore, it is recommended to include one or more custom-made question regarding trust in both patients' and staff's final questionnaire.

Satisfaction
Both patients and staff

While the construct of satisfaction is one of the most pervasive measures of experience in RPM and health quality improvement initiatives at large, challenges exist regarding its assessment, especially in terms of precision and standardizations

of definitions. Mair (2000) observes how the precise meaning of the 'satisfaction' construct is often not defined for participants in telemedicine studies, leaving secondary researchers 'unable to discern whether the participants said they were satisfied because telemedicine didn't kill them, or that it was "OK," or that it was a wonderful experience'. Similar observations were made in the specific RPM field by Kraai et al. (2011), who reports, in an extensive systematic review of RPM applications for heart failure, that none of the articles examined included a clear definition of patient satisfaction, none used the same questionnaire or telephonic survey to measure patient satisfaction as another, and only one questionnaire was assessed for validity and reliability.

Existing RPM-relevant tools for assessing patient satisfaction include the Telehealth Satisfaction Scale (Cheng et al., 2020), the Home Monitoring Acceptance and Satisfaction Questionnaire (Artico et al., 2019), the Telemedicine Satisfaction Questionnaire (Dechêne et al., 2011), and the Telemedicine Perception Questionnaire (TMPQ) (Finkelstein et al., 2004). General tools that have not been designed specifically for -but have been used in- RPM research include the Patient Satisfaction Questionnaire (PSQ) (Nijland et al., 2020) and the Customer Satisfaction Index (CSI) (Eivazzadeh et al., 2018).

The Telemedicine Perception Questionnaire (TMPQ), the Patient Satisfaction Questionnaire (PSQ), the Home Monitoring Acceptance and Satisfaction Questionnaire and the Telemedicine Satisfaction Questionnaire all appear to be relatively long (respectively comprising of a 15-items, a 18-items, an 11-items and a 15-items questionnaire) and not particularly tailored to an intervention such as the Peri-operative Box.

Conversely, the Telehealth Satisfaction Scale appears to be a relatively brief questionnaire (10-items) whose content can be easily adapted to the Perioperative Box proposition and whose questions touch on sub-measures mentioned as potentially relevant in the workshop, such as privacy and comfort. It is therefore recommended to include a modified version of this tool in the final questionnaire for patients.

For what concerns staff satisfaction, an adapted version of the Clinician Feedback on the CareLink System (Marzegalli et al., 2008) is recommended, which also includes questions on aspects such as training quality and information completeness.

Workload
Staff

Increased staff workload brought about by the introduction of the Peri-operative box should be carefully monitored, since such a trend might negatively affect both staff's performance and staff's work satisfaction and wellbeing.

In this sense, the definition of workload that appears to be more meaningful for the project appears to be closer to Lysaght et al. (1989), who define workload as "the relative capacity to respond" than to other, broader definitions such as Backs et al. (1994), who define workload as "a construct that is used to describe the extent to which an operator has engaged the cognitive and physical resources required for a task performance".

Ideally, workload would be assessed through both subjective and objective measures.
Several instruments to measure subjective staff workload exist, including the Cooper-Harper Scale, the perceived workload scale, the Subjective Workload Assessment Technique (SWAT), the Workload Profile (WP), the Rating Scale Mental Effort (RSME) and the NASA-Task Load Index (NASA-TLX).

The latter instrument has been indicated as particularly reliable, valid, and applicable to the healthcare domain (Hoonakker et al., 2011), and as such is recommended for inclusion in the study.

At the same time, as previously mentioned, objective measures on staff time expenditure on specific tasks (e.g. time spent on trying to contact patients, time between alarm and resolution) would ideally be collected to break down the reasons behind possible increases in staff workload and highlight opportunities for future system improvement.

Alarm fatigue
Staff

Alarm fatigue has been defined as 'sensory overload when clinicians are exposed to an excessive number of alarms, which can result in desensitization to alarms and missed alarms' and constitutes a serious patient safety concern (Sendelbach & Funk, 2013). Few validated tools were retrieved that assess subjective alarm fatigue. Among them, Torabizadeh et al. (2017) have developed a questionnaire for assessing alarm fatigue, which while validated appears to be excessively long for inclusion in the study. As such, for this study it is suggested to rely on both objective measures (particularly, number of alarms and response times) and on one or more custom-made questions in the final staff questionnaire to assess alarm fatigue.
In case the issue of alarm fatigue would be revealed as central for the Perioperative Box proposition, future studies focusing specifically on this aspect could include more extensive questionnaires such as Torabizadeh et al.'s.

Attitudes about AI
Staff

As previously mentioned, the introduction of an element of artificial intelligence (specifically a machine learning algorithm) constitutes an element of novelty of the Peri-operative Box proposition. As such, it is recommended to collect information about the impact of this specific element of novelty on staff experience through the inclusion of a short questionnaire on attitudes towards artificial intelligence (AI), based on Romero-Brufau et al. (2020).

Appendix III

Search strategy

The keywords defined for the search strategy should be found in the summary or title or be one of the main subjects of the document. Also, some global terms, commonly used for certain healthcare topics, were used (“MeSH” and “Emtree”).

Pubmed
Concept 1: Remote Patient Monitoring (RPM)
"Telemedicine"[majr] OR "Telemonitoring" [Tiab] OR "Remote Monitor*" [Tiab] OR "Telehealth" [Tiab] OR "Remote follow-up" [Tiab] OR "eHealth" [Tiab] OR "Remote Consultation" [Tiab] OR "Remote Sensing Technology" [Mesh] OR "Self-monitor*" [Tiab]

Concept 2: Workflow
"Workflow" [Majr] OR "Outcome and Process Assessment, Health Care" [Majr] OR "Task Performance and Analysis" [Majr] OR "Workflow" [Tiab] OR "staffing" [Tiab] OR "Attitude of Health Personnel" [Tiab] OR "alarm fatigue*" [Tiab] OR "alert fatigue" [Tiab] OR "professional burnout" [Tiab] OR "workload" [Tiab] OR "Patient Care Management" [Mesh] OR "Nursing Process*" [Mesh] OR "Clinical Competence" [Mesh] OR "Caregiver Burden" [Mesh] OR "Time and Motion Studies" [Tiab] OR "Work Simplification" [Mesh] OR "Practice Patterns, Nurses'" [MeSH] OR "Nursing Audit"[Mesh]

Concept 3: Perioperative care
"Surgical Procedures, Operative" [Majr] OR "General surgery" [Majr] OR "Perioperative" [Tiab] OR "Surgery" [Tiab] OR "Post-operative" [Tiab] OR "post-discharge" [Tiab]

Embase
Concept 1: Remote Patient Monitoring (RPM)
exp *telemedicine/ or exp *remote sensing/ or (telemonitoring* or Remote Sensing Technology* or Remote Monitor* or Telehealth* or Remote follow-up* or eHealth* or Remote Consultation* or Self-monitor*).ti,ab,kw.

Concept 2: workflow
exp *workflow/ or exp *outcome assessment/ or *exp task performance/ or exp *caregiver burden/ or exp *nursing audit/ or exp *patient care/ or exp *clinical competence/ or exp *health personnel attitude/ or (workflow* or outcome assessment* or task performance* or caregiver burden* or nursing audit* or patient care* or clinical competence* or health personnel attitude* or staff* or professional burnout* or workload* or nursing process* or clinical competence* or time and motion studies* or work simplification* or practice patterns*).ti,ab,kw.

Concept 3: Perioperative care
exp *surgery/ or exp *general surgery/ or exp *perioperative medicine/ or (surgery* or general surgery* or perioperative* or post-operative* or post-discharge*) .ti,ab,kw.

Appendix IV

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Title
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Abstract
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Introduction
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Introduction
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Methods and Suppl. file III
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Suppl.file II
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Suppl.file II
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Methods Suppl.file II
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Methods Suppl.file II
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	n/a
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Methods Appendix I
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	n/a
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	n/a
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	n/a
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Methods
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Methods
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	n/a
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	n/a
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	n/a
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	n/a
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	n/a
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Methods
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	n/a
Study characteristics	17	Cite each included study and present its characteristics.	n/a
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	n/a
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	n/a
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	n/a
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	n/a
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	n/a
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	n/a
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	n/a
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	n/a
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Discussion
	23b	Discuss any limitations of the evidence included in the review.	n/a
	23c	Discuss any limitations of the review processes used.	Discussion
	23d	Discuss implications of the results for practice, policy, and future research.	Discussion
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Methods
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Methods
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	n/a
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	n/a
Competing interests	26	Declare any competing interests of review authors.	Competing interest statement
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Suppl. file IV

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

Appendix V

Criteria for RPM and experience measuring

For the scope of our review, we considered as RPM any intervention meeting the following criteria:

- Sensor-based patient monitoring, intended as the use of at least one sensor to collect patient information at a distance. Therefore, we excluded interventions that were purely based on the collection of 'sensor-less' self-reported measures from patients. This is because we believe the use of sensors to constitute a key element of RPM, and one strongly contributing to aspects of patient and staff experiences in this domain. However, we adopted a broad definition of 'sensor', considering as such smartphone cameras (for instance in the case of postoperative wound monitoring applications) as well as analog scales or thermometers (for instance in the case of interventions relying on patients submitting manually entered weight or temperature). By 'at a distance', we meant not only cases in which data was transferred from non-clinical environments, as in the case of home monitoring; but also cases, such as tele-ICU's, in which data was transferred from one clinical environment to another. Furthermore, we included interventions relying on both continuous and intermittent monitoring.
- Clinical decision-making as an intended use of the remotely collected data. Therefore, we excluded interventions in which the collected data was meant to be used exclusively for research purposes, and not as a stage of development of an RPM intervention to be adopted in patient care. For instance, we excluded cases in which the remotely collected patient data was only used to test research hypotheses unrelated to the objective of implementing RPM interventions (e.g. for drug development purposes). This is because in this review we are interested in RPM as a tool for the provision of remote patient care, rather than as a mere instrument for research. We also excluded interventions in which patients themselves were the only recipients of the collected data, and no healthcare professional was involved in the data analysis and utilization.

Furthermore, we excluded:

Interventions only involving GPs and primary care practices as healthcare providers of the RPM intervention. This is because we expect marked differences between the implementation of RPM in primary and other levels of care. Particularly, we expected these differences to affect comparability of data regarding staff experience, due to the dissimilarity in settings, workflows and routines between primary and other levels of care.

- Contributions in which only general attitudes towards RPM were investigated, rather than one or more specific RPM interventions.
- Contributions not focusing on the evaluation of one or more specific RPM interventions, for instance in the case of papers providing theoretical perspectives on the field (such as research frameworks or theoretical models).
- Contributions only focused on evaluating RPM-related technology, for instance in the case of papers focused on testing sensors, software, or other service components on isolation rather than as a part of any specific RPM intervention.
- Contributions not specifically focused on RPM but including RPM interventions in their scope of research, for instance in the case of papers reporting on surveys obtained from broad cohorts of patients including RPM recipients in a non-controlled way.
- Contributions reporting on interventions exclusively directed at staff, for instance on the case of papers reporting on RPM methods aimed at monitoring stress levels of healthcare workers.
- Contributions aimed at collecting experience measures in target groups other than patients or staff, for instance in the case of papers investigating the experience of RPM for informal caregivers.

Following, we provide an extended flowchart diagram detailing the number of records excluded for each of the mentioned categories.

Appendix VI

Search strategy

For both databases, the sets of keywords for each concepts were first searched separately.

Concept 1: Remote Patient Monitoring
Concept 2: Measures and indicators
Concept 3: Staff experience
Concept 4: Patient experience

Following, the separate searches were merged through Boolean operators following the scheme:

[Concept 1] AND [Concept 2] AND (Concept 3 OR Concept 4)

to find all papers containing mentions of patient experience measures used in RPM research, staff experience measures used in RPM research, or both.

The search entries for both databases are reported hereafter. The query was performed on both databases on the 12th of February 2021, including papers published from the 1st of January 2011.

Medline (PubMed) search entry

CONCEPT 1. Remote Patient Monitoring

"Telemedicine"[Majr] OR "telemedicine*"[tiab] OR "telehealth"[tiab] OR "Wearable Electronic Devices" [Majr] OR "Wearable Electronic Device*" [tiab] OR "Wearable Electronic*"[tiab] OR "Wearable Technolog*" [tiab] OR "Wearable Device*"[tiab] OR "Wearable computer*"[tiab] OR "Wireless Technology"[Majr] OR "Wireless Technolog*"[tiab] OR "Wireless sens*"[tiab] OR "Wireless monitor*"[tiab] OR "Monitoring, Physiologic"[Majr] OR "physiologic monitor*"[tiab] OR "vital signs monitoring*"[tiab] OR "Patient Monitor*"[tiab] OR "self-monitor*"[tiab] OR "self monitor*"[tiab] OR "continuous wireless monitor*"[tiab] OR "continuous monitor*"[tiab] OR "remote monitor*"[tiab] OR "Remote Sensing Technology"[Majr] OR "Remote Sensing*"[tiab]

CONCEPT 2. Measures and indicators

"Quality Indicators, Health Care"[Majr] OR "Outcome and Process Assessment, Health Care"[Majr] OR "Patient Reported Outcome Measures"[Majr] OR "Patient Reported Outcome Measure*"[tiab] OR "proms"[tiab] OR "Patient reported Outcome*"[tiab] OR "Patient-reported Outcome*"[tiab] OR "Patients reported Outcome*"[tiab] OR "Patients-reported Outcome*" [tiab] OR "patient-reported experience measure*"[tiab] OR "patient reported experience measure*"[tiab] OR "Surveys and Questionnaires"[Majr] OR "survey*"[tiab] OR "measurement instrument*"[tiab] OR "assessment tool*"[tiab] OR "measurement tool*"[tiab] OR "assessment instrument*" [tiab] OR "variable*"[tiab]

CONCEPT 3. Staff experience

"Ergonomics"[Majr] OR "Ergonomic*"[tiab] OR "Cognitive Ergonomic*"[tiab] OR "Engineering Psychology"[tiab] OR "Attitude of Health Personnel"[Majr] OR "Attitude to Computers"[Majr] OR "attitude of health personnel"[tiab] OR "staff attitude*"[tiab] OR "staff acceptance*"[tiab] OR "Alert Fatigue, Health Personnel"[Majr] OR "alarm fatigue*"[tiab] OR "alert fatigue*"[tiab] OR "Burnout, Professional"[Majr] OR "burnout*"[tiab] OR "Occupational Diseases"[Majr] OR "occupational disease*"[tiab] OR "occupational risk*"[tiab] OR "occupational hazard*"[tiab] OR "occupational dysfunction*"[tiab] OR "Job Satisfaction"[Majr] OR "job satisfaction*"[tiab] OR "professional satisfaction*"[tiab] OR (("Attitude" [Majr] OR "attitude*"[tiab] OR "acceptance*"[tiab] OR "Perception"[Majr] OR "perception*"[tiab] OR "staff experience*"[tiab] OR "physician experience*"[tiab] OR "physicians experience*"[tiab] OR "doctor experience*" [tiab] OR "doctors experience*" OR "nursing experience*"[tiab] OR "nurse experience*"[tiab] OR "nurses experience*"[tiab] OR "caregiver experience*"[tiab] OR "caregivers experience*" [tiab] OR "Personal Satisfaction"[Majr] OR "satisfaction"[tiab] OR "Stress, Psychological"[Majr] OR "Psychological Stress*"[tiab] OR "Occupational Stress"[Majr] OR "Occupational Stress*"[tiab]) AND ("Health Personnel"[Majr] OR "personnel"[tiab] OR "Medical Staff, Hospital"[Majr] OR "staff*"[tiab] OR "Nursing Staff, Hospital"[Majr] OR "nurs*"[tiab] OR "Caregivers"[Majr] OR "caregiver*"[tiab]))

CONCEPT 4. Patients experience

"Attitude to Health"[Majr] OR "Patient Satisfaction"[Majr] OR "Patient Satisfaction*" [tiab] OR "patient experience*"[tiab] OR "patients experience*"[tiab] OR "patient-centered care"[Majr] OR "patient-centered care" [tiab] OR "patient-centred care" [tiab] OR "Patient Acceptance of Health Care"[Majr] OR "Health Behavior"[Majr] OR (("ergonomics"[Majr] OR "Ergonomic*"[tiab] OR "Cognitive Ergonomic*"[tiab] OR "Engineering Psychology"[tiab] OR "Stress, Psychological"[Majr] OR "Psychological Stress*"[tiab] OR "Attitude to Computers" [Majr] OR "attitude*"[tiab] OR "acceptance*"[tiab] or "acceptabilit*"[tiab] OR "Perception"[Majr] OR "perception*"[tiab] OR "Emotions"[Majr] OR "emotion*"[tiab] OR "Personal Satisfaction" [Majr] OR "satisfaction*"[tiab] OR "usability"[tiab]) AND (patient* [tiab]))

EMBASE search entry

CONCEPT 1. Telemonitoring

*telehealth/ or *wearable computer/ or *wireless communication/ or *physiologic monitoring/ or *remote sensing/ or *telemedicine/ or (Wearable Electronic Device* or Wearable Electronic* or Wearable Technolog* or Wearable Device* or Wearable computer* or Wireless Technolog* or Wireless sens* or Wireless monitor* or physiologic monitor* or vital signs monitoring* or Patient Monitor* or self-monitor* or self monitor* or continuous wireless monitor* or continuous monitor* or remote monitor* or Remote Sensing* or telemedicine* or telehealth).ti,ab,kw.

CONCEPT 2. Measures and indicators

*health care quality/ or *patient-reported outcome/ or *outcome assessment/ or *health care survey/ or (Patient Reported Outcome Measure* or Proms or Patient reported Outcome* or Patient-reported Outcome* or Patients reported Outcome* or Patients-reported Outcome* or patient-reported experience measure* or patient reported experience measure* or measurement instrument* or assessment tool* or measurement tool* or assessment instrument* or variable*).ti,ab,kw.

CONCEPT 3. Staff experience

*attitude to computers/ or *"alert fatigue (health care)"/ or *professional burnout/ or *occupational disease/ or *job satisfaction/ or *mental stress or *job stress/ or (Ergonomic* or Cognitive Ergonomic* or Engineering Psychology or attitude* of health personnel or staff attitude* or staff acceptance* or alarm fatigue* or alert fatigue* or burnout* or occupational disease* or occupational risk* or occupational hazard* or occupational dysfunction* or job satisfaction* or professional satisfaction* or attitude* or acceptance* or perception* or experience* or mental stress* or job stress*).ti,ab,kw. or (*attitude/ or attitude*.ti,ab,kw. or *perception/ or perception*.ti,ab,kw. or *satisfaction/or satisfaction*.ti,ab,kw.) AND (*personnel/ or personnel.ti,ab,kw. or *staff/ or staff.ti,ab,kw. or *caregiver/ or caregiver*.ti,ab,kw.)

CONCEPT 4. Patient experience

*attitude to health/ or *health behavior/ or *patient satisfaction/ or (patient* satisfaction or patient experience* or patients experience* patient-centred care or patient cent?ed care).ti,ab,kw. or ((*ergonomics/ or ergonomic*.ti,ab,kw. or usability.ti,ab,kw. or *attitude/ or *attitude to computers/ or attitude*.ti,ab,kw. or *perception/ or perception*.ti,ab,kw. or *mental stress/ or stress.ti,ab,kw. or *emotion/ or emotion*.ti,ab,kw. or *satisfaction/or satisfaction*.ti,ab,kw. or acceptability.ti,ab,kw. or acceptance*.ti,ab,kw.) AND (patient*.ti,ab,kw.))

Appendix VII

Overview of merged constructs for Correspondence Analysis

Table 15. merged constructs for Correspondence Analysis

Construct formulation as extracted	Construct formulation after cleaning
User satisfaction	Satisfaction
Helpfullness	Usefulness
User-friendliness	Usability
Utility	Usefulness
User experience	Experience
Desired information	Information quality
Service evaluation	Service quality
Time to review	Time effort
Time to response	Time effort
Time for task	Time effort
Technical problems	Technical performance
Participation	Engagement
Proactive management	Engagement
Patient activation	Engagement
Usage and potential problems	Usage problems
Self-care agency	Self-efficacy
Self-care behavior	Self-efficacy
Health education	Health literacy
Knowledge	Health literacy
Functioning	Functional status
Functional recovery	Functional status
Mental status	Mental health
Use and adoption	Adoption
Uptake	Adoption

Acknowledgements

At the moment of writing these acknowledgements, I am in the UK, locked out of my laptop because my TU Delft password doesn't seem to work anymore, on a videocall with my boyfriend who is helping me to try and recover the thesis files to be sent to the printer tomorrow. This situation is, I think, quite representative of my PhD journey: never a dull moment, and only possible because of the continued patience, support, and trust of a large support network made of colleagues, family and friends.

Maaike and Dirk, to begin with: the very reason this project started is because you went out of your way to give me a chance, deliberately ignoring the excess of honesty in my intake interview. Since then, you never stopped fighting for me. You allowed me to explore direction I came up with, took the time to discuss ideas and problems in minute detail, shared your knowledge, network, professional experience, recipes, and heroically read through countless drafts full of monstrously long sentences. You have been formidable supervisors, and made this journey enjoyable and meaningful even in its toughest bits. I am in grave debt for the amount of hard work and emotional labour you put into me, and feel lucky to have had the chance to get to know you a bit as individuals in the process, too. While I am sure you're both ecstatic to be finally relieved of your responsibility over my PhD research, I am sorry to inform you that you're not rid of me just yet. Should have thought it through more carefully!

Speaking of people I owe, Jeroen, you're right next – although you were there even before Maaike and Dirk. To be precise, I owe you every 'real' job I've had in my life apart from this last Cambridge one – which anyways was only possible because of the previous two. The fact that I was intimidated by you when I first met you as a student is an old joke by now. I think I should add to it that I now realize I value especially your 'scary' sides: your honesty and directness, which stems from your real dedication to the topic. It was extremely helpful for me to be able to access your knowledge and experience throughout these years, and I do hope to continue enjoying this privilege in the future. Thank you for all you've done for me, and more in general for your outstanding contribution to health design practice as a whole, including through the mentoring and management of an army of designers in healthcare.

Hosana and Jiwon, my beloved paranymphs, you've saved me in countless occasions and have been brilliant colleagues and friends. It's quite likely that without either of you two I would have never made it, and it would have certainly been a much more miserable and lonely process. Thank you so much for supporting me all the way up until the day of my defence – I could have not asked for better, brighter and more inspiring peers. As Jiwon said: 화이팅 !

Thanks to my committee members, who carved time from extremely busy schedules for reading and discussing my work. Professor Chavannes, Professor Meijer, Professor Ludden, Professor Jun, Professor Goossens and Professor Desmet: I am honoured to have had the chance to share my work and the defence day with you, and am grateful for your valuable feedback which has considerably improved the quality of the thesis.

I majorly owe my students as well, especially the ones I had the luck to mentor in their graduation projects: Guillermo, Carolina, Karen, Edda, Maria, Eveline, and Lisa. You've all been a real pleasure to work with, and have inspired or directly contributed to important aspects of the research in this thesis (especially Carolina for Chapter 3 and Maria for Chapter 6). I am very happy to be in touch with some of you even years after you've left Delft, and to see you shine in your current roles around the world, both in industry and academia. Please keep on shining, and never hesitate getting in touch whenever you'd like a chat with your old mentor.

Fredrik and Julian, I'm so happy you chose to join us in the Cardiolab: you're both ridiculously sharp and motivated, and there is no doubt in my mind you will do great in your respective PhDs and beyond. Thank you for all the help and for tolerating my delays and last-minute changes of plans, especially in the last few hectic steps of my PhD journey. Looking forward to have more fun disguised as research, and to finally convince you of the superiority of Italian poker over the travesty that is Texas Hold'em.

TU Delft crew, including PhD buddies (Renske, Niya, Brian, Ahmee, Frithjof, Bart, Karlheinz, Sagar, Mahshid, Theresa, Kars, Gubing, Meng, Pelin, Jasper, Gerbera, Jelle, Marie and Alex - the ontwerpers from Antwerp!) – and DOS gems (Rebecca, Agnes, Sander, Milene, Marina, Sylvia, EJ, Giulia, Judith, Lianne, Margreet, Ruud, Lianne, Hanneke, Leandra, Lisette and many more): thank you, finally time to celebrate! A special mention goes to Ehsan (dangerously good conversationalist, refined design scholar, and poignant emergency psychologist) and Nina (unparalleled anaesthesiologist, house renovation expert and ideal audience of bedtime stories).

LUMC researchers, including Robert, Margot, and especially Hine, have contributed to this thesis through their insightful clinical perspective, particularly in Chapter 8. A very special mention in this regard goes to Douwe, a real silent designer who combines clinical excellence with a uniquely innovative mindset, enabling tangible health system improvement at scale.

Douwe, thank you for your dedication to medicine, your openness and curiosity towards other disciplines, and your vision. Sofie, thank you for the Cambridge tips, and looking forward to working together on the Healthbox!

In addition to Jeroen, I would like to extend my gratitude towards many other Philips partners and (ex) colleagues, including Geert Christiaansen, Paul Gardien, and Peter Lovei (who contributed to chapter 4).

On the personal side, I need to thank my family for a lifetime of support. Even though you have been surprised about my unpredictable career directions, confused about my precise field (design? medicine? engineering?) and saddened by my distance, you have always accepted, trusted and encouraged my choices, all while supplying me with plenty of love, caciocavallo and olive oil. Not only you went through the pain of raising me, you also understood my wish to be in another country and came all the way here to be with me and celebrate. Now we do need to have a proper party to make the trip worth it!

Rushil, you quite simply carried me through it all. I love you very much.

Marcello, Tanvi, Haya, Trisha, Anand, Sergio, Roos, Chanmi, Ayesha, and more friends in the Netherlands, you have contributed to this thesis through taking me way from it when needed, and more generally through being great friends. Magalli crew, you're a guarantee – special mention to Chicca to straighten up an injustice from 2016.

As I was almost done writing this, my account magically re-appeared! As I said, never a dull moment. It's all yet to be seen if I will manage to print this and defend, but if I do, it really is because of you all!

May 30th 2023
Cambridge, UK

Doctoral candidate's CV

EDUCATION

2018-2023 **Delft University of Technology**
PhD at the Cardiolab in the faculty of Industrial Design Engineering, with a research focus on health systems design.

2014-2016 **Delft University of Technology**
MSc cum laude in Design for Interaction, specialisation Medisign, graduation project for Philips Design awarded with a 9,5/10.

2011-2014 **Politecnico di Milano**
BSc in Industrial Product Design, graduation project for the Italian Red Cross awarded full marks with honours.

SELECTED AUXILIARY CERTIFICATIONS

2023-now **Delft University of Technology**
Currently attending the *Develop* module of the *University Teaching Qualification (UTQ)* program.

2017 **Harvardx**
Readings in Global Health, verified nine months online course from the Harvard T. H. Chan School of Public Health covering global disease patterns and predictions, infectious and non-communicable diseases, and health systems and institutional responses.

2017 **MITx**
Measuring Health Outcomes in Field Surveys, eight weeks online course covering types of measures and measurement error, measurement of individual and population health, selection of health outcomes and indicators, and development and selection of measurement tools.

2017 **MITx**
Designing Health Information Systems, verified three months online course covering national eHealth strategy and enterprise architecture, databases and registries, implementation of a global health informatics project, and analysis of selected case studies.

PROFESSIONAL EXPERIENCE

2023-now **University of Cambridge**
Research Assistant. Working on interdisciplinary research projects across the Engineering Design Centre and Cambridge Public Health.

2022-2023 **Qaring**
R&D advisor. Facilitating research and development in this Cardiolab-originated, NWO-funded startup.

2016-2018 **Philips Experience Design**
Service Designer. Conducted user research, developed service concepts, fostered internal ventures, and partnered with external clinical partners in innovation projects in acute and emergency care, population health, and chronic disease management.

TEACHING EXPERIENCE

Delft University of Technology

2022- 2023 Co-developed, co-coordinated and delivered the *Health Systems Transformation* master elective course
2022 Coached for the *Design Strategy Project* master core course
2022 Coached for the *Data* bachelor core course
2019-2021 Lectured and coached for the *Health Psychology* master elective course
2019-2021 Coached for the *Business, Culture and Technology* bachelor core course

EIT Health

2022 Co-developed and prepared material for the *Service Design for Digital Healthcare Transformation* professional course, part of the Healthcare Transformation Academy on Digital Health Transformation, in partnership with researchers from Karolinska University Hospital, Hospital Germans Trias i Pujol, and Institut Catala de la Salut.

MENTORING EXPERIENCE

Delft University of Technology

2022- now Currently acting as a daily supervisor of first-year PhD student Fredrik Karlsson and Junior Researcher Julian Houwen.
2018-now Mentored six master's graduation projects in the health domain, a seventh ongoing.

ACADEMIC SERVICE

2021-2022 **Journal reviewer**
Reviewed for *Health Systems; Artificial Intelligence for Engineering Design, Analysis and Manufacturing*; and *International Journal of Design.*

2019- now **Steering Committee member for the Health Systems Design Special Interest Group**
Collaborated on the organization of SIG workshops at international conferences, organized the 4th International Meeting on Healthcare Systems Design Research, started and managed SIG social media presence.

2018-2021 **University PhD Council member**
Represented PhD students from the IDE faculty at a university level. In this capacity, I organized and contributed to several initiatives, including the negotiation of university-wide PhD contract extensions for COVID-related research delays.

2018-2021 **Graduate School Council member**
Represented PhD students from the DOS department at a faculty level. In this capacity, I collaborated organizing the faculty *PhD days* for three consecutive years.

AWARDS

2017 **People's Choice Award**
A project I worked on together with a multidisciplinary team of six won the People's Choice Award 2017, an internal Philips recognition. The prize was awarded for the development of a wearable sensor called the Healthdot, now implemented in clinical practice.

2017 **Exceed! '17 IDE exhibition of Excellence in Design, Research & Engineering**
My master's graduation project, *Effortless Interactions for Emergency Care*, was selected as one of 25 outstanding projects conducted in the faculty of Industrial Design Engineering at TU Delft. The project was showcased in an exhibition for the faculty's 50th anniversary.

GRANT PROPOSALS

Awarded

2022 Title: **Data-driven design methods for system-level change from disease to vitality: the case of scaling remote patient management systems**
Granting agency: Topsector Creatieve Industrie
Type of grant: PPP grant (Private-Public Partnership)
Amount awarded: € 100,000
Partners: Philips XD, Leiden University Medical Centre
Role: I co-led this proposal, which builds upon the results of my PhD research.

2023 Title: **The HealthBox: A personalized, home-based eHealth intervention to treat metabolic syndrome and prevent its complications**
Granting agency: NWO
Type of grant: Access to care in the living environment (KIC)
Requested amount: €2,144,687
Partners: Leiden University Medical Centre, National eHealth Living Lab (NeLL), Pharos, Patiënten Federatie Nederland, UTwente, Ancora Health, Diabetes Fonds, Unilabs, Hogeschool Utrecht.
Role: I co-led a work package worth € 129,699 within this proposal. This work package is dedicated to the application of results from my PhD research.

Under review

2023 Title: **Edison – Remote Patient Management**
Granting agency: Nationaal Groeifonds
Type of grant: R&D en Innovatie
Requested amount: € 130,4 million
Selected partners: Leiden University Medical Centre, Erasmus Medical Centre, Reinier de Graaf, Charité, Universitätsklinikum Münster, Centro Cardiologico Monzino, UTwente, InHolland, HS Rotterdam, HS Leiden, TNO, Sananet, Ancora Health, Philips, Medtronic, Luscii.
Role: I contributed to various aspects of the proposal preparation and finalization, and will be involved in the project in case the grant is awarded.

PUBLICATIONS

Published work

2022 León, M. A., **Pannunzio, V.**, & Kleinsmann, M. (2022). *The Impact of Perioperative Remote Patient Monitoring on Clinical Staff Workflows: Scoping Review*. JMIR Human Factors, 9(2), e37204.

2020 **Pannunzio, V.**, Lovei, P., Neutelings, I., Deckers, E., Jansen, J. M., & Burghoorn, A. W. (2020). Exploring the service system perspective on designing intelligent health ecosystems: the co-responsibility study. In *6th International Conference on Design4Health2020/Online* (pp. 469-477). Sheffield Hallam University.

2020 **Pannunzio, V.**, Kleinsmann, M., Duarte, C., & Snelders, D. (2020,). Finding the land, planting first seeds; lead user research in early stage design for intelligent ecosystems. In *Proceedings of the Design Society: DESIGN Conference* (Vol. 1, pp. 2099-2108). Cambridge University Press.

2019 **Pannunzio, V.**, Kleinsmann, M., & Snelders, D. (2019). Three approaches to design engineering in the health domain: a systemic perspective. In *Proceedings of the Design Society: International Conference on Engineering Design* (Vol. 1, No. 1, pp. 1005-1014). Cambridge University Press.

2019 **Pannunzio, V.**, Kleinsmann, M. S., & Snelders, H. M. J. J. (2019). Design research, eHealth, and the convergence revolution. In *IASDR 2019: International Association of Societies of Design Research Conference 2019.* (Vol. 4, pp. 354-369). Manchester Metropolitan University.

Unpublished work

2023 **Pannunzio, V.,** Morales Ornelas, H.C., van Kooten, R.T., Gurung, P., van Os, H. J. A., Wouters, M.W.J., Tollenaar, R.A.E.M., Kleinsmann, M., Snelders, D., Atsma, D.E. *Patient and staff experience evaluation in Remote Patient Monitoring; what to measure and how? A systematic review.* Manuscript submitted to a peer-reviewed journal.

2023 **Pannunzio, V.**, Kleinsmann, M., Snelders, D., Raijmakers, J. *From digital health to learning health systems: four approaches to using data for digital health design.* Manuscript undergoing second round of review in a peer-reviewed journal.

SELECTED PRESENTATIONS

2023 Invited pitch: *The role of patient and staff experience in Remote Patient Monitoring*
Presented at the Leiden, Delft and Erasmus (LDE) Healthy society network event, Erasmus Universiteit Rotterdam, the Netherlands.

2022 Invited talk: *Key concepts of systems thinking in (digital) cardiovascular care*
Presented at the Dutch CardioVascular Alliance (DCVA) Steering group meeting on digital cardiovascular care (online).

2022 Inspiring bite: *Patient and staff experience measuring in Remote Patient Monitoring: the need for interdisciplinary data strategies*
Presented at Philips Experience Design, Eindhoven, the Netherlands.

2019 *Convergent design integration for cardiovascular prevention: The Quantified Heart example*
Presented at the 3rd International Meeting on Healthcare Systems Design Research, University of Cambridge, UK.

2019 Invited talk: *Designing smart health technology: the CardioLab vision*
Presented at the Dyson School of Design Engineering, Imperial College, London, UK.

PATENTS

2021 Atallah, L., Xu, M., Patel, P., **Pannunzio, V.**, & Van Zon, C. (2021). *Clinical decision support scheduling and alerts.* WO Patent No. WO 2021/052884 A1; US-provisional-application US 62900854 20190916.

This thesis is the account of a journey across data-related digital health design practices, touching on a series of key themes including digital health, patient and staff experiences, health systems transformation, and data strategies. This exploration was conducted through active involvement in real-world digital health innovation efforts, informed by the analysis, critique and revision of literature relevant to each step of the doctoral research.

TOWARDS A CONVERGENT APPROACH TO THE USE OF DATA IN DIGITAL HEALTH DESIGN

VALERIA PANNUNZIO | 2023

TU Delft