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MANAGING REAL-WORLD PARTICIPATORY DESIGN AND EVALUATION OF DIGITAL HEALTH INTERVENTIONS: A SYSTEMIC MODELLING PERSPECTIVE

SALOMÉ GUEDES SEQUEIRA DE PÁDUA AZEVEDO

Supervisor: Doctor Ana Catarina Lopes Vieira Godinho de Matos
Co-supervisor: Doctor Ana Rita Londral
Co-supervisor: Doctor Teresa Cipriano Rodrigues

Thesis approved in public session to obtain the Ph.D. Degree in

Engineering and Management

Jury final classification: Pass with Distinction and Honour

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Jury

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Resumo

Os serviços de saúde digital são frequentemente fundados em desenhos irrealistas de intervenções de saúde digital por negligenciarem a complexidade do processo de digitalização e a sua dependência do contexto socio-técnico-económico. Este trabalho de investigação teve como objetivo analisar sistemicamente o desenho e a avaliação de intervenções participativas de saúde digital em condições de vida real. Defendo que um serviço digital é um sistema complexo adaptativo, moldado por intervenções complementares e não lineares, e que requer um pensamento sistémico crítico.

A tese resultou duma revisão sistemática, dois estudos de investigação participativa aplicada ao contexto da digitalização dum serviço público de acompanhamento pós-cirúrgico e dum estudo de modelação.

No primeiro estudo, foi aplicada a metodologia de investigação científica orientada para o desenho de artefactos, para, em conjunto com doentes, cuidadores e uma empresa de telecomunicações, desenhar e testar uma intervenção digital num hospital. Resultaram a caracterização dos agentes, atividades e artefactos facilitadores de comunicação e adoção de tecnologia, associados a processos iterativos de colaboração.

No segundo, a equipa recorreu a uma abordagem de investigação participativa orientada para ação, para planear colaborativamente a expansão da intervenção. Demonstrou-se a necessidade de agir e refletir ciclicamente sobre o planeamento, considerando os contextos socioeconómico e tecnológico.

No estudo de modelação, a análise sistémica retrospetiva das intervenções, fundamentada pelas teorias de Ator-Rede e de Atividade, demonstrou a complementaridade e a sequenciação não linear das intervenções ao longo da digitalização do serviço. Os fenómenos mais relevantes foram a intencionalidade em procurar financiamento, a reorganização após financiamento e o surgimento de novos grupos para produção científica e comunicação com a sociedade.

Esta tese avança conhecimento no estudo sistémico e crítico de intervenções transdisciplinares e participativas em contexto real de cuidados de saúde, que acompanham a transformação digital complexa de serviços e contribui para a acumulação estruturada de conhecimento.

Palavras-chave:
Investigação científica para o desenho; investigação participativa para ação; pensamento sistémico crítico; serviços de saúde digitais; sistemas complexos adaptativos

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Abstract

Digital health services often rely on unrealistic designs of digital health interventions, overlooking the complexity of the digital transformation process and its dependence on the socio-technical-economic context. This research aimed to systematically analyse the design and evaluation of participatory digital health interventions in real-life conditions. I argue that a digital service is a complex adaptive system, shaped by complementary and nonlinear interventions, requiring critical systemic thinking.

The thesis resulted from a systematic review, two studies of participatory research applied to the digitization of a public post-surgery follow-up service, and a modelling study.

In the first study, a design science research methodology was applied to collaboratively design and test a digital intervention in a hospital, involving patients, caregivers, and a telecommunications company. This resulted in the characterization of agents, activities, and communication and technology adoption facilitating artifacts, associated with iterative collaboration processes.

In the second study, a participatory action research approach was used to collaboratively plan the expansion of the intervention, highlighting the need for cyclic action and reflection on planning, considering socio-economic and technological contexts.

In the modelling study, a retrospective systemic analysis of interventions, grounded in Actor-Network and Activity theories, demonstrated the complementarity and nonlinear sequencing of interventions throughout the service digitalisation. Relevant phenomena included the intentional search for funding, reorganisation after funding, and the emergence of new groups for scientific production and communication with society.

This thesis advances knowledge in the systemic and critical study of transdisciplinary and participatory interventions in real-world healthcare contexts, accompanying the complex digital transformation of services, and contributes to the structured accumulation of knowledge.

Keywords:
Complex adaptive systems; critical systems thinking; design science research; digital healthcare services; participatory action research

Acknowledgments

For those who may not have the time to read through the entirety of this thesis, I provide an overview through the acknowledgments section.

Over the course of these four years, I have come to realize that I am a critical systems thinker. This means that I view individuals not in isolation, but rather as part of a larger interconnected system. While individuals certainly possess their own identity, it is truly captured through their interactions with others. As a critical systems thinker, I understand that attempting to compel behaviour from individuals only yields temporary results, often requiring power dynamics that are unsustainable in the long run. Adaptation is key to survival in any complex system. Interestingly, despite breaking down a system into its constituent parts for analysis, a critical systems thinker ultimately focuses on the connections between these parts, where true transformative potential lies. Ultimately, a critical systems thinker is aware that her research affects her, and her context affects her research. This is my context.

I owe profound thanks to Professor Helena and Professor Pedro for igniting this journey. It is hard to put into words just how distinct they are, yet together, they propelled me forward. While one, with her graceful waltz-like approach, broadened my perspective on innovation adoption in the healthcare sector, the other, with his rhythmic Beethoven-like style, introduced me to a realm of innovation where patients are not only creators but also the ultimate end users. To Pierre, Rute, and Ana Rodrigues, who, once again, are distinct individuals, each played a role in helping me understand that innovation in healthcare demands a profound understanding of human behaviour and motivations and it serves as a means to an end rather than the end goal itself. To Professor David Patient, Paula, and Tatiana, I extend my gratitude for the enlightening coffee breaks that provided insightful glimpses into organizational behaviour and qualitative methods, which, as an engineer, I initially found daunting.

To Ana Rita, I express my heartfelt gratitude for her investment in providing me with the opportunity to pursue this Ph.D. in a recently established laboratory and for sharing with me the challenges of building something from the ground up. Her guidance, both personally and professionally, has played an integral role in shaping me into who I am today, even though I can be stubborn at times. To Ana Vieira, I am thankful for her bravery in accepting to mentor me midway through this journey. Her dedication, time, and effort in grounding my work in a strong theoretical background and introducing me to critical systems thinking have been invaluable. To both, I must say that I am fortunate to have earned your trust, allowing my creativity to flourish without fear of failure. Lastly, to Teresa and Professor Mónica Oliveira, my gratitude for their scientific provocations to my critical reasoning.

I am deeply grateful for the collaboration with the team at St. Marta's Hospital. To Professor Fragata, Dr. Pedro Coelho, and Dr. Jorge Santos, I express my sincere appreciation for providing me with the opportunity to delve into your insights on how technology can be tailored to enhance surgical departments' functionality. Again to Dr. Jorge Santos and Nurse Clara Vital, Helena Semedo, and Jesus Falcão, I am indebted to you for offering your time amid your demanding schedules, often interrupting breaks between long hospital shifts, to engage in discussions, challenge assumptions, and contribute to my knowledge base. Your invaluable insights and unwavering support have been instrumental. I would also like to extend my heartfelt thanks to all the patients who participated in this project. Your willingness to share your experiences, emotions, and ideas during the challenging weeks following cardiac surgery has been truly inspiring. Your belief in the power of sharing your stories to advance scientific knowledge has been pivotal to the success of this thesis.

To my colleagues at VOH.CoLAB, I extend my gratitude for your unwavering patience and support throughout this past year, time to Go Juu. Special thanks to Pedro for the uplifting beers, to Francisco for his enduring support and willingness to go above and beyond, including fetching coffee during moments of fatigue, and to António for the ingenious microwave rice pot solution, saving precious time. Lastly, to Federico, *muchas gracias por todo*. Your emotional support and technical guidance in the final months were indispensable, and without them, I would not have achieved the desired outcome. "*Mientras hay vida, hay esperanza*". To Lils, Cats, and Mags, I am profoundly grateful for demonstrating that work and friendship can harmoniously coexist. Thank you for accompanying me on strolls through Lisbon streets, patiently listening to my ideas without questioning their validity.

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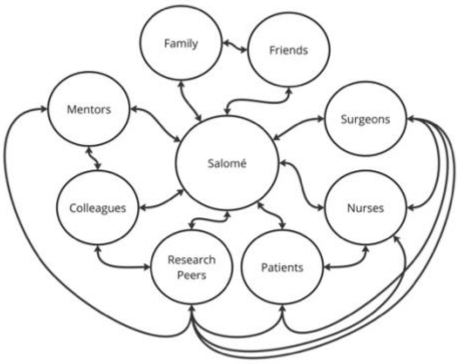
To my parents, with whom I learned to navigate the complexities of dealing with contrasting personalities. From my father, I gained insight into expansive thinking, as his boundless imagination often leads to discussions that push the boundaries of conventional wisdom. When sharing breakfast at dawn while I worked on my thesis, our conversations fuelled my dreams for the impact of my work. His optimistic outlook bordered on the fantastical, making me opt at times to preserve his visions rather than shatter them with reality. From my mother, I acquired a sense of pragmatism, learning that while dreams are essential, they must be grounded in a feasible plan for realization. Our discussions, never at dawn, centred around the practicalities of turning dreams into tangible achievements. She reminded me that reality may diverge from our perceptions, highlighting the importance of realism in the pursuit of our goals. My network has been integral to my progress, and without their support and interactions – both with me and among themselves – this Ph.D. journey would not have reached its conclusion.



My Network *– thanks to Miro. I am grateful to Miro for providing me with a creative outlet to visually organize my thoughts in a safe space, serving as an alternative to the walls of my bedroom. Reflecting back, I believe my former landlord, during my MSc thesis, would have greatly appreciated the existence of Miro as well.*

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List of Abbreviations

AI	Artificial Intelligence
ANT	Actor-Network Theory
AT	Activity Theory
BPMN	Business Process Model and Notation
CAS	Complex Adaptive System
CAT	Chronic Obstructive Pulmonary Disease Assessment Test
CHULC	Central Lisbon University Hospital Centre
CIMIT	Consortia for Improving Medicine with Innovation and Technology
CROM	Clinical-Reported Outcome Measure
CSH	Critical Systems Heuristics
CST	Critical Systems Thinking
DEDHI	Design and Evaluation of Digital Health Interventions
DEDHI	Design and Evaluation of Digital Health Interventions
DHI	Digital Healthcare Intervention
DHIRS	Digital Healthcare Intellectual Resources System
DHIS	Digital Healthcare Intervention System
DHK	Digital Health Kit
DHS	Digital Healthcare Service
DHSPCS	Digital Healthcare Service Problem Content System
DHT	Digital Health Technologies
DSR	Design Science Research
DSRM	Design Science Research Methodology
EC	European Commission
EQ-5D-5L	EuroQol 5-Dimensions 5-Levels
EQF	European Qualifications Framework
ES	Engineering Sciences
ESS	Epworth Sleepiness Scale
EU	European Union
EXPH	Expert Panel on effective ways of investing in Health
FCT	Foundation for Science and Technology
HIC	Health Innovation Cycle
HRQoL	Health-Related Quality of Life
HS	Health Sciences
ICT	Information and Communications Technology
IoT	Internet of Things
IS	Information Systems
ISAT	Intervention Scalability Assessment Tool
ISAT	Intervention Scalability Assessment Tool
IT	Information Technology
ITER	Iteration
LC	Life cycle
MeSH	Medical Subject Heading
mHealth	mobile Health
MIS	Management Information Systems
MOST	Multiphase Optimisation Strategy
MOST	Multiphase-Optimization Strategy

MS	Management Science
MVP	Minimal Viable Product
NPS	Net Promoter Score
OR	Operational Research
PAR	Participatory Action Research
Ph.D.	Doctor of Philosophy
PRESM	Patient-Reported Experience Measures
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
PROM	Patient-Reported Outcome Measure
PSM	Problem Structuring Method
PSQIII	Patient Satisfaction Questionnaire Form III
QSQ	Quebec Sleep Questionnaire
R&D	Research and Development
RCT	Randomised Controlled Trials
RPM	Remote Patient Monitoring
SIM	Subscriber identify module
SNA	Social Network Analysis
SoC	Standard of Care
SPIDER	Sample, Phenomenon of Interest, Design, Evaluation, Research type
STE	Socio-technical-economic
TCQ	Thought Control Questionnaire
TRL	Technology Readiness Level
UEQ	User Experience Questionnaire
UHC	Universal Health Coverage
UST	Unified Services Theory
VBHC	Value-based Healthcare
VOH.CoLAB	Value for Health CoLAB
WHO	World Health Organization

List of Publications

This thesis was based on the following manuscripts (international peer-reviewed papers):

Londral, A., **Azevedo, S.**, Dias, P., Ramos, C., Santos, J., Martins, F., Silva, R., Semedo, H., Vital, C., Gualdino, A., Falcão, J., Lapão, L.V., Coelho, P. & Fragata, J.G. Developing and validating high-value patient digital follow-up services: a pilot study in cardiac surgery. BMC Health Serv Res 22, 680 (2022). https://doi.org/10.1186/s12913-022-08073-4

Azevedo, S., Rodrigues, T. C. & Londral, A. Domains and methods used to assess home telemonitoring scalability: A systematic review, JMIR mHealth and uHealth. 14/07/2021:29381. https://doi.org/10.2196/29381.

Azevedo, S., Guede-Fernández, F., von Hafe, F., Dias, P., Lopes, I., Cardoso, N., Coelho, P., Santos, J., Fragata, J., Vital, C., Semedo, H., Gualdino, A. & Londral, A. (2022) Scaling-up digital follow-up care services: collaborative development and implementation of Remote Patient Monitoring pilot initiatives to increase access to follow-up care. Front. Digit. Health 4:1006447. doi: https://10.3389/fdgth.2022.1006447

The research work also resulted in the following publications, posters, oral publications, and masters' thesis:

Peer-reviewed paper:

Oertzen, A. S., Vink, J., Odekerken-Schröder, G., Mager, B., & **Azevedo, S.** (2022). Navigating the tensions of integrating lived experience in participatory healthcare design. The Design Journal, 25(6), 997-1018. https://doi.org/10.1080/14606925.2022.2113223

von Hafe, F., **Azevedo, S.**, Fragata, J. & Londral, A. Initial steps for the Portuguese Atlas of geographical variation in healthcare. Res Health Serv Reg 2, 7 (2023). https://doi.org/10.1007/s43999-023-00022-w

Chapters:

Oliveira P., **Azevedo S.**, & Canhao H., (2019) Empowering patients to innovate: the case of Patient Innovation, in Iakovleva, T., Oftedal, E. M., & Bessant, J., Responsible Innovation in digital health. (pp. 42-53). Cheltenham, U.K.: Edward Elgar Publisher.

Londral A., **Azevedo S.** & Silva, R. (2022) - A informação gerada pelo doente. In Transformação Digital em Saúde - Contributos para a mudança. Coord. Teresa Magalhães. Coleção: APAH. Portugal: Almedina. ISBN: 9789894001102

Peyroteo, M., Maia, M., **Azevedo, S.**, Londral, A., Lapão, L. The rise of AAL in Portugal: From the Hospital to the Health Center and Patients Homes. In A Century of Telemedicine: Curatio Sine Distantia et Tempora A World Wide Overview – Part V. Edited by M. Jordanova, F. Lievens, 2022. ISBN 978-619-90601-6-2

Conference Proceedings:

Azevedo, S. & Londral, A. (2020). Digital Innovation in Outpatient Healthcare Delivery Services: A Common Methodology to Introduce IoT Technologies in Two Use-cases. In Proceedings of the 13th International Joint Conference on Biomedical Engineering Systems and Technologies - Volume 5: HEALTHINF, ISBN 978-989-758-398-8, ISSN 2184-4305, pages 821-826. DOI: 10.5220/0009394908210826

Mollaei, N., Londral, A., Cepeda, C., **Azevedo, S.**, Pinheiro, J., Coelho, P., Fragata, J., Gamboa, H. (2021) Length of Stay Prediction in Acute Intensive Care Unit in Cardiothoracic Surgery Patients, ICBSII_2021, 2021 Seventh International Conference on Biosignals, Images, and Instrumentation, 25-27 March 2021 https://doi.org/10.1109/ICBSII51839.2021.9445145

Other Publications:

Londral, A., **Azevedo, S.**, Santos, J. & Coelho, P. (2021) CardioFollow.AI - A Digital Follow-up Service Expanded Beyond the Hospital Walls, HealthManagement.org, 21(6). https://healthmanagement.org/uploads/article_attachment/hm6-cardiofollow-ai-a-digital.pdf

Oral Presentations:

Azevedo S., Rodrigues T. C., Londral A. R. Domains and Methods Used to Assess Home Telemonitoring Scalability: Systematic Review (2020). 2020 CHRC Annual Summit

Azevedo, S., and **Londral, A. R.** (2020). Digital Innovation in Outpatient Healthcare Delivery Services: A Common Methodology to Introduce IoT Technologies in Two Use-cases. In Proceedings of the 13th International Joint Conference on Biomedical Engineering Systems and Technologies - Volume 5: HEALTHINF, ISBN 978-989-758-398-8, ISSN 2184-4305, pages 821-826. DOI: 10.5220/0009394908210826

Mollaei, N., Londral, A., Cepeda, C., Azevedo, S., Pinheiro, J., Coelho, P., Fragata, J., Gamboa, H. (2021) Length of Stay Prediction in Acute Intensive Care Unit in Cardiothoracic Surgery Patients, ICBSII_2021, 2021 Seventh International Conference on Biosignals, Images, and Instrumentation, 25-27 March 2021

von Hafe, F., Azevedo, S., Londral, A. R. (2021). The cost-analysis of digitizing the care process in a nursing home: a pilot study. 17th Portuguese National Conference on Health Economics

Santos, J., Gualdino, A.; Falcão, M.; Semedo, H.; Vital, C.; Londral, A.; Azevedo, S.; Dias, P.; von Hafe, F.; Coelho, P.; Fragata, J. (2021) CardioFollow.AI - The Value of a Digital Cardiothoracic Follow-up Service, presented in Congresso da SPCCTV - 4D Visions, Albufeira, Portugal, 26-28 November.

Azevedo, S., von Hafe, F., Vieira, Ana C. L., Londral, A. R. (2022) Value scorecard - What matters the most? A tool to iteratively improve and successfully implement Remote Patient Monitoring service after cardiothoracic surgery. ISPOR Europe 2022 - Collaborating Across Borders: Building & Using Evidence to Enable Access, Vienna, Austria, 7 - 9 November

Azevedo, S., von Hafe, F., Vieira, Ana C. L., Londral, A. R. (2022) Implementing Value For Health Scorecards co-created with healthcare professionals to measure the value of remote patient monitoring (RPM)-based services for cardiothoracic surgery. ICHOM Conference 2022 - Outcomes Driving Positive Changes: The New Era of Healthcare, Boston, U.S.A, 1 - 3 November

Master's Students Co-supervision:

Brum, P. (2022) Exploring scalability of a digital health intervention: A value network approach.

Ramiro, A. (2023) Digital health scorecard utilisation evaluation using eye-tracking technology.

Teixeira, A. (on-going) Will RPM-based services remain in the mainstream of healthcare?

Belo, J. (on-going) The impact of the General Data Protection Regulation (EU GDPR) on Digital Health Solutions.

PART I – General Introduction

Part I introduces the research problem, the thesis rationale, and a review of the relevant literature related to the Quadruple Value model, digital health service interventions and services, and critical systems thinking research.

CHAPTER 1 | Problem, research opportunity, objectives, and thesis structure

Chapter 1 frames the research problem within the practical context of inadequately designed and evaluated digital health interventions, emphasising the imperative for a systemic approach to optimise the potential of digital health services in achieving the universal health coverage. Providing a historical overview, the chapter elucidates the significance of this issue for agents involved. It identifies the design and evaluation of systemic digital health interventions as a pivotal research opportunity, articulating the primary argument and objective of the thesis. Lastly, the chapter delineates the structure of the thesis.

1.1. The Problem

Within health systems, the ongoing challenges of achieving universal health coverage (UHC) and controlling healthcare spending persist across generations (Palm et al., 2021). Proposals to digitalise health systems for enabling universal care delivery, anytime and anywhere, emerged as promising solutions (Cummins & Schuller, 2020). However, digital health services, a main outcome of this effort, have faced criticism for failing to effectively address these issues (Black et al., 2011).

In the European Union (EU), health is unequivocally recognised as a fundamental human right, with a commitment to UHC ensuring access to quality healthcare and financial protection for every resident (WHO, 2006). Despite advancements in quality and safety, the imperative to trim health expenditure persists (Jani et al., 2018). To confront these challenges, Gray advocates for a systems approach in redesigning or establishing new health services, recognising the interconnected nature of health systems and inherent complexities (Gray, 2017). This approach involves reallocating resources to high-value activities meeting patient preferences and needs, while controlling health spending.

In response to an oversimplified efficiency-based value proposed by management consultants (Porter & Teisberg, 2006), the European Commission (EC) convened a multidisciplinary expert panel (EXPH) to contextualise value-based healthcare (VBHC) in the EU. The EXPH extended Gray's work and proposed the "*Quadruple Value Model*" to guide health services design and evaluation (EXPH, 2019) based on four value dimensions: (1) *personal* (ensuring patient inclusion and awareness); (2) *allocative* (ensuring cost-effective distribution and equity); (3) *technical* (ensuring optimal resource allocation and care suitability); and (4) *societal* (fostering social cohesion and inclusive growth).

Many argue that the digitalisation of health services, i.e., the process of creating new health services through the integration of information and communications technology (ICT), promises to enhance health systems' performance, narrow the gap to reach UHC, and empower patients by facilitating interaction with healthcare professionals (Cummins & Schuller, 2020; Devine, 2022; EXPH, 2018; Ricciardi et al., 2019). However, the EXPH urges caution, emphasising the need for realistic expectations and evidence-based approaches in developing new digital health services. They emphasise the need for research and development (R&D) methodologies and interventions to collect evidence in real-world contexts to assess its impacts (EXPH, 2018). The EXPH's recommends the use of the Quadruple Value Model to guide investment and R&D efforts in digital health interventions. This will ensure alignment with high-value care and broader health system goals. Notably, this recommendation emerged in the intersection of two time periods, before and after the COVID-19 pandemic.

Before COVID-19, despite substantial R&D spending on healthcare digitalisation (Black et al., 2011), the failure of digital health services to improve appropriate access to quality care without financial hardship was attributed to low uptake of ICT in clinical practice (Bakalar, 2022). This stemmed from two main reasons: a lack of understanding of digital health services' added value among agents with conflicting interests (Blandford et al., 2018; Collins et al., 2016), and the high-burden of poorly designed services and fragmented technological infrastructure (Ricciardi et al., 2019).

After COVID-19, there was a widespread uptake of digital health solutions in clinical practice (Bakalar, 2022), fuelled by increased government budgets for digitalisation (Fahy & Williams, 2021). While this expanded access to health services, it also exacerbated health inequalities, challenging the goal of UHC. Contrary to expectations, issues like low digital literacy and limited access to digital health technologies due to financial constraints and uneven technology coverage emerged as key factors in digital health's shortcomings (Fahy & Williams, 2021). Additionally, sociotechnical challenges persisted, including a lack of trust, support, and training among professionals and the public, due to poorly designed implementation strategies and inadequate ICT infrastructure (Crawford & Serhal, 2020; Fahy & Williams, 2021; Mogessie et al., 2021).

Overall, it remains evident that a key challenge in both time periods is the lack of robust evidence to guide the design and evaluation of digital health services. This challenge stems from the use of unrealistic and non-participatory frameworks for designing and evaluating digital health interventions. These frameworks overlook the complex and context-dependent nature of the digitalisation process, as well as value judgments and socio-technical-economic factors that influence decision-making about participants inclusion in interventions. Without a systemic and transdisciplinary approach, efforts to translate R&D into practical implementation will fall short of achieving UHC (Blandford et al., 2018; Mingers, 2015).

Hence, I argue for the adoption of a critical systems thinking (CST) approach to gain a more comprehensive understanding of the environment in which the digitalisation of health services unfolds.

It will support recognising the dynamic nature of the process, which involves several interventions shaped by complex interactions among technology, individuals, organisations, and governments (Figure 1). The CST approach has three fundamental commitments: critical awareness, action for improvement, and methodological pluralism (Jackson, 2001; Mingers, 2014). A CST researcher should cultivate critical awareness by questioning assumptions, demonstrate social responsibility by addressing temporally and locally defined problems, acknowledge power dynamics, and be adept at using and combining methods coherently and informatively.

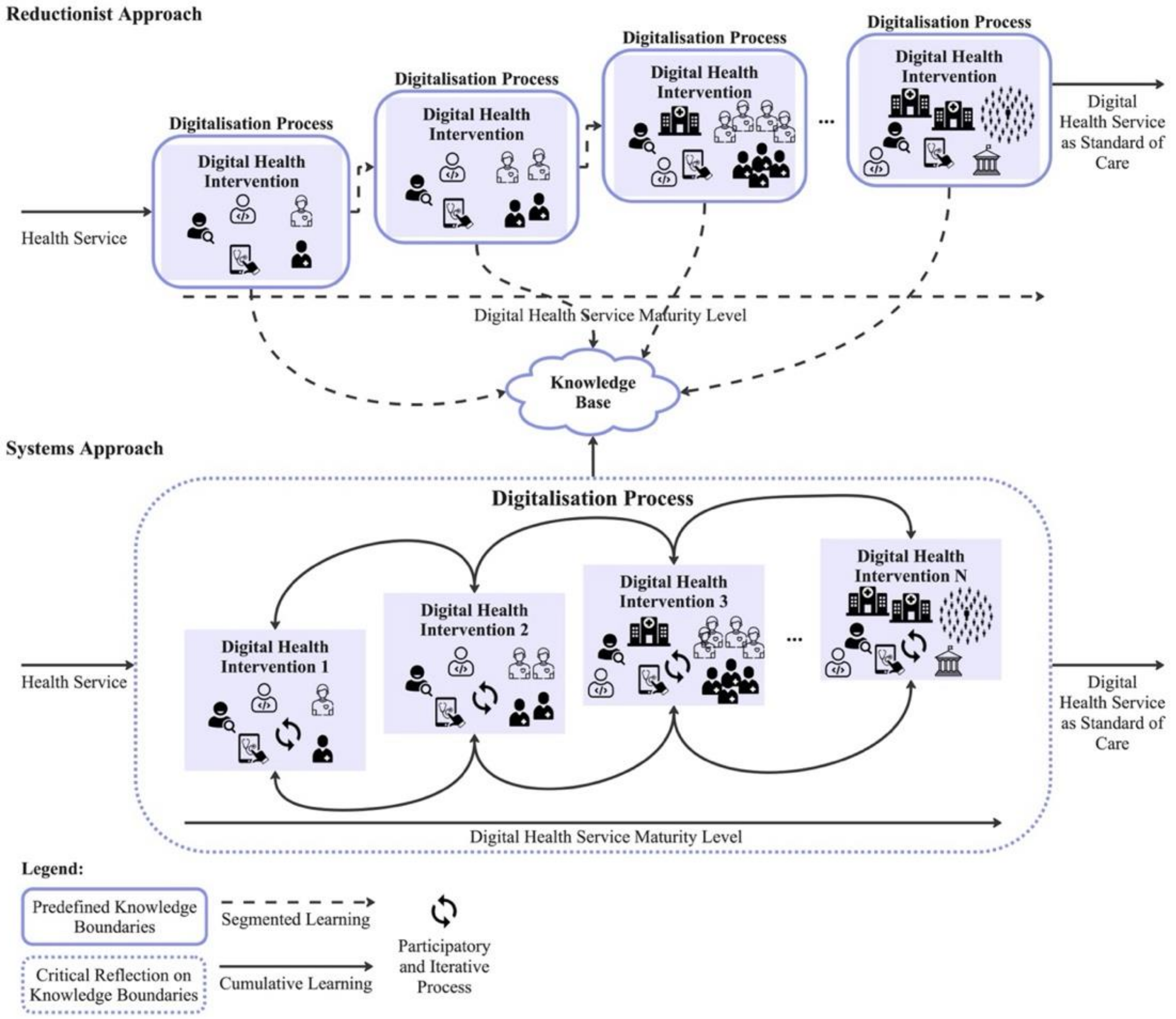

Figure 1 – Thesis research problem: Reductionist approach confines digitalisation within predefined boundaries, leading to fragmented learning. Conversely, the systems approach offers a comprehensive understanding by accommodating reflections on knowledge boundaries influenced by value judgments, acknowledging digitalisation's dynamic nature.

1.2. The Research Opportunity

The current Ph.D. thesis aims to model the digitalisation process of a health service through a series of real-world participatory digital health interventions, employing a CST research approach. This research was conducted as part of a collaborative Portuguese project involving a public hospital, two R&D laboratories, and a telecommunications company. The shared goal of this collaboration was to digitalise a cardiac surgery follow-up service. First, a concise overview of this project is provided followed by the outline of the primary argument and objectives of this research thesis.

The cardiac surgery follow-up service digitalisation project started in February 2019 and is scheduled to conclude in June 2024. Originating from a need experienced by a surgical team at St. Marta Hospital in Lisbon, the project seeks to digitalise an existing cardiac follow-up service to enable continuous patient monitoring during the critical postoperative period (characterised by hospital readmission rates of 15 to 20% (Khoury et al., 2020; McElroy et al., 2016)).

St. Marta Hospital, supervised by the Central Lisbon University Hospital Centre (CHULC), collaborates with NOVA University, one of the founding partners of Value for Health CoLAB (VOH.CoLAB). VOH.CoLAB, established as “Collaborative Laboratory” by the Portuguese Foundation for Science and Technology (FCT), aims to bridge the academia-industry gap by accelerating R&D translation into health products and services. VOH.CoLAB engaged Fraunhofer Portugal and Vodafone Portugal to contribute their technological expertise to digitalise the new health service. Fraunhofer Portugal specialises in Artificial Intelligence (AI)-based technology development, with prior success in cardiology-focused digital health solutions. Vodafone Portugal, a telecommunications operator, specialises in developing ICT solutions and services. The four partners committed to the project with the constraint of minimal investment and technology adaptation. Initially, there were limited studies on digital health interventions benefits in cardiac surgery, but positive results in chronic heart failure were observed in quality of life, mortality, readmissions, and expense reduction (Pekmezaris et al., 2012; Seto, 2008; Yun et al., 2018). Beginning their collaboration without public funding, the partners sought to validate the new digital health service, secure public funding for expansion, conduct a clinical study to identify the most beneficial patient groups, and address challenges related to managing a larger patient population. In October 2020, the project received national funding through FCT with the reference: "*CardioFollow.AI - An intelligent system to improve patients’ safety and remote surveillance in follow-up for cardiothoracic surgery*” (DSAIPA/AI/0094/2020) in the scope of “*AI 4 COVID-19: Data Science and Artificial Intelligence in the Public Administration to strengthen the fight against COVID-19 and future pandemics – 2020*”.

The research conducted in this thesis, funded by VOH.CoLAB, has followed the project since its initiation until December 2023, focusing on the digitalisation process of the cardiac surgery follow-up service as an unstructured problem, with a complex adaptive system (CAS) nature. The digitalisation process is an unstructured problem due to its inherent characteristics, which include: multiple agents (patients, healthcare professionals, technology developers, researchers, etc.), diverse perspectives (aiming to provide high-quality and efficient remote care), conflicting interests (such as providing high-quality care while minimising R&D investments), critical intangibles (such as caregiver support and digital health literacy), and key uncertainties (such as technology and organisation adaptability to a new service) (Rouse, 2008; Sittig & Singh, 2015; Tan et al., 2005). In this context, various agents collaborate to address inherent challenges over time with a non-linear and dynamic behaviour, demonstrating the ability to self-organise and adapt (Basole & Rouse, 2008; Paté-Cornell et al., 2016; Tan et al., 2005). There were four anticipated challenges and corresponding action plans realised by the partners:

The first challenge involved designing, developing, and testing a digital health service through a real-world, participatory digital health intervention while minimising resource allocation for each partner. To address this challenge, the partners planned to adopt the Design Science Research (DSR) methodology, as it has been suggested to be effective in promoting collaboration in the development of Information Systems (IS)/Information Technology (IT) artifacts (Hevner et al., 2004).

The second challenge entailed determining the most pertinent domains and methods to evaluate the scalability of the digital health intervention. To address this, the partners planned a systematic literature review to identify the most relevant domains and methods in the scalability assessment of digital health interventions.

The third challenge revolved around securing funding, devising a technological and organisational scale-up roadmap for a broader patient population, and conducting a clinical study to assess the performance of the new digital health service with a larger patient population. To address this challenge, the partners planned to adopt the Participatory Action Research (PAR) approach, as it has been effective in bringing about social change and promoting collaboration through problem-solving (Taylor et al., 2015).

The fourth challenge revolved around establishing theoretical and methodological foundations for retrospectively analysing the digitalisation process as a CAS. The strategy involved framing the digitalisation process as a comprehensive intervention consisting of interconnected micro-interventions and examining it using a systemic intervention methodology (Midgley, 2006) informed by Activity Theory (AT) and Actor-Network Theory (ANT) (White et al., 2016). Within the scope of this project, the main argument and research objectives set for this thesis will be clarified in the following section.

1.3. The Main Argument and Objectives

The main argument of this Ph.D. thesis is that the digitalisation process of a health service should be perceived as an unstructured problem with a CAS nature and studied as a systemic digital health intervention. It asserts that the digitalisation process of a health service entails a complex and iterative journey involving interconnected interventions, where agents self-organise and adapt using various research approaches and techniques across different phases of the systemic digital health intervention. Beginning with an action research approach and proceeding to process model design and analysis, the study of the digitalisation process was driven by four primary objectives which are aligned with the four aforementioned challenges:

1. Collaboratively design, develop, and test a digital health service in a real-world digital health intervention using the DSR methodology.
2. Identify the most relevant domains and methods used to assess digital health interventions scalability.
3. Collaboratively evaluate the digital health service intended use and develop a scale-up plan in a real-world digital health intervention adopting a PAR approach.
4. Model and study the digitalisation process as a system of interconnected micro-interventions shaped by complex interactions of people and artefacts within a dynamic context, employing a systemic intervention methodology informed by AT and ANT.

Throughout this doctoral research, the philosophical position of critical realism (Bhaskar, 2008) was adopted. This position is grounded in the alignment between critical realism and systems thinking key concepts such as open/closed systems and system boundaries; the observed/observer and the intransitive/transitive domains; emergent properties and powers, among others (Mingers, 2000). Ontologically, critical realism delineates the world into the realm of the real (beyond our knowledge), the actual (observable phenomena), and the empirical (our experiences). Epistemologically, it acknowledges the contextual and temporal nature of knowledge, advocating for critical reasoning to navigate between different perspectives. Methodologically, critical realism supports pluralism in research and intervention methods, endorsing a retroductive approach where hypotheses are formulated to explain observed events or experiences, and then tested for confirmation or rejection (Mingers, 2000).

1.4. Thesis Structure, Specific Objectives, and Contributions

Figure 2 outlines the Ph.D. thesis structure and the research workflow to support content navigation. The following section elaborates on Figure 2 by providing a brief introduction to each chapter, outlining its specific objective, and explaining its contribution to the overall objectives discussed earlier.

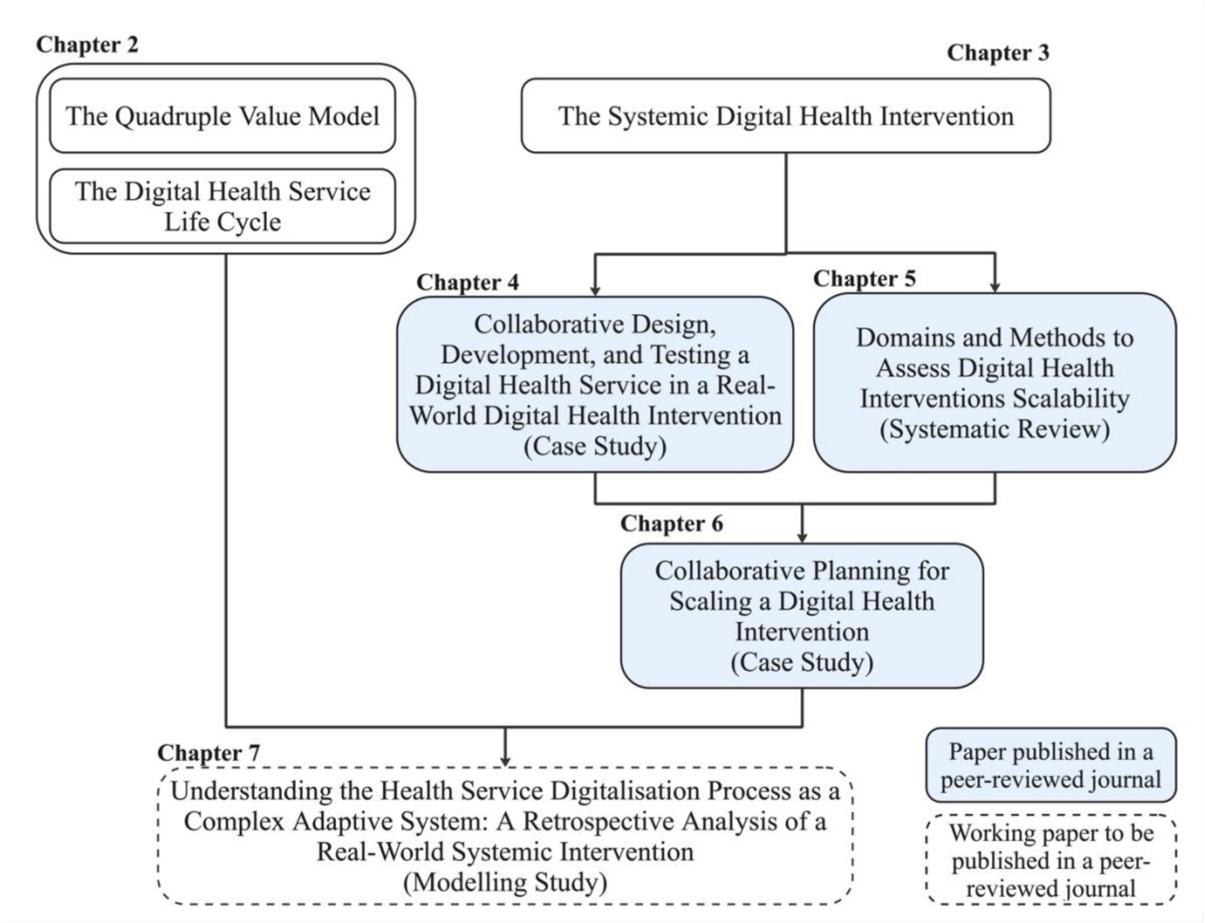

Figure 2 – Ph.D. thesis structure: blue rounded lined squares denote chapters published in peer-reviewed journals; dashed rounded lined square indicates a chapter presented as a working intended for a publication in a peer-reviewed journal).

Part I is the first section and is organised in three chapters. It introduces the research problem, the thesis rationale, and a review of the relevant literature on the research subject.

Chapter 1 positions the research problem within a real-world situation, provides an historical constitution of the situation, and justify its relevance for the different agents affected and the need for research. After a clear identification of the research opportunity, main argument and objectives, the chapter ends with an overview of the thesis outline.

Chapter 2 presents a brief contemporary debate on the use of *value* and *values*, emphasising the Quadruple Value Model as a guiding framework for designing and evaluating digital health services within the EU member states context. Furthermore, it consolidates findings from a literature review on life cycle models for health innovations, proposing a model capable of accommodating various digital health interventions across the service life cycle and informing the dimensions of the Quadruple Value Model.

Chapter 3 advocates for a CST approach to frame the digitalisation process of a health service as a systemic intervention and suggests combining methods for comprehensive understanding. It covers the use of DSR and PAR in health ICT systems collaborative and participatory design and scalability planning, along with methods for understanding the digitalisation process as a systemic intervention.

Part II showcases applied action research addressing the defined objectives. Through chapters 4 to 6, the collaborative efforts in design, development, and real-world testing of digital health interventions are emphasised, along with capturing agents' perspectives on scalability. These studies lay the groundwork for Chapter 7, which proposes a retrospective systemic analysis of the digitalisation process. Grounded in Complexity Theory, Actor Network Theory (ANT), Activity Theory (AT), this analysis explores intervention dynamics concerning the digital health service maturity levels. All four chapters are or will be published in peer-reviewed journals. When writing this thesis, three **(**Chapters 4, 5, and 6) out of the four chapters were already published in peer-reviewed journals.

Chapter 4 corresponds to the first study conducted in the scope of this Ph.D. research project. Chapter 4 introduces an improvement to the DSR methodology, validated through the design, development, and testing of a digital health intervention in a real-world setting. This chapter delineates the process and artifacts facilitating the design and testing of a digital health intervention within a real-world context, elucidating the roles and activities of the agents throughout the technological iterative development cycle.

Chapter 5 corresponds to the second study conducted in the scope of this Ph.D. research project. Chapter 5 provides a comprehensive systematic review of the domains and methodologies used in existing literature to evaluate the scalability of digital health interventions, with a specific emphasis on interventions leveraging remote patient monitoring technologies for home-based care. By focusing on the nuanced realm of home telemonitoring interventions, the chapter aims to deliver more pertinent and insightful findings tailored to the thesis's overarching objectives. Notably, the chapter identifies a critical gap in scalability assessment studies, highlighting the oversight of evaluating key domains such as strategic, socio-economic, organizational, and technological factors. Furthermore, it underscores the challenge posed by the disparate methods employed within a single domain, hindering meaningful comparisons and comprehensive evaluations.

Chapter 6 corresponds to the third study conducted in the scope of this Ph.D. research project. This chapter presents a case study detailing collaborative planning activities and the crucial roles and contributions of key agents in scaling a digital health intervention. Employing a PAR approach with a transdisciplinary team, this chapter underscores the efficacy of such an approach in providing a thorough comprehension of agents' collaborative efforts across the design, development, testing, and evaluation stages of a digital health intervention. Furthermore, it emphasises the importance of considering contextual, technological, and environmental factors in scaling endeavours.

Chapter 7 presents a retrospective systemic analysis of a digitalisation process of a health service. This study, rooted in Complexity Theory, AT, and ANT, argues for viewing the digitalisation process as a CAS and approaching it as a systemic intervention. A systemic intervention methodology is proposed to qualitatively model and evaluate the complex interactions among agents over time. The analysis examines methodologies used, generated artifacts, and meeting notes to characterise agents and their actions within a localised, time-bound context. Key findings include the multiple roles of agents, intentional pursuit of funding, post-funding reorganisation of teams and technology, and the emergence of new working groups for scientific production and societal communication.

Part III is the third and final section of the thesis and provides the reader with a general discussion and future insights for research on managing real-world participatory design and evaluation of digital health interventions and studying the digitalisation process as a CAS from CST approach.

Chapter 8 offers a comprehensive discussion of the principal theoretical and methodological contributions and practical implications stemming from the research findings, consolidating insights gleaned from preceding chapters, while also addressing certain limitations encountered.

Chapter 9 outlines potential avenues for future research driven by this thesis.

CHAPTER 2 | The Quadruple Value Model and the Digital Health Service Lifecycle

Chapter 2 presents a brief contemporary debate on the use of *value* and *values*, emphasising the Quadruple Value Model as a guiding framework for designing and evaluating digital health services within the EU member states context. Additionally, it consolidates the findings from a literature review on existing life cycle models for health innovations, encompassing services, products, or technologies. Drawing from this review, the chapter proposes a model capable of effectively framing various digital health interventions across the digital health service life cycle, along with the corresponding evidence generated to inform the four dimensions of the Quadruple Value Model.

2.1. The Value Debate and the Quadruple Value Model

This section refrains from offering a definitive definition of "*value*" or "*values*", but rather delves into the intricate historical debate surrounding these terms encountered throughout my doctoral journey. It aims to elucidate the diverse interpretations of "*value*" and "*values*" among scientific communities, practitioners, and society. While the theoretical analysis of "*values*" typically falls within the realm of philosophy (axiology), research at the intersection of multiple disciplines has revealed a fragmented knowledge in addressing this subject (Graeber, 2001). In everyday life, people use the term "value" as a bridge between monetary worth (value as price) and personal significance (values as inalienable). For example, "*value*" can represent the effort exerted in determining the monetary worth of a service, like assessing the value of receiving remote care, closely resembling the concept of price. Conversely, "*value*" can also signify the importance we assign to certain life aspects that go beyond monetary assessment, such as the value we place on being close to family and in the comfort of home while recovering, which hold intrinsic significance (Miller, 2008). To address these complexities, the Quadruple Value Model's four dimensions are explored to aid in designing and evaluating digital health interventions across the digitalisation process.

2.1.1. The debate on *Value* and *Values*

In my exploration of the concepts of "*value*" and "*values*" from a CST perspective, I have found valuable insights from anthropological research. Anthropology's fundamental purpose, as the comparative study of cultural and social life, resonates with this pursuit (quoted from Eriksen 2001 in Miller et al., 2019). David Graeber and Daniel Miller, two renowned anthropologists, offer contrasting approaches towards developing a value theory, enriching my examination of this historical debate.

On one hand, Graeber provides an historical overview of anthropological thought and proposes a theory of value centred on actions rather than objects (Graeber, 2001). On the other hand, Miller begins his theory by observing how people use the term "*value*" in everyday life, applying it to diverse contexts such as mobile phone usage in Jamaica (Miller, 2008). While Graeber's perspective starts with Marx's labour theory of value, Miller focuses on comprehending the colloquial usage of value as a bridge economic discourse with broader social and cultural dimensions. I refrained from debating the legitimacy of each author's approach, as it is irrelevant to my thesis. Instead, I draw insights from both approaches to contextualise the four dimensions of the Quadruple Value Model in the next section.

Graeber identifies three major streams of anthropological thought that converge under the concept of "*value*": in the **sociological sense**, "*values*" pertain to what is deemed good or desirable in human life, acting as criteria for evaluating desires and actions; in the **economic sense**, "*value*" quantifies the degree of desire for objects, often determined by what others are willing to sacrifice to obtain them (incorporates microeconomic principles focused on individual gain maximisation); in the **linguistic sense**, "*value*" refers to meaningful differences conveyed through language, reflecting emotional significance and influencing social behaviour. Graeber integrates these perspectives to propose a theory of value centred on actions, within society seen as interconnected networks. He suggests adopting a Heraclitan perspective, emphasising dynamic forces and acknowledging the inherent complexity and partiality of reality. This approach aligns with Bhaskar's philosophy (Bhaskar, 2009), advocating for humility in social science and recognising the intricate nature of social phenomena.

Miller also argues that *value* should be understood as a dynamic social process, examined through people's usage of the term. He identifies two extremes in value usage: one where value is reduced to single measures, diminishing its complexity and potential, and another where the relationship between value and values is acknowledged, fostering welfare through bridging economic and non-economic realms. Miller illustrates these points through examples such as McKinsey's missionary position, Best Value in the British government, and New Age Value, showing how attempts to reduce value to a bottom-line metric often fail to enhance its actual worth. Instead, value creation flourishes when it serves as a bridge between different realms, as seen in the examination of concubines in 5th-century BC Athens and the Swedish social democratic state. Miller suggests that recognising the uses of value can inform research and analysis in social studies, particularly in grasping the interplay between economic and non-economic elements. Overall, Miller emphasises that value is dynamic, continually shaped by its diverse applications and associations, and understanding these dynamics is crucial for effective policymaking and social analysis.

From a systems perspective, both Graeber and Miller view value and values as dynamic and dialectical constructs within social wholes. However, they diverge in their conceptualization of these wholes. Graeber sees society as open-ended networks, shaped by actors' social creativity in pursuing diverse forms of value. In contrast, Miller's understanding of social wholes stems from how people use value rather than intellectual discourse. The primary difference lies in their methodological approaches, with Graeber relying on literature review and Miller adopting an ethnographic approach.

As noted by Miller in his fieldwork, the term "*value*" has become pervasive in the healthcare sector, with a widespread focus on creating or adding value in patient care and health systems (EXPH, 2019; Zhang et al., 2021). This mirrors the concept of value-based healthcare (VBHC) as a remedy to enhance health systems, akin to Miller's analogy of McKinsey's missionary position case (Porter & Thomas, 2013). Porter's attempt to simplify value in healthcare to a single equation, balancing patient values with healthcare provider costs, represents a reductionist and flawed perspective of "value" in both economic and sociological senses. In contrast, the EXPH proposed the Quadruple Value Model as a framework to contextualise VBHC in the EU (EXPH, 2019), which is the following section's focus.

2.1.2. The Quadruple Value Model

The Quadruple Value Model, as proposed by the EXPH, builds upon Sir Muir Gray's research on population-based health systems and the triple value healthcare model (Gray, 2017). It also critiques and analyses the Porter and Teisberg version of value-based healthcare in the United States, highlighting the need for significant adaptations to align with European health systems. Despite its function as a policy-making report, the model omits explicit theoretical foundations, justifying previous investigation into anthropological research to elucidate underlying meanings.

The authors begin by outlining the geographical scope of their analysis, focusing on EU member states, and drawing from Chapter IV of the Charter of Fundamental Rights, which addresses "Solidarity". Solidarity encompasses various rights related to work, family life, welfare provision, and health and is a fundamental principle enshrined in the EU Treaties, with the modern European welfare state revolving around it. The authors highlight a commitment to solidarity wherein individuals contribute according to their ability and receive benefits according to their needs, with the state ensuring this through resource collection and distribution to the least advantaged. Consequently, solidarity is recognised as a cornerstone of *shared values* among EU citizens. Sociologically, this entails a belief in distributing resources based on individual needs for the benefit of both individuals and society as a whole. Economically, there is a preference for maximising societal gains over individual gains.

Additionally, as citizens of EU member states, individuals have the right to participate in a democratic governance system that acknowledges their capacity to contribute and their need to receive.

Building upon the concept of solidarity, the EXPH panel extends its significance beyond being a shared value to serving as a guiding principle for operationalising another fundamental social right in the EU: universal access to timely, affordable, preventive, and curative healthcare of good quality. To ensure fair distribution of healthcare resources, the EXPH introduces core principles encompassing access and equity, which emphasise the universal availability of care regardless of socio-economic status or geographical location, while addressing disparities through equitable resource allocation. Quality healthcare is emphasised as providing safe, effective, and patient-centred care, guided by evidence-based practices and continuous improvement. Performance in healthcare is aimed at enhancing population health, responsiveness to community needs, and fairness in financial contributions, measured by tangible improvements in health outcomes and reduced disparities. Efficiency is highlighted as crucial for maximising the value of available resources, optimising allocation, and minimising waste for the benefit of patients and communities. Lastly, productivity in healthcare involves enhancing delivery effectiveness through technology and innovation to increase service output while maintaining or improving quality standards. Drawing insights from anthropological studies, the EXPH seeks to provide constructs, in the form of indicators, that bridge the economic value and sociological values for EU member states and elucidate their use.

While acknowledging the diverse interpretations and dimensions of value, the EXPH simplifies the concept by defining it as something deemed good or beneficial. However, they make a crucial distinction between intrinsic and extrinsic value, particularly in the context of health. Intrinsic value refers to qualities valued for their own sake, while extrinsic value serves as a means to attain other goods. In healthcare, health itself is seen as possessing both intrinsic and extrinsic value, as it is fundamental to individual well-being and essential for pursuing other life goals. As a result, the notion of “value-based healthcare” becomes complex, aiming to promote health as the ultimate objective. However, defining health proves challenging, with the World Health Organization’s comprehensive definition posing practical application difficulties. An alternative perspective defines health as the ability to achieve vital goals, aligning with individuals’ subjective experiences and aspirations for *minimal* happiness. Thus, VBHC in the EU prioritises the equitable attainment of health across individuals, groups, and populations, emphasising its role in enabling fulfilling lives. Ultimately, the value of health is shaped by individual perspectives and goals, while the value of healthcare lies in facilitating equitable health outcomes for collective well-being.

The EXPH panel offers an insightful overview of the VBHC term's origins and its inadequacy in aligning with EU values. Much like Miller's analysis of McKinsey's missionary position, the EXPH panel concludes that Porter's use of the term "value" in defining value-based healthcare conflicts with the EU's solidarity concept, particularly regarding equity. Porter's narrow approach mirrors what countries committed to UHC classify as technical efficiency, rather than embodying the broader values of equity and solidarity. Notably, the panel subtly adjusts the terminology, referring to it as "value(S)-based healthcare" underscoring the significance of this linguistic nuance.

Building upon the groundwork established by the Triple Value model, the EXPH introduces the Quadruple Value Model to advance the notion of VBHC in EU member states committed to the principle of solidarity. This model comprises four dimensions, each geared towards enhancing healthcare delivery while upholding the commitment to UHC. These dimensions are:

1. ***Personal value*** focuses on ensuring that individual patients receive appropriate care aligned with their unique values and goals. This dimension emphasises shared decision-making and communication to tailor healthcare interventions to meet patients' needs effectively.
2. ***Technical value*** also known as utilisation value, emphasises the efficient use of allocated resources to achieve the best possible outcomes. It pertains to optimising systems efficiency and minimising waste while maximising the benefits derived from available resources.
3. ***Allocative value*** pertains to the equitable distribution of resources across different population sub-groups, ensuring that healthcare resources are allocated fairly and justly among various patient groups, regardless of their conditions or socio-demographic characteristics.
4. ***Societal value*** underscores the broader impact of healthcare interventions on social cohesion, solidarity, and mutual respect within society. It evaluates how healthcare contributes to fostering connectedness and supporting fundamental social values, such as equity and diversity.

The EXPH underscores the complexity of the matter, underscoring the necessity for a systemic approach that elicits value judgments from diverse parties: patients, healthcare professionals, providers, industry, government, and individual citizens within society. Reflecting on these discussions has instilled in me a sense of humility regarding the concept of value. The key insight gleaned is that value is dialectical, dynamic, and socially constructed, manifesting in individuals' minds, in their interactions with others, or within established social structures. Understanding these constructs necessitates acknowledging the limitations of our comprehension of the reality in which they operate.

2.2. The Digital Health Service Life Cycle

This section addresses the need to structure the design and evaluation of digital health interventions within a comprehensive digital health service life cycle model, aimed at managing expectations among the various agents involved.

The development of digital health services involves a digitalisation process characterised by multiple interventions and contributions from diverse agents over time. This understanding is informed by the Unified Services Theory (UST) (Sampson, 2010), which elucidates the fundamental components of service processes. According to UST, a crucial aspect of service processes involves the active engagement of customers who contribute with significant inputs to the production process, establishing a necessary criterion for categorising a process as a service. Aligned with UST, digital health services rely on customer inputs, epitomising the core of service provision in a digitally transformed environment. Customers in the digital health context may include patients, healthcare professionals, providers, government entities, or a combination thereof.

The design, development, implementation, utilisation, and evaluation of digital health services as a standard of care (SoC) are essential for facilitating universal healthcare delivery, accessible anytime and anywhere (Cummins & Schuller, 2020). However, the lack of robust evidence to inform the design and evaluation of digital health services has been criticised (Black et al., 2011), leading to poorly designed interventions and misguided expectations regarding potential benefits (Crawford & Serhal, 2020; Fahy & Williams, 2021; Mogessie et al., 2021). In contrast to the pharmaceutical product innovation life cycle model (Wilson et al., 2018), emerging literature underscores the need for increased involvement of patients and healthcare professionals in the early phases of the digital health service life cycle to mitigate the risk of failure (Fahy & Williams, 2021).

The primary objective of this section is to identify a suitable digital health service life cycle model capable of effectively framing various digital health interventions. This model should delineate common goals, main actions, and technological and organisational maturity across the phases of the digitalisation process.

2.2.1. The research methods

To accommodate the scope of the thesis, a rapid review was conducted (Haby et al., 2016). As Khangura and colleagues (2012) refer, rapid reviews involve customising specific components of the systematic review process in order to generate timely information that can aid in decision-making. The search strategy followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) guidelines to conduct the review (Moher et al., 2009) and involved five steps.

Firstly, Table 1 presents the rationale used to build the final query used in the database. The SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) was used as a search strategy tool as it has been successfully applied as a search strategy tool for qualitative and mixed methods research (Cooke et al., 2012).

Table 1 – Queries used to search each database according to the SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) tool.

Sample (S)	Programmes, interventions, or innovations (in the format of technologies, products, services, or procedures) in health or in digital health.	(("health") OR ("health care") OR ("healthcare")) AND ((("health") OR ("health care") OR ("healthcare")) OR (“intervention”) OR (“innovation”) OR (“invention”) OR (((("new") OR ("innova*t") OR ("novel")) AND (("technolog*") OR ("product*") OR ("service*")))))
Phenomenon of Interest (P)	Life cycle models that encompass the research and development stages involved in identifying problems, generating solutions, and achieving the standard of care.	(("commercialisation") OR ("commercialization") OR ("diffusion of innovation") OR ((("scale-up") OR ("scalability")) AND ("implementation"))) AND (("life cycle") OR ("cycle") OR ("model") OR ("process")))
Design (D)	Published scientific articles that present or use a life cycle model to guide or contextualise the conducted research and development on health innovations or interventions.	Non applicable.
Evaluation (E)	Life cycle model ability to illustrate or describe the programme, intervention, or innovation progress throughout the research and development stages involved in identifying problems, generating solutions, and achieving the standard of care. The illustration or description involves highlighting characteristics such as: model intended users, process type, stages, actions, barriers, research areas, study design, development, and evaluation domains and criteria, etc.	((("design") OR ("development") OR ("assessment") OR ("assessing") OR ("evaluation")) AND (("efficiency") OR ("innovation capacity") OR ("quality") OR ("effectiveness") OR ("cost effective")))
Research Type (R)	Peer-reviewed studies utilizing qualitative, quantitative, and mixed methods. Models derived from deductive reasoning (e.g., literature review and theorisation) or inductive reasoning (e.g., case study analysis).	Non applicable.
Final Query	Non applicable.	#S AND #P AND #E

Secondly, Figure 3 illustrates the search performed in PubMed, Scopus, and Web of Science published between January 2015 and December 2020 (Figure 3 – Set #1).

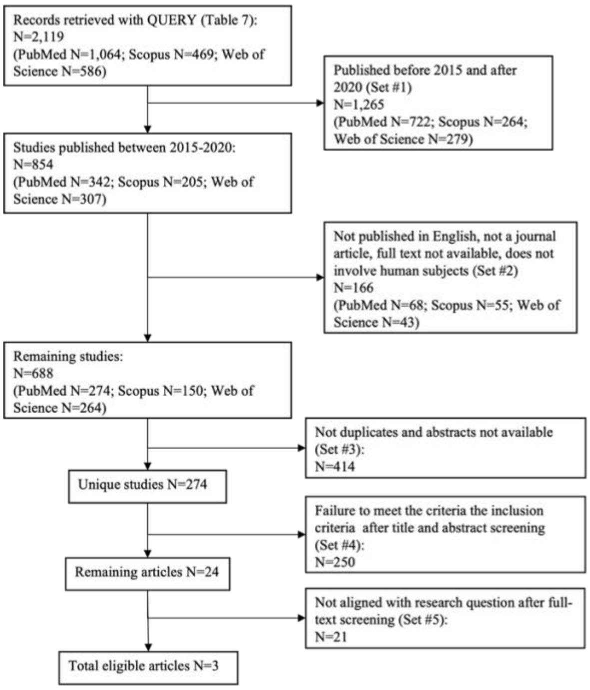

Figure 3 – PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) flow diagram showing the included studies.

The five-year timeframe ensured that the reviewed models represented the most recently proposed ones. I selected full-text and peer-reviewed papers written in English (Figure 3 – Set #2).

After removing duplicates and references without abstracts (Figure 3 – Set #3), the titles and abstracts identified in the literature search were scanned and filtered by the inclusion and exclusion criteria (Figure 3 – Set #4). The inclusion criteria included: models derived from systematic reviews or from case studies reporting the actions associated with the intervention progression and the model must reflect the evolution of an intervention from its ideation until it is accepted as standard of care (SoC). All models that were used as the basis for the most recently proposed model were excluded, due to an assumption that the newer model represented an improvement. Then the remaining full-text articles were scanned to guarantee that the article referred to a health intervention or innovation life cycle model (Figure 3 – Set #5).

Thirdly, to better explore each model and summarise relevant and well-specified data, an integrative synthesis was conducted. The main variables were the name of the framework or tool associated with the model, publication year, predecessor framework or tool, model's main goal and characteristics, and health intervention life cycle phases (Dixon-Woods et al., 2005).

Fourthly, a comparative analysis of the final list of models was conducted. The frame of reference, i.e., the context within which the model was compared reflects the evolution of an intervention or innovation from its ideation until it is SoC. The three criteria used to compare the models were based on the recognised characteristics of the digitalisation process: 1) adaptability to deal with the non-linear evolution of a digital health intervention; 2) acknowledgement of the context, and 3) acknowledgement of the socio-technical-economic aspects across the life cycle phases.

To evaluate the adaptability of each model, the categories used were highly adaptable, moderately adaptable, or having low adaptability, depending on their capacity to illustrate non-linear processes. The degree of recognition of the context and socio-technical-economic aspects of a digital health intervention or innovation was determined by the number of life cycle phases in which the authors explicitly proposed to consider them.

Finally, the strengths of each proposal were identified to advance the overarching objective of establishing a model capable of providing a comprehensive perspective on the evolution of a digital health service, from its inception to its acceptance as suitable for use, while considering the characteristics of non-linearity, context dependency, and socio-technical-economic aspects. In these two final steps, any disparities were resolved through discussion between two researchers until a consensus was reached.

2.2.2. Towards a Digital Health Service Life Cycle Model

The final list consisted of three peer-reviewed models: the Health Innovation Cycle (HIC) proposed by the Consortia for Improving Medicine with Innovation and Technology (CIMIT) (Parrish et al., 2015; Siefert et al., 2019), the Framework for the Design and Evaluation of Digital Health Interventions (DEDHI) proposed by Kowatsch and colleagues (2019), and the Intervention Scalability Assessment Tool (ISAT) proposed by Milat and colleagues, (2020). While ISAT and DEDHI models were developed through systematic literature reviews, the HIC derived from the analysis of case studies based on United States documenting the processes involved in creating innovative products, procedures, and care delivery systems.

The HIC's main goal is to guide innovators in designing, developing, and evaluating their solutions considering four domains: clinical, market/business, regulatory/approvals, and technical. Following the same approach of the Technology Readiness Level (TRL) framework, this model proposes deliverables across the different phases to support the innovators assessing their solution's progress. As their targeted audience are innovators, the authors highlighted explicitly that the cycle starts with a clinical need. The model is represented by an ongoing cyclic process with the purpose to complete each iteration with a higher SoC (Collins & Dempsey, 2019).

The DEDHI model is associated with a framework for the design and evaluation digital health interventions. With researchers and practitioners as target intended users, the framework guides them to systematically design and evaluate a digital health intervention. Its predecessor is Multiphase-Optimization Strategy (MOST). The framework considers evaluation criteria, technology-related aspects (e.g., maturity level or scalability), and implementation barriers for each phase of this life cycle.

The ISAT model is centred on supporting health policy makers and practitioners assessing systematically the scalability of health interventions. The model aims to guide its users to collect evidence in domains to support the scalability decision such as problem, context, and intervention, and domains to support implementation planning such as potential reach, adoption, acceptability, and potential resource requirements. The results of the comparative analysis are presented in Table 2.

Table 2 – Comparative analysis of health innovations and interventions life cycle models. Target means target intended users to use the framework; LC phases means Life cycle phases; Adapt means adaptability to digital health intervention non-linearity evolution; DHI context means acknowledgement of the digital health intervention (DHI) context; STE aspects means acknowledgement of the DHI socio-technical-economic aspects.

Model, Year	**Predecessor**	**Target**	**LC phases**	**Adapt**	**DHI context**	**STE aspects**	**Strengths**
HIC, 2019	TRL	Innovator	Invention, Development, Commercialisation	Low	Only in development and commercialisation stages	In all stages	Phases and expected deliverables in four domains: clinical, market/business, regulatory/approvals, and technical
DEDHI, 2019	MOST	Researcher, Practitioner	Preparation, Optimisation, Evaluation, Implementation	Moderate	Only in the implementation phase	Technical in all phases Socio-economic only in implementation phase	Expected technical maturity, evaluation criteria, and barriers in each phase
ISAT, 2020	-	Policymaker, Practitioner	Pre-scale-up, Scale-up, Implementation	High	In all stages	In all stages	Three phases based on the scalability decision. Domains that address context, and socio-technical-economic aspects

Although the three models use different terminology, they all outline phases that depict the journey from the inception of the intervention or innovation to its recognition as Standard of Care (SoC). In terms of adaptability to illustrate the non-linear evolution of digital health interventions, HIC and DEDHI demonstrate low and moderate adaptability, respectively, as progression to subsequent phases for intended users hinges on successfully completing a series of tasks. The discrepancy in adaptability level arises from HIC's high number of detailed tasks in each phase. In contrast, the ISAT model is highly adaptable because it does not prescribe specific tasks but divides the life cycle into three phases corresponding to critical moments for considering intervention expansion.

The second criterion examines the extent to which the models prompt users to consider the dependency of a digital health intervention on its context. ISAT dedicates one domain in its first two life cycle phases to characterise strategic, political, and environmental contextual factors influencing scale-up decisions and five domains in the third phase to describe the needs and requirements of the implementation context. Conversely, the other two frameworks address the intervention's context only in later phases.

The third criterion assesses the models' sensitivity to intervention socio-technical-economic aspects. HIC and ISAT consider all aspects across all phases, while DEDHI focuses more on technical aspects throughout and incorporates socio-economic aspects only in the implementation phase.

After thorough analysis, key insights emerge: HIC outlines expected deliverables for each phase, providing a clear roadmap. DEDHI offers anticipated maturity levels, evaluation criteria for each phase, and identifies potential barriers. ISAT presents three comprehensive phases (Pre-scale-up, Scale-up, Implementation), ensuring interventions transition effectively to real-world conditions without compromising effectiveness or access to the eligible population.

The proposed model (Table 3) aligns with the ISAT phases, albeit with a minor adjustment to the name of the final phase. This modification aims to enhance clarity and inclusivity for all agents, hence termed as the Implementation and Commercialisation phase. These adjustments align with recommendations from Blandford et al. (2018) and maintain consistency with descriptions used by the other two models for similar phases. Each phase in the proposed model delineates objectives, activities, and technological and organisational maturity, synthesising strengths observed in the three models.

The Pre-Scale-up phase focuses on validating the intended use and identifying potential benefits of digital health services. Main actions include design, development, testing with end-users, and conducting pilot studies to explore benefits, organisational opportunities, and challenges. Technology maturity evolves from TRL 1 to TRL 6, with initial integration involving a small number of healthcare professionals, resulting in ad-hoc organisational processes.

The Scale-up phase aims to expand the service to a larger eligible population while maintaining identified benefits. Main actions include planning technological scale-up roadmaps, reorganising teams, and conducting trials for feasibility and acceptability. Technology progresses from TRL 7 to TRL 8, with refined procedures and workflows developed as deployment sites and healthcare teams increase.

The Implementation and Commercialisation phase establishes the service as standard healthcare practice. Main actions include regulatory approval, validating business models, and continuous enhancement through monitoring. Technology maturity reaches TRL 9, capable of effective operation in all environments, with well-defined organisational processes for efficiency and quality care.

Table 3 – Phases of the Digital Health Service Life Cycle and their main goals, actions, and technological and organisational maturity characteristics.

Life Cycle Phase	Main Goals	Most Relevant Actions	Technological Maturity	Organisational Maturity
Pre-scale-up	Proof the intention of use and identify the potential benefits of using the digital health service	Design, develop, and test with end-users; conduct pilot studies to identify potential benefits and side effects for patients and study healthcare professionals' adaptation	TRL 1-6	Ad-hoc nature - case-by-case handling; Initial organisational processes defined; low number of professionals involved
Scale-up	Expanding the digital health service to reach a greater proportion of the eligible population	Planning and implementing a technological scale-up roadmap; reorganising and training teams; initial clinical trials; search for funding or fundraising opportunities; project impact; apply for market certifications (e.g., CE mark in EU)	TRL 7-8	Conscious iteration of organisational processes; increased number of professionals and deployment sites involved
Implementation & Commercialisation	Establish the digital health service as a standard of care practice	Pursue regulatory approval if required; validate business models and exploit commercially the service or product; continuously improve the service or product, monitor reach, impact, and side effects	TRL 9	Well-defined organisational processes iterated to improve efficiency and quality of care

One primary limitation of this model is the overlap of certain actions across different phases, such as seeking funding. The decision to distinguish these activities in specific phases was made after careful consideration of their relevance to accomplishing the main goals of each phase. Acknowledging the non-linear nature of the digitalisation process, these phases are intended to establish overarching goals rather than dictate a strict sequence of activities.

A second limitation concerns the ambiguity surrounding the type of evidence expected to be generated in each phase. While all models recognise the importance of involving various agents throughout the phases and generating evidence to demonstrate potential positive and negative consequences, there is a lack of clarity regarding the intended audience for this evidence.

2.3. The Quadruple Value Model and the Digital Health Service Life Cycle

In addressing the second limitation of the model, which concerns the involvement of various agents throughout the phases, the Quadruple Model was employed to inform the design and evaluation of digital health interventions. This approach aligns with the commitment to UHC, and the shared values of solidarity and equity upheld by the EU member states.

As discussed in the preceding section, the ***Personal value*** dimension centres on ensuring that individual patients receive personalised care that aligns with their unique values and goals. This dimension underscores the importance of shared decision-making and effective communication to tailor healthcare interventions to meet the specific needs of patients. Therefore, in order to appropriately design and evaluate digital health interventions within this dimension, it is essential not only to involve patients and healthcare professionals but also to employ appropriate research methods that legitimately inquiry value judgements. These methods should facilitate patients in expressing their values, preferences, and expectations while also providing them with realistic information about what can be achieved. Healthcare professionals play a critical role in this process as they can legitimately employ these methods to help patients understand both the possibilities and desirability of different healthcare options.

The ***Technical value*** dimension, also referred to as utilisation value, underscores the importance of efficiently using allocated resources to achieve optimal outcomes. It involves maximising benefits while minimising waste, thereby enhancing system efficiency. It is crucial to recognise that we may encounter different “systems” at different stages of this dimension. The key agents with a vested interest in efficient resource allocation include the government, representing the health system, healthcare providers, and technological providers. Each of these entities prioritises efficiency for various objectives. However, throughout the digital health service life cycle, it may not be feasible to inform all interested parties simultaneously. During the Pre-Scale-Up and Scale-up phases, real-world data can inform the technical value dimension from the perspectives of healthcare and technology. During these stages, the health system may only have projections of potential efficiency gains. It is only in the final phase that real-world evidence will offer genuine insights into the intervention’s efficiency for the health system.

The ***Allocative value*** dimension focuses on the equitable distribution of resources among diverse population sub-groups, ensuring fair allocation of healthcare resources regardless of patients’ conditions or socio-demographic characteristics. Therefore, it is essential to involve patients, citizens, healthcare professionals, and government. Employing methods in all phases that facilitate determining who should be involved can enhance the inclusivity of interventions. In the latter two phases, with more comprehensive information on the eligible population, the allocative value can also be informed at the level of healthcare providers and the health system.

The ***Societal value*** dimension highlights the broader impact of healthcare interventions on social cohesion, solidarity, and mutual respect within society. It assesses how healthcare contributes to fostering connectedness and upholding fundamental social values such as equity and diversity. Upon analysing various examples provided by the EXPH on how to create societal value, it becomes clearer that societal value can be generated in all phases of the digital health service life cycle. Throughout each phase, it is crucial to transparently communicate the research being conducted and the expected outcomes to patients and society at large, involving them in providing feedback and recommendations. As one progresses through the life cycle of the service, it is essential to responsibly communicate and disseminate both positive and negative results and lessons learned in a manner that is easily understood by society.

Figure 4 presents a visual representation of how future studies on digital health services can be conceptualised throughout their life cycle, guided by the Quadruple Value model. This visual tool, known as the cone of uncertainty, aids in conveying and elaborating on this complex and challenging concept (Gall et al., 2022). Drawing inspiration from Chesbrough & Vanhaverbeke' (2018) open innovation funnel, which illustrates a diminishing level of uncertainty over time and the potential for external collaboration and ideas, as well as Cirule & Uvarova' (2022) conceptual model of sustainable value creation, Figure 4 aims to demonstrate how value across the four dimensions can be influenced by R&D across the three phases of the life cycle model. To achieve this, collaborative, participatory, and iterative approaches should be employed (Chesbrough & Vanhaverbeke, 2018; Cirule & Uvarova, 2022; Wilson et al., 2018). It is essential to highlight a notable departure from Chesbrough’s model. In this study, it is acknowledged that uncertainty may initially increase at the onset of each phase due to shifts in the goals of the phases.

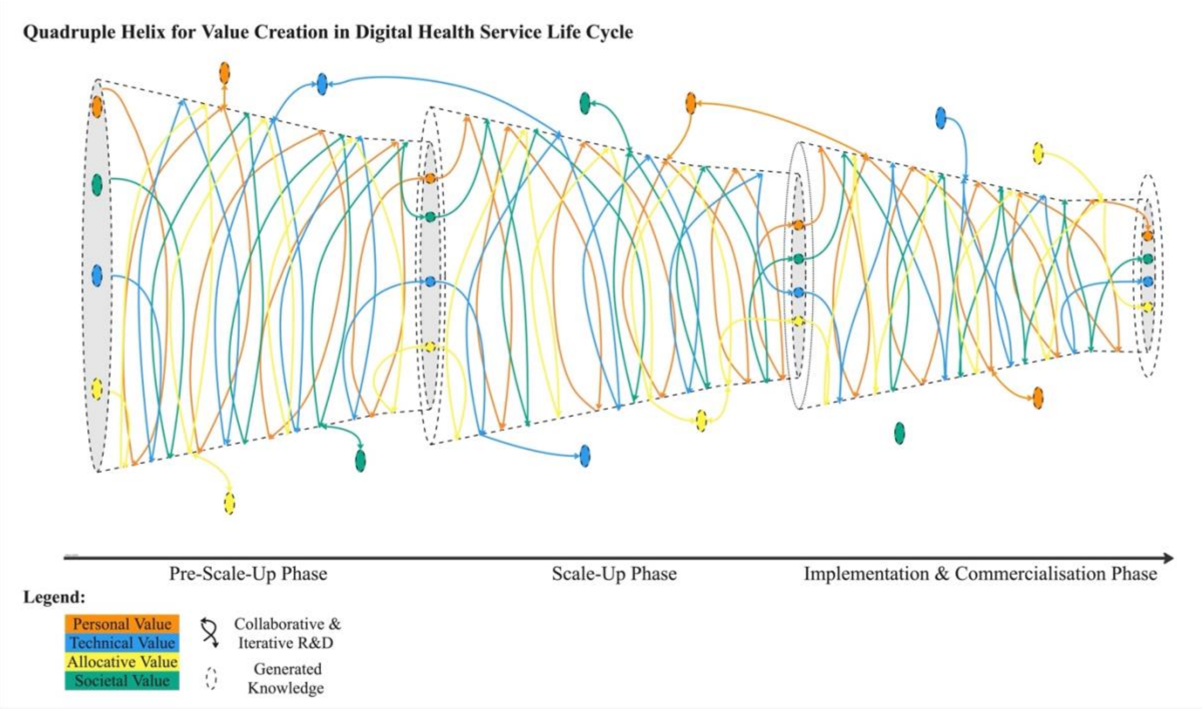

Figure 4 – Quadruple Helix for Value Creation in Digital Health Service Life Cycle.

In summary, Figure 4 highlights that the reduction of uncertainty linked to the digitalisation process of the digital health service is greatly influenced by iterative R&D methodologies that promote collaboration and participation. Engaging agents in cyclic processes of action and reflection is essential to inform the four value dimensions and generate value effectively.

While the Quadruple Value model offers guidance on how digital health interventions in various phases of the life cycle model can inform the four dimensions of value, it remains unclear which domains and methods are utilised when assessing the scalability of these interventions. Chapters 3 and 5 aim to address this gap by providing more information on the domains and methods employed by current literature to evaluate the scalability of digital health interventions, both from Management Sciences and Health Sciences perspective.

CHAPTER 3 | The Systemic Intervention Methodology for Digital Health

Chapter 3 presents a framework for the critical understanding of the digitalisation process as a set of interconnected participatory interventions using a systemic intervention methodology. This methodology aims to facilitate the collection of evidence over the digitalisation process of a health service. Therefore, the proposed framework aims to fulfil two main objectives: 1) the acknowledgement of the roles, adaptative behaviours, and impact of relevant agents (such as patients, researchers, healthcare professionals, and technology developers) in the digitalisation process; and 2) the ability to explain the digital health intervention's inherent technological aspects, social relations, structures, and context.

3.1. Setting the Context of a Systemic Digital Health Intervention

Before embarking on the study of the digitalisation process of a health service using a systemic intervention methodology, as proposed by Midgley (2003), and framing it within a multimethodological research intervention, as advocated by Mingers & Brocklesby (1997), it is imperative to establish a common understanding of key terms. Adhering to the definitions outlined by Mingers (2003, p. 559), methodology refers to a structured set of methods or techniques designed to aid in research or intervention endeavours. Moreover, methods and techniques are specific tasks with well-defined purposes, such as building a simulation model or developing a rich picture in soft systems methodology. Furthermore, intervention, as defined by Midgley (2003), signifies purposeful action taken by an agent to effect change.

Another crucial aspect to consider is the distinction between activities, actions, and operations, drawing upon Activity Theory (AT) (Engeström, 2005). Within this framework, an activity encompasses the collective and sustained effort directed towards achieving an objective, possessing a systemic character that elucidates the underlying motives behind individuals' actions. Activities provide the "why" behind people's endeavours. In contrast, actions represent the specific behaviours individuals engage in within a bounded timeframe to pursue their goals. Actions derive their significance from their role within a broader activity, with individuals primarily focused on executing these actions. On the other hand, operations refer to spontaneous adjustments made in response to circumstances, characterised by actions that have been internalised and become automatic. All three—activities, actions, and operations—are mediated by artifacts, including models, tools, instruments, and linguistic symbols. These artifacts facilitate and mediate the execution of related actions and operations within the overarching activity, thereby shaping individuals' interactions and outcomes (White et al., 2016).

In clarifying these definitions, it is crucial to distinguish between "human agent" and "stakeholder" within this context. Here, a "human agent" represents an individual or entity driving purposeful action within the intervention, while a "stakeholder" is a broader group of human agents defined by common roles, objectives, and system of actions (activity) within the intervention. Importantly, a human agent may belong to multiple stakeholder groups simultaneously, emphasising the dynamic nature of stakeholder relationships.

As initially posited, the digitalisation process should be viewed as a comprehensive intervention characterised by the continuous flow of interconnected digital health interventions over time. Therefore, it warrants examination through a systemic intervention methodology to effectively capture its complexity and interconnectedness.

Midgley (2006, p. 467) defines systemic intervention as a "*purposeful action by an agent to create change in relation to reflection on boundaries*" and proposes the systemic intervention methodology with three main principles: **boundary critique** (methods should be used to draw intervention boundaries on knowledge and participation and should allow reflection on the choices made), **action for improvement** (commitment to intervene in order to improve the initial situation), and **theoretical and methodological pluralism** (engage and be open to use different theories and methods to conduct the intervention). Both Mingers and Midgley have highlighted the importance of using different methods in addressing real-world situations, whether the objective is pure research or practical intervention. Their conceptualisations of multimethodology and methodological pluralism (Midgley, 2003; Mingers, 2014) emphasise the interconnection between these two concepts. As Mingers aptly stated, "*All research involves some form of intervention or effect, and all interventions involve research.*" (Mingers, 2014, p. 184). In this section, the term '*digital health intervention*' is used to encompass both research interventions and practical interventions in the field of digital health while the term "systemic digital health intervention" corresponds to the digitalisation process of a health service.

The systemic digital health intervention was conceptualised in terms of three notional systems as proposed by Mingers & Brocklesby (1997): the **Problem Content System** of the health service digitalisation process characterised by the real-world situation of concern, the **Intervention System** of the health service digitalisation process which involves all the agents involved in the intervention, the **Intellectual Resources System** of the health service digitalisation process, which includes the available theories and methodologies relevant to the problem content system and the agents involved.

As the authors suggest, these three systems, their history, and their inter-relations constitute the context at the point of engagement in a research situation. This conceptualisation should serve not only as a basis for designing and planning the research intervention, but also a continual reference for critical reflection. This decision was made because of two main characteristics of their framework: recognising that a research or intervention is a process with distinct phases (appreciation, analysis, assessment, and action) that require different methods and to consider the multidimensionality of the real world and within each intervention (material, social, and personal aspects). Figure 5 illustrates the context of the systemic digital health intervention according to the three systems. In the following subsections, I describe each system considering the context of a digital health intervention.

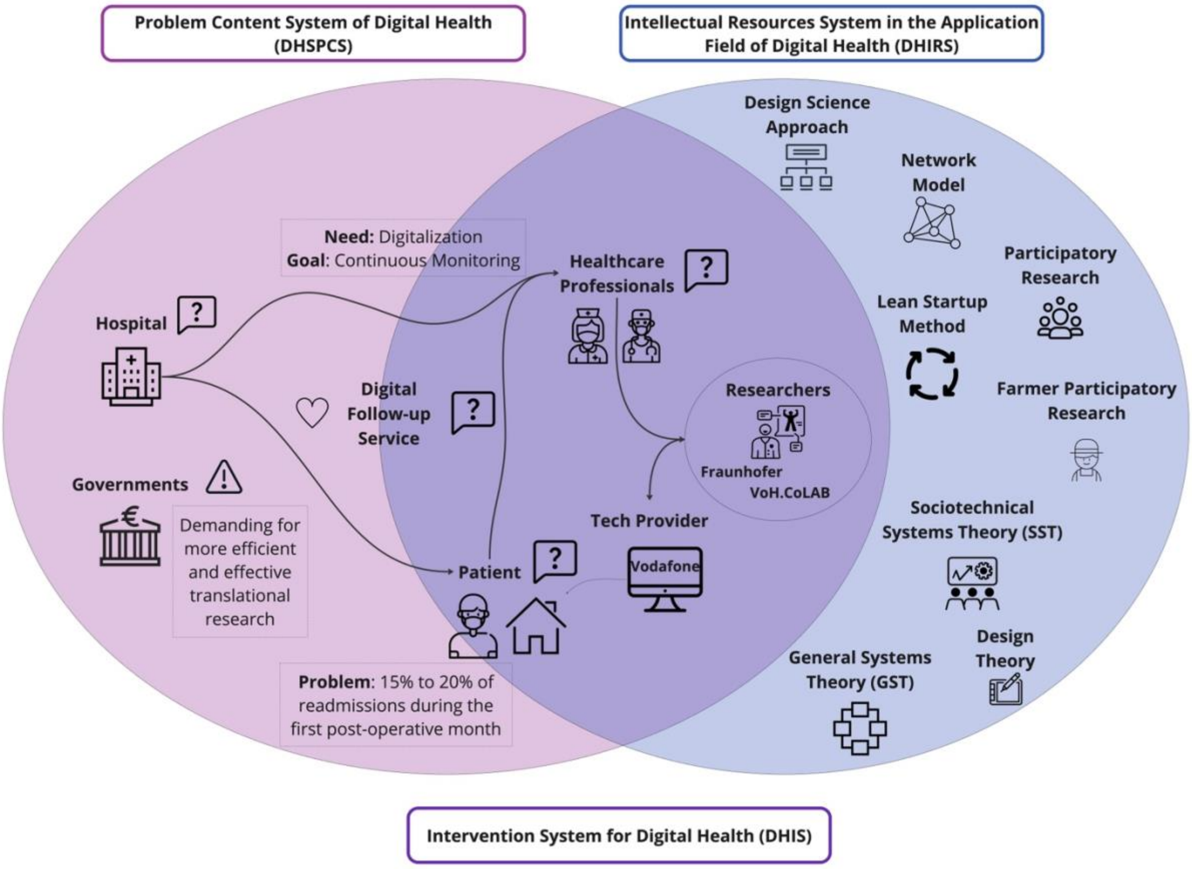

Figure 5 – The context of a Systemic Intervention for the Digitalisation Process of a Health Service.

3.1.1. Setting the Digital Health Intervention Problem Content System

The real-world situation of concern consists of an inadequate design and evaluation of digital health interventions that makes research in this field insufficient and irrelevant for most of the agents involved. Consequently, worldwide, but in particular in the EU, research funding bodies have been demanding for more efficient and effective translational research to increase the access to digital health services that improve the health and wellbeing of people (Collins et al., 2016; EXPH, 2019; Ricciardi et al., 2019).

In the case of the cardiac surgery follow-up service at St. Marta Hospital, a public hospital in Lisbon, Portugal, the surgical team (surgeons and nurses) felt the need to digitalise the existing service to be able to continuously monitor patients during the first month of the postoperative period associated with hospital readmissions of 15 to 20% of patients (Efthymiou & O'Regan, 2011; Khoury et al., 2020; McElroy et al., 2016). At the beginning of the research intervention there were few studies evaluating the benefits of digital health interventions in cardiac surgery, but there were some showing positive results in chronic heart failure in the domains of quality of life improvement, mortality, hospital readmissions, and hospital expenses reduction (Pekmezaris et al., 2012; Seto, 2008; Yun et al., 2018).

St. Marta Hospital, supervised by the Central Lisbon University Hospital Centre (CHULC), collaborates with NOVA University, one of the founding partners of Value for Health CoLAB (VOH.CoLAB). VOH.CoLAB, established as "Collaborative Laboratory" by the Portuguese Foundation for Science and Technology (FCT), aims to bridge the academia-industry gap by accelerating R&D translation into health products and services. VOH.CoLAB engaged Fraunhofer Portugal and Vodafone Portugal to contribute their technological expertise to digitalise the new health service. Fraunhofer Portugal specialises in Artificial Intelligence (AI)-based technology development, with prior success in cardiology-focused digital health solutions. Vodafone Portugal, a telecommunications operator, specialises in developing ICT solutions and services. The four partners committed to the project with the constraint of minimal investment and technology adaptation.

3.1.2. Setting the Digital Health Intervention System

The aim of the digital health intervention was to design, develop, test in real-world context a remote patient monitoring (RPM)-based follow-up service. Remote patient monitoring (RPM) non-invasive technologies allow healthcare professionals, patients, and caregivers to record and collect patient health- and well-being-related data from a distance (adapted from (Devine, 2022)). RPM technologies have demonstrated initial evidence of enhancing diagnosis and treatment decision-making, promoting patient adherence and compliance, supporting self-management care, facilitating health education, and fostering digital therapeutics innovation (Rowland et al., 2020).

The four partners were categorised into three groups according to their position in the health system proposed by Basole & Rouse (2008) to better explain the different skills and responsibilities of each one in the research intervention:

- **Hospital:** Hospital de Santa Marta is one of the Country's leading Internal Medicine schools and one of Portugal's main reference centres for diagnosing and treating cardiovascular disease (Hospital Santa Marta, 2023). The hospital was responsible to allocate the resources to guarantee the provision of the DHS and host the intervention.
- **Research Laboratories:** One of the research laboratories, Fraunhofer Portugal, focuses on applied and project-oriented research in Artificial Intelligence-based (AI) technology development for predictive, preventive, personalized, and participatory medicine (Fraunhofer Portugal, 2023). The second research laboratory, VOH.CoLAB focuses on validating methodologies to measure outcomes and costs and provide trustful scientific evidence under Value-based Healthcare principles (Value for Health CoLAB, 2023). Fraunhofer was responsible to provide the smartphone and the respective mobile application, and Internet of Things (IoT) devices to collect patient-related information: weight, symptoms, blood pressure, heart rate, number of steps, and picture of the surgical wound. VOH.CoLAB was responsible to coordinate the design, develop, test in the real-world, and evaluate the intervention.
- **Telecom Provider:** Vodafone Portugal is a telecommunications operator that specialises in developing new technology solutions and digital services based on unified communications, IoT, edge computing, mobile private networks and Open RAN (Vodafone Portugal, 2023). Vodafone was responsible to provide a subscriber identify module (SIM) card to patients have access to a mobile network.

With the goal to improve collaboration, reduce power disparities and have a real constitution of the intervention from different perspectives, each partner was responsible for selecting the research intervention team participants and classifying the members' roles according to their interests in the research process without requiring a minimum number of participants. The team was composed of 12 members split according to three role types (act as a proxy for human agents' roles):

- **Researchers:** the main interest of this group was to conduct research and test methodologies to generate and contribute knowledge to their scientific area. The research laboratories selected six researchers based on their expertise in digital health solutions design, digital health literacy, cost analysis, and previous relationship with the healthcare professionals team.
- **Developers:** the main interests of the developers include designing, programming, building, deploying, and maintaining features using different skills and programming tools. The research laboratories selected six software developers based on their skills in artificial intelligence (AI) and software development and previous relationship with the healthcare professionals' team.

- **Healthcare professionals (service end-users):** the main interest of healthcare professionals was to use RPM technology to enhance their performance and provide high-quality patient care. In the context of the proposed technological solution, the end-users are physicians and nurses of the Cardiac Surgery service selected by the service's director. The director selected three physicians and three nurses to collaborate with the developers and researchers to digitalise the existent follow-up service based on their previous relationship with the researchers and developers and expertise in RPM-based follow-up services.
- **Patients and caregivers (service end-users)**: the main interests of the patients were to feel safe and in surveillance by the surgical team and have a successful recovery. These patients were described by the healthcare professionals as very insecure and fragile due to their own perception of surgery severity. The caregivers were patients' relatives that were providing support to the patient during the follow-up period. The patients were selected by the healthcare professional team. All patients submitted to the cardiac surgery were eligible. The team selected the patients during the post-surgery hospitalisation period based on the following criteria: ability to read and write, having a mobile phone and willingness to participate. Patients who could not manage the smartphone or the remaining digital health devices, either due to functional limitations or very low digital literacy and did not have the daily support of a caregiver, were excluded. Due to long duration of the intervention the patients involved were not always the same.

3.1.3. Setting the Digital Health Intellectual Resources System

The research field of digital health is the result of the intersection of different forms of research and disciplines (Blandford et al., 2018). In this subsection, the theoretical concepts and methodologies that were available and known to the agents involved in the intervention are presented. This subsection starts with the conceptualisation of the digitalisation process of a health service as a network-based CAS and put forward methodologies for guiding and understanding artifact production in IT/IS, problem-solving, and practice improvement. Lastly, the selected research methods are mapped within the different stages of the research intervention framework proposed by Mingers & Brocklesby (1997).

The conceptualisation of the digitalisation process of a health service as a network-based CAS: Several authors have framed the health system and its services delivery systems as CASs (Basole & Rouse, 2008; Paté-Cornell et al., 2016; Tan et al., 2005). Shortell (2008) reinforces the system's structure as a network-based complex system by stating that this structure will enable to access and allocate resources and capabilities to assure outcomes effectively. In line with the Quadruple Value model, the added value of a digital health service is dependent on the capacity of multiple agents recognise its benefits and contribute towards its development. Recognising the profile of each agent in the network and how each one contributes to high-value care will make the agents act as value streams or networks that provide the balance between desired outcomes and affordable costs (Basole & Rouse, 2008). Both conceptual and empirical research has demonstrated that a network-based structure effectively captures and models the inter-organizational relationships within complex socio-technical-economic systems (Basole & Rouse, 2008). In this architectural framework, nodes represent various system components, such as firms, suppliers, and customers, while the links between nodes illustrate the relationships between individuals and organisations (Bellamy & Basole, 2013). This doctoral thesis will focus on mapping the network's evolution throughout the systemic intervention using a qualitative modelling approach, aiming to provide valuable insights into the dynamics of the digitalisation process (Heath et al., 2009). By monitoring changes in the network structure over time, the study seeks to clarify how digitalisation influences the interconnectedness and behaviour of system components, thus improving our comprehension of the overarching transformation process.

The available methodologies for producing IT/IS artifacts:

All DSR methodologies share the same principle of developing two types of knowledge: 1) from the designed IS/IT artifact itself and 2) from the design process characterised by an iterative cycle of design, development, and evaluation phases (Hevner et al., 2004; Johannesson & Perjons, 2021; Mingers & Standing, 2020). This methodology's inherent pragmatism towards the demonstration of the system working effectively as it was previously defined and with an efficient use of resources makes it a perfect candidate to guide the design and evaluation of the digital health service in the pre-scale-up phase. Recent literature shows that it poses as an adequate methodology for designing IT/IS artifacts for these type of services (Lapão et al., 2021; Mulgund et al., 2021).

Although user-centred design is the crux of DSR, Buis & Huh-Yoo, (2020) highlight some common challenges, including not being able to capture the clinical context, identifying user requirements, and designing the right solution. Therefore, special attention will be given to the selection of surgeons and nurses from the hospital that could embrace the role of designer. Moreover, to cope with the last two challenges, the concepts from the *Lean Start-up* method (Eisenmann et al., 2011) will be incorporated to start designing a minimal viable product (MVP) from the available technology and resources (provided by the clinical team and the research team). The lean start-up approach will guide the team to bear uncertainty by quickly starting a pilot study and developing an overall solution in short deployment cycles. The entrepreneurial mindset will drive the research team to validate learning during the DSR process and follow a "*Build-Measure-Learn*" sequence. In summary, DSR will orient the researchers to develop a rigorous design-oriented framework centred on the actual context and needs of patients and healthcare professionals by continuously communicating with them.

The available methodologies for solving problems and improving practice:

Scalability and rapid implementation of digital health services require social change and active collaboration between the ones involved. Therefore, a PAR approach is needed to support the collaborative development of the technological component while simultaneously implementing and evaluating the digital health service through critical action-reflection cycles (Keahey, 2021). Throughout a research process characterised by nonlinear, recursive cycles of action and reflection, the research team characterises problems in specific contexts, understands the required changes in socio-technical systems, and consequently defines, implements, and evaluates actions to improve practice (Burdette, 1926).

There are several expected outcomes from following a PAR approach. For the scope of this thesis, the farmer participatory research model (Selener, 1997) highlights some of the most relevant outcomes that can be adapted for the digitalisation of a health service: (1) generation and adoption of new appropriate technologies by healthcare professionals and patients to increase the service uptake in surgical follow-up; (2) better understanding, on the part of researchers, of the existing surgical follow-up service; (3) scientific characterisation and understanding of the socio-technical-economics constraints to sustainable digital health care delivery; (4) development of digital health technologies that meet patients and healthcare professionals needs; (5) improved research and technological systems as a consequence of a close collaboration; (6) empowerment by improving healthcare professionals' capacity for self-directed technology development; and finally (7) ability to adapt healthcare systems to changing conditions. The PAR approach will be used to define and prioritise the development of the technological features. One of the most relevant reasons is its application as a bottom-up research and development strategy for technology transfer (Pine, 2009; Selener, 1997; Sumberg & Okali, 1988) within the hospital walls. More specifically, the PAR approach is very relevant when trying to improve real-world practices because it involves a research team that includes researchers and practitioners who contribute actively with their scientific and practical knowledge in all research procedure phases (Selener, 1997). The process to be used will be an adaptation from the cycle described by Pine (2009) and the model for Participatory Action Research in Organisations and the Farmer Participatory Research described by Selener (1997).

The available methodologies for understanding problem solving and structuring interventions:

At the core of all Operational Research (OR) interventions lies the emphasis on improving the complex systems and processes that form the foundation of everyday life for everyone (*Operational Research Society*, 2023). These interventions can serve various purposes, such as aiding in problem-solving, problem structuring, and more.

Considering the digitalisation process of a health service as a series of interventions overtime shifts the focus towards the process rather than solely on the content. Consequently, it becomes imperative to delve into the actions of actors concerning the methods and processes they employ, their execution, and the resultant implications for shaping intervention processes and outcomes (Franco et al., 2021). This inquiry belongs to the evolving domain of Behavioural Operational Research (BOR).

Franco and colleagues (2021) advocate for a process-oriented methodology when examining interventions as a series of events shaping behaviour. This approach views an evolving agent experiencing events or instigating them as the unit of analysis. Thus, Franco and colleagues (2021) state that both the definition of an event and the temporal sequence of events are crucial in process studies. Narrative explanations of behaviour within the context of OR interventions tend to be intricate due to the complexity and dynamic nature of intervention events, as they are interlinked. Referencing Poole & Van de Ven (2021), Franco and colleagues (2021) assert that process narratives may encompass various effects, including critical events, turning points, contextual influences, formative patterns directing overall change, and causal factors influencing event sequencing.

In considering the agents' decisions regarding knowledge and participation boundaries throughout the various interventions involved in the digitalisation process, the Critical Systems Heuristics (CSH) methodology, as proposed by Ulrich (1987), appears to be apt. This methodology has previously been employed to investigate matters of motivation, control, expertise, and legitimacy within the realm of public health (Midgley, 2006).

Another significant contribution to the field of problem structuring methods (PSM) was Yearworth & White (2014) formulation of a generic constitutive definition aimed at identifying the non-codified utilisation of PSMs. Stemming from the thesis that PSMs are widely employed in engineering contexts without agents being fully conscious of it, the establishment of a generic constitutive definition would aid in substantiating how problem structuring unfolds in practice. The thesis in this work posits a similar scenario in the digitalisation process of a health service, where agents engage in structuring problems without a full awareness of utilising PSM methods, driven by the necessity to resolve them.

Additionally, White and colleagues (2016) proposed the use of the Activity Theory (AT) to understand behaviour in PSM interventions. The analysis helped hypothesising identities, relationships, and goals of different actors and how they engage in problem structuring. In the same paper, the authors also propose to use both AT and Actor-Network Theory (ANT) to have a more comprehensive understanding of both human and nonhuman agents. This is crucial to the digitalisation process of a health service as IT artifacts influence how healthcare teams are organise and vice-versa. In this thesis, ANT will be used to inform the mapping of how human agents establish new groups over time, while, AT will be used to understand the complex interactions and mutual influence among different human an non-human agents (artifacts).

3.2. Multimethodological Approach for a Systemic Digital Health Intervention

The framework for mapping methods proposed by Mingers & Brocklesby (1997) was used to be able to understand which methods are more appropriate and required in different phases of the project. According to the authors, this framework (Table 4) allows a more comprehensive overview of the research intervention since it relates the three dimensions of the real world (material, personal, and social) with the four different phases of the intervention process (appreciation, analysis, assessment, and action). Table 4 demonstrates that the proposed systemic intervention has methods and methodologies that cover the three dimensions and phases.

Table 4 – Mapping the research methods and methodologies used in the systemic intervention.

Dimensions of the Problem Situation / Phases of a project	**Appreciation of the intervention (What is happening?)**	**Analysis of the phenomenon (Why is happening?)**	**Assessment of the explanations (How could the situation/explanation be different?)**	**Action to bring change (How could the difference be made real?)**
Social (human construction, power, social practices, and rules)	*Social practices, power relations:*	*Distortions, conflicts, interests:*	*Ways of altering existing structures:*	*Generate empowerment and awareness:*
	1. CSH, AT & ANT-driven thematic content analysis of interviews, participant observations, and organisational affiliations) **2. Social descriptive statistics**			
Personal (subjectivity, individual thoughts, experiences, and beliefs)	*Individual beliefs, meanings, emotions:* **1. DSRM & PAR** (problem definition & observation phases) **2. Interviews** **3. Participant observation**	*Differing perceptions, personal rationality:* **1. DSRM & PAR** (problem definition & reflection phases) – **Map *as-is* processes** **2. Interviews** **3. Participant observation**	*Alternative conceptualisations and constructions:* **1. DSRM & PAR** (planning & reflection phases) – **Map *to-be* processes; role play**	*Generate accommodations and consensus:* **1. DSRM & PAR** (planning, action & reflection phases) – **Lean startup and prioritisation methods**

Material (objectivity, outside and independent of human beings)	*Physical circumstances:* **1. DSRM & PAR** (problem definition & observation phases) **2. Literature review** **3. Questionnaires** **4. Statistical analysis**	*Underlying casual structure:* **1. Pilot studies in real-world setting and statistical analysis**	*Alternative physical and structural arrangements:* **1. DSRM & PAR** (planning & reflection phases) **2. Pilot studies in real-world setting and statistical analysis**	*Select and implement best alternatives:* **1. DSRM & PAR** (planning, action & reflection phases) – **Lean startup and prioritisation methods**

3.3. Outline of Digital Health Interventions in the Digitalisation Process

The central thesis of this Ph.D. dissertation posits that the digitalisation of a health service should be viewed through the lens of a systemic digital health intervention. It argues that the process of digitalising a health service is a multifaceted and iterative endeavour characterised by interconnected interventions.

Throughout this journey, agents within the system self-organise and adapt, employing diverse research approaches and techniques across various phases of the systemic digital health intervention. Thus, the study of the digitalisation process encompasses the following three interventions: i) Collaborative design, develop, and test a digital health service in real-world settings using a DSR methodology; ii) Collaboratively evaluate the digital health service intended use and develop a scale-up plan using a PAR approach; iii) Evaluate a scaled-up digital health service using a randomised clinical two-arm study. The analysis of the digitalisation process will rely on evidence gathered from each intervention, focusing on the involved agents, their actions, interactions, and the artifacts generated. Figure 6 provides a visual representation of the digital health interventions studied within the context of the digitalisation process.

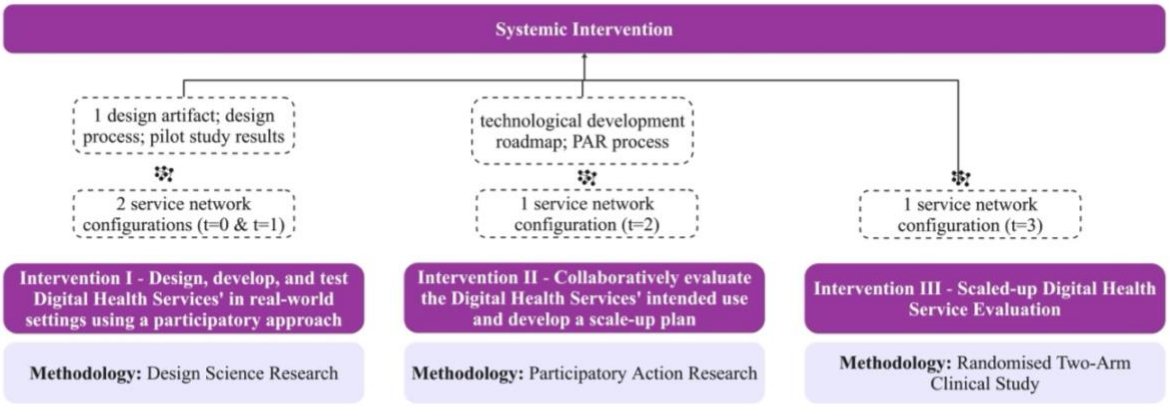

Figure 6 – The three digital health interventions analysed within the context of the digitalisation process of a health service.

PART II – Applied Research on Design and Evaluation of Digital Health Interventions

Part II illustrates collaborative applied research in digital health intervention design, development, and testing, setting the stage for a retrospective systemic analysis in Chapter 6, employing Actor-Network Theory and Activity Theory to explore intervention dynamics across service maturity levels.

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CHAPTER 4 | Collaborative Design, Development, and Testing a Digital Health Service in a Real-World Intervention: Enhancing the Design Science Research Methodology

Chapter 4 introduces an improvement to the Design Science Research (DSR) methodology, validated through the design, development, and testing of a digital health intervention in a real-world setting—a cardiac surgery follow-up service at a public hospital in Portugal. This chapter delineates the process and artifacts facilitating the design and testing of a digital health intervention within a real-world context, elucidating the roles and activities of the agents throughout the technological iterative development cycle.

This chapter has been published as Londral, A., Azevedo, S., Dias, P. et al. *Developing and validating high-value patient digital follow-up services: a pilot study in cardiac surgery*. BMC Health Serv Res 22, 680 (2022). https://doi.org/10.1186/s12913-022-08073-4
Some minor adjustments were implemented to align the conducted work with the scope and specific objectives of this thesis. Notably, the term "stakeholder" was revised to "agent" to better reflect the terminology and framework utilized within the thesis.

Azevedo S. played a main role in refining the study design by integrating the concepts of minimum viable product (MVP) and the Lean Startup Method into the DSR framework. Her insights were instrumental in enhancing the DSR methodology, particularly through the identification and characterization of agents and their activities. Additionally, she actively participated in both data collection and analysis and provided valuable assistance in preparing the paper.

4.1. Introduction

Emergent digital solutions can impact healthcare positively, but it remains a challenge for service providers and developers to demonstrate the value of their digital innovations in healthcare (Drummond et al., 2009; Peirce et al., 2011). Conventional methodologies based on high investment for technology development followed by a robust clinical study for validation fail to cope with the fast pace of digital health innovations (Guo et al., 2020). More pragmatic approaches are needed to support evidence gathering, incremental development, and accumulated knowledge base that cope with low initial resources and gradually demonstrate the value in real-world healthcare environments to support scale-up (Drummond et al., 2009; Guo et al., 2020; Murray et al., 2016).

DSR develops knowledge from the design, development, and iterative evaluation of artefacts, i.e., incrementally improved solutions to real context problems (Hevner et al., 2004). DSR methodologies have been applied to innovation in digital services for healthcare and demonstrated to allow both a theoretical and experimental approach to real-world healthcare problems (Lapão et al., 2021; Mulgund et al., 2021).

Patient follow-up is essential in cardiovascular patients’ health pathway (Driggin et al., 2020). In cardiac surgery, complications during surgery or hospitalization may occur (T. C. Crawford et al., 2017). However, risk also extends to the postoperative period, leading to hospital readmission of 15 to 20% of patients during the first month and 30% in the first year (Efthymiou & O’Regan, 2011; Khoury et al., 2020; McElroy et al., 2016). Post-discharge telemonitoring can be a valuable tool to maximize surgery outcomes (Park et al., 2011). Despite limited studies on such programs in cardiothoracic surgery, its use is well implemented in chronic heart failure, positively impacting the quality of life and preventing hospital readmission and mortality (Pekmezaris et al., 2018; Yun et al., 2018). It also allows for a reduction of costs, both for the patient (hospital commutes and consultations) and the hospital (patients’ transportation, treatment of complications, and complementary diagnostic exams) (Seto, 2008). When applied to post-surgery follow-up, there are not enough studies demonstrating value from these digital services, namely reducing readmissions and costs of care (McElroy et al., 2016). Alongside, studies of postoperative patient-reported outcomes measures (PROMs) are low in volume, and evidence needs to be strengthened, namely with more digital resources (Mori Makoto et al., 2019). This project started with minimal investment, based on the collaboration of technology partners that made available a set of Digital Health Kits (DHK), composed of smartphones with internet connection and IoT devices developed for cardiac insufficiency (Silva-Cardoso et al., 2020). Driven by the need to use the available resources to develop the Remote Patient Monitoring (RPM) system in such a way that could add value to the established follow-up program, we followed a participatory approach to implement a pilot study with the active involvement of all human agents (Clemensen et al., 2017). We used the design science research methodology (DSRM) as a baseline framework to develop the digital solution, supporting the research team to iteratively respond to the real context challenges and assess its value (Hevner et al., 2004; Peffers et al., 2007). A *Lean Startup* approach was needed to help researchers to quickly start with the minimal development needed to initiate patients’ and clinicians’ experience with the new service.

This paper presents the work undertaken to implement a postoperative digital telemonitoring service for patients submitted to cardiac surgery in Hospital de Santa Marta, a central public hospital in Lisbon, Portugal. The service was developed from existing technological equipment supplied by technology partners that supported the project.

The primary objective of this study was to develop a digital transformation of the patients' follow-up service of a cardiac surgery department, that would collect patient reported outcomes and respond to the real context challenges. The secondary objective was to evaluate the feasibility of such digital follow-up service for delivering high-value care to the patients.

4.2. Methods

4.2.1. Methodology

This study followed the framework of DSRM and incorporated concepts from the *Lean Startup method* (Eisenmann et al., 2011) to start designing a minimal viable product (MVP) from the available equipment (DHK) and resources (provided by the clinical team and the research team). DSRM oriented the researchers to develop a rigorous design-oriented framework centred on the actual context and needs of patients and healthcare professionals by continuously communicating with them. The *Lean Startup* approach guided the team to bear uncertainty by quickly starting a pilot study and developing an overall solution in short deployment cycles. The entrepreneurial mindset drove the research team to validate learning during the DSR process and follow a "*Build-Measure-Learn*" sequence. During the pilot study, the overall RPM service was co-designed and developed by researchers, patients, and the clinical team, relying on short cycle times and rapid iteration with small batches of patients submitted to cardiac surgery (Bhattacharyya et al., 2019; Eisenmann et al., 2011; NEJM Catalyst, 2018). We started with an MVP based on the available DHK. Furthermore, we developed a digital platform artifact to support the clinical team in managing patients' data reported from the DHK.

The applied methodology followed a 6-step workflow, based on the DSRM, as depicted in Figure 7 and described below.

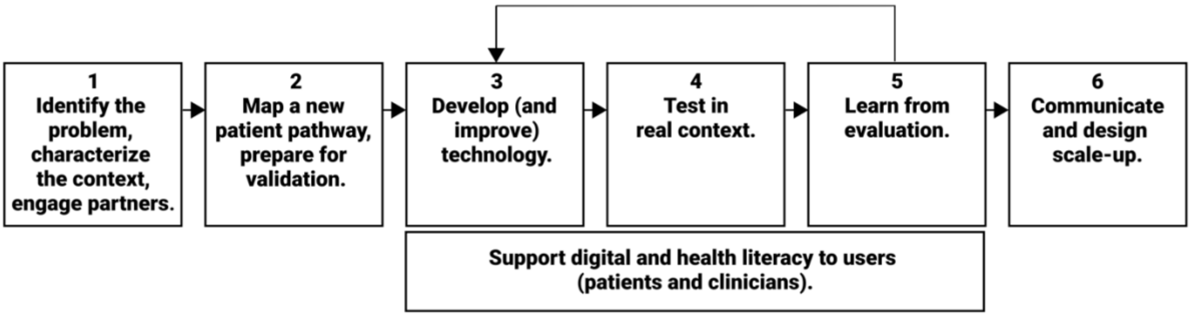


Figure 7 – Methodology to design and develop-test-learn cycles of the RPM service for cardiac surgery follow-up.

Step 1 – Identify the problem, characterize the context, and engage the human agents.

According to DSRM, the specification of the problem and motivation should anticipate any design or development to involve the teams and develop sustainable solutions. The project started with a core team of surgeons and nurses responsible for postoperative care in cardiac surgery patients. From four visits to the hospital service and conversations with the clinical team, a description of the existing postoperative follow-up procedure was made to understand the need for an RPM service that effectively collects patients' outcomes helps to minimize post-surgery complications and provides reassurance to patients. From each conversation, notes were taken to prepare drafts of the pathway and requirements of follow-up, that were discussed in the next meeting, until a final version was reached. Concerns on its feasibility to engage patients and nurses were discussed; patients' adoption and nurses' adherence to the service were set as requirements for the digital innovation. The output of this step was the design of the as-is patient care pathway. It describes the postoperative care program, which was agreed by the clinical team.

The used process design was based on a Business Process Model and Notation (BPMN), that is used to support process modelling in healthcare and identify opportunities for quality improvement (Pufahl et al., 2022). Also, we identified human agents relevant to the healthcare design and characterized their working needs, values, and expected benefits and contributions. This step allowed us to define a strategy for creativity of the involved human agents, and improvement of understanding of their potential contributions to the new digital service design. Not only were patients and clinical teams considered to participate, but technology providers who invested in this proof-of-concept were engaged and motivated towards optimal collaboration, as well.

Step 2 – Map a new patient pathway with the clinical team for an RPM service and prepare a validation study.

This step was a creative stage of the project, where, according to the DSRM, the objectives are defined. In two meetings at the hospital, we moderated a research discussion with the clinical team on use cases and scenarios for a digital remote follow-up service after cardiothoracic surgery. First, the technological opportunities (the DHK) were presented to the clinical team as the available resources to implement an RPM service. Then, the requirements for the service (target population, the outcome variables with relevance for follow-up, and the period for telemonitoring) were discussed and agreed upon by the clinical team. By suggestion of the clinical team, a patient whom we called the patient zero voluntarily tested the available technology as-is to assess its feasibility in terms of patient easiness-to-use and technological robustness.

Finally, technology providers assessed and discussed the viability (based on the constraints of the low initial investment in technological development) of the proposed requirements. After making necessary adjustments, we discussed these with the clinical team, and a final viable consensus was reached to a new patient pathway that included an RPM service. The output of this step was a new to-be patient pathway and the design of a pilot study to test the new digital follow-up service. The protocol for the pilot study was submitted to the Ethical Committee of the hospital.

Step 3 to 5 – Develop-test-learn in iterative cycles (DSRM cycles)

After the objectives were set and the new follow-up path- way was defined and validated by the clinical team and the technology providers, an iterative method of consecutive develop-test-learn cycles supported the development of the telemonitoring service. For each cycle, we developed new features, tested these with the participants in the study and collected their experience at the end of their 30-day follow-up period, with interviews taken in presence at the hospital.

We developed the first instantiation of the RPM service with an MVP based on minimal development efforts for a rapid move to a demonstration. The MVP was developed and tested in real context. The first patient was selected with the criteria of being admitted for cardiac surgery and having high potential motivation to collaborate on a digital remote monitoring experience. After the first MVP, we conducted significant improvements. Successive instantiations were developed, tested, and evaluated with patients, following an iterative method of consecutive develop-test-learn cycles. After the 30-day telemonitoring period of each patient in each cycle, the patient experience was collected through interviews in person, at the hospital. From the reported experience, and clinicians' feedback, we identified new requirements and defined a roadmap for further development iterations and the number of patients to test each iteration. During in presence weekly follow-up meetings with the research team, nurses and surgeons were asked for feedback on their experience with the RPM and returned necessary inputs on their needs and suggestions. These were noted and considered the priority requirements to implement in the next iteration cycle.

Software development and User Experience were relevant skills to perform the develop-test-learn cycles. The output of the pilot study was a telemonitoring solution with all the necessary features to make it feasible for cardiothoracic surgery care.

Step 6 – Communicate and prepare for scale-up

According to the literature, following the DSRM, communication "*establishes repeatability of the research project and builds the knowledge base for further research extensions*" (Hevner et al., 2004). We developed a communication plan for each human agent involved to raise awareness of the project progression, opportunities, and pitfalls.

Step parallel to Steps 3 to 5 – Support digital and health literacy to patients

It has been demonstrated that patients' active role significantly impacts the innovation of services, products, or processes in healthcare (Hibbard & Greene, 2013). Some authors highlight responsiveness and reflectiveness to be part of the process (Iakovleva et al., 2019; Stilgoe et al., 2013). This step is fundamental to inform and involve the patient, as well (Iakovleva et al., 2019).

A two-page written guide illustrating the reporting procedure was delivered to the patient as supportive material. Furthermore, text messages to support health literacy during the recovery period were implemented. The nurse team defined a set of messages organized in a 30-day schedule to be sent to patients' smartphones when they daily reported data. At the end of each telemonitoring period, when patients returned to the hospital for a clinical appointment, two researchers assessed each patient's experience by a questionnaire and a structured interview.

4.2.2. Pilot study and evaluation

Participants

Participants were both the clinical team responsible for the follow-up service and 30 patients. The sampling size was based on a flat rule of thumb based on theoretical optimal values of pilot trial sample size, which the clinical team considered a feasible dimension for the context of this pilot study (Whitehead et al., 2016).

All patients submitted to the cardiac surgery ward were eligible. The clinical team selected the patients during the post-surgery hospitalization, with the following selection criteria: ability to read and write, having a mobile phone and willingness to participate. Patients who could not manage the smartphone of the DHK, either due to functional limitations or very low digital literacy and did not have the daily support of a caregiver, were excluded. Due to specific pandemic organization of the public health system, the hospital was COVID-19 free, i.e., patients with COVID-19 were transferred to another hospital that was referenced for that purpose.

After being selected by the clinical team, each patient was invited to participate in a 30-minute education session. One nurse and two researchers from the telemonitoring support team were present in each session. Four parts composed the session: 1) the nurse explains the project's main goals and the telemonitoring data process and assures that the patient understands them; 2) the support team shows all the steps that the patient needs to perform when at home, and checks the patient's ability to perform each action; 3) the patient independently repeats the routine by following the provided guidelines, and self-assessed his/her performance deciding whether he/she wants to participate, and if so, 4) the patient voluntarily signs the study informed consent, receives a 1-page instruction and the support team provides their phone contact, in case of any equipment failure or misuse. Whenever the patient was willing to participate but had very low digital literacy, the caregiver received the instructions to support the patient.

Instruments and evaluation metrics

The DHK included a smartphone with a SMARTBEAT app to collect data from a smartwatch (to measure steps and continuous heart rate), a sphygmomanometer (to measure blood pressure and heart rate), and a scale (to measure bodyweight) (Silva-Cardoso et al., 2020). A chatbot application was also included to exchange messages and a picture of the wound. The selection of patients was independent of their home conditions related to internet connection because each kit included a 4G card to exchange data via a telecom network.

Patient experience: At the end of the telemonitoring program, patients' experience was collected using a Portuguese validated version of User Experience Questionnaire (UEQ), the Net Promoter Score (NPS), and three open questions related to the recovery period: "*What was most important to you during the recovery period?*", "*What was most difficult?*" and "*What would you recommend to improve the* *follow-up service?*" (Cota et al., 2014; Hamilton et al., 2014). NPS was used in this study as a metric for patient adoption that is simple to apply to patients with low literacy. This scale is based on a single question: "*How likely are you, on a scale from zero to 10, to recommend telemonitoring to a friend or a colleague?*". Responders are grouped according to scores: promoter (9, 10), passive (7, 8) and detractor (<7). UEQ assesses user experience and contains 26 items organized in 6 scales: attractiveness, perspicuity, efficiency, dependability, stimulation, novelty. Each item is scored from − 3 (horribly bad) to + 3 (extremely good), 0 is a neutral answer. Each scale is based on a set of items and its score is calculated as the mean of its items' scores. The questionnaires were applied in a paper-pencil form at the hospital.

Feasibility of digital service:

Feasibility was measured by: (i) patient's adoption and adherence, (ii) clinical team's adherence to the telemonitoring service and engagement (iii) the rate of technical support occurrences during the pilot. Further, we observed how the RPM service was used for clinical support to patients, by analysing actions that were triggered by patients' reported data.

Patient adoption was assessed with the NPS. Patient adherence was measured as the ratio of the number of days that each patient-reported outcomes to the total days that the patient had the DHK. Indicators for clinical adherence were the number of daily accesses to the platform and the number of clinical interventions generated from data in the telemonitoring platform. Indicators for clinical engagement were the total number of clinical users of the RPM platform.

Clinical effectiveness:

The clinical effectiveness of the RPM service was analysed by comparing the critical incidents observed in the group of patients that participated in the pilot study with a control group of patients. Each participant was compared with patients from a hospital surgery follow- up registry of critical incidents (readmissions, surgeries, death) that matched the age, sex, and type of cardiac surgery.

Develop-test-learn cycles:

During the pilot study, patients were recruited in 4 stages. Each stage corresponded to a develop-test- learn cycle, as described in previously. The defined strategy was to follow a 4-cycle iterative process, with batches of a growing number of patients: 1, 5, 10 and 14, respectively.

Data analysis

Simple descriptive statistical analysis was used for evaluating the results. We used the Wilcoxon Signed-Rank Test to compare the critical incidents of the participants with the average of the registration of critical incidents for a control group from the same cardiothoracic surgery department (Woolson, 2008). The control group was selected from a database of patients that were operated in the same cardiothoracic surgery department in the last 10 years. Patients in the study were compared on a 1-to-n matching, where the n was the group of patients that matched age/sex/type of surgery (the 3 main factors influencing the risk of surgery) of each participant. A p-value of 0.05 was considered the threshold for statistical significance.

Interviews with the patients were manually transcribed. An inductive thematic analysis was used to identify the most relevant topics raised by patients concerning the clinical support in postoperative rehabilitation.

4.3. Results

4.3.1. Implementation

This overall methodology was implemented for 16 months, from June 2019 to October 2020.

Step 1

Human agents were identified and interviewed to identify their specific requirements for the context of the digital telemonitoring service. Table 5 describes each agent's expectations and their level (low/medium/ high) of importance and influence in the design of the digital health service. The clinical leaders were identified as the ones with more influence in the design of the RPM service. The actual follow-up service and the process were characterized and validated by clinicians.

Step 2

Researchers met the clinical team in three meetings to design the new pathway and define the outcomes to be monitored Figure 8. It was defined that patients had to report, once a day, measures that were relevant to prevent most common complications being blood pressure, heart rate, weight, and steps. Also, a picture of the wound had to be sent. Symptoms related to pain, dyspnea, feet edema, blackouts, palpitations, and wound, were collected via a six-item questionnaire. The RPM service was set for the first month after hospital discharge, a critical period of higher complication rate. Alarm rules based on the collected outcomes were defined. The nursing team had to access to patients' data every day, between 2 pm and 4 pm, and patients were instructed to daily report until 12 pm. Researchers worked with DHK suppliers to adjust it to the defined pathway. Moreover, the requirements and resources needed to cover the missing parts, i.e., features not implemented in the available DHK, were identified.

Steps 3–5

The pilot study started 3 months after the first step. Between October 2019 and October 2020, 30 patients accepted to participate in the study and used the RPM service after being discharged from cardiac surgery ward. From this group, one patient left the telemonitoring program after the first week, due to mental health conditions. The patients' average (±standard deviation) age was 60.6 ± 13.5 years old, 15 (50%) of the participants were female. In terms of geo- graphical distribution, half of the patients lived more than 100km away from the hospital, the furthest district being 277 km. Patients' average education level was 2, according to the European Qualifications Framework (EQF).

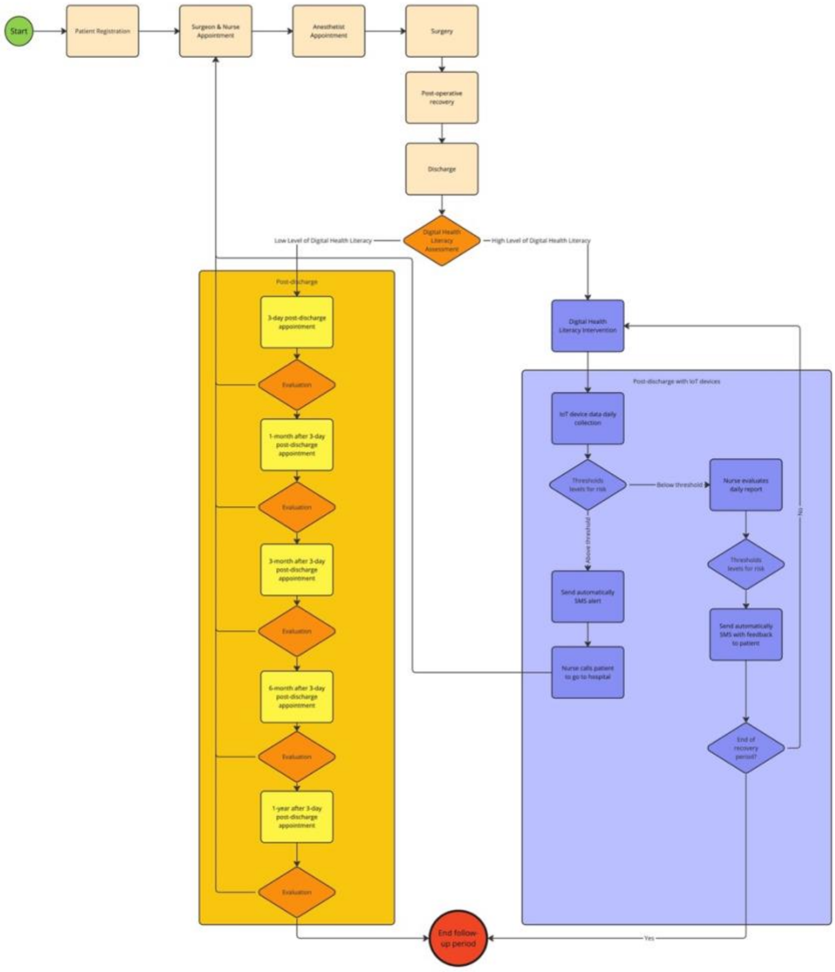
As we were informed, none of the patients was infected with the new coronavirus since the cardiac surgery service was set to accept non-covid patients exclusively. Patients' recruitment was interrupted from March to May 2020 due to workflow reorganization to cope with the pandemic. Nevertheless, none of the patients already using the telemonitoring system interrupted the follow- up during that period. Besides the interruption of recruitment for 2 months, there were no other specific problems related to the COVID-19 context with the pilot study.

The DHK suffered no modifications; all patients had the same setting. This helped us to identify the need for development of an application to manage the telemonitoring data, engage the clinical team and assess value indicators. The pilot study started without developments from the application to manage patients' data (secure links to patients' reports were manually sent to one contact of the clinical team by email). Nurses and surgeons were proactive in suggesting features and modifications to the system or reporting satisfaction.

Table 5 – Characterisation of the human agents in the current project

Agent group	**Profile**	**Identification of motivations and objectives**	**Solution benefits**	**Importance**	**Influence**	**Relationship with other human agents**
Patients	Individuals submitted to cardiac surgery and were selected for the digital telemonitoring follow-up.	Be safe and in surveillance by the clinical team; have a successful recovery.	Increased patient's perception of safety; increased participation through recovery; better adherence to the clinical recommendations.	High	Medium	Surgeons and nurses; Family caregivers; R&D team.
Family caregivers	Patient's relatives that are providing support to the patient along with the follow-up.	Support the patient in successful recovery; be supported in patient's care. Guarantee that the patient is well treated.	Ensure the best patient recovery and clinical support; be aware of the patient's health status; accessibility to care delivery.	Medium	Low	Patients; Surgeons and nurses; R&D team.
Surgeons and nurses from the cardiothoracic department	Healthcare professionals providing healthcare services.	Improve patients' reassurance; improve outcomes through recovery; be informed about patient's status to detect complications early.	Decrease the number of critical incidents; increase patient's perception of safety; ability to close monitor a higher group of patients.	High	High	Patients; Family caregivers; R&D team.
R&D team	R&D organisation that ensures that the technological pilot adds value to the digital health service provided and meets the human agents' needs.	Provide a valid solution to the actual healthcare context. Study the value of a digital telemonitoring service in healthcare.	Development of new methods to effectively collect outcomes in outpatient environments; assessment of the solution's impact.	High	High	Patients; Family caregivers; Surgeons and nurses; DHK providers.
DHK providers	Fraunhofer AICOS, and R&D organisation providing technology research; Vodafone Portugal, a telecommunications operators.	Provide solutions that are usable, interoperable, safe, and compatible with medical device regulation. Provide tools for digital transformation in healthcare.	Development and validation of digital solutions; value assessment of new digital products; collaboration with partners.	High	High	R&D team.

Figure 8 – The new telemonitoring process: process underwent in the hospital (yellow) and process implemented by the RPM service (blue).



The iteration process, developments, and feedback used to iterate the next cycle are summarized in Table 6. Most of the developments were for the clinical side of the RPM system. The patient side of the RPM was kept the same: a smartphone to collect weight, steps, blood pressure, six questions related to symptoms, and the receipt of the picture of the wound. A minor change was implemented for the patient: to receive literacy text messages from nurses, just after the daily data reporting procedure. This feature was introduced in the fourth develop-test-learn cycle.

Step 6

Further research funding was obtained from dissemination activities to develop intelligent interaction and risk prediction from telemonitoring data. Also, communication of the results to technology partners is moving investment interest to scale up the solution.

Support to patients' literacy

Education session for digital literacy

All selected patients received the DHK and learned how to use it during the education session. During this session, one withdrawal was registered from a patient that lost interest in participating after trying the measurement procedure. Three other patients with very low digital literacy but willing to participate involved the informal caregivers in the education session to ensure data reporting with the DHK.

Text messages for health literacy

As a feature that was suggested by the clinical team, a list of text messages was created to send to the patients via the chatbot. These messages were based on the contents of the hospital flyer that nurses provide to the patients. Messages were divided into six categories: informative, educational/preventive, motivational, commemorative, technical support, and alert. Withal, the nurse team defined a scheduled plan to deliver recommendations for better recovery during the 30 days, weekly.

Messages were implemented in the last develop-test-learn cycle, applied to 14 patients (Table 6). We divided the scheduled messages by the days of the week so patients would not receive them all on the same day.

Table 6 – Description of the four iterations performed during the pilot study to develop the digital platform for managing data from the clinical side, based on clinicians' and patients' feedback.

Iteration	**Description of the instantiation concerning the development of the data management tool for the clinical team**
Iteration 1 Patient 1	Clinical team daily receives patient's data in a report by email. **Feedback from clinicians:** Graphics received are not well perceived, daily reports are very extensive, historic data should be strict to a 7-day period.
Iteration 2 Patients 2–6 (1 dropout)	Clinical team daily receives patient's data in a report by email. **Improvements:** Data reports were improved with the feedback given by the clinical team. Alerts were introduced in the patients' report, based on rules defined by the clinical team. **Feedback from clinicians:** Need for registering clinical notes related to each patient's reported data. Difficulty in managing information of one email (daily report) per patient. **Feedback from patients:** Problems with the Bluetooth connection with the smartwatch was reported by some patients.
Iteration 3 Patients 7–16	**Improvements:** The first version of the RPM web application to manage patients' data was launched. Data monitoring process became more efficient for the clinical team as they had a monitoring list with

	the individual patient alerts. Email reports were eliminated. Access to each patient record allows the access to the historic data and registering notes from the clinical team. Patient instructions were improved to reduce problems with Bluetooth connection. **Feedback from clinicians:** Concern of using their time in phone calls related to technical issues of the equipment. Also, text messages could save time for communicating simple literacy reminders.
Iteration 4 Patients 17–30	**Improvements:** Added a feature in the RPM application for sending literacy text messages to the patients. This feature included a set of predefined messages that can be sent on demand or in a scheduled scheme. Patients received the text messages once a day, after reporting the photo of the wound. To better manage the technical issues, a ticket system was added to allow the clinical team to report to our support team a problem with a DHK, avoiding phone calls. Service quantitative metrics were made available to the clinical team, in the RPM application (e.g. number of alerts and their type, type of actions taken by the clinical team based on those alerts). **Feedback from clinicians:** Preference for the predefined scheduled messages as can optimize their work. **Feedback from patients:** the app asks to daily answer to the same questions even if the answer is the same as in the previous days ("*I was reporting every day that I didn't feel tired*").

The trigger mechanism for sending the text messages was the daily receipt of the photograph of the wound from the patient, as depicted in Figure 9. This was a deliberate strategy to increase patients' attention to these educational messages, as these were immediately sent in response to patient's message.

Figure 9 – Simulation of a literacy message sent in reply to the daily picture of the surgical wound that is sent by the patients (this image includes a fiction name and is translated to English language).

Hi Mr. John! We received 1 file(s) and we are monitoring you closely. Thanks!

A nursing team will contact you throughout the recovery.

During the 1st month after surgery, monitor your temperature daily.

If you notice any abnormalities such as pain, redness, yellow fluid or pus on the scar, go to the Health Center.

4.3.2. Evaluation

Patient experience: We interviewed 26 participants after the 30-day telemonitoring period. It was not possible to interview 3 of the participants on the 30-day appointment at the hospital. This is justified by difficulties in coordinating the patients', clinical, and researchers' schedules. Nevertheless, these participants engaged in the whole telemonitoring process and reported data that supports this study. From the responses to the three open questions, it was observed that ten patients (38%) explicitly reported that the remote monitoring allowed them to feel safer, with 3 (12%) referring to the relevance of the collected health data and 9 (35%) highlighting the support and interest demonstrated by the healthcare professionals in their recovery. Four patients (15%) reported difficulties in using the equipment related to taking the wound pictures. It is to note that the questions did not relate directly to the DHK but to what was most relevant in postoperative rehabilitation. Some statements of the patients that relate to the use of DHK are:

- "*I felt like I was at the hospital, that I was being accompanied by them all...*"
- "*Yesterday, I was thinking: when I get there to return the devices, I am going to have a surprise, they will give me one of this [referring to the DHK]...*"
- "*It is a friend that we do not see, but that is there with us every day* [referring to the literacy messages in the chatbot]."

An NPS of 84 was obtained, reflecting an excellent level of patient satisfaction (Reichheld, 2003; Sauro & Lewis, 2012). Furthermore, 88% of patients were promoters (score of 9 or 10), enthusiastically using the technology and referring it to others, 8% were passives (score of 7 or 8), i.e., satisfied but not enthusiasts of the service, and 4% detractors (scores of 0 to 6), i.e., non-supporters of the service. After applying the full UEQ questionnaire to 4 patients, we observed that this group of patients was not able to answer most of the questions, due to their low literacy level and complexity of the UEQ concepts. For the following participants, we applied only the scale UEQ-Stimulation (items 5,6,7,18 of UEQ), which refers to concepts that we had observed that patients could understand and relate to their experience (Table 3). From the 26 answers collected for the UEQ-Stimulation, the estimated mean value was 2.49 (confidence interval: 2.32–2.6, p = 0.05), as described in Table 7. The technology achieved an excel- lent evaluation (score higher than 1.55).

Table 7 – Results of the Simulation items of the UEQ.

Item	**Mean**	**Variance**	**Std. Dev.**	**Left**	**Right**
5	2.9	0.1	0.3	Valuable	Inferior

6	1.5	1.5	1.2	Boring	Exciting
8	2.8	0.2	0.4	Not interesting	Interesting
18	2.8	0.2	0.4	Motivating	Demotivating

Feasibility: The mean score of NPS of 84 indicates high patient adoption of the digital telemonitoring ser- vice. Two patients even mentioned their willingness to use the DHK for some more time. Patients' adherence was, on average, 91.6 (±15.1), all above 88 except for 4 patients: two had difficulties in using technology and were depended on caregivers' availability, and two others had been readmitted to the hospital due to clinical complications. Every day during the pilot study, the clinical team assessed patients' reported data. Three nurses and two surgeons were engaged to develop the first iterations of the telemonitoring system. A scale-up was observed in iteration 4. A larger group of 25 nurses requested to be assigned to have login access to full use the web application that supported the telemonitoring process to follow patients. Evaluation related to quantitative service metrics was only possible from cycle 3 since we had not implemented the telemonitoring management platform in the first two iterations. For the total actions registered by the clinical team on the platform, we observed an average of 7 (±4.45) occurrences per patient, most (84.3%) related to clinical interventions (Table 8).

Table 8 – Results of the analysis of the occurrences registered by the nurse team in the telemonitoring platform during the pilot study.

Total number of occurrences	**420**
Total number of occurrences registered by nurses	210
Number of clinical occurrences	177
Number of occurrences for technical support	33
Number of occurrences per patient (mean ± standard deviation)	mean (std): 7.2 ± 4.45 median (min, max): 7.0 (0,17)

The most frequent interventions were related to nursing calls to the patient for clarification about the outcomes (measured or reported), and the least frequent were related to hospital readmission (Table 9). These interventions were triggered by data reported by the patients in the RPM system and accessed by the clinical team through the telemonitoring platform.

Table 9 – Description of the clinical interventions that were triggered by the telemonitoring system.

Total number of interventions	184 (100.0%)
Total number of interventions from the surgeon	45 (21.4%)
Medication adjustments	25 (11.9%)
Clarifications on outcomes (measured or reported)	101 (48%)
Reinforcement of education (e.g., wound hygiene instructions)	58 (27.6%)
Anticipation of the first postoperative medical consultation	4 (1.9%)
Request for reassessment of measured results	9 (4.3%)

Hospital readmission	3 (1.6%)

Occurrences related to technical support (15,7%) were due to the synchronization of the smartwatch, or when the patient did not send the daily picture of the wound. Most of these problems were solved by phone calls between the patient and the technical support team. Clinical interventions were labelled by nurses when they registered them in the telemonitoring application. Most of the clinical interventions were related to abnormal systolic blood pressure (19.5%) or issues related to the wound (12.9%). The number of entries in the registry of critical incidents that matched each participant varied from 3 to 47 (mean:16,97). We used the Wilcoxon Signed-Rank Test (Woolson, 2008) to compare the critical incidents between each participant and the mean of his/her control group. The average of critical incidents of the telemonitored group was 0.07±0.26, and the average of the control group was 0.13±0.13. The result of the test was w=41 (p-value = 0.01), rejecting the null hypothesis that there is no difference between means.

4.4. Discussion

This paper presents a collaborative and iterative method developed to drive a digital innovation context in a cardiac surgery department of a public hospital in Portugal. The aim was to design, implement, and validate an RPM service for post-surgery follow-up.

Due to the COVID-19 outbreak, the pilot study was interrupted for just two months due to necessary organisational rearrangement. However, it continued with recognised added value to the patients when there were clinical guidelines to strictly avoid hospital visits after cardiac surgery. The average age of the participants is slightly below the expected average in cardiac surgery, probably biased by the small sample and a higher willingness of younger patients to participate in the study and use the DHK. Regarding the sex distribution, it is coherent with the population in the hospital department is balanced with similar proportions of males and females (Coelho et al., 2019).

DSRM enabled us to design an artifact in a participatory way, responding to the identified problem and engaging human agents. After the artifact was built, the *Lean Startup* approach was used to start experimentation with a minimal valuable instantiation, based on available resources and minimal investment.

Our approach responds to the need to research novel methodologies to support faster technology development-validation cycles while ensuring its value demonstration. The high pace of technological innovation, in contrast to the long process of clinical validation is challenging in healthcare (Drummond et al., 2009; Peirce et al., 2011). The traditional product development process dedicates a long effort to analysing the needs, defining the requirements, developing a prototype, and ultimately, testing and validating before market entry (Cooper, 2008). In healthcare, this process is heavier due to the need to validate and certificate products before reaching the market. This classical approach for product development to be validated is slow, and the delay risks digital technologies: being too late when getting to the market, being unable to prove value after a long development process, and failing to test stakeholders' adoption in real-world settings (Pham et al., 2016; W. T. Riley et al., 2013). In this work, we developed the RPM service while simultaneously performing validation in different domains during the pilot study. According to the global digital health scorecard proposed by Mathews et al., (2019), our methodology included the necessary elements for usability (satisfaction and adoption from patients and clinical team), clinical (reduction of critical incidents), and technical (overall performance of the system in real-world context) validation. Although it is out of the scope of this paper, we already have preliminary results of a cost analysis, which will fill the cost element of the validation scorecard (Pham et al., 2016).

The results from this study suggest the potential of patient-reported outcomes monitoring to reduce critical clinical incidents. However, a larger study is needed to support the statistical robustness of the comparison between groups of patients. Moreover, we observed that the most frequent complications solved with the RPM service in this study are comparable with a previous study, which used a similar RPM setup in post-cardiac surgery care (McElroy et al., 2016). For validation of patient experience, we found that UEQ was difficult to apply due to complex concepts that were not in the context of the patients with low literacy. Further research is needed to identify adequate instruments to evaluate the experience with technology that fits the healthcare context, being the short version UEQ-S (Maramba et al., 2019; Schrepp et al., 2017). Nevertheless, the reduced rate of dropouts (only one patient) and high patient satisfaction in our study suggest that most patients' needs were addressed.

While the clinical benefits of digital technologies in RPM have been recognized, the adoption is challenging (Vegesna et al., 2017). Participatory methodologies may be a catalyser for successful implementation and adoption of digital technologies in healthcare (Cresswell et al., 2013; Dugstad et al., 2019; Hanley et al., 2018; Morton et al., 2020). In opposition, disruption in clinical workflows by imposing an external digital tool hamper the adoption and demonstration of its value to the patients and the hospital. Accordingly, the co-design of a new digital service, along with its iterative integration in the clinical workflows, as we used, is an essential part of our contribution to optimize the feasibility and adoption of the technology (Ware et al., 2018). Our method considered the human agents' needs and motivations, the process, and the digital tools, as parts of the RPM service design. This shift from focusing on product implementation to service design has been suggested as a needed approach to ensure value co-creation through patients' and healthcare professionals' experiences (Lee, 2019; Shaw et al., 2018).

The continuous involvement of the research team with patients and clinical professionals improved their compliance with the technology, as previously identified in other studies and stressed in the Responsible Research and Innovation guidelines (Cresswell et al., 2013; Lettice et al., 2017; Maeder et al., 2015; Peirce et al., 2011).

The role of the researchers was also to challenge the clinical team by proposing new features and assessing acceptance and adoption. A combined strategy of demand-pull and technology-push successfully engaged the clinical team in the innovation process (Di Stefano et al., 2012; Shaw et al., 2018). Our iterative methodology and interdisciplinary research team stimulated innova- tion and promoted the adoption under this scenario.

A limitation of this study is that, despite the concern of providing a stable instantiation to the patient, the iterative method imposed different experiences to the clinical team and may hinder the reliability of the results. Another limitation is the small number of participants, which did not allow a robust statistical analysis to claim clinical effectiveness of the RPM service. Also, the small number facilitated close support of the technical team and clinicians to patients, probably increasing their adoption and masking potential outliers in terms of negative experiences with the RPM. A clinical study with higher number of patients and a stable version of the RPM service, implemented as a final iteration of our methodology, would increase the robustness of the results. From the results presented in this paper, we plan the scale-up to a randomized clinical trial with 300 patients to test the impact of a more extended digital follow-up period and analyse for which groups of patients the RPM returns higher value. Furthermore, we are working on intelligent prediction models based on patients' outcomes, that can support a personalized care plan and high-value decisions for this follow-up service (Mollaei et al., 2021).

The future application of the method proposed in this work to other use-cases will be essential to validate, generalize, and improve it.

4.5. Conclusions

We present the method we undertook to develop, implement, and validate a digital telemonitoring follow-up service in cardiac surgery care. We parted from a need to improve follow-up in cardiac surgery and the opportunity to use resources from our technological partners.

This study contributes to identifying methods that can be applied by digital health innovators, considering the demand for addressing clinicians' and patients' needs, available resources, and demonstration of value in short cycles of development and real-context validation.

CHAPTER 5 | Domains and Methods used to Assess Digital Health Interventions Scalability: A Systematic Review

Chapter 5 provides a comprehensive systematic review of the domains and methodologies utilised in existing literature to evaluate the scalability of digital health interventions, with a specific emphasis on interventions leveraging remote patient monitoring technologies for home-based care. By focusing on home telemonitoring interventions, the chapter aims to deliver more pertinent and insightful findings tailored to the thesis's overarching objectives. The chapter identifies a critical gap in scalability assessment studies, highlighting the oversight of evaluating relevant domains such as strategic, socio-economic, organizational, and technological factors. Furthermore, it underscores the challenge posed by the disparate methods employed within a single domain, hindering meaningful comparisons and comprehensive evaluations.

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Azevedo S. contributed to the study design, conducted the systematic review, and assisted in preparing the paper.

5.1. Introduction

The Universal Health Coverage (UHC) commitment aligned with the emergence of COVID-19 reinforced the value of telemedicine services and elected these services crucial to coping with the pandemic's challenges in the health care sector. Since the pandemic reached the western countries, home telemonitoring offered an alternative to control the health status of infected non-severe patients at their homes to avoid unnecessary visits to the hospital (Annis et al., 2020).

During the early part of 2020, from a social perspective, the fast-track solution to prevent the spread of COVID-19 focused on social distancing (Adolph et al., 2020). Governments forced people to stay at home, cancelled mass gatherings, imposed teleworking, and closed all educational institutions (Anderson et al., 2020). From a health care perspective, governments took some extreme measures to increase the capacity to cope with the virus, namely reduction or deferral of nonurgent care and hands-on visits, and postponement of nonurgent surgeries (ECDC, 2020). These measures exposed high-risk groups, such as the elderly at home, people at long-term care facilities, patients with chronic conditions, and hidden diseases (Carter et al., 2020). Inevitably, physicians started following-up with their patients through video calls and remote monitoring to continue treatment and avoid long-term complications (Srivatana et al., 2020). In parallel, health care providers launched new telehealth services to assist patients in their homes (Fisk et al., 2020). Policy makers and practitioners did not have enough information to decide which pilot intervention they should disseminate into real-world settings, considering different financial reimbursement strategies, health care system organizations, and workforce acceptance levels (Smith et al., 2020).

With technological progression and decreasing equipment costs, remote patient monitoring emerged as a telemedicine application. It comprises interactive and noninteractive technologies to support health care and monitor patients' health status in their homes (Strode et al., 1999).

Home telemonitoring is one type of remote patient monitoring, which has shown and is showing potential to improve clinical and patient-reported outcomes and ensure cost reductions for health care practices (Meystre, 2005). In this work, the authors consider the definition given by Paré and colleagues (Pare et al., 2007) for home telemonitoring. A service based on home telemonitoring consists of health care professionals monitoring the patient's health status at a distance. Patients or caregivers transmit their health-related data to a responsible health care professional through information and telecommunication technologies. Research on home telemonitoring showed benefits concerning health care systems' capacity constraints (Mengden et al., 2001), patient empowerment, and treatment commitment (J. P. Riley et al., 2013). It revealed significant improvement in clinical outcomes even in some diseases (Pare et al., 2007). Despite the considerable investment in accelerating health information technology (Makhni et al., 2017), there is not enough information on determining whether home telemonitoring is appropriate and feasible for implementation in a real-world context (Milat et al., 2013). Scaling up a health intervention requires wise and efficient spending of resources (EXPH, 2019). Therefore, it is crucial to assess the suitability of scaling up home telemonitoring interventions with proven efficacy to provide answers to the following two questions (Haynes et al., 1979): *Does it work in practice? Is it worth it?*

To answer these questions and decide which technology-based health intervention can be scaled up for mainstream care delivery, one must assess its scalability (i.e., the ability to be expanded to real-world conditions without compromising on effectiveness and access to the eligible population) (Milat et al., 2020).

Most of the studies focus only on assessing the effectiveness and costs of a health intervention. Nevertheless, these are two of many considerations to address when evaluating the potential of scaling up an intervention (Kidholm et al., 2012). Other domains such as the feasibility and adaptability of the health intervention and the political or strategic contexts are rarely analysed. As emphasized by Milat and his colleagues (Milat et al., 2013) in their recently proposed Intervention Scalability Assessment

Tool (ISAT), assessing a health intervention's scalability involves considering multiple domains, such as the political and strategic contexts, workforce, and infrastructure, among others.

There is a need to conduct evidence-based studies that assess pilot interventions' potential to achieve population-wide benefits (Ben Charif et al., 2017). Scalability studies that also consider the intervention's suitability to the socioeconomic context in question are important to estimate the success of deploying these interventions in different contexts (Milat et al., 2013).

Owing to the lack of research on scalability analysis, in this paper, the authors present a systematic review, based on Milat and colleagues' domains (Milat et al., 2013), to identify and characterize methods used to assess the potential to scale-up home telemonitoring interventions in the context of a growing telehealth service in the industry. This study focuses on peer-reviewed studies conducted to evaluate the scalability of follow-up interventions based on home telemonitoring. The authors aim to provide a comprehensive overview of these studies concerning the domains and methods used and identify gaps for future research to address when evaluating the potential to implement or scale-up home telemonitoring interventions. As the authors are not aware of other systematic reviews focusing on this aspect, they believe that this review will enlighten researchers, practitioners, and policy makers regarding the most used strategies to assess the scalability of home telemonitoring interventions.

5.2. Methods

The search strategy followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) guidelines to conduct the review (Moher et al., 2009). The population, intervention, comparison, outcome (PICO) framework (Moher et al., 2009) allowed the identification of key concepts such as "Home Telemonitoring," "Follow-up," "Scalability," and "Assessment" to formulate a well-focused question and facilitate the literature search. To optimize the search through effective queries, the authors used PubMed's Medical Subject Headings (MeSH) to identify indexed terms (Higgins & Cochrane Collaboration, 2020). This step was fundamental as this review emerges from the combination of research fields with different terms for the same concept. Textbox 1 presents the rationale used to build the final query used in each database.

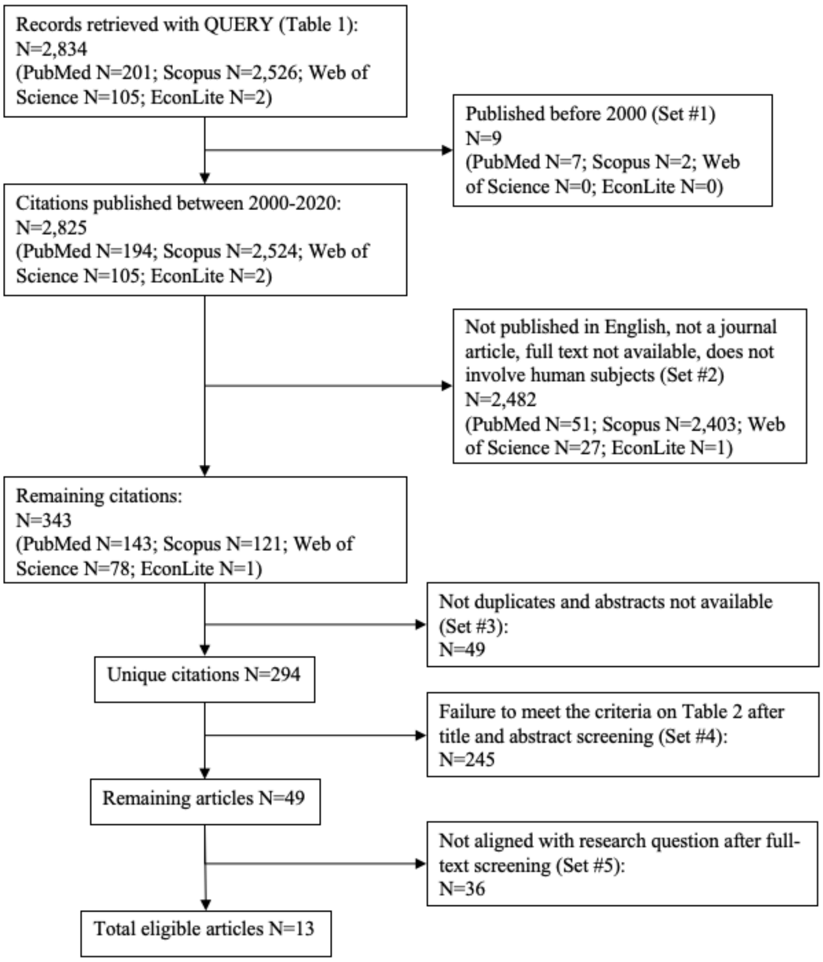
Textbox 1 – Queries used to search each database.

1. (((Telemonitoring) OR (Home remote monitoring)) AND (Mobile Health OR health OR mHealth OR eHealth OR Telehealth OR Telemedicine)) OR (Telehomecare)
2. (Scalability) OR (Feasibility) OR (Scaling up OR scale up OR upscale OR up-scale OR scale-up) OR ((Deployment OR Implementation OR Application) OR (Broad-scale OR Wide-scale OR Widespread OR Mainstream)) OR (((Efficienc*) AND (Program OR Intervention)) OR Economic* Viability)
3. (Follow-up Care* OR Follow Up Care* OR Care*) OR (Case Management OR Patient Care Planning)

4. ((Appraisal* OR Evaluation* OR Assessment* OR Appropriateness) AND ((Impact) OR (Cost-Effective* OR Qualitative OR Quantitative OR Index* OR Methodolog*) OR (Clinical Trial* AND (Pragmatic OR Naturalistic Randomized OR Practical OR Real World)) OR (Sustainability) OR (Profitability) OR (Risk*)))
5. #1 AND #2 AND #3 AND #4

Figure 10 illustrates the search performed in PubMed, Scopus, Web of Science, and EconLit covering studies from 2000 to 2020 (Figure 10 – Set #1). The authors chose to explore EconLit owing to the economic evaluation required to assess a health care intervention’s scalability. The authors selected full-text and peer-reviewed papers written in English (Figure 10 – Set #2).

Figure 10 – PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram showing the included studies.



After removing the duplicates and references without abstracts (Figure 10 – Set #3), two authors independently scanned the titles and abstracts identified in the literature search and applied the selection criteria presented in Textbox 2 (Figure 10 – Set #4).

Textbox 2 – Systematic review inclusion and exclusion criteria.

Inclusion criteria

- Health interventions shown to be efficacious on a small scale or under controlled conditions.
- Assessment of the health intervention’s ability to be expanded to real-world conditions to reach a more significant proportion of the eligible population while retaining effectiveness.
- Studies assessing at least one domain of scalability through the evaluation of feasibility, acceptability, costs, sustainability or, adaptability (ie, to suit the needs of the context in which it is to be scaled up).
- Described methods to assess the scalability of a health intervention.

Exclusion criteria

- Telemonitoring involving invasive medical devices.
- Studies that use telemonitoring “not involving the patients, their relatives, or informal caregivers, their relatives, or informal caregivers.
- Studies that described the concept of scalability without providing an assessment method.
- Studies just focusing on describing disease risk patterns or intervention efficacy testing.
- Study protocols or medical testing procedures for potential scalability assessment and possible scale-up.
- Statistical or conceptual modelling without a real-world study.
- Facilitators and barriers to scale-up within specific interventions or general experiences of scale-up that did not provide a scalability assessment method.
- Studies recommending an assessment method (of feasibility or acceptability or costs or sustainability or adaptability), but that did not assess the potential to scale-up a telemonitoring-based health intervention.

To guarantee that the article’s topic aligned with the research question, the same authors scanned the 49 full-text articles, which reduced the number of studies considered for review to 13 (Figure 10 – Set #5).

The authors analysed 13 full-text articles, corresponding to 13 studies, in detail and registered all the observations in a literature matrix (Kruse, 2019). First, to better explore each intervention and summarize relevant, well-specified, and secure data, the authors conducted an integrative synthesis. The main variables were the country of origin, publication year, sample size, setting, duration of follow-up, comparator arms, type of technology, and study outcomes (Dixon-Woods et al., 2005).

Second, the authors assessed the strength of each eligible study’s evidence according to the 9-level classification system proposed by Jovell and Navarro-Rubio (Jovell & Navarro-Rubio, 1995).

Finally, they conducted narrative and thematic analyses to identify themes and patterns in the eligible articles and outline the findings under specific headings (Dixon-Woods et al., 2005) to better examine how each study assessed the potential of scaling up an intervention. When disagreements occurred, the authors reached a consensus via discussion. One author extracted data from the studies and completed quotes, and the second author validated the data according to the definition of each category. The authors conducted this analysis based on the work undertaken by Milat and colleagues (Milat et al., 2020) in the development of a tool to perform systematic assessments of the suitability of health interventions for scale-up (ISAT). ISAT comprises three parts: setting the scene, planning the intervention implementation, and summarizing the scalability assessment. The first two parts made it possible to classify each study according to the stage of scale-up, context, and focus area. Moreover, Milat and colleagues' domains enabled the authors to identify the methods and instruments used by the researchers to assess the intervention's scalability (Milat et al., 2020).

The research conducted for each domain assessed in the eligible papers was classified as qualitative or quantitative. The research was classified as qualitative if it was based on the description of experiences, emotions, behaviours, events, or actions (University of Newcastle Library Guides, 2021) and quantitative when the respective authors used numerical data to measure, categorize, or identify patterns, relationships, or generalizations through statistical analysis (University of Newcastle Library Guides, 2021).

5.3. Results

5.3.1. Country of Origin and Year of Publication

From 2009 to 2020, the authors analysed 13 studies in seven countries, which focused on the potential to scale-up home telemonitoring health care interventions; however, more than half (n=7) were published between 2018 and 2020. Most of the articles (n=8) were from Canada and the United States, whereas the rest were from five European countries—Denmark (n=1), Italy (n=1), Lithuania (n=1), Netherlands (n=1), and Spain (n=1).

5.3.2. Population and Home Telemonitoring Intervention Assessment

5.3.2.1. Target Condition or Disease

The studies addressed either chronic or acute conditions, with a higher number of studies addressing only chronic conditions (n=8). The full spectrum of chronic conditions covered were cardiovascular diseases (n=4), chronic obstructive pulmonary diseases (n=2), cerebrovascular diseases (n=1), chronic obstructive sleep apnoea (n=1), cystic fibrosis (n=1), and diabetes mellitus (gestational [n=1] and type 1 and 2 [n=1]). Further, one study only characterized the patients' condition as chronic or acute, and the remaining studies addressed multiple conditions (e.g., surgical patients, cardiovascular and pulmonary diseases, diabetes mellitus).

5.3.2.2. Duration and Setting of Home Telemonitoring Intervention

Home telemonitoring was integrated into a follow-up service in the 13 studies and required a responsible health care professional (or a team) to manage the patient's care. The minimum duration of the follow-up was 3 consecutive nights (sleep apnoea (Lugo et al., 2019)). However, the 1-year (n=4) and 6-month (n=4) follow-up interventions were the most implemented. In particular, authors reporting the secondary prevention of cerebrovascular disease (Padwal et al., 2019) defined the intervention according to recommended monitoring protocols, assuming a 20-year time horizon for the modelling strategy. Moreover, 10 studies had two dedicated teams for executing the intervention; one was responsible for the patient's holistic care management and the other for telecare management. In two studies, the conventional care team was accountable for usual care and telecare management, and in the other, there was no traditional care team.

5.3.2.3. Types of Technologies

The technologies used in the studies ranged from a kit with just one regular telephone (1) to an integrated communication and data collection system with mobile devices (5). Moreover, six studies conducted home telemonitoring interventions with an integrated clinical data system, remote monitoring digital technology (mobile devices that collect physiological signs), and a telephone.

5.3.3. Study Design Assessment

5.3.3.1. Study Characteristics

The average total sample size of the studies was approximately 436 (maximum: 3086, minimum: 34), with an average treatment and control group size of 260.

To better understand the type of research conducted, it is essential to highlight that six out of the 13 studies were experimental. Therefore, the authors of these studies allocated participants to different treatment groups. As the other seven studies were observational, there was no allocation of the participants. Most of the studies (n=10) were comparative studies (control group) with conventional care services, and the other three were single-arm studies.

5.3.3.2. Study Design Classification

According to the 9-level classification system proposed by Jovell & Navarro-Rubio (1995), the studies conducted by Padwal and colleagues (2019), and Vestergaard and colleagues (2020) were classified as "*very good*" as they conducted randomized controlled trials with large samples. The studies by Lugo and colleagues (2019), and Paré and colleagues (2013) were classified as "*good*" as these studies were randomized controlled trials with small samples. Furthermore, the studies of Ware and colleagues (2019), as well as Zaliūnas and colleagues (2009), were classified as "*poor*" because they consisted of noncontrolled clinical series or descriptive studies. The other seven were classified as fair and included nonrandomized controlled prospective studies (n=3), cohort studies (n=3), and case-control studies (n=1).

5.3.4. Scalability Assessment

Table 11 displays the scalability assessment domains for each study.

5.3.4.1. Scale-Up Stages

The authors classified eight studies as being in the pre–scale-up stage because their descriptions consisted of steps or activities conducted before scaling up the evidence-based home telemonitoring intervention. Two studies described steps or actions involved in the dissemination of the intervention. The authors classified the other three studies as being in the implementation stage because their descriptions indicated using or integrating the evidence-based intervention within a setting.

5.3.4.2. Domains Considered for Scale-Up

Although all the studies described the problem under intervention and the target population, one study [study number 4] did not provide details concerning the proposed home telemonitoring intervention to address the issue. All studies referred to the level of evidence available to support the proposed intervention’s scale-up, either by referring to their work or other scientific literature. Three studies did not consider the known costs and benefits of delivering the intervention [study numbers 11, 12, and 13], and three more did not consider the strategic/political/environmental contexts that influence the scaling up of the intervention [study numbers 3, 4, and 5].

5.3.4.3. Domains Considered for Implementation Planning

Seven studies considered intervention changes when assessing fidelity, and nine studies assessed the level of acceptability perceived by the program deliverers or recipients of the intervention. Further, nine studies referred to the definition of the intervention settings and the workforce required to scale-up, and 10 described the necessary infrastructure. All the studies accounted for the sustainability of the home telemonitoring service by either referring to the long-term outcomes of the scale-up or the medium- and long-term sustainability of the intervention following scale-up.

5.3.4.4. Methods for Scalability Assessment

This section explains the research foci and methods used by the eligible studies in each domain of scalability assessment. When describing the problems, interventions, and contexts of their studies, all the researchers adopted qualitative research methods, as Table 10 shows. The definitions of the domains and research foci are given in Appendix B. We have included six publications (Drummond et al., 2015; Eldridge et al., 2016; Haynes et al., 1979; Moncher & Prinz, 1991; Velentgas et al., 2013.; Walton et al., 2015) in this appendix.

Table 10 – Qualitative studies on scalability assessment considering the problem, intervention, and context domains for scale-up.

Domain	**Research Focus**	**Research Type**	**Data Collection Technique**	**Data Analysis Technique**	**Studies, n**	**Studies number**
Problem	Problem Description	Qualitative	Document Analysis	Narrative summary	13	All 13
Intervention	Intervention Description	Qualitative	Document Analysis	Narrative summary	12	All except study 4
Context	Context Description	Qualitative	Document Analysis	Narrative summary	10	All except studies 3; 4

Table 11 – Scalability assessment domains for each study.

		Domains for scale-up					**Domains for implementation planning**				
Application Field	**Stage of scale-up**	**Problem**	**Intervention**	**Context**	**Effectiveness**	**Costs & benefits**	**Fidelity & Adaptability**	**Reach & acceptability**	**Setting & workforce**	**Infrastructure**	**Sustainability**
1. Improve health outcomes in a rural area (Hicks et al., 2009)	Pre-scale-up	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No
2. Diabetes (Nundy et al., 2014)	Pre-scale-up	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3. Cystic Fibrosis (Tagliente et al., 2016)	Pre-scale-up	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes
4. Chronic heart failure (Grustam et al., 2019)	Pre-scale-up	Yes	No	No	Yes	Yes	No	No	No	No	No
5. Obstructive sleep apnoea (Lugo et al., 2019)	Pre-scale-up	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6. Secondary prevention of cerebrovascular disease (Padwal et al., 2019)	Pre-scale-up	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes

7. Heart failure (Vestergaard et al., 2020)	Pre-scale-up	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No
8. Gestational Diabetes Mellitus (Lemelin et al., 2020)	Pre-scale-up	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
9. Rural home health agencies (Hansen et al., 2011)	Scale-up	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
10. Chronic obstructive pulmonary (Paré et al., 2013)	Scale-up	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
11. Ischemic heart disease (Zaliūnas et al., 2009)	Implementation	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
12. Heart failure (P. Ware et al., 2018)	Implementation	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
13. Chronic obstructive pulmonary disease (R. Farias et al., 2019)	Implementation	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes

All the studies adopted quantitative research methods to assess clinical outcomes namely surveys or questionnaires (n=10), published databases (n=2), and observations (n=1) (Table 12).

Table 12 – Quantitative research studies involving data analyses using descriptive and inferential statistics for scalability assessment considering the effectiveness domain for scale-up.

Research focus and data collection technique	**Studies, n**	**Studies number**
Clinical outcome assessment		
Observation; published databases	3	[4, 6, and 9]
Non-validated surveys or questionnaires	9	[1, 2, 3, 4, 7, 8, and 13]
Validated surveys or questionnaires	1	[5]
Humanistic outcome assessment		
Non-validated surveys or questionnaires	3	[1, 2, and 11]
Validated surveys or questionnaires	3	[5, 7, and 13]
Satisfaction assessment		
Non-validated surveys or questionnaires	7	[1, 2, 5, 7, 8, 10, and 13]
Validated surveys or questionnaires	1	[11]

To assess humanistic and satisfaction outcomes, the researchers chose surveys or questionnaires; however, for assessing for usage outcomes, they either conducted observations (n=9) or used published databases (n=3). As for validated instruments, only one was used in one study (Lugo et al., 2019) to assess clinical outcomes, namely the Epworth Sleepiness Scale (ESS) (Johns, 1991). For assessing humanistic outcomes, three validated questionnaires were used: EuroQol 5-Dimensions 5-Levels (EQ-5D-5L) (Herdman et al., 2011) in the contexts of heart failure (Vestergaard et al., 2020) and obstructive sleep apnoea (Lugo et al., 2019); Quebec Sleep Questionnaire (QSQ) (Lacasse et al., 2004) for obstructive sleep apnoea; and Chronic obstructive pulmonary disease Assessment Test (CAT) (Jones et al., 2009) for chronic obstructive pulmonary disease (R. Farias et al., 2019). In the context of ischemic heart disease (Zaliūnas et al., 2009), two more validated questionnaires were used: Patient Satisfaction Questionnaire Form III (PSQIII) (Ware et al., 1983) and Thought Control Questionnaire (TCQ) (Wells & Davies, 1994).

For the domains of fidelity and acceptability, quantitative research methods involving observations were more predominantly used as the main data collection methods, as shown in Table 13 and Table 14. Contrarily, for analysing infrastructure, setting, and workforce, most of the studies chose qualitative techniques (n=8).

Table 13 – Studies on scalability assessment concerning the reach and acceptability domain for implementation planning involving data analyses using descriptive and inferential statistics.

Research focus and data collection technique	Data collection technique	Studies, n	Studies number
Acceptability assessment			
Quantitative	Observation	7	[1, 2, 3, 5, 8, 10, 11, and 13]
Qualitative	Semi-structured interviews	1	[9]
Compliance assessment			
Quantitative	Non-validated surveys or questionnaires	1	[12]
Qualitative	Validated surveys or questionnaires	1	[10]
Penetration assessment			
Quantitative	Observation	2	[10 and 8]

Table 14 – Research focus and methods found in the studies for planning.

Research focus and data collection technique	Data collection technique	Data analysis technique	Studies, n	Studies number
Adaptability assessment				
Quantitative	Observation	Descriptive statistics; inferential statistics	1	[5]
Qualitative	Observations; oral history or life stories	Narrative summary	2	[9 and 11]
Feasibility assessment				
Quantitative	Observation	Descriptive statistics; inferential statistics	2	[8 and 12]

When conducting economic evaluation (Table 15), the authors found seven different types of techniques used across 10 studies (see Appendix B for the main results of the studies that conducted economic evaluation of home telemonitoring). The most popular technique was cost-effectiveness analysis used in three studies with different fields of application. These three studies were able to show outcome improvements and cost savings.

Table 15 – Quantitative research studies focusing on data collection using document screening and published databases for scalability assessment considering the costs and benefits domain for scale-up (research focus: economic evaluation).

Data analysis technique	Studies, n	Studies number
Cost analysis	2	[2 and 3]
Cost-benefit	1	[9]
Cost-effectiveness	3	[1, 5, and 8]
Cost minimisation	1	[10]
Cost utility	2	[6 and 7]
Cost-saving simulation	1	[3]

Value of information analysis	1	[4]

Table 16 presents the scalability assessment studies concerning the setting and workforce, infrastructure, and sustainability domains for implementation planning.

Table 16 – Studies on scalability assessment concerning the setting and workforce, infrastructure, and sustainability domains for implementation planning.

Domain and research focus and type	**Data collection technique**	**Data analysis technique**	**Studies, n**	**Studies number**
Setting and workforce				
Setting and workforce assessment				
Qualitative	Observations; oral history or life stories	Narrative summary	8	[2, 3, 5, 6, 8, 11, 12, and 13]
Quantitative	Observation	Descriptive statistics	1	[10]
Infrastructure				
Infrastructure assessment				
Qualitative	Observations; oral history or life stories	Narrative summary	9	[2, 3, 5, 6, 8, 9, 10, 11, and 13]
Qualitative	Semi-structured interviews	Descriptive statistics	1	[12]
Sustainability				
Opportunity and challenge assessment				
Qualitative	Observations; oral history or life stories	Narrative summary	12	All except 12
Qualitative	Semi-structured interviews	Descriptive statistics	1	[12]

5.3.5. Scalability Assessment

All the 13 articles assessed scalability based on the results achieved in the respective studies. Table 17 summarizes the assessments obtained through narrative analysis. On the one hand, two studies provided positive assessments regarding the potential to scale-up the intervention. On the other hand, eight studies highlighted the need for cost-effectiveness or cost-benefit analysis before proceeding to scale-up the intervention.

Table 17 – Scalability assessment based on the authors' conclusions in each study.

Scalability assessment	**Studies, n**	**Studies number**
Not able to be expanded	1	[5]
Able to be expanded, *but* the diffusion and sustainability will depend on a supportive policy environment	1	[2]
Able to be expanded *but* requires cost-benefit analysis for reimbursement planning	3	[4, 6, 9, and 13]
Able to be expanded *but* requires cost-effectiveness analysis	3	[3, 7, and 10]
Able to be expanded *but* requires some technical changes, cost-benefit analysis for reimbursement planning, and solutions for regulatory issues	2	[1 and 11]

Able to be expanded under real-world conditions	2	[8 and 12]

5.4. Discussion

5.4.1. Principal Results

Despite the rapid growth of telemedicine applications in the last few years, particularly after the emergence of COVID-19, scientific studies assessing the scalability of these health interventions are scarce (Kidholm et al., 2012).

In this review, all the eligible studies are from developed countries, particularly the United States and Canada. The absence of such studies in developing countries could be owing to the lack of specialized human resources, ICT infrastructure, and equipment (Combi et al., 2016). Besides, the significant difference found between North America and Europe might be related to the requirement of evidence to justify private payer reimbursement for health care interventions (Whitten & Buis, 2007) or the investment in developing strategies to encourage telemedicine adoption (Gheorguiu & Ratchford, 2015). Nevertheless, this review has not identified studies from countries that invested significantly in telehealth solutions, such as the United Kingdom or Australia (Combi et al., 2016). The justification for this might be the frequent research focus of health interventions on clinical effectiveness (Pare et al., 2007), instead of assessing their scale-up potential. More than half of the studies were published between 2018 and 2020. Thus, this research area is receiving more attention from the scientific community as a logical next step after demonstrating robust evidence regarding the effectiveness and technological maturity of such interventions.

The use of one of the most recent scalability assessment frameworks (Milat et al., 2020) granted the opportunity to compare the strategies used to assess the scale-up potentials of interventions in each study. The advantage of this framework is that it allows the analysis of different domains considering the stage of the transference process of an intervention from a research setting into the practical implementation stage.

This review suggests an agreement in some analysed domains, such as problems, interventions, effectiveness, costs, and benefits, to support the decision to scale-up interventions. However, this is not the case for the methods and instruments used. For example, although cost-effectiveness was the most common approach across the 13 studies, researchers used seven different cost analysis methods. Moreover, to demonstrate effectiveness, studies provided evidence of different outcomes, such as clinical, humanistic, and utilization outcomes. This inconsistency leads to different scalability assessments and does not enable comparing interventions with home telemonitoring technologies.

There is a recognized methodological gap in understanding other relevant domains such as the socio-political context, setting, workforce, and implementation infrastructure to provide the home telemonitoring intervention to the target population. A common framework will allow determining if interventions demonstrated as effective are appropriate and feasible in other settings (Craig et al., 2008; Milat et al., 2020).

Lastly, another relevant result obtained from this systematic review was that researchers assigned different weights to the analysed domains when concluding the intervention scalability. On the one hand, 12 studies concluded their ability to scale- up based on the costs and outcomes of the interventions, although they had analysed other domains. On the other hand, one study restrained the decision to scale-up the intervention based on the policy environment. Future research should address the influence that each domain has on the final decision to scale-up the interventions with sound and transparent methods, avoiding mistakes reported in the literature (Keeney, 1996).

5.4.2. Limitations

This relevant limitation of this review might be associated with the low maturity of this research area, despite its recent growth. Additionally, one database filter concerned peer-reviewed journals, which influenced the rejection of studies with no statistical significance but could have been relevant in this review with respect to the domains and methods used when assessing scalability. This review only considered studies published in English, which might have influenced the number of eligible studies. Moreover, the authors did not conduct a meta-analysis owing to the limited number of studies on this subject. Finally, the domains used to analyse the scalability assessment strategies were predefined, thus limiting the spectrum of domains studied.

5.5. Conclusions

Studies on home telemonitoring interventions integrated into follow-up care have already proved their efficacy. Although some studies focused on including domains such as effectiveness, costs, and benefits, these are not enough to assess the potential of scaling up these interventions. As technology progresses and the need for providing care to more people in their homes increases, it is extremely important to conduct more studies on scalability assessment considering domains such as workforce and infrastructure characteristics and the strategic context.

Future research should establish rigorous study designs and scientific methods to assess scalability based on the results of this systematic review. Further understanding of the usage of health services and medium- and long-term sustainability of interventions would yield more robust evidence to support their future integration into mainstream care delivery systems. This research area, although still emerging, will advance knowledge on the factors that influence the successful scale-up of interventions.

CHAPTER 6 | Collaborative Planning for Scaling Digital Health Intervention: A Participatory Action Research Approach

Chapter 6 presents a case study detailing collaborative planning activities and the crucial roles and contributions of key agents in scaling a digital health intervention. Employing a participatory action research approach with a transdisciplinary team, this chapter illuminates the efficacy of such an approach in providing a thorough comprehension of agents' activities across the design, development, testing, and evaluation stages of a digital health intervention. Furthermore, it emphasizes the importance of considering contextual, technological, and environmental factors in scaling endeavours.

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Azevedo S. contributed to the study design by integrating the Farmer’s Model into the Participatory Action Research approach, conducted both data collection and analysis, and assisted in the preparation of the paper.

6.1. Introduction

The last two decades of research and development (R&D) on remote patient monitoring (RPM) technologies mainly focused on the technicalities of providing care in unusual environments (Vegesna et al., 2017). Although RPM pilot design changes on a case-by-case basis, the system should comprise three components: the care team organization, the technology used, and patient engagement activities (Ferrua et al., 2020). Several pilot initiatives emerged from chronic diseases (Pare et al., 2007) to episodic care [e.g., surgical follow-ups (Vegesna et al., 2017)] to exploit the benefits of RPM, such as, continuity of outpatient care (Baginski et al., 2021), improved healthcare decision-making (Vegesna et al., 2017), complications anticipation (Baginski et al., 2021), and cost reduction (Pekmezaris et al., 2012). In surgical follow-up care, RPM can significantly reduce severe complications and increase patient safety in the most critical period after hospital discharge (Park et al., 2011) by supporting healthcare professionals in the continuous surveillance of clinical and patient-reported outcome measures (PROMs). However, research on implementation is scarce (Farias et al., 2020). In addition, after coronavirus disease 2019 (COVID-19) pandemic outbreak, the increasing demand for RPM-based services to cope with postponing surgeries (Werger et al., 2022) and shifting in-person to remote care

(Mehrotra et al., 2020) drove ongoing pilot initiatives to scale up faster without planning (Doraiswamy et al., 2020). Constrained by time and resources, the design, development, and implementation of the scaled-up services pose risks to the access and quality of care (Gordon et al., 2020).

After COVID-19, some peer-reviewed work focused on RPM implementation and two generated relevant knowledge (Annis et al., 2020; Ferrua et al., 2020). A French case study documents the design methodology used by a multidisciplinary team for an RPM system for cancer care (Ferrua et al., 2020). The authors position the RPM implementation as both a technological and organizational innovation. Therefore, an RPM service is a socio-technical system framed within a local context. The authors also reinforce the collaboration between multidisciplinary groups for proper needs identification. In a rapid implementation of a COVID-19 RPM intervention in the United States of America (USA), a team with industry, healthcare delivery, and academia members repurposed an existing application. Their study revealed an increased patient perception of safety and the emergence of an organizational method of resident and staff rotation (Annis et al., 2020). Nevertheless, both works are context-specific and different from the surgical follow-up context, which is this paper's focus. On top of that, the first work lacks deeper knowledge of how the design, implementation, and evaluation phases are related. The second work had limitations on feature customization, reducing the opportunity to absorb feedback through iterative development cycles.

Scalability and rapid implementation of RPM services require social change and active collaboration between human agents. Therefore, a participatory action research (PAR) approach is needed to support the collaborative development of the technological component while simultaneously implementing and evaluating the RPM service through critical action-reflection cycles (Keahey, 2021). Throughout a research process characterized by nonlinear, recursive cycles of action and reflection, the PAR team characterizes problems in specific contexts, understands the required changes in socio-technical systems, and consequently defines, implements, and evaluates actions to improve practice (Burdette, 1926). There are several expected outcomes from following a PAR approach. For the scope of this paper, the farmer participatory research model (Selener, 1997) highlights some of the most relevant outcomes that can be adapted for the implementation of RPM services: (1) generation and adoption of new appropriate technologies by healthcare professionals and patients to increase RPM uptake in surgical follow-up; (2) better understanding, on the part of researchers, of the existing surgical follow-up service; (3) scientific characterization and understanding of the socio-technical-economics constraints to sustainable RPM care delivery; (4) development of RPM technologies that meet patients and healthcare professionals needs; (5) improved research and technological systems as a consequence of a close collaboration; (6) empowerment by improving healthcare professionals' capacity for self-directed technology development; and finally (7) ability to adapt healthcare systems to changing conditions.

In this paper, we propose a PAR approach to guide researchers, developers, and healthcare professionals in scaling up RPM pilot initiatives and implementing RPM-based surgical follow-up services. Based on a case study in the cardiothoracic surgical department, in a Portuguese public hospital, we analysed feedback from interviews, reports, and meeting minutes from different human agents in the context of three previous different RPM pilot initiatives, to identify and prioritize the features required to efficiently scale up an RPM-based system.

6.2. Methods

6.2.1. Context, procedure, and participants

6.2.1.1. Context

In 2020, in the scope of the COVID-19 pandemic, the Portuguese Foundation for Science and Technology (Fundação Portuguesa para a Ciência e Tecnologia – FCT) launched a tender to support Research and Development (R&D) projects in the areas of data science and artificial intelligence (AI) in Public Administration (FCT, 2022). The main objective was to promote projects that could cope with pandemic-imposed challenges, improve public health services, and support citizens in better decision-making concerning health behaviours. FCT required the participation of at least one public administration entity providing health care committed to using the project results and the R&D activities. Another requirement was to provide a Data Management Plan that preserved the use of data ethical and legal aspects, such as privacy and consent issues in citizens' data access, data sharing across different sources, and transparency of the analysis and utilization. The projects could last 24 to 36 months with a maximum funding limit per project of 240 thousand euros. This tender allocated 3 million euros from a national-based fund budget.

A consortium of four partners working with RPM technologies received approval and funding for a 36-month project, evaluated with 7.3 on a 10-point scale as a "High-Impact" proposal. With a total budget of approximately 240 thousand euros, the main goal was to leverage an ongoing RPM-based follow-up pilot service at the Cardiothoracic Surgery Department of Hospital de Santa Marta, Lisbon, Portugal. The challenge involved consolidating each partner's previous work with RPM technologies to make the system more robust and ready to integrate intelligent and adaptable digital tools that could allow the redesign and value assessment of the RPM surgical follow-up service for at least 150 patients.

6.2.1.2. Procedure

The four partners, familiar with the PAR approach and respective expected outcomes, agreed to conduct this type of research to define and prioritize the development of the RPM platform features. One of the most relevant reasons is its application as a bottom-up research and development strategy for technology transfer (Pine, 2009; Selener, 1997; Sumberg & Okali, 1988) within the hospital walls. More specifically, the PAR approach is very relevant when trying to improve real-world practices because it involves a research team (PAR team) that includes researchers and practitioners who contribute actively with their scientific and practical knowledge in all research procedure phases (Selener, 1997).

This paper describes, using a case study strategy, how and why the PAR team identified features from previous projects and prioritized the development of an enhanced RPM-based platform in a real-world setting when there was no control over contemporary events (Aberdeen, 2013). The case study has been referred to as an appropriate research strategy to enhance the phases and the transitions across the reflection and action phases (Aberdeen, 2013; Hancock et al., 2021). This strategy becomes particularly useful in health services research (Bentley et al., 2014), particularly in this paper, to better evaluate the essential RPM-based follow-up services' features to each relevant human agent and why in the context of cardiothoracic surgery (Wong et al., 2012).

The participatory research process presented in Figure 11 involved four phases that lasted 27 months. The process is an adaption from the cycle described by Pine (Pine, 2009) and the models for Participatory Action Research in Organizations and the Farmer Participatory Research described by Selener (1997). In the following sections, we describe the activities conducted in each phase.

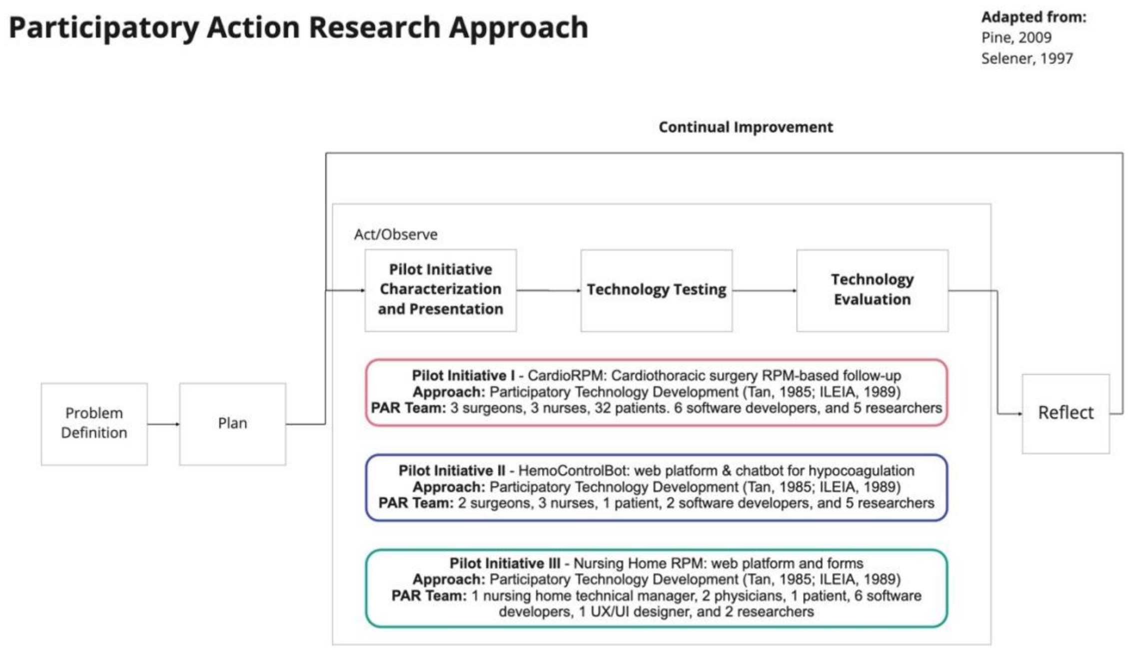


Figure 11 – Participatory research process adapted from Selener (1997) and Pine (2009).

6.2.1.3. Participants

The four partners were categorized into two groups according to the type of organization:

- **Hospital:** Hospital de Santa Marta is a state-owned public Central Hospital serving the Greater Lisbon area as part of the Central Lisbon University Hospital Centre (CHULC). It is one of the Country's leading Internal Medicine schools and one of Portugal's main reference centres for diagnosing and treating cardiovascular disease (Centro Hospitalar Lisboa Central, 2022).
- **Research Laboratories:** One of the research laboratories focuses on applied and project-oriented research in technology development for predictive, preventive, personalized, and participatory medicine (Fraunhofer, 2022). The second research laboratory focuses on supporting, developing, and fostering clinical, public health, and health services research (NOVA Medical School, 2022). The third research laboratory focuses on validating innovative methodologies to measure outcomes and costs and provide trustful scientific evidence under Value-based Healthcare principles (Value for Health CoLAB, 2022).

Each partner was responsible for selecting the PAR team participants and classifying the members' roles according to their interests in the research process without requiring a minimum number of participants. The team was composed of 12 members split according to three role types (act as a proxy for the human agents' groups):

- **Researchers:** the main interest of this group was to conduct research to generate and contribute knowledge to their scientific area. The research laboratories selected six researchers based on their expertise in digital health services design, digital health literacy, cost analysis, and previous relationship with the healthcare professionals team.
- **Developers:** the main interests of the developers include designing, programming, building, deploying, and maintaining features through the use of different skills and programming tools. The research laboratories selected six software developers based on their skills in AI and software development and previous relationship with the healthcare professionals' team.
- **Healthcare professionals (end-users):** the main interest of healthcare professionals was to use technology to enhance their performance and provide high-quality patient care. In the context of the proposed technological solution, the end-users are physicians and nurses of the Cardiothoracic Surgery service selected by the service's director. Therefore, the PAR team included three physicians and three nurses to collaborate with the developers and researchers to solve RPM-related problems. They were selected based on their previous relationship with researchers and developers and expertise in RPM-based follow-up services.

6.2.2. Problem definition phase

The Problem Definition Phase aimed to clarify the problem and involved three activities at two different moments: the first at the time of the grant proposal writing and the second, in a 90-min video conference group meeting, after the grant award notification. The activities for the problem formulation are the ones suggested in Design Science Research: precise problem definition, problem positioning and justification, and root causes identification (Johannesson & Perjons, 2021).

The grant proposal writing included two activities. First, the PAR team conducted a literature review of academic publications (fields of cardiothoracic surgery, AI and data science, and decision support systems engineering). The team defined the problem through online collaboration using a web-based word processing application because it allows keeping track of changes and comments. To formulate the problem more precisely, the team used the web application to leave comments with feedback on others' contributions. The final version of the problem was: in the COVID-19 pandemic context, characterized by a high demand for remote care to avoid infection, there is limited access to RPM-based surgical follow-up services.

The second activity aimed to position and justify the problem so the different PAR groups could engage in the proposal writing. Therefore, each group consolidated their perceived reasons for the problem to be relevant. The PAR team's opinions of why the problem is significant and to whom can be split into two human agents' groups: (i) Healthcare professionals and providers and (ii) Software developers and Researchers. On the one hand, the first group contextualized the problem as an obstacle to providing treatment to a larger sample of patients while maintaining essential high-quality healthcare using RPM and transferring the acquired knowledge and technology to other surgical follow-up services. "*(Senior Surgeon) stressed that the objectives are to continue and expand the monitoring of patients undergoing cardiothoracic surgery and that this monitoring can be extrapolated to other units.*". On the other hand, the second group positioned the problem considering its scalability and the need to implement a clinical study with real-world evidence to analyse the costs and benefits of a generalized RPM service. "*(Senior researcher) mentioned that it could be interesting in making the RPM platform available for other problems.*"

After the grant award notification, during the project kick-off session, the PAR team focused on finding the root causes of the problem. The meeting was planned to last one hour, and all PAR team members were invited. Due to COVID-19 constraints, the meeting occurred via a video-based communication platform. To guarantee that the researchers were seen as colleagues, there was no moderator (Selener, 1997). There was only a note-taker, which was randomly assigned at the beginning of the meeting. The note-taker (Johannesson & Perjons, 2021) wrote down all mentioned root causes, which were analysed by the researchers using content analysis (Krippendorff, 2013). Finally, the root causes were represented using an Ishikawa diagram (Mind Tools, 2022). Additional details on the root causes and respective categories of the defined problem are described in the Ishikawa diagram (Appendix C).

6.2.3. Planning phase

As mentioned in the context subsection, the PAR team had to identify features from previous projects and prioritize the development of a more robust RPM-based platform capable of integrating AI-based and value assessment tools. Therefore, the planning phase aimed at promoting the discussion on the required actions to reach two objectives: (i) decide which pilot initiatives should be investigated for feature extraction; (ii) define the data collection and analysis plan for features' characterization, evaluation, and prioritization, and reflection on the PAR approach performance.

The PAR team planned one 60-min video conference meeting to achieve these goals. The study selection was based on three inclusion criteria: the project followed a participatory approach, involving at least one of the four partners, who had the ownership of the intellectual property rights.

The researchers used Table 18 to guide the rest of the team in deciding on the appropriate data sources and collection and analysis methods to answer the research questions associated with each pilot initiative characterization. In this phase, 10 PAR team members met in one meeting, which lasted approximately one hour. The two main results of this phase are: the list of pilot initiative studies to extract features and the data collection and analysis plan to characterize each pilot initiative and respective features (Table 19); and the data collection and analysis plan to evaluate and prioritize each feature and reflect on the PAR approach performance.

Table 18 – Research questions and the respective data collection and analysis methods.

Research question (RQ)	**Data collection methods**	**Data analysis methods**	**Literature examples**
RQ_1 – What are the most important features of RPM-based follow-up services for patients?	Interviews, Reports	Transcription and Grounded Theory, Content Analysis	(Douglas et al., 2010)
RQ_2 – What are the most important features of RPM-based follow-up services for healthcare professionals?	Meeting minutes, Reports	Content Analysis	(Granström et al., 2020)
RQ_3 – What are the topics and focus of the interactions among PAR team members while defining the requirements and features for a new solution?	Meeting minutes, PAR team data	Content Analysis, Descriptive Statistics	(van Tol et al., 2021)
RQ_4 – What is the type and frequency of contribution from each PAR team role?	Meeting minutes, PAR team data	Content Analysis, Descriptive Statistics	(Johannesson & Perjons, 2021)
RQ_5 – How requirements and features definition is described by the PAR iterative cycle?	Meeting minutes	Content Analysis	(Selener, 1997)

The PAR team decided that for each pilot initiative, the features should be presented, tested, and evaluated in web- based or in-person (hospital visits) group meetings. They also agreed to use meeting minutes to report participants’ observations and to use content analysis to support the decision of the final list of features and the evaluation of the PAR approach using content analysis (Appendix C). The format of the group meeting was also a result of the planning phase. At the beginning of each session, the researcher responsible for writing the minute asked for the consent of the participants to take notes on the interventions made by the participants and their respective reactions to the team. At the end of the meeting, the researcher read the out loud minute, requested approval, and proposed a date and agenda for the following meeting.

Table 19 – List of pilot initiatives and respective data collection and analysis plan.

Pilot Initiative	**Data collection methods (data analysis methods)**
1 – CardioRPM: Patient follow-up after cardiothoracic surgery	Video-recorded in-person semi-structured interviews (grounded theory) Meeting minutes (content analysis) Reports (grounded theory) PAR team data (descriptive statistics)
2 – HemoControlBot: Oral anticoagulation therapy management	Phone call-based semi-structured interviews (grounded theory) Meeting minutes (content analysis) PAR team data (descriptive statistics)
3 – NursingHomeRPM: Remote care delivery in nursing homes	Meeting minutes (content analysis) Reports (grounded theory) PAR team data (descriptive statistics)

6.2.4. Action/observation phase

This phase involved two main activities through several not pre-planned group meetings: (i) the researchers characterized and presented the pilot initiative, its resulting features, and respective end-users feedback evaluation; and (ii) the PAR team tested and evaluated the features.

In the first activity, the researchers described the pilot initiative goal, deployment site, targeted population, previous and new intervention, RPM period, RPM collected outcomes, responsible team, the technology used, pilot activities, pilot duration, end-users involved, and end-users feedback data collection methods. For each identified feature, the researchers presented its originator, and end-users' feedback. This information was obtained through content analysis of internal and external reports and minutes, and grounded theory analysis of interview transcripts. Internal and external reports were used to record activities execution, bugs and issues identified, and consolidate generated knowledge. Two researchers read each report, extracted all the relevant information, and combined it in a spreadsheet. For each information extracted, the researcher recorded the report date, author, and role. Similarly, all minutes' observations were copied to spreadsheets, one spreadsheet per meeting. For each observation extracted, the researcher recorded the author. A defined in the planning phase, minutes and reports were coded according to the categories (topic, focus, interaction, reaction, outcome, and agent) described in Appendix C.

In two pilot initiatives, semi-structured interviews were used to collect patient emotions, attitudes, opinions, and experiences through two different formats: video recording and phone calls. For both, there was one researcher that transcribed each interview in Portuguese. The grounded-theory method was used and included three rounds (Glaser & Strauss, 2010). In the first round, two researchers coded the interviewer's and interviewee's quotes as units of text to identify the most frequently covered themes. The researchers combined the emerging themes (feedback on existing features, improvements and new ideas, generated learning, proof of acceptance, and reflections) according to their similarity and deleted the duplicates. The output of the second round allowed the researchers to define a list of possible values for each theme. The third and final round allowed the researchers to code each unit of analysis according to Appendix C. In the three rounds, when disagreements occurred, the authors reached a consensus via discussion.

The PAR team tested and evaluated the features in the second and final activity. For each feature, the team assessed the required effort, type of changes, and value for the end-user. The format and analysis of the group meetings followed the configuration and data analysis methods agreed on during the planning phase. It is crucial to notice that the presentation, testing, and evaluation occurred cyclically per feature or set of features. However, we present the features' evaluation per pilot initiative to demonstrate the results better.

6.2.5. Reflection phase

The reflection phase involved several not pre-planned group meetings to define the final set of features and prioritize the development based on reflections on (i) the pilot initiative participatory level assessment; and (ii) the team's evaluation of each feature. The participatory level assessment in each pilot initiative consisted of descriptive statistics of the type and level of participation and representation of each human agent group. The team used the MoSCoW (must have, should have, could have, and will not have this time) prioritisation method (Clegg & Barker, 1994) to help define agile and fast development sprints based on the previous reflections (Miranda, 2022). When disagreements occurred, the PAR team reached an agreement via discussion, considering time and budget constraints and expected outcomes. Finally, the team reflected on the PAR approach performance through descriptive statistics of the meeting minutes content analysis concerning the number of participants and contributions made per phase, focus, topic, and research outcome more frequently referred per phase.

6.3. Results

The next subsections describe the results obtained in the two main phases of the PAR approach in the context of this work: action and reflection.

6.3.1. Action/observation phase

This phase involved 11 meetings with an average participation of nine PAR team members and a duration of 44 min (8 h and 5 min in total). Each pilot initiative followed an iterative development approach illustrated in Appendix C, the corresponding study was approved by each deployment site's ethical committee, and all participants signed informed consent.

The first pilot initiative refers to the RPM follow-up pilot service that the PAR team proposed to leverage in the scope of the funded project (Textbox 3).

Textbox 3 – Pilot initiative 1: CardioRPM: Patient follow-up after cardiothoracic surgery (Londral et al., 2021)

Motivation: The healthcare professionals from the cardiothoracic surgery needed to automatize health-related outcomes collection during the follow-up period after cardiothoracic surgery.

Goal: Digitize the follow-up service of patients after cardiothoracic surgery.

Deployment Site: Hospital de Santa Marta, Lisbon, Portugal.

Population: Cardiothoracic surgery patients.

Previous intervention: The standard follow-up version of this service consisted of phone calls to the patient at three days, one month, three months, six months, and 12 months after the hospital discharge.

New intervention: The responsible surgical team proposed the integration of IoT devices to monitor patients remotely in the comfort of their homes during the first month after surgery to detect problems and avoid acute problems early.

RPM Period: 30 days.

RPM Outcomes Measurements: 11 in total: blood pressure and heart rate, weight, number of steps, the occurrence of blackouts, perceived alterations in surgical wound healing, picture of the surgical wound, presence of palpitations, presence of edemas, presence of dyspnea, chest pain intensity level.

Responsible Team:

- Nurses: total 3 (3 female, average age of 48 + 4:9 years old);
- Physicians: total 3 (2 male, average age of 49:5 + 18:5 years old);
- Developers: total 4 (1 female and 3 male, average age of 29:5 + 3:6 years old);
- Researchers: total 5 (4 female and 1 male, average age of 35:2 + 10:4 years old) with expertise in digital health services design, digital health literacy, and cost analysis.

The technology used: The surgical team agreed with the existing version of the IoT kit, which includes a weight scale, blood pressure monitor, smart wristband, and an Android smartphone.

Pilot activities: A mobile application allowed patients to report outcomes through four (Yes/No) questions survey and two 4-point Likert scale questions, and a smartphone camera, and collect automatically clinical parameters from the IoT devices.

Pilot duration: The mobile application and the IoT devices' main development was conducted in the context of heart failure and served as a basis for a customized version for this pilot. The team worked together to create an RPM platform that could ensure interoperability with the existing mobile application and IoT devices.

Pilot Duration: February 2019 to January 2021 (22 months).

End-users involved:

- Patients: total 35 (18 male and 17 female, average age of 59:9 + 13:4 years old);
- Nurses: total 24 (2 male and 22 female);
- Physicians: total 3 (3 male).

End-users feedback data collection methods: On the last day of the follow-up period, the patient replied to a service satisfaction survey and provided feedback on the overall experience through a video-recorded semi-structured interview.

Therefore, the motivation, goal, deployment site, digitization model, and groups of end-users are the same. The main difference is the new project's requirement of covering at least 150 patients. The pilot initiative 1 characterization resulted in nine features (Table 20) which are: (1) outcome collection using a mobile app connected to IoT devices; (2) outcome collection using smartphone camera; (3) RPM-based therapy management; (4) web-based RPM care management platform; (5) outcome-based automated alerts; (6) RPM dynamic table; (7) RPM activities management and resource allocation monitoring; (8) an integrated ticket reporting system; and (9) periodic data fetching. The PAR team evaluated the first eight providing the most value for the end-users (patients, nurses, and physicians) since the patient, nurse, and physician feedback was very positive. Finally, the ninth feature was excluded because there was a need to have data available more frequently. The features of outcome collection using a smartphone camera, web-based RPM care management platform, and RPM activities management and resource allocation monitoring were evaluated has requiring major changes and, consequently, high effort, because of the integration of AI-based tools for optimal follow-up resources prediction based on patient risk stratification.

Table 20 – List of features of pilot initiative 1.

Feature (originator)	**Utilization feedback**	**HP feedback (N)**	**Patient feedback (N)**	**PAR team evaluation**
1 – Outcome collection using a mobile app connected to IoT devices (Physicians)	On average, a patient answered 92.9% of the questionnaires.	Suggestion to add a new PROM question (1); Suggest that answers should cope with intermediate improvements (4); Suggest improvements to instructions (2)	Patient/caregiver share that measuring the outcomes were part of his/her daily routine (8); Good, but found some problems/ challenges (12); Did not like it or could not use it, due to problems (2) Suggest that answers should cope with intermediate improvements (3); Suggest improvements to instructions (2)	Minor changes, low effort, high value
2 – Outcome collection using smartphone camera (Nurses)	Average number of pictures sent from the patient is 44.	Good, but found some problems/ challenges (2)	Good, but found some problems/ challenges (6); Did not like it or could not use it, due to problems (3)	Major changes, high effort, high value

3 – RPM-based therapy management (PAR team)	Total number of messages sent to patients: 300	Suggestion to add a new feature (1)	No feedback recorded	Minor changes, low effort, high value
4 – Web-based RPM care management platform (PAR team)	27 registered accounts; average session time of 9 min and 45 s	Suggest improvements (6)	Patient/Caregiver highlights the perceived support he/she got from the HCP (13); Patient/Caregiver recommends the RPM service to other patients (12); Having access to high-quality remote care delivery at the comfort of home (10)	Major changes, high effort, high value
5 – Outcome-based automated alerts (Nurses)	No metric recorded	Suggest improvements (6)	Having access to high-quality remote care delivery at the comfort of home (10); Patient/Caregiver highlights trusting in the system because of HCP calls (9); Being able to recover in a safe and friendly environment (8)	Minor changes, low effort, high value
6 – RPM dynamic table (Nurses; Developers)	No metric recorded	Suggest improvements (2)	No feedback recorded	Minor changes, low effort, high value
7 – RPM activities management and resource allocation monitoring (Physicians; Researcher; Developers)	Total number of clinical actions and notes reported: 242	Suggest improvements (2)	No feedback recorded	Major changes, high effort, high value
8 – An integrated ticket reporting system (Developers)	0 tickets recorded	No feedback recorded	No feedback recorded	Minor changes, low effort, high value
9 – Periodic data fetching (Developers)	No metric recorded	No feedback recorded	No feedback recorded	Excluded

The second pilot initiative refers to another RPM follow-up pilot service in the same hospital and surgical department as the funded project (Textbox 4). This case was selected because part of the population submitted to cardiothoracic surgery might require oral anticoagulation therapy in the long term. Therefore, understanding the technological features to provide continuous care to these patients is relevant.

Textbox 4 – Pilot Initiative 2: HemoControlBot: Oral anticoagulant therapy management (Dias et al., 2022)

Motivation: A private medical device company needed to demonstrate the added value of the coagulometer when integrated into an RPM service.
Goal: Digitize the oral anticoagulation therapy management after cardiac surgery.
Deployment Site: Hospital de Santa Marta, Lisbon, Portugal.

Population: Patients under oral anticoagulation therapy after cardiac surgery.
Previous Intervention: The standard oral anticoagulation therapy involves frequent patient visits to the hospital to measure the International Normalized Ratio (INR) value to assess the blood's ability to clot. Based on this and other relevant outcomes, the physician adjusts medication to avoid the risk of bleeding.
New Intervention: The responsible surgical team and a private medical device company proposed the combination of a coagulometer and a mobile text message-based RPM system to allow patients to report remotely therapy-relevant outcomes.
RPM Period: 180 days.
RPM Outcomes Measurement: seven in total: INR, the dosage of antibiotic and anti-inflammatory drugs, the occurrence of bruises, hemorrhages, feces, nausea, and the number of trips to the hospital or health center.
Responsible Team:

- Nurses: total 3 (3 female, average age of 42 + 10:5 years old);
- Physicians: total 2 (2 male, average age of 42 + 15:6 years old);
- Developers: total 2 (2 male, average age of 26 + 1:4 years old);
- Researchers: total 5 (2 male, average age of 36 + 11:6 years old) with expertise in digital health services design and cost analysis.

The technology used: The surgical team demanded that the RPM system should not be dependent on the type of mobile phone to increase accessibility. Therefore, patients reported the outcomes by answering seven 4-point Likert scale questions via the lowest cost communication channel, i.e., short message service (SMS).
Pilot Activities: The team worked together to create an SMS-based RPM platform that automatically generates SMSs asking the patient to report the required outcomes.
Pilot Duration: December 2019 to June 2022 (7 months).
End-users involved:

- Patients: total 19 (9 male and 10 female, average age of 53:1 + 12:5 years old);
- Physicians: total 2 (2 male).

End-users feedback data collection methods: On the last day of the follow-up period, the researcher conducted a phone call-based semi-structured interview to collect the patient's feedback, considering the interaction with technology and the overall experience.

The pilot initiative 2 characterization resulted in four features (Table 21), which are: (1) outcome collection using a mobile-based chatbot; (2) RPM-based therapy management using chatbot; (3) surgical team alert email notification; and (4) instant data availability. The PAR team evaluated the second and fourth features providing the most value for the end-users (physicians) since the physician feedback was very positive. The first feature was assessed as low value as the IoT devices were already selected as the channel to collect the outcomes. In addition, the third feature was also evaluated as low value since physicians and nurses had to assess the patient's RPM data daily.

Table 21 – List of features of pilot initiative 2.

Feature (originator)	**Utilization feedback**	**HP feedback (N)**	**Patient feedback (N)**	**Evaluation**
1 – Outcome collection using a mobile-based chatbot (Physicians)	Total of questionnaires replied (231); Total number of questionnaires replied on average per patient (12.2)	Good, but found some problems/challenges (6)	Good, but found some problems/challenges (5); Did not like it or could not use it, due to problems (1); Patient totally agreed that he/she felt well supported with this service (7); Patient totally agreed that the service interferes with patient's daily routine (3); Patient totally agreed that the service should be recommended to people with a health condition similar to his/her (8); Patient totally agreed that he/she was satisfied with this service (8)	Major changes, high effort, low value
2 – RPM-based therapy management using chatbot (Physicians; Developers)	Total prescriptions (206); Total prescriptions on average per patient (10.8); Total of questionnaires requested (239); Total number of questionnaires requested on average per patient (12.6)	Good, but found some problems/challenges (7); Good, did not find problems/challenges (2)	No feedback recorded	Minor changes, low effort, high value
3 – Surgical team alert email notification (Developers)	Total of emails generated (231); Total number of mails generated on average per patient (12.2)	Good, did not find problems/challenges (1)	No feedback recorded	Minor changes, low effort, low value
4 – Instant data availability (Developers)	Median time elapsed between the question and the answer was 12 min	Good, did not find problems/challenges (1)	No feedback recorded	Major changes, high effort, high value

The third pilot initiative refers to an RPM follow-up pilot service conducted by one of the partners of the PAR team in the scope of the COVID-19 pandemic (Textbox 5). The main similarity between the pilot initiative and the funded project was the isolation context of the target population during follow-up. The second similarity consists of adapting existing technology to the needs of an elderly population, maximizing user interaction and experience.

Textbox 5 – Pilot initiative 3: NursingHomeRPM: Remote care delivery in nursing home (EasyHealth4Covid, 2021)

Motivation: Portugal 2020 funded research and development projects for testing and optimization of technological infrastructures in the context of COVID-19.

Goal: Digitize the care provided in a nursing home during the COVID-19 pandemic with each partner's existing technology.

Deployment Site: Private nursing home, Cascais, Portugal.
Population: Nursing home residents.
Previous Intervention: The standard care provided in the nursing home required formal caregivers to register physical needs, including personal hygiene or grooming, dressing, toileting, transferring or ambulating, and eating in a notebook.

New Intervention: The digital transformation consisted of developing and implementing a mobile application that could connect with IoT devices to monitor its residents.
RPM Period: 30 days.
RPM Outcomes Measurements: seven in total - blood pressure, temperature, blood oxygen levels, blood glucose levels, daily mood tracker, ability to conduct activities of daily living, and quality of life.
Responsible Team:

- Nursing Home Professionals: total 1 (1 male, age of 45 years old);
- Physicians: total 1 (1 female, age of 45 years old);
- Developers: total 8 (3 female and 5 male, average age of 34 + 8:9 years old);
- Researchers: total 3 (2 female and 1 male, average age of 32:3 + 10:7 years old) with expertise in digital health services design, digital and cost analysis;
- User Interaction/User Experience (UX/UI) designer: total 1 (1 female, age of 30 years old).

The technology used: The developers proposed an existing IoT kit to be used in the nursing home to collect outcomes, which includes an oximeter, blood pressure monitor, thermometer, glucometer, and an Android tablet. A mobile application allowed nursing home staff to report outcomes through several (Yes/No) questions survey and 4-point Likert scale questions, automatically collecting clinical parameters from the IoT devices.
Pilot Activities: The team worked together to create an RPM platform with multiple user roles (manager, physician, nurse, informal caregiver, and patient) to collect patient outcomes.
Pilot Duration: June to November 2020 (5 months).
End-users involved:

- Patients: total 10 (5 male and 5 female with an average age of 81:0 + 8:0 years old);
- Physician: total 1 (1 female);
- Nurses: total 1 (1 male);
- Nursing Home: 1 director (male), 6 staff (6 female).

End-users feedback data collection methods: User experience and interaction testing sessions were conducted with the nursing home director, one staff member, and one nursing home resident.

The pilot initiative 3 characterization resulted in four features (Table 22), which are: (1) outcome collection using a mobile app connected to IoT devices; (2) RPM-based therapy management; (3) interoperability using FHIR; and (4) role definition. The PAR team evaluated the first three providing the most value for end-users (Nursing Home director and physicians) since the director and physician considered as a must-have requirement. Although the fourth feature was considered to provide moderate value, the PAR team considered that it required significant changes and high effort to develop.

Table 22 – List of features of pilot initiatives 3.

Feature (originator)	**Utilization feedback**	**NH quotes**	**Evaluation**
1 – Outcome collection using a mobile app connected to IoT devices (Developers)	The total percentage of questionnaires replied was 35.1%.	**Nursing Home Director**: "*does not recommend presenting past data, senior is interested in how it is now. The "Start" button comment could be larger and colored green*" **Nursing Home Director:** "*add interaction with smileys when the quiz is completed/gamification.*" **Nursing Home Director and Physician**: "*To avoid errors in the measurement of signals, the Protocol should be the same for all Users, that is, all sensors must be used by all Users that will participate in the pilot, except those referring to methods invasive, for example capillary blood glucose, which should be exclusive to Patients with Diabetes.*"	Minor changes, low effort, high value
2 – RPM-based therapy management (Nursing Home Director)	No metric recorded	**Nursing Home Director:** "*The most difficult thing for us is to manage the medication prescribed by the physician. During this time (COVID) the physician calls us and reviews the medication prescribed to all seniors. What I do is to write it down on a table and then I put the paper on the wall so the staff don't forget to give the right medication to each senior.*"	Minor changes, low effort, high value
3 – Interoperability using FHIR (Developer)	No metric recorded	No feedback recorded	Major changes, high effort, high value
4 – Role definition (Nursing Home Director)	No metric recorded	**Nursing Home Director:** "*Each assistant must end their session as the tablet is shared.*"	Major changes, high effort, moderate value

6.3.2. Reflection phase

This phase involved five meetings with an average participation of eight PAR team members and an average of 42 min (3 h and 30 min in total).

6.3.2.1. Pilot initiative participatory assessment and features prioritization

An overview of Figure 12 reveals that the participation level according to each group was Developers (33.1%), Researchers (31.5%), Physicians (17.1%), Nurses (15.0%), and Patients (3.2%). The Researchers played the leading role in the *Problem Definition* and *Planning phases* (73.9% and 58.3%, respectively). In the *Action* and *Observation phases*, the Researchers group was the most participating group (34.3% and 53.9%, respectively). Finally, in the *Reflection phase*, the most participating role was the Nurses (34.2%). A more detailed analysis of each pilot initiative informs that the Researchers participated more in the first pilot initiative (39.7%), Developers and Physicians share the first position in the second pilot initiative (29.4%), and the Developers in the third pilot initiative (45.8%). In contrast, the patients were only present, with minor participation, in the first and third pilot initiatives (5.5% and 4.5%, respectively). In the first pilot initiative, the *Reflection phase* was the phase with the highest participation roles diversity, and the *Planning phase* was the lowest. In the second pilot initiative, the *Problem Definition*, *Action*, and *Observation* were the phases with the highest participation roles diversity. Finally, the third pilot initiative had no participation in *Planning* and *Observation phases* and the highest participation role diversity in the *Action phase*.

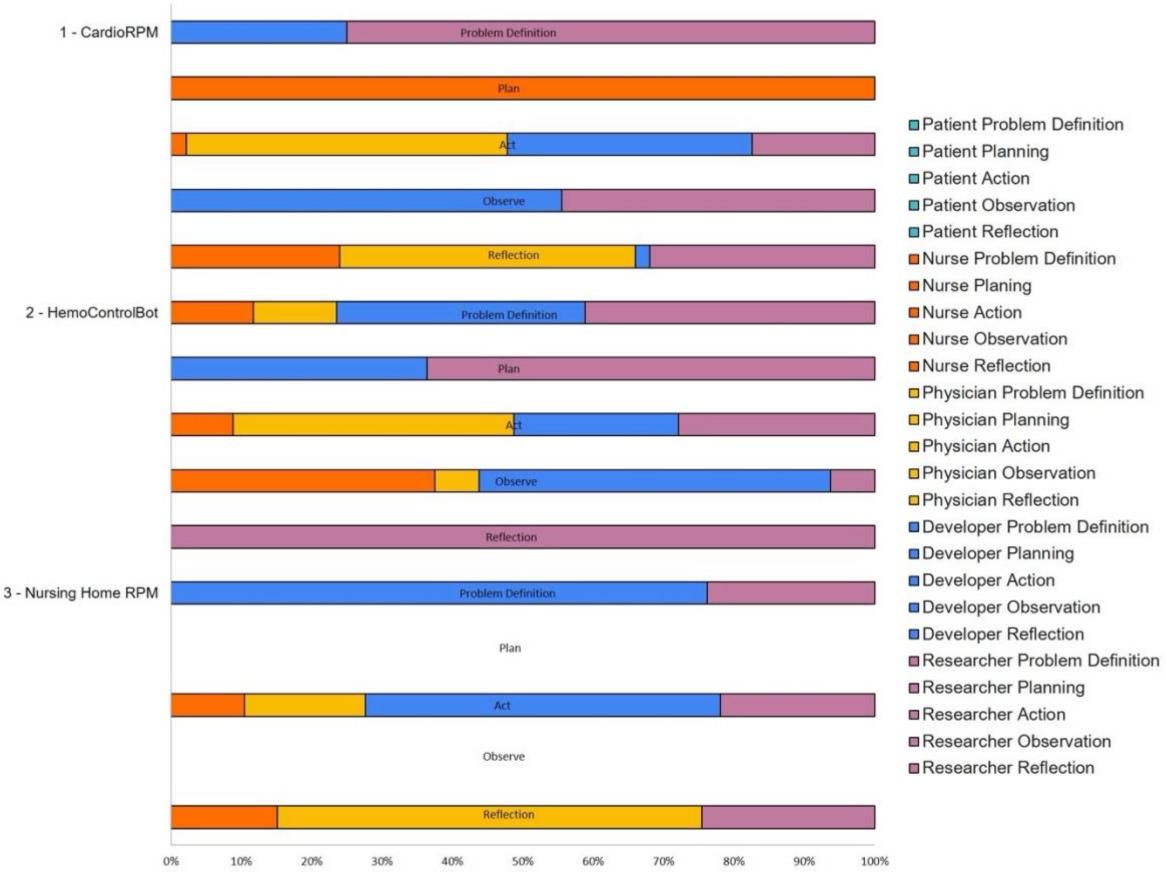
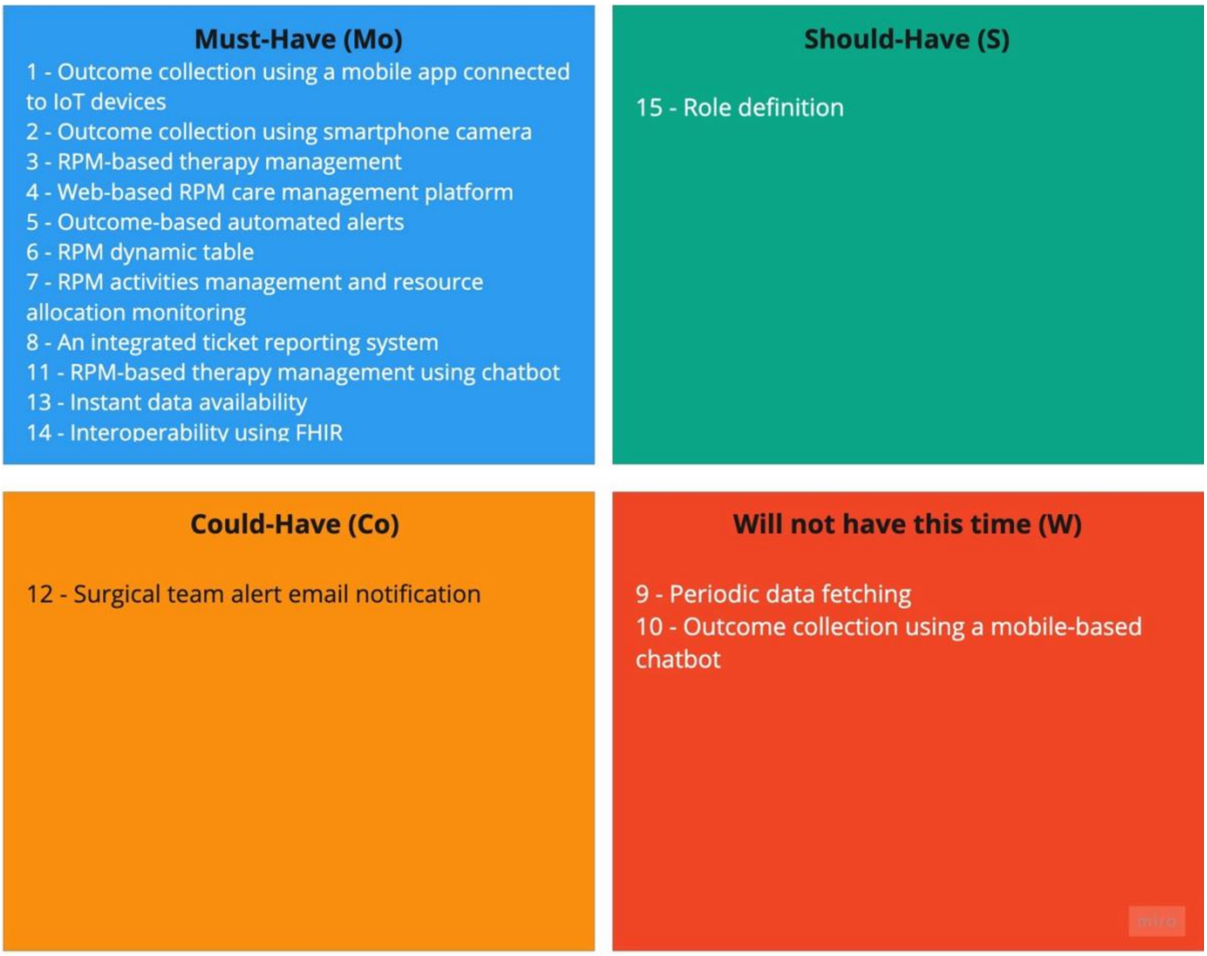


Figure 12 – Level of participation of each team role per PAR phase per pilot initiative.

From the three pilot initiatives the PAR team extracted 15 features and classified 11 as *Must-Haves*. Figure 13 illustrates the feature prioritization for development. All the features classified with high value for the end-users were prioritized as *Must-Have* on the enhanced version of the RPM-platform. The feature of *Role definition* was prioritized as *Should-Have* because although it was evaluated as a moderate-value feature, it implied significant changes and, consequently, high effort to implement. In contrast, the email notification feature was prioritized as *Could-Have* because although it imposes lower changes and minor effort, it was evaluated to bring low value to the end users.



Must-Have (Mo)
1 - Outcome collection using a mobile app connected to IoT devices
2 - Outcome collection using smartphone camera
3 - RPM-based therapy management
4 - Web-based RPM care management platform
5 - Outcome-based automated alerts
6 - RPM dynamic table
7 - RPM activities management and resource allocation monitoring
8 - An integrated ticket reporting system
11 - RPM-based therapy management using chatbot
13 - Instant data availability
14 - Interoperability using FHIR

Should-Have (S)
15 - Role definition

Could-Have (Co)
12 - Surgical team alert email notification

Will not have this time (W)
9 - Periodic data fetching
10 - Outcome collection using a mobile-based chatbot

Figure 13 – Diagram of the features of the three previously developed pilot initiatives. Each category is represented with a letter and a color: must-have – Mo (blue), should-have – S (green), could-have Co (yellow), and will not have this time – W (red).

6.3.2.2. Evaluation of the PAR approach

The top three topics most covered across the phases were *Design* (39.7%), *Development* (22.2%), and *Execution and Implementation* (18.5%). The top three meeting focus were *Data Analysis Framework Requirements* (23.4%), *Study Protocol Writing* (16.6%), *Modelling and Simulation* (15.6%). The top three meeting outcomes contributions were: *Improved research and development system* (35.0%), *Better characterization and understanding of the complex socio-technical-economic constraints to sustainable software development production and care service provision* (25.2%), and *Better* *understanding, on the part of researchers, of systems used by healthcare professionals and patients* (22.0%). The participation level according to each role in the meetings was: Researchers (52.9%), Developers (47.5%), Physicians (46.7%), and Nurses (5.8%). The top three contributions of the participants involve suggesting or planning actions (42.2%), sharing, or generating knowledge (22.4%), and discussing the solution (13.5%). Figure 14 exposes the most frequent type of contribution by each PAR team role. Physicians, Researchers, and Developers suggest and plan more actions (44.2%, 39.1%, and 47.8%, respectively), while Nurses are more dedicated to share and generate knowledge (71.4%). The participation level according to of each role in the meetings was: Researchers (52.9%), Developers (47.5%), Physicians (46.7%), and Nurses (5.8%).

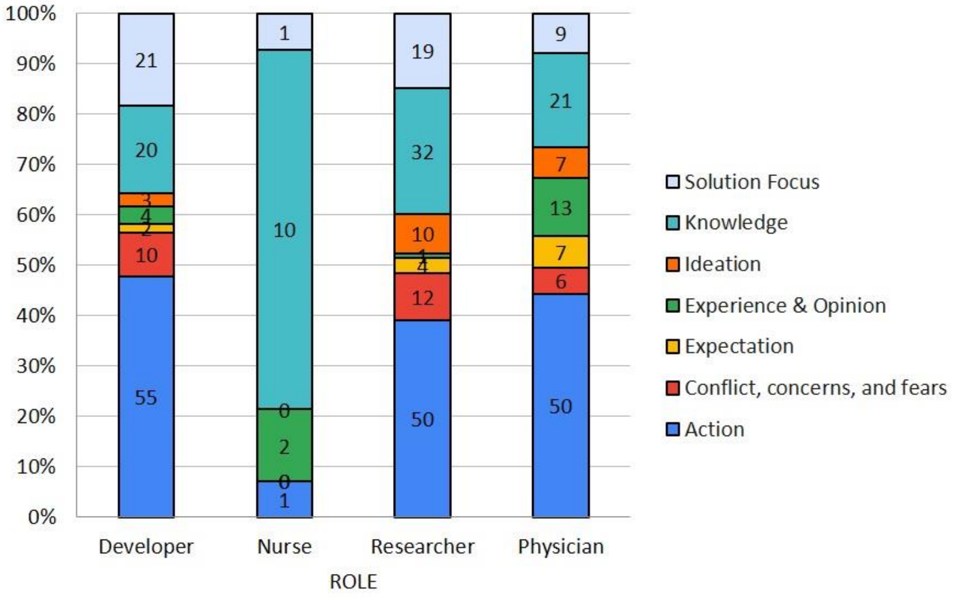


Figure 14 – Different contributions according to PAR team role.

The approach involved two action-reflection cycles illustrated in Figure 15. In this figure, it is also illustrated the distribution of the meetings per phase to define the final list of features and prioritize the development. Most of the meetings were dedicated to the *Action phase* (9 meetings), followed by the *Reflection Phase* (5 meetings), *Observation* (2 meetings), and *Problem Definition* (1 meeting) and *Planning* (1 meeting).

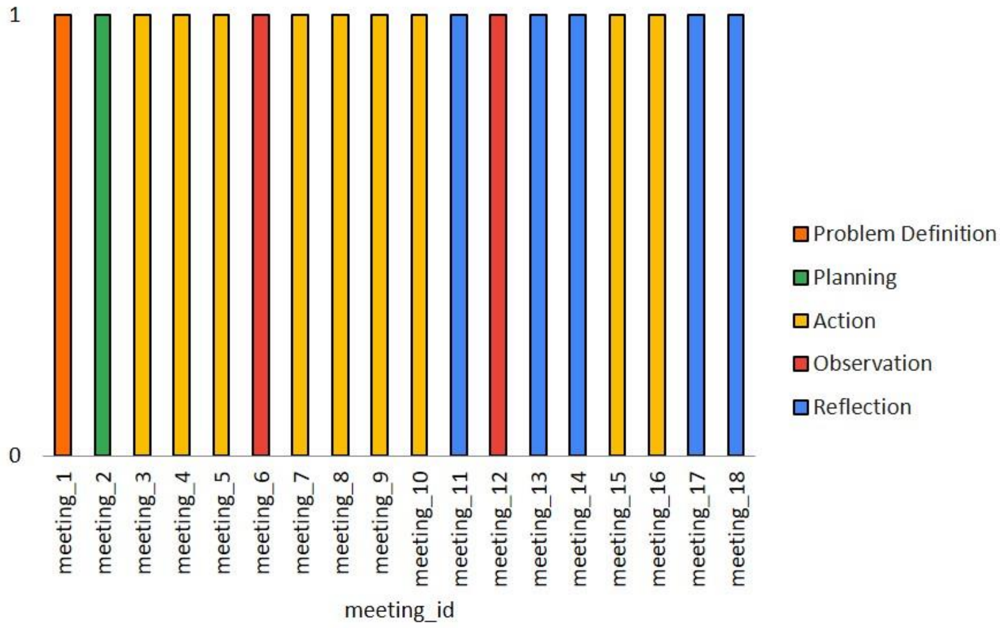


Figure 15 – Distribution of meetings per phase.

6.4. Discussion

The proposed RPM-based platform (Appendix C) is the result of a PAR approach and comprises features suggested, tested, and evaluated by different relevant human agents, from end-users, such as patients and healthcare professionals, to software developers and researchers. These features make the platform more robust and ready to integrate value assessment and AI-based decision support tools to increase access to RPM surgical follow-up care in pandemic contexts.

The PAR project was initiated by a consortium of partners, funded by a Portuguese national research agency, that aimed to ensure that the following cycle of technological development would allow the provision of care to a larger and diversified sample of patients in a public hospital. Therefore, patients and healthcare professionals had to be part of the research process so that their needs were not compromised at the expense of scalability (Kvedar & Fogel, 2017). Problem definition and context characterization are two important domains usually neglected by researchers in scalability assessment (Azevedo et al., 2021). The most important features for the patients were the outcomes collection using a mobile application, smartphone camera, and IoT devices, outcome-based automated alerts, and the web-based RPM care management platform. Patients refer to these features by highlighting how they changed their daily routines to provide information to physicians and nurses and how the latter called them every time the outcome values were not the ones expected. In addition to the patient-preferred features, physicians also showed a preference for the feature of RPM dynamic table and RPM-based therapy management using a chatbot. This is explained by the healthcare professionals' need to act quickly on generated alerts, automatize some of their actions, and provide personalized care accordingly. In contrast, developers and researchers showed a preference for backend features. On the one hand, developers suggested features related to interoperability using standard data formats and instant data availability. On the other hand, researchers suggested features that would support their research, such as concerning the feature of RPM activities management and resource allocation monitoring (Schlieter et al., 2022).

The PAR approach allowed the aggregation of different human agents' opinions of the problem, guaranteeing their engagement throughout the project and the general interest of the research. As discussed by experts in digital health the interdisciplinary co-creation is an enabler for scaling up digital solutions (Schlieter et al., 2022). The flexibility inherent to this approach enabled collaboration among partners to select the final set of features by sharing previously conducted work, experience, and acquired knowledge. Therefore, the proposed RPM solution may have a high agreement with the users' needs avoiding wasting time and resources, which is particularly relevant in healthcare providing services (EXPH, 2019). This RPM platform helps to give more personalised care: the platform provides useful patient information to be used by the clinical team to make patient-centred medical decisions from the collected data. In addition, the high reported levels of adherence concerning some features may indicate that the patients are prone to use these RPM systems to interact and to be followed up by clinical teams. Some patient testimonials revealed they felt they were being followed up closely, conveying a greater sense of safety (Ferrua et al., 2020).

The proposed platform data infrastructure allows data collection considering the patient pathway. Contrary to most hospitals' information systems (Gooch & Roudsari, 2011), this platform collects data associated with the different activities of the patient journey during the intervention. For each activity in the patient pathway, the allocated resources type, quantity, and time are recorded. This information is integrated with the outcomes' stability analysis allowing the intervention's value assessment.

The dynamic and iterative nature of the research process allowed the different human agents to cover distinct topics from design to execution and implementation and focus, such as data analysis framework requirements and modelling and simulation simultaneously, rather than sequentially, as in other research approaches. This work also emphasized how the information flows and is exchanged among physicians, nurses, researchers, and developers, revealing that all should be in the different phases of software development cycles.

This work has some limitations considering the implementation of the PAR approach since the patients were only part of the research process indirectly through feedback evaluation in two of the three case studies. This limitation was caused by the COVID-19 context that excluded the option of group meetings with the patients. Another limitation was the lack of observations considering the topics that generated more or less agreement during meetings. This would allow a better analysis of leadership dominant and oppressive roles in the PAR team (Schlieter et al., 2022).

The PAR approach encourages the researchers to focus on the practitioners' problems and work collaboratively on solutions to those problems (Selener, 1997); therefore, another limitation might be related to the generalizability of the RPM platform to other contexts. Two significant limitations of the proposed RPM-based platform are, first, the lack of integration with the hospital's information system. Second, the limited sample of patients that tested each feature. However, the PAR team is already running a clinical study with 150 patients.

Future work should focus on the evaluation of the implemented value assessment and AI-based decision- support tools' impact on the clinical practice to increase access to high-quality RPM-based surgical follow-up services. outcomes' stability analysis allowing the intervention's value assessment.

6.5. Conclusion

RPM-based follow-up services were highly adopted during the pandemic, driving healthcare organizations to scale-up ongoing pilot initiatives. The scalability of RPM services must consider contextual factors, such as individuals' and organizations' interests and needs, that influence its uptake into routine use.

The PAR approach allowed to simultaneously design, develop, test, and evaluate the RPM platform features with the contribution of patients, healthcare professionals, developers, and researchers. Participatory research is needed to scale up RPM technologies into widespread clinical routine usage.

CHAPTER 7 | Understanding the Health Service Digitalisation Process as a Complex Adaptive System: A Retrospective Analysis of a Real-World Systemic Intervention

Chapter 7 presents a retrospective systemic analysis of a digitalisation process of a health service. This study, rooted in Complexity Theory, Actor-Network Theory, and Activity Theory, argues for viewing the digitalisation process as a Complex Adaptive System and approaching it as a systemic intervention. A systemic intervention methodology is proposed to qualitatively model and analyse the complex interactions among agents over time. The analysis examines methodologies used, generated artifacts, meeting notes, and reports to characterise agents and their actions within a localised, time-bound context. This elucidates phenomena of non-linear relations, self-organisation, adaptation, and emergence. Key findings include the multiple roles of agents, intentional pursuit of funding, post-funding reorganisation of teams and technology, and the emergence of new working groups for scientific production and societal communication.

This chapter will derive in two peer-reviewed papers submitted for publication in the Systems Practice and Action Research Journal and the European Journal of Operations Research. The first paper will aim to support the argument that the digitalisation of a health service should be viewed as a Complex Adaptive System and studied as a systemic intervention. The second paper will propose a new methodology for studying the digitalisation of a health service as a systemic intervention, considering its complex and adaptive characteristics.

7.1. Introduction

This study aims to explore the digitalisation process of health services through real-world interventions, understanding its complexities and dynamic nature. The central argument posits that the digitalisation of health services, i.e., the process of creating new health services through the integration of ICT, presents a CAS nature, shaped by diverse agents such as patients, healthcare professionals, engineers, and researchers, with conflicting interests and critical uncertainties such as providing high-quality care while minimising R&D investments. Over time, these agents collaborate in a non-linear and adaptive manner, showcasing self-organising behaviours (Basole & Rouse, 2008; Paté-Cornell et al., 2016; Tan et al., 2005).

To comprehensively understand the digitalisation process, a CST approach is essential. While prevailing frameworks often oversimplify this process, CST offers a holistic perspective by acknowledging the intricate interactions among various agents and contextual factors (Crawford & Serhal, 2020; Fahy & Williams, 2021; Mogessie et al., 2021). Without such an approach, the translation of R&D efforts into practical implementation may fall short of achieving Universal Health Coverage, a social-shared value among EU member states (Blandford et al., 2018; Mingers, 2015).

The CST approach encapsulates three fundamental commitments: critical awareness, action for improvement, and methodological pluralism (Jackson, 2001; Mingers, 2014). Critical awareness entails questioning assumptions, addressing locally-defined problems, and recognising power dynamics. Action for improvement involves purposeful actions to enhance the initial situation, while methodological pluralism underscores the use of diverse theories and methods cohesively and informatively.

Viewing the digitalisation process of a health service as a series of interventions unfolding throughout the digital health service life cycle, as discussed in Chapter 2, redirects attention towards the process itself rather than solely fixating on the content. Recent work in BOR proposes interesting insights into understanding human behaviour and interactions within interventions, with emphasis on enhancing complex systems and processes (Franco et al., 2021). However, there is a scarcity of literature on a legitimate methodology available to comprehensively study the unfolding of real-world interventions from a CAS perspective. Drawing upon the systemic intervention methodology proposed by Midgley (2006) informed by Activity Theory (AT) and Actor-Network Theory (ANT) (White et al., 2016), this study aims to elucidate the complex interactions among agents and generated artifacts during the digitalisation process of health services, therey showcasing its CAS nature. The primary research questions to address are: How do human agents construct models in real-world interventions? In what ways do individuals and groups interact with methods, processes, and tools? How do the interactions of agents with the material and conceptual elements of an intervention evolve over time?

This chapter unfolds as follows: first, it delves into the theoretical and methodological foundations underpinning the proposed methodology. Subsequently, the systemic intervention methodology is detailed and applied to a case study of cardiac follow-up health service digitalisation. Finally, the chapter concludes with a discussion of the findings and their implications for future research.

7.2. Theoretical and Methodological Foundations for Understanding the Health Service Digitalisation Process as a Complex Adaptive System

7.2.1. Conceptualising the Digitalisation Process of a Health Service as a Complex Adaptive System

CAS are distinguished by their ability to adapt to environmental interactions, resulting in emergent, unexpected, unpredictable behaviours (Cilliers, 1998; Plsek & Greenhalgh, 2001; Rouse, 2000). Cilliers (1998), Plsek & Greenhalgh, (2001), and Rouse (2000) emphasise the significance of emergence, adaptation, self-organisation, and non-linearity as pivotal phenomena and mechanisms for gaining deeper insights into the system under analysis. CAS attributes include dynamic interactions among elements, open systems with feedback loops, and continual adaptation under non-equilibrium conditions. Emergence, a holistic phenomenon, arises from agent interactions, contributing to creative adaptations in complex systems.

The health system, akin to other socio-technical-economic systems, has been explored through the CAS lens (Holden, 2005). Holden (2005) depict nursing homes as CAS, highlighting collaborative learning and self-organised staff interaction, resulting in improved patient outcomes. With the rise of ICT, CAS modelling approaches have been employed to analyse their impact on the health market (Basole & Rouse, 2008).

Shortell (2008) reinforces the recognition of the health system with a network-based structure as crucial for effective resource allocation and outcome assurance. The Quadruple Value model underscores the importance of multiple agents recognising and contributing to the development of digital health services (EXPH, 2019). Network-based structures effectively capture inter-organisational relationships within complex systems, with nodes representing various components and links illustrating relationships (Basole & Rouse, 2008).

Grounded in graph theory, quantitative Social Network Analysis (SNA) has gained traction among social scientists, involving the numerical mapping of networks to quantify their formal characteristics. This approach seeks to measure properties like the strength, intensity, frequency, and direction of network connections. According to Knoke and Yang (2008), the structural relations between concrete entities serve as the foundational principle guiding SNA, where these entities—whether individuals, groups, or organisations—constitute the network, defined as a structure composed of actors linked by one or more relationships.

The consistent patterns of relationships among entities form macro-social contexts that shape perceptions, beliefs, decisions, and actions. Network analysis aims to accurately gauge and represent these structural relations while elucidating their origins and ramifications (Knoke and Yang, 2008). Notably, this definition does not prescribe a specific methodology for investigating network relations, recognising the qualitative heritage underpinning SNA.

Despite advancements in SNA-based quantitative and qualitative approaches to study CAS, insufficient attention has been given to the evolution of digital health services across the service life cycle model (Ricciardi et al., 2019). There is a gap in understanding how human agents interact during the design and development of technology or other artifacts to improve current practices, highlighting a pertinent issue within the OR field. Subsequently, the theoretical and methodological foundations for investigating the digitalisation process are delineated in the ensuing section.

7.2.2. Studying the Health Service Digitalisation Process from a Systemic Perspective

OR interventions are fundamentally aimed at enhancing the complex systems and processes that underpin daily life for individuals (*Operational Research Society*, 2023). These interventions can serve various purposes, including problem-solving, and problem structuring. To approach the digitalisation process of health services as a series of interventions overtime shifts the focus towards understanding the process rather than just the content. Consequently, it is crucial to examine the actions of actors, including the methods and processes they employ, their execution, and the resulting implications for shaping intervention processes and outcomes (Franco et al., 2021). This inquiry aligns with the evolving domain of BOR.

There are five main contributions in the OR/BOR field that inspired the development of the proposed methodology to study the digitalisation process as a CAS.

First, Franco and colleagues (2021) classify as a process-oriented methodology the studying of interventions as a series of events shaping behaviour. This approach considers an evolving agent experiencing or instigating events as the unit of analysis. Thus, the definition of an event and the temporal sequence of events are deemed crucial in process studies. Narrative explanations of behaviour within the context of OR interventions can be intricate due to the complexity and dynamic nature of intervention events, which are interconnected.

Second, Midgley’s boundary critique principle of a systemic is helpful in drawing intervention boundaries on knowledge and participation and reflecting on the choices made. When considering agents’ decisions regarding knowledge and participation boundaries throughout the various interventions in the digitalisation process, the Critical Systems Heuristics (CSH) methodology, as proposed by Ulrich (1987), appears apt. This methodology has previously been employed to investigate sources of motivation, power, knowledge, and legitimacy within public health research (Midgley, 2006). Firstly, it examines the source of motivation, uncovering the values and motivations linked to problem understanding that drive agents' efforts. Secondly, CSH evaluates the source of control, which encompasses the power structures that define the problem and dictate the approach to addressing it. Additionally, CSH investigates the sources of knowledge, including relevant information, expertise, and skills employed by agents. Lastly, it scrutinises the source of legitimacy, which establishes the moral foundations guiding affected agents in handling the outcomes of intervention actions.

Third, Mingers & Brocklesby' (1997) notional systems provide a comprehensive framework for delineating intervention contexts. The problem content system offers insight into each group's perceptions and needs regarding the problem, illuminating their understanding of underlying issues. Concurrently, the intellectual resources system outlines the methodologies and theoretical concepts selected by agent groups, guiding their actions and decisions throughout the intervention process. Additionally, the intervention system provides a detailed account of the actions undertaken by each group to address or structure the problem, including the duration of intervention and the participating groups involved.

Fourth, a significant contribution to the field of problem structuring methods (PSM) was Yearworth & White' (2014) formulation of a generic constitutive definition aimed at identifying the non-codified utilisation of PSMs. Stemming from the thesis that PSMs are widely employed in engineering contexts without agents being fully conscious of it, the establishment of a generic constitutive definition would aid in substantiating how problem structuring unfolds in practice. A similar scenario can be posited in the digitalisation process of health services, where agents engage in structuring problems without full awareness of utilising PSM methods, driven by the necessity to resolve them.

Fifth, White and colleagues (2016) proposed the use of AT to understand behaviour in PSM interventions. The analysis helped hypothesise the identities, relationships, and goals of different actors and how they engage in problem structuring activities. In the same paper, the authors also explore how both AT and ANT could be used to gain a comprehensive understanding of both human and nonhuman agents and their interactions. In the study of the digitalisation process, ANT will be used to inform the mapping of how human agents establish new groups over time, and AT helps understand the complex interactions and mutual influence among different human and non-human agents (artifacts). Furthermore, it is essential to differentiate between activity, action, and operation, as outlined by White and colleague (2016) in their examination of Activity Theory (AT) proposed by Engeström. Activity encompasses the broader context within which individuals engage in purposeful interactions with their environment, reflecting collective practices and societal norms towards particular motives. Actions represent the specific behaviours and tasks performed by individuals within this activity, reflecting their time-bounded goals. They serve as observable manifestations of human behaviour and are the means by which individuals achieve their objectives within the activity. Supporting these actions are operations, which entail the tools, techniques, and conditions facilitating their execution. Operations play a crucial role in mediating the interaction between individuals and their environment within the activity context. By delineating between activity, action, and operation, AT provides a comprehensive framework for analysing the dynamic relationships between individuals, their behaviours, and the socio-cultural context.

Building upon the aforementioned contributions and to fill the gap in studying the digitalisation process of a health service as a CAS, a new methodology is proposed in the following section.

7.3. Methodology

The retrospective analysis of the digitalisation process of a health service proposed in this section adopts the principles of a systemic intervention methodology (Midgley, 2006) and follows the operational steps of a process study (Franco et al., 2021). Therefore, the digitalisation process is examined as a series of interventions that bring about or lead to some behaviour, using different theories and methods. There are two unit of analysis: the agents (humans – individuals, groups, organisations, and non-human – IT artifacts, models) that are involved in the intervention and the activities conducted by the agents in the intervention. As Franco and colleagues (2021) emphasise, there are two critical aspects in process studies: what counts as an intervention, and the temporal ordering of these interventions. The boundary critique principle was adopted to address these aspects (Midgley, 2006). Therefore, what counts as an intervention and the temporal ordering of these interventions will be based on the agents' reflection on boundaries of their actions to create change.

To illustrate the applicability of this analysis, the case of the digitalisation of cardiac surgery follow-up service will be used, but this proposed retrospective analytic strategy could be applied to other health service digitalisation processes. To ensure the applicability of this retrospective analysis to other research studies, only secondary data sources generated from the digitalisation process are used. These sources include interview transcripts, notes from project meetings, reports, presentations, and public curriculum vitae of the human agents involved.

This retrospective analysis consists of three primary phases: 1) reviewing the empirical material and generating concise summaries; 2) identifying what constitutes an intervention and establishing the chronological sequence of these interventions; and 3) analysing the CAS nature of the digitalisation process. For each phase, a series of steps and corresponding methods are proposed.

Phase 1 – Reviewing the empirical material and generating concise summaries:

Step 1 – Conduct a theory-driven thematic analysis (Hayes, 1997): Extract relevant information to achieve a thorough comprehension of the units of analysis based on the following themes guided by AT and ANT:

- **Human agents'** self-reported social and professional position and affiliation, skills, and responsibilities, and when they joined or left the digitalisation process. Human agents' needs, perceptions of the problems, objectives, expectations, and value conflicts.
- **Main actions** undertaken within specific time intervals to address or structure the problems or pursuit time-bounded goals in the digitalisation process, along with the agents involved in these actions and any related contradictions, tensions, or conflicts.
- **Main artifacts (non-human agents)** generated within specific time intervals. These artifacts can be tools, instruments, or models used to identify and describe objects, guide and direct processes, diagnose and explain object properties and behaviour, and envision future states of development (Engeström, 2005).

Step 2 – Generate concise summaries: Summarise the occurrences in the digitalisation process, detailing human agents, their actions, and involved artifacts. This summary should consider temporal and spatial aspects, focusing on relevant phenomena while excluding extraneous ones (White et al., 2016). Define the temporal context by the emergence of significant challenges prompting new efforts or direction changes and conclude when these challenges are addressed or abandoned.

Phase 2 – Identifying what constitutes an intervention and establishing the chronological sequence of these interventions:

Step 1 – Defining the groups of human agents involved in the digitalisation process: Identify the human agents involved, their self-reported roles, and the actions undertaken throughout the digitalisation process as the basis to establish groups of human agents based on common roles and actions. Identify similarities and differences in agents' roles and actions to establish main groups of agents based on common roles and actions.

Step 2 – Characterise the main artifacts and its evolution: To characterise the artifacts, two main attributes need to be considered: the type and the process of how they were generated. Wartofsky, (1979) proposes three types of artifacts: primary – used in production, secondary – internal and external representation of primary artifacts, and tertiary – imaginary artifacts. When encountering artifacts that potentially indicate the use of non-codified PSMs, Yearworth & White', (2014) set of testable propositions offers valuable guidance for evaluating whether the artifact indeed reflects the application of a PSM. This evaluation informs the establishment of rules governing the generation of artifacts.

Step 3 – Characterise each time-bounded context of the interventions in the digitalisation process: Using Mingers & Brocklesby (1997) three notional systems and Ulrich's (1987) CSH framework, characterise each intervention's context and time interval. Identify potential conflicts in problem perceptions, intervention purposes, and methodology selection among different agent groups. Explain how these conflicts were addressed.

Phase 3 – Analysing the CAS nature of the digitalisation process:

Step 1 – Map the digitalisation process' interventions timeline: while any graphical representation of transitions and sequences can be used, it should ensure clear depiction of potential overlapping interventions within the timeline of the digitalisation process, the intervention main problem, methodology, and agents involved (Blanchard et al., 2022; Brzinsky-Fay, 2014).

Step 2 – Identify dominant types of interaction mechanisms between the agents: this can be achieved by computing summary descriptive statistics and/or applying techniques for collapsing qualitative data (DeSanctis & Poole, 1994).

Step 3 – Modelling the network of agents over pertinent timeframes within the digitalisation process timeline: this can be achieved by employing either quantitative, or qualitative, or a combination of both social network analysis techniques. Different network mappings can result from this step, such as egocentric network (focuses on a central agent, known as an ego, and their direct connections with other agents, termed alters – commonly used in AT-driven case studies, where non-human agents are also considered), complete network (includes all possible connections within a defined group or community, providing a comprehensive overview of relationships among all agents) (Heath et al., 2009), multigraph (multiple relations connecting the same pair of agents and the possibility of loops – an agent is connected to itself by another relation) (Shafie, 2013), among others.

7.4. Case Study: Digitalisation Process of a Cardiac Surgery Follow-Up Service

The case of the cardiac surgery follow-up service digitalisation project is used to illustrate the application of the retrospective analysis proposed. The project started in February 2019 and is scheduled to conclude in June 2024. However, this analysis covers the period from February 2019 to January 2024. Originating from a need experienced by a surgical team at St. Marta Hospital in Lisbon, the project seeks to digitalise an existing cardiac follow-up service to enable continuous and remote patient monitoring (RPM) during the critical postoperative period (characterised by hospital readmission rates of 15 to 20% (Khoury et al., 2020; McElroy et al., 2016)).

St. Marta Hospital, supervised by the Central Lisbon University Hospital Centre (CHULC), collaborates with NOVA University, one of the founding partners of Value for Health CoLAB (VOH.CoLAB). VOH.CoLAB, established as "Collaborative Laboratory" by the Portuguese Foundation for Science and Technology (FCT), aims to bridge the academia-industry gap by accelerating R&D translation into health products and services. VOH.CoLAB engaged Fraunhofer Portugal and Vodafone Portugal to contribute their technological expertise to digitalise the new health service. Fraunhofer Portugal specialises in Artificial Intelligence (AI)-based technology development, with prior success in cardiology-focused digital health solutions. Vodafone Portugal, a telecommunications operator, specialises in developing ICT solutions and services. The four partners committed to the project with the constraint of minimal investment and technology adaptation. Initially, there were limited studies on digital health interventions benefits in cardiac surgery, but positive results in chronic heart failure were observed in quality of life, mortality, readmissions, and expense reduction (Pekmezaris et al., 2012; Seto, 2008; Yun et al., 2018). They used two policy-making reports to inform their work, which contextualised value-based healthcare and investment in the digitalisation of health services in the EU. One report introduced the "*Quadruple Value Model*" (refer to Chapter 2) to guide the design and evaluation of health services (EXPH, 2019). This model incorporates four dimensions of value: *personal* (ensuring patient inclusion and awareness), *allocative* (ensuring cost-effective distribution and equity), *technical* (ensuring optimal resource allocation and care suitability), and *societal* (fostering social cohesion and inclusive growth). Additionally, another report focused on the opportunities and concerns associated with the digitalisation of health services (EXPH, 2018). The EXPH recommends employing the Quadruple Value Model to guide investment and R&D efforts in digital health interventions.

Collaborating without public funding, the partners aimed to demonstrate proof-of-concept for the new digital health service, secure public funding for service scale-up and implement a clinical study. In October 2020, the project received national funding through FCT with the reference: "*CardioFollow.AI - An intelligent system to improve patients' safety and remote surveillance in follow-up for cardiothoracic surgery*" (DSAIPA/AI/0094/2020) in the scope of "*AI 4 COVID-19: Data Science and Artificial Intelligence in the Public Administration to strengthen the fight against COVID-19 and future pandemics – 2020*".

7.4.1. Data Collection and Analysis

Information regarding the digitalisation of the cardiac surgery follow-up service was collected through written documentation such as papers published, internal and external reports, meeting minutes, interviews, patients' health electronic records, and healthcare professionals and researchers' notes. Appendix D.1 provides a detailed list of the data sources used in this case study. Table 23 provides a summary of the information collected to generate concise summaries of each intervention in the digitalisation process.

Table 23 – Main themes, data collection sources, and data analysis.

Theme	Characterisation	Data Source	Data Analysis
Human Agent			
Self-reported position and affiliation	Patients and Caregivers – two status – as consumers of a health service and healthcare provider organisation; as citizens and residency characterisation Other agents – self-reported professional position and workplace organisation characterisation	Patients: Health Electronic Records and interviews transcripts. Caregivers: interviews. Other agents: reports and public curriculum vitae.	Directed content analysis (codes defined before data analysis) and descriptive statistics (Hsieh & Shannon, 2005) – Appendix D.2
Roles	Competencies and tasks assigned to an agent within the project.	Actions from meeting notes, and self-reported position and affiliation	Cross analysis
Time the agent joined and left the project	For the digitalisation process, the "join date" refers to the date when an individual or entity becomes actively involved in the process, while the "left date" denotes the date when they disengage or no longer participate in the digitalization process.	Patients: Health Electronic Records, RPM data, and interviews transcripts. Caregivers: interviews transcripts. Other agents: reports and public curriculum vitae.	Directed content analysis (codes defined before data analysis) and descriptive statistics (Hsieh & Shannon, 2005)
Needs	Requirements or demands of agents involved in the project to effectively carry out their roles or tasks.	Patients & Caregivers: interviews transcripts. Other agents: meeting notes and reports.	
Perceptions of the problem	Subjective understandings, viewpoints, or interpretations that individuals or groups have regarding the issues, challenges, or goals addressed by the project or intervention.	Patients & Caregivers: interviews transcripts. Other agents: meeting notes, and reports.	
Objectives	Specific goals or aims that individuals or groups involved in the project or intervention seek to achieve. These objectives outline the desired outcomes or results that agents aim to accomplish within their roles or responsibilities.	Patients & Caregivers: interviews transcripts. Other agents: meeting notes, and reports.	
Expectations	Anticipated outcomes, results, or conditions that individuals or groups participating in the project or intervention foresee or hope to realise.	Patients & Caregivers: interviews transcripts Other agents: meeting notes, and reports.	
Actions			
Start and end date of action	Specific time period during which a particular action within the project or intervention begins and concludes.	Patients & Caregivers: interviews transcripts; RPM data	Directed content analysis (codes defined before data

		Other agents: RPM data, meeting notes, and reports.	analysis) (Hsieh & Shannon, 2005)
Action description	Nature, scope, and objectives of the action, offering insights into what was done, how it was carried out, and its intended outcomes.	Patients & Caregivers: interviews transcripts; RPM data Other agents: RPM data, meeting notes, and reports.	
Action resources	Materials, tools, equipment, or human resources used to execute a particular action within a project or intervention.	Patients & Caregivers: interviews transcripts; RPM data Other agents: RPM data, meeting notes, and reports.	
Artifacts			
Artifact description	Artifact intended purpose and users.	RPM data, meeting notes, and reports.	Directed content analysis (codes defined before data analysis)
Artifact creation process	Agents, steps, and procedures involved in the creation of an artifact.	RPM data, meeting notes, and reports.	
Artifact type	Type of artifact created.	Artifact description and creation process	Classification of the artifact type proposed by Wartofsky, (1979)
Artifact evolution	Changes in the artifact throughout a time-bounded period.	Artifact creation process	Identify what changed and when changed. Visual representation of the most relevant changes.

7.4.2. Results

This section is divided into two main subsections of results. The first three sections present the main results yielded by the application of the new proposed methodology (phase 1 and 2). Key findings encompass the diverse roles of human agents and the principal groups involved in the digitalisation process, the created artifacts, challenges encountered in agent interactions, and the characterisation of interventions within the digitalisation process. The fourth and final section (phase 3) illustrates results supporting the argument that the digitalisation of a health service exhibits a CAS nature.

7.4.2.1. The groups of human agents involved in the digitalisation process:

Table 24 illustrates the groups of human agents involved in the digitalisation process. This result is noteworthy because many studies in this field typically approach the issue by predefining groups of agents (referred to as stakeholder groups in the literature) from a top-down perspective, then identifying agents who could potentially best represent each group. However, this preliminary analysis reveals that agents may indeed fulfil more than one role within the system, impacting how they perceive the problem, engage in, and influence the intervention The analysis of the human agents joining and leaving the digitalisation process resulted in 389 unique individuals (41.13% female), with 82.3% of the agents reporting two or more social or professional positions in the system. There are two important insights from this analysis.

First, there was a need to create two self-reported positions for patients and caregivers in the system. Both patients and caregivers in their interviews explicitly referred the relevance of the new digital health service had more potential benefits to patients that live in cities more distant from the hospital: <Patient>: "*The experience was very good, it's a project that can, and will help those who live outside of Lisbon, to be monitored during the period until they come for the appointment, it's knowledge and assistance every day. If something happens, you are automatically notified, that was my case. The medications were removed, through the project, I found out the medication without any problems without the need to go to the hospital. This is very good for those who mainly live in the province.*".

The second significant insight is that even when not considering the dual roles of patients and caregivers within the system, 45% of other human agents within the system hold two or more professional positions and affiliations. A strong example is one human agent that self-reported seven positions (Clinical Area Director, Clinical Service Director, Surgeon, Professor, University Vice-Rector, Investigator, Directors Board Member) with three different organisations affiliation (Public Hospital Centre, Public Higher Education Institution, and Collaborative Laboratory).

Table 24 – Groups of agents involved in the digitalisation process.

Group name	Affiliation	Main Actions	Roles
1. Surgeons	St. Marta Hospital NOVA University	1) Provide follow-up care by evaluating patients screened by nurses as at risk, changing medication, anticipating appointments, and directing to emergency care. 2) Provide ideas and guidance in product & service development. 3) Test the product and service. 4) Contribute to research study design and data collection and analysis. 5) Patient selection for joining the digital health service.	1) Surgeon 2) Designer 3) Tester 4) Researcher
2. Nurses	St. Marta Hospital	1) Provide follow-up care by evaluating patients' data daily, providing care instructions, and call patients periodically. 2) Manage nurses to provide follow-up care. 3) Provide ideas and guidance in product & service development. 4) Test the product and service. 5) Contribute to research study design and data collection and analysis.	1) Nurse 2) Designer 3) Tester 4) Researcher 5) Manager
3. Researchers	VOH.CoLAB Fraunhofer NOVA University	1) Review the literature. 2) Contribute to research study design and data collection and analysis. 3) Provide ideas and guidance in product & service development. 4) Design and develop product and service	1) Researcher 2) Designer 3) Developer 4) Research mentor 5) Internship mentor 6) PhD student

		5) Interview patients. 6) Assist patient in technology-related issues. 7) Establish co-authoring relations. 8) Mentoring students in internships, M.Sc.' and Ph.D.'s dissertations. 9) Write grant calls proposals.	7) MSc student
4. Developers	VOH.CoLAB Fraunhofer	1) Design and develop product and service. 2) Interview patients. 3) Assist patient in technology-related issues.	1) Designer 2) Developer
5. Telecom Provider	Vodafone	1) Provide SIM cards to patients in order to establish communication between patients and healthcare professionals.	1) Telecom provider
6. RPM Patients	St. Marta Hospital; City of residency	1) Provide health-related data daily. 2) Follow care instructions. 3) Give an interview providing feedback on the service and give ideas to improve. 4) Answer satisfaction evaluation questionnaire. 5) Answer nurses and surgeons phone calls.	1) RPM Patient 2) Tester 3) Designer
7. SOC Patients	St. Marta Hospital; City of residency	1) Follow care instructions. 2) Answer satisfaction evaluation questionnaire. 3) Answer nurses and surgeons phone calls.	1) SOC Patient
8. Caregivers of RPM patients	St. Marta Hospital; City of residency	1) Support patients in provide health-related data. 2) Support patients in recovery. 3) Give an interview providing feedback on the service and give ideas to improve.	1) Caregiver 2) Tester 3) Designer
9. Advisory Board	VOH.CoLAB Fraunhofer NOVA University Vodafone	1) Define resource allocation to the project. 2) Evaluate project results. 3) Establish relations with external networks.	1) Advisory Board 2) Facilitator
10. External members	St. Marta Hospital VOH.CoLAB Fraunhofer NOVA University Other organisations	1) Produce scientific publications. 2) Produce non-scientific publications. 3) Provide mentoring. 4) Provide ethical approval.	1) Researcher 2) Academic professor 3) PhD student 4) MSc student 5) Publisher 6) Ethics Commission Member 7) Hospital Directors Board member

By cross analysing the dates of human agents' involvement in the digitalisation process with information presented in meeting notes and patient interviews, it became possible to distinguish between agents actively involved in defining problems or interventions, and those serving as external relations tasked with specific assignments. The analysis of meeting notes revealed a clear distinction between the categories of "team members", "participants", and "external members". The team members identified in the digitalisation process were 68 with at least one affiliation to five organisations (St. Marta Hospital, Fraunhofer, VOH.CoLAB, Vodafone, and NOVA University). The team members used their affiliation to create working groups (example extracted from meeting notes "*The team of St. Marta is responsible to …*"). The most common working groups referred throughout meetings were: "Hospital", "CoLAB", "Fraunhofer", "Vodafone", and "Advisory Board". The number of agents in each working group changed throughout the digitalisation process. The participants involved patients

(250) and caregivers (12). The team members divided patients in two groups: patients that received the digital health follow-up service (115) and the ones that received the standard of care follow-up service (135). The external members (71) were referred as publications co-authors, scientific and non-scientific editors-in-chiefs, conference chairpersons, data protection officers, ethics commission board members, policy consultants, among others.

7.4.2.2. The main generated artifacts and their evolution in the digitalisation process

Table 25 illustrates the eight primary artifacts identified through artifact analysis. Among these, three are primary artifacts designed to assist users in achieving their goals. Additionally, four secondary artifacts serve as representation models of primary artifacts, aiding in guiding or capturing R&D-related actions and assisting patients in using the digital health kit for their daily self-care routines. The eighth artifact is a linguistic artifact, initially introduced by developers and researchers and later adopted by surgeons and nurses to establish R&D-related actions and corresponding goals within a defined timeframe.

Table 25 – Generated artifacts over the digitalisation process.

Artifact Name	Artifact Creator and Creation Process	Artifact Intended Purpose and User	Artifact Type
1. Patient digital health kit	**Creators:** developers (Fraunhofer & VOH.CoLAB), telecom provider, researchers (Fraunhofer & VOH.CoLAB), nurses, surgeons, patients, and caregivers. **Creation process:** 1) Fraunhofer first developed the digital health kit in another R&D project: it consisted of Internet-of-Things (IoT) health-related devices (blood pressure monitor, weight scale, and step counter wristband), a smartphone with a fourth generation (4G) subscriber identity module (SIM) card and the SmartBEAT user mobile application. 2) Six versions derived from an iterative process: 2.1) identify user needs; 2.2) develop features; 2.3) test features usability with patients in real-world setting; 2.4) collect feedback and new ideas.	**User:** patients. **Purpose:** daily self-report and monitor health status during the recovery period.	Primary
2. Daily patient monitoring report	**Creators:** surgeons, nurses, researchers, and developers (VOH.CoLAB). **Creation process:** four versions derived from an iterative process: 1) identify relevant patient-related information to report daily; 2) identify data visualisation methods; 3) generate report; 4) test the usability of the report in a real-world setting; 5) collect feedback.	**User:** surgeons and nurses. **Purpose:** Monitor daily patient health status to personalise care delivery.	Primary
3. RPM follow-up platform	**Creators:** surgeons, nurses, researchers, and developers (VOH.CoLAB). **Creation process:** four versions derived from an iterative process: 1) identify relevant surgeons and nurses' needs; 2) identify data visualisation methods; 3)	**User:** surgeons and nurses. **Purpose:** Monitor daily patient health status to personalise care delivery.	Primary

	generate report; 4) test the usability of the report in a real-world setting; 5) collect feedback.		
4. Patient Pathway	**Creators:** surgeons, nurses, researchers, and developers (VOH.CoLAB). **Creation process:** three versions derived from an iterative process: 1) literature review; 2) hospital databases review; 3) identification of health-related data and timestamps to be collected; 4) identification of data collection instruments; 5) *as-is* and *to-be* data collection process mapping.	**User:** surgeons, nurses, researchers. **Purpose:** map data collection timestamps to evaluate patient health status throughout the follow-up care period.	Secondary
5. Digital health solution technological infrastructure architecture	**Creators:** researchers and developers (Fraunhofer and VOH.CoLAB). **Creation process:** Six versions derived from an iterative process: 1) identification of technological components and their interactions; 2) identification of end-users; 3) map the technological components considering their respective end-users.	**User:** researchers and developers. **Purpose:** model the technological components and the interactions within technological components and with end-users.	Secondary
6. Care delivery process	**Creators:** researchers, surgeons, and nurses. **Creation process:** Three versions derived from an iterative process: 1) examination of the current care delivery process main actions (goals, involved resources, time, costs, and dependencies) based on observation and healthcare professionals and patients input; 2) *as-is* and *to-be* care delivery process mapping; 3) map validation with healthcare professionals.	**User:** nurses, surgeons, and researchers. **Purpose:** identify and model the set and sequence of operations, the resources, time, and costs – representation of the remote care delivery process.	Secondary
7. Patient Recovery Self-Management Guide: Daily Instructions Brochure	**Creators:** researchers, nurses, and patients. **Creation process:** three versions derived from an iterative process: 1) role play on how the patient should use the digital health solution to identify main steps; 2) design a step-by-step instructions brochure; 3) test the usability of the report with patients; 4) collect feedback from patients after the follow-up period.	**User:** patients and caregivers. **Purpose:** guide patient in using the digital health kit in their daily self-care routine.	Secondary
8. Iteration	**Creators:** developers and researchers **Creation process:** the term "iteration" was adopted by developers and researchers, drawing from common terminology in software development. It was used to delineate periods during which they developed technological components and tested them in real-world settings. As a result of the digitalisation process, six iterations of technological R&D were conducted.	**User:** developers, researchers, surgeons, and nurses. **Purpose:** define time-bounded R&D goal-oriented actions – linguistic artifact	Tertiary

Further elaboration is provided on the evolution of artifacts, specifically focusing on the patient pathway, technological architecture, and care delivery process, while considering the evolution of the iteration artifact.

Figure 16 illustrates the artifact evolution analysis of the patient pathway the SoC patient pathway alongside the two versions of the digital patient pathway resulting from the digitalisation process. The SoC patient pathway encompasses eight timestamps and seven-time intervals for data collection. For the purpose of this analysis, focus is placed on the intervals during the patient follow-up period, spanning from discharge to 12 months post-surgery. Three main types of data collected: case-mix variables collected at discharge, clinician-reported outcome measures (CROMs), and patient-reported outcomes measures (PROMs) obtained via phone calls at three days, one, three, six-, and 12-months post-surgery.

The primary distinction between the SoC and the two digital patient pathways lies in the digitalisation of post-hospital discharge follow-up intervals, which constitutes the RPM period. During the RPM period, patients use digital health kit to collect more PROMs on a daily basis, alongside a one-time collection of Patient-Reported Experience Measures (PREMs) at the conclusion of the RPM period. The main differences between the two versions of the digitalized pathway include the duration of the RPM period, the frequency of data collection, and the data collection instruments. In the initial version, implemented from iterations 0 to 5, patients reported daily PROMs for 30 days post-hospital discharge. However, in the second version, implemented during the 6th iteration, the RPM period extended from 30 to 90 days post-hospital discharge, with patients reporting measures once a week following the 30th day of the follow-up period. This change stemmed from the surgeon's decision to focus on high-risk patients prone to complications, necessitating an extension of the surveillance period (allocative value dimension – Quadruple value model).

Throughout the six iterations, the data collection instruments changed in response to feedback from patients, nurses, and surgeons regarding the effectiveness of the instruments in measuring the relevant phenomena. The following patients' experience illustrates one example of feedback that emerged as an experienced contradiction or dilemma encountered when choosing data collection instruments capable of delivering patient-reported data suitable for remote monitoring to tailor personalised care while addressing the unique requirements of individual patients (personal value dimension of the Quadruple Value model):

Patient 1 after iteration 3: "*I think the questionnaire is too short. I don't know, together with a professional, the healthcare professionals from this hospital could adjust it, because they are very repetitive, you know? I've been answering for a month and a half that I don't have palpitations, I don't have whatever... The questions should change as the post-operative time passes, right? Even the question about physical effort. It's difficult, if I climb two flights of stairs, I don't get tired. But then, the first question was "when you make great efforts...". There should be an intermediate question, or a few meters, or a few kilometres, right? Because I never know if I climb... On the one hand, I climbed seven flights of stairs, but I could climb at least two more, I could climb one or two more. And when I climbed seven flights of stairs, I didn't feel tired, I felt strong enough to... So, the limit, the limit of tiredness*."

Patient 2 after iteration 3: "*It's having this care that ultimately ends up being a bit personalized, isn't it? Or totally personalized, and... it makes us much more reassured in that sense because any doubts that arise, and even if we can't be very attentive to the values, we have a medical team that does* *it for us, right? They called me many times... I don't know, I was thinking that maybe they could try to suggest step goals for the first week, second week, for example, but that also depends on each person's ability, right? So... or maybe, for example, give us some feedback about other patients, the type of activity they have been able to do, to make us more motivated to reach that too, because I would say things like "I must be terrible, I must be one of those who walk less. I'm sure that older people who really like to walk must have many more steps than me." But otherwise, I think... just for additional motivation, nothing else. Curiosity.”*

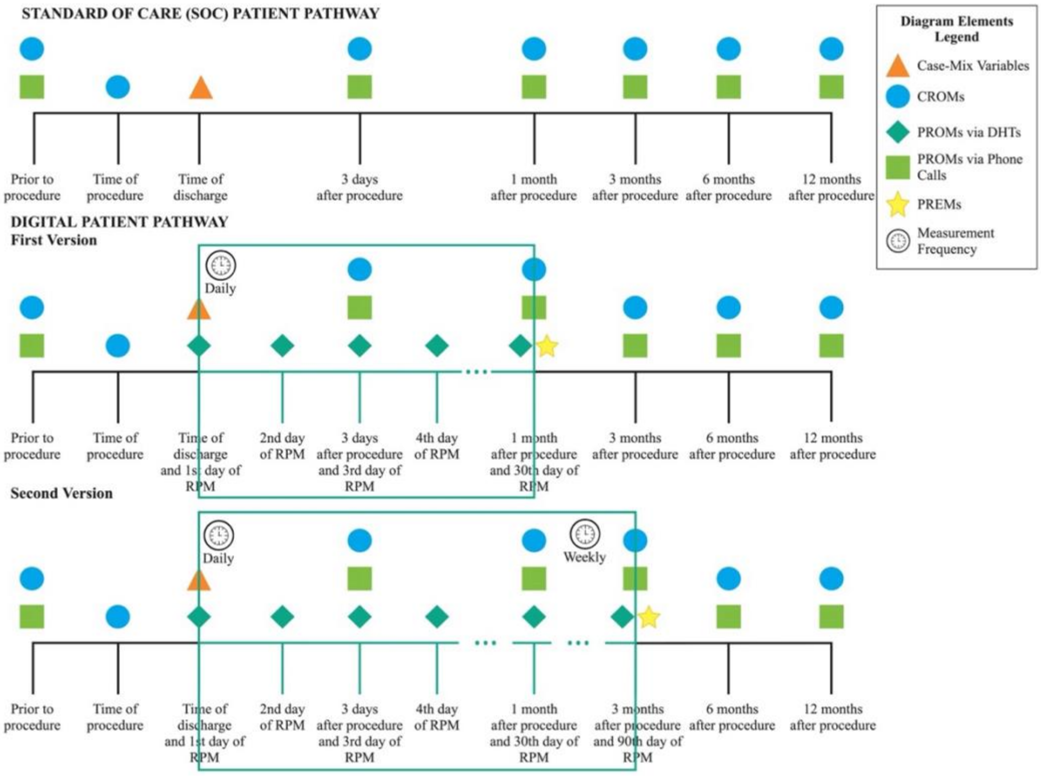


Figure 16 – Characterisation of the Standard of Care (SoC) and the First and Second Versions of the Digital Patient Pathways. RPM indicates remote patient monitoring; CROMs indicate clinician-reported outcomes measures; PROMs indicate patient-reported-outcome measures; PREMs indicate patient-reported experience measures; DHTs indicate digital health technologies.

Figure 17 provides the artifact evolution analysis of the digital health solution technological infrastructure architecture underpinning the two versions of the digital patient pathway, as detailed Figure 16. This evolution unfolds over six iterations of technological development, encompassing Iteration 0 to Iteration 5 for the first version and Iteration 6 for the second. Within Figure 17, the technological progression is illustrated across three distinct technology interfaces tailored for different user groups. Notably, there are two separate end-user technology interfaces designed for patients and caregivers (Group 1) and surgeons and nurses (Group 2), alongside a third interface for facilitator users (developers and researchers). The facilitator interface comprises essential technological elements for communication between the two main end-user groups. For simplicity, the facilitator users are not visually represented.

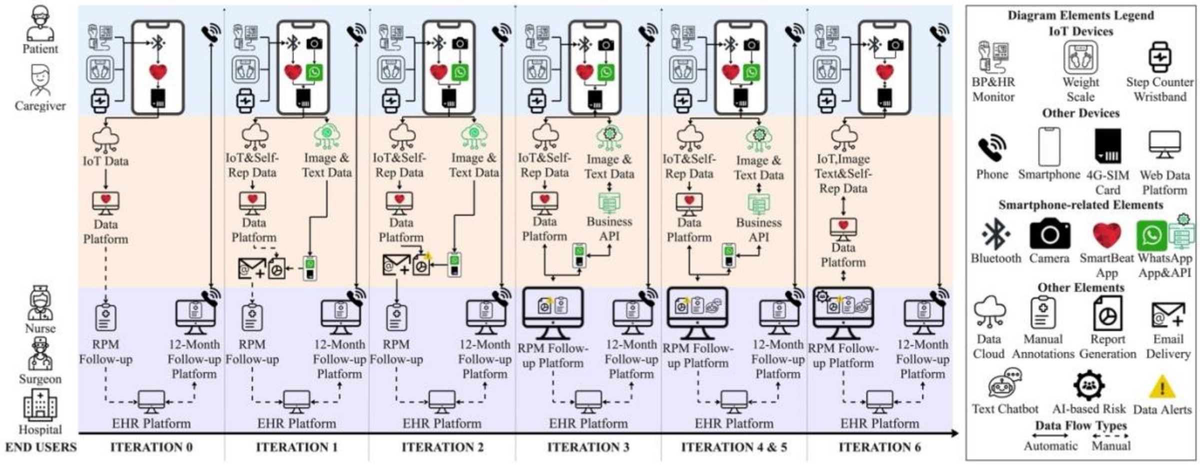


Figure 17 – The Technological Trajectory Across Six Iterations of Technological Development.

The key finding is the establishment of two distinct ICT systems serving the two end-user groups, with no automatic data flow integration observed across the iterations. The first ICT system corresponds to the RPM system, enabling the digitalisation of the follow-up period. In contrast, the second system represents the existing SOC follow-up system, which remained unchanged throughout the technology development cycle. In the RPM system, with the exception of Iteration 0, all the subsequent iterations involved technological changes in the three technology interfaces affecting user interaction. In Iteration 0, RPM technological elements were added to the existing follow-up technological system without adaptation.

Three main contradictions emerged during the study of this artifact’s evolution. Firstly, surgeons and nurses expressed the need for patients to capture images of their surgical wounds to reduce infection risks, but Fraunhofer could not allocate resources to create a camera feature (technical value dimension – Quadruple Value model). Consequently, WhatsApp served as a communication tool between patients and healthcare professionals in iterations 0 to 5. Positive patient feedback and project funding prompted Fraunhofer to develop the camera feature within their mobile application, enhancing patient experience. Secondly, nurses felt overwhelmed by patient information they could not process in time during the initial three iterations, leading to the development of an RPM Follow-up platform to help manage historical and real-time data more efficiently.

Nurse 1, following iteration 2, remarked, “*I print all the patient reports to ensure a comprehensive overview of the patient’s recovery history*.”

Nurse 1, providing feedback after using the platform in iteration 3, stated, "*Now it’s easier. It saved me a lot of time and paper* (laughs). *I can just go there and check the patient’s first-week data.*"

Lastly, the lack of integration between two distinct ICT systems posed an ongoing challenge, resulting in nurses and surgeons duplicating notes and complicating data analysis. This challenge was never solved because of the hospital structure. Implementing changes to the hospital's technological infrastructure is a bureaucratic process that requires demonstrating that the benefits outweigh the costs to justify the investment. The following excerpt from a meeting note reflects the contradiction between the healthcare professionals need to integrate both systems to improve personalised care delivery and the hospital executive board:

Meeting note excerpt from iteration 5: “*The senior surgeon explained that the hospital* (executive board) *will only invest in interoperability between systems if the study demonstrates clinical benefits and reduced costs.*”

7.4.2.3. Contextual and Time-Bound Interventions in the Digitalisation Process

Table 26 covers the three distinct temporal contexts identified. The first context revolved around the design, development, and testing of a digital service for cardiac surgery follow-up care. The second context pertained to securing funding and planning a scaled-up technological roadmap for conducting a clinical study with a larger patient population. Finally, the third context entailed designing and implementing a clinical study involving 150 patients to ascertain which patient groups would derive greater benefits from the service, and how the healthcare team would manage the increased patient load.

Table 26 – Contexts of the interventions in the digitalisation process using the framework Mingers & Brocklesby (1997) and the CSH boundary issues proposed by Ulrich (1987).

Context & Boundary Issues	Context 1	Context 2	Context 3
Problem Content			
Defined Problem	Lack of reliable and continuous information from patients during the first 30 days after surgery	Scale the service to be able to provide care to more patients and seek funding to support service scale-up	Identifying the patient groups that derive the greatest benefit from the digital health service and addressing the challenges related to managing a larger patient population in a post-pandemic scenario
Source of Motivation	Surgeons, nurses, patients, and caregivers	Surgeons, nurses, researchers (VOH.CoLAB), patients and caregivers	Surgeons, nurses, and researchers (VOH.CoLAB & Fraunhofer)

Source of Control	Surgeons and nurses	Fraunhofer, VOH.CoLAB, surgeons, and nurses	Surgeons, Funding Body
Intellectual Resources			
Intellectual Resources Selection	Follow-up care delivery practices; DSR methodology	PAR approach	Clinical Research Methodology
Source of Knowledge	Surgeons, nurses, and researchers (VOH.CoLAB)	Surgeons, nurses, and researchers (VOH.CoLAB & Fraunhofer)	Surgeons, nurses, and researchers (VOH.CoLAB & Fraunhofer)
Intervention			
Set of actions to create change	Design, develop, and test a digital health service in real-world settings (4 iterations)	Collaboratively write a grant proposal to seek funding and devise a technological development roadmap (2 action-reflection cycles)	Randomised two arm clinical study of a digital health service in real-world settings (2 iterations)
Source of Control	Fraunhofer, VOH.CoLAB	Fraunhofer, VOH.CoLAB	Surgeons, Funding Body
Source of Legitimacy	Patients and caregivers in the digital health service	Patients and caregivers in the digital health service	Patients and caregivers in the digital health service and SOC service
Time boundaries			
Time Intervals	February 2019 to February 2021 (23 months)	January 2020 to April 2022 (27 months)	March 2021 to December 2023 (33 months)
Source of Control	VOH.CoLAB and surgeons	Surgeons, nurses, and researchers (VOH.CoLAB & Fraunhofer)	Funding body

7.4.2.4. Main results of the analysis of the digitalisation process as a CAS

The main results of this section demonstrate phenomena of non-linearity, self-organisation, adaptation, and emergence.

Figure 18 illustrates the nonlinear nature of the interventions in the digitalisation process. Human agents, motivated by internal challenges such as developing a digital health service with minimal investment, and external opportunities like receiving public funding, engage in reorganisation and take on various roles to collaborate effectively. These collaborative efforts are depicted as interventions aimed at addressing or structuring local and time-bound issues. The iterative methodologies employed for technological design and development assist them in adapting to constraints and contradictions that arise. The non-linear sequence of these interventions highlights that the digitalisation process cannot be viewed as a predetermined series of events.

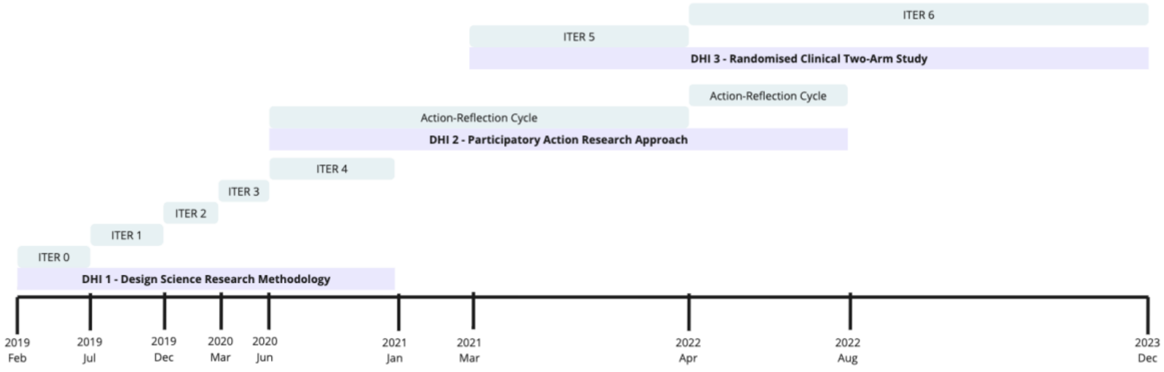


Figure 18 – Systemic Intervention Timeline: Association of Digital Health Intervention with Technological Iteration. DHI means Digital Health Intervention and ITER means iteration.

Figure 19 depicts the adaptive nature of the digitalization process. It showcases the technological development and user adoption before (iterations 0 to 4) and after (iterations 5 to 6) securing funding. Prior to funding, technological advancements were incremental, and user adoption was minimal. However, after securing funding, there was a notable increase in both technological improvements and user adoption.

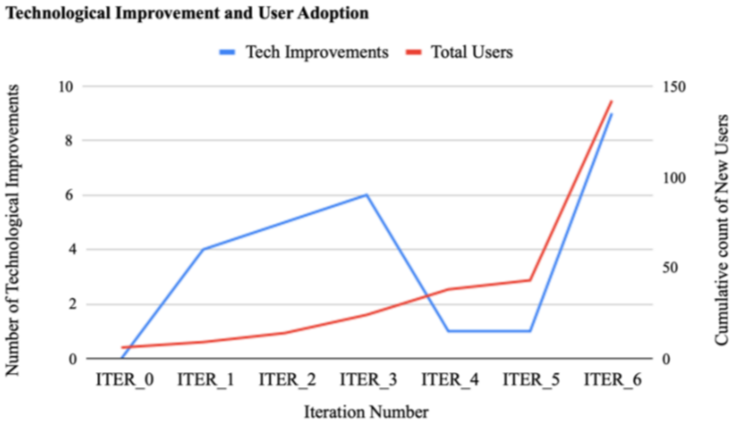


Figure 19 – The technological improvements and user adoption over the six iterations of technology development.

Figure 20 illustrates the emergent behaviour of the digitalisation process through the visualisation of two complete network structures in two different time stamps of the digitalisation process. Each node is a human agent which are linked through their personal or professional affiliation. Team members, participants, and external members were considered. The results of the clustering analysis generated seven groups of agents in iteration 0 (DHI 1) and 17 groups of agents in iteration 6 (DHI 3). The new working groups created were mainly driven for scientific production and societal communication.

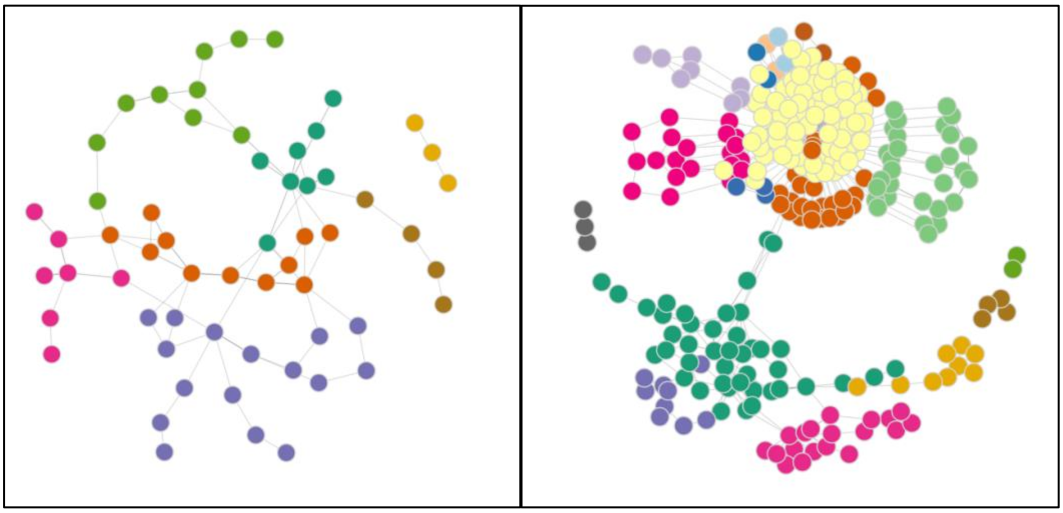


Figure 20 – Social network analysis: Figure on the left – network structure in iteration 0, DHI 1, Figure on the right – network structure in iteration 6, DHI 3. Each node is a human agent which are linked through their personal or professional affiliation. In iteration 0, there are seven groups of agents. In iteration 6, there are 17 groups of agents.

7.5. Discussion

This study presented a methodology to conduct a retrospective systemic analysis of the digitalisation process of health services as a CAS, grounded in ANT and AT. The respective analysis enabled the examination of the role, individual actions, and interactions of agents within interventions across various phases of digital health service maturity. Through dynamic evaluation, complex interactions among agents were mapped over time, revealing the complementary and nonlinear sequencing of interventions during service digitalisation, demonstrating how technology-related artefacts interact with human agents during the digitalisation process. As referred by Yearworth & White' (2014), the analysis of methodologies used in each intervention unveils common agent objectives and their evolution such as designing and developing a digital health service that copes with the healthcare professionals and patients' needs while minimising investment. As referred by Yearworth & White' (2014), qualitative and quantitative examination of artifacts, meeting notes, and reports were important source of information to characterise actions and agents in a localised and time-bound context. This analysis brought to light the phenomena of reorganisation, adaptation, and emergence (Knoke and Yang, 2008). Key findings include agents' intentional pursuit of funding, organisational and technological reorganisation post-funding, and the emergence of new working groups for scientific production and societal communication.

In terms of limitations and future work, while this study established a foundation for actor network and activity-based theories of digital health interventions as operational research interventions, several open issues remain unaddressed or only partially addressed. Firstly, while theoretical arguments were supported with a case study analysis tailored to the study's needs, a comprehensive disclosure of the case study from start to finish was lacking. The selective use of the case study limits the depth of insights provided, suggesting that a full analysis could offer more guidance to researchers conducting similar studies. Secondly, the focus was limited to a single context of digitalisation process, leaving open the possibility of alternative interactions in different contexts or when employing different methodologies. Future studies could explore the extent and significance of the analysis across multiple digitalisation process contexts or with different methodologies.

The findings presented in this thesis provide valuable insights into potential avenues for future research. Initial results indicate that human agents involved in R&D projects often assume multiple roles and organizational affiliations. This realisation prompts researchers in stakeholder analysis to explore innovative methods for defining stakeholder groups that dynamically evolve over time (Midgley et al., 1998). By adopting such approaches, researchers can better analyse stakeholder preferences and goals throughout the intervention process, thereby enhancing stakeholder engagement strategies.

Furthermore, an opportunity arises for leveraging graph theory to model interactions between human agents and artifacts within R&D projects. By constructing activity networks based on real-world data, stakeholders can gain a deeper understanding of individuals' influence within the network, facilitating proactive identification and mitigation of potential issues while maximising collaborative learning opportunities. By employing graph-theoretic techniques and activity-based theories, researchers can develop sophisticated models capturing the complexity of human-agent interactions, enabling more informed decision-making and enhancing the overall success of R&D endeavours (Ba et al., 2023; Beaman et al., 2018; Shafie, 2013; White et al., 2016).

7.6. Conclusions

The systemic modelling analysis proposed for the digitalisation process of health services confirms the complex adaptive nature of their behaviour. This results in a model that facilitates comparison across various service digitalisation processes and holds potential for generalisability to other sectors. This comparison is achieved through dynamic analysis of agents, their roles, and actions within the socio-technical-economic context of intervention and service maturity level. This study contributes to the structuring of a more robust and cumulative knowledge base concerning digital health interventions, highlighting the importance of transdisciplinarity, patient and industry involvement, and funding as crucial mechanisms for the ongoing design and evaluation of digital health services.

PART III – General Discussion and Conclusions

Part III provides the reader with a general discussion and future insights for research on managing real-world participatory design and evaluation of digital health interventions from a critical systems thinking approach.

CHAPTER 8 | Discussion

Chapter 8 provides a discussion of the main theoretical and methodological contributions and findings of this research, integrating the knowledge developed throughout all the previous chapters and highlighting the practical implications of this research. Moreover, it discusses the potential limitations of this research.

8.1. General Discussion

The pursuit of UHC requires strategic investments in the effective design and management of digital health services. These services play a pivotal role in facilitating remote and efficient healthcare delivery while providing essential evidence to guide decision-making for patients, healthcare professionals, providers, policymakers, and other stakeholders (Cummins & Schuller, 2020). However, the inherent challenge in the digital health research lies in confronting unrealistic proposals regarding the design and evaluation of digital health interventions. Such proposals often overlook the complex nature of the digitisation process, its context dependence, and the multifaceted interplay of social, economic, and technical factors. Consequently, the accumulation of robust knowledge in this field is hindered (EXPH, 2018; Fahy & Williams, 2021).

Throughout this thesis, significant emphasis was placed on addressing the challenge of managing real-world participatory design and evaluation of digital health interventions comprising the digitalisation process of a health service, from a CST perspective. Unlike a reductionist approach, which confines digitalisation process of health services within predefined boundaries and promotes fragmented learning across isolated digital health interventions, the CST approach provides a broader understanding of how the digitalisation process unfolded. It supports the examination of the dynamic nature of the process, which involves numerous interventions shaped by intricate interactions among technology, individuals, organizations, and governmental entities (Midgley, 1996).

The research undertaken in this thesis closely aligned with a collaborative project aimed at digitalising the cardiac surgery follow-up service. This project, started in February 2019 and is scheduled to conclude in June 2024, represented a joint effort involving a public hospital, two research laboratories, and a telecommunications company. Its overarching goals included digitalising patient care while navigating constraints related to minimal investment and technological adaptation. To achieve these goals, the project formulated four action plans encompassing the design, development, and testing of the digital health service in a real-world context, securing funding to scale up the service, and evaluating its impact on various patient groups while addressing the challenges associated with managing a larger patient population.

At the core of this Ph.D. thesis is the argument and theoretical contribution that the digitalisation process of a health service should be viewed as an unstructured problem with a CAS nature. This perspective proposes studying it as a systemic digital health intervention, highlighting its dynamic and iterative nature, characterised by interconnected interventions and the adaptive behaviour of agents. The study began with an action research approach, evolving into process model design and analysis, laying the foundation for the pursuit of four primary objectives.

Firstly, the thesis endeavoured to collaboratively design, develop, and test a digital health service within a real-world framework using the Design Science Research (DSR) methodology (Chapter 4). Secondly, it aimed to identify the most relevant domains and methodologies for assessing the scalability of digital health interventions (Chapter 5). Thirdly, the thesis sought to evaluate the intended use of the digital health service and devise a scale-up plan within a real-world context using the Participatory Action Research (PAR) approach (Chapter 6). Finally, it endeavoured to model and study the digitalisation process, acknowledging its CAS nature, through a systemic intervention methodology and Activity Theory (AT) (Chapter 3 and 7). This comprehensive approach represents a significant methodological contribution of this thesis as it facilitated a retrospective analysis of each intervention's execution by agents. It addressed considerations such as knowledge and participation boundaries to derive actionable insights for improvement.

Following the comprehensive analysis presented in Part II’s chapters, a general discussion on the theoretical, methodological, and practical implications of this work is warranted, laying the groundwork for future study perspectives.

8.2. Main Theoretical and Methodological Contributions

The Model of the Digital Health Service Life Cycle aligned with the Quadruple Value Model

This doctoral thesis introduces a novel digital health life cycle model, drawing upon the Unified Services Theory and a rapid review of existing models for designing and evaluating digital health innovations. Guided by the Quadruple Value Model, this framework effectively organises various digital health interventions, outlining their objectives, activities, and technological and organizational maturity throughout the digitalisation process. The proposed Digital Health Service Life Cycle offers a visual roadmap for conceptualizing future studies on digital health services, encompassing three phases of service maturity: Pre-scale-up, Scale-up, and Implementation and Commercialisation. It demonstrates how value across four dimensions can evolve through transdisciplinary research and development efforts across these phases. To achieve this, collaborative, participatory, and iterative approaches are advocated (Chesbrough & Vanhaverbeke, 2018; Cirule & Uvarova, 2022).

This contribution holds practical significance for funding bodies, policymakers, practitioners, and researchers in EU member states, assisting in setting realistic expectations regarding the type of evidence to be gathered, the participants to be included, and the methodologies and study designs to be employed. By providing a structured framework, it facilitates informed decision-making and enhances the effectiveness of digital health interventions, thereby advancing the broader goals of improving healthcare delivery based on EU societal values (EXPH, 2019).

Furthermore, the analysis of historical thought from an anthropological perspective and through the lens of the Quadruple Value model illuminates the ongoing discourse surrounding the concept of value. This analysis contributes to raising awareness about the diverse interpretations and applications of the term "value" aiming to foster closer connections among various interested parties, including academia, industry, and society. The key insight derived from this exploration is that value is dialectical, dynamic, and socially constructed, manifesting in individuals' perceptions, their interactions with others, and within established social structures (Graeber, 2013; Miller, 2008).

An Enhanced Design Science Research Methodology for Digital Health Services Design

This thesis introduces an innovative approach to digital health services design through an enhanced DSR Methodology, applied within a cardiac surgery department of a public hospital in Portugal. The methodology was specifically tailored to design, implement, and validate an RPM service for post-surgery follow-up. By integrating DSRM with Lean Startup principles, this study pioneers novel strategies to expedite technology development-validation cycles in the healthcare sector. In contrast to traditional product development processes characterised by lengthy analysis and validation phases, our agile methodology enables rapid validation across usability, clinical, and technical dimensions (Drummond et al., 2009; Peirce et al., 2011). Empirical findings highlight the potential of patient-reported outcomes monitoring in reducing critical clinical incidents, while acknowledging the need for larger-scale studies to ensure statistical robustness.

Moreover, this research sheds light on the challenges associated with adopting participatory methodologies in healthcare and underscores the significance of co-designing digital services to optimise feasibility and adoption. The continuous involvement of the interdisciplinary research team with patients and clinical professionals proved instrumental in enhancing compliance and adoption rates. Overall, the approach fosters innovation and facilitates the uptake of digital health solutions, providing valuable insights for digital health innovators striving to meet the diverse needs of clinicians and patients within compressed development-validation cycles.

Furthermore, the methodology contributes to advancing scholarly understanding in Health Sciences research by advocating for comprehensive and participatory scientific approaches to clinical research. By emphasising the importance of robust evidence generation and interdisciplinary collaboration, this work encourages scholars to embrace innovative methodologies that bridge the gap between theory and practice in healthcare settings.

Additionally, this research holds implications for scholars in Management Sciences by offering insights into how organisations can enhance their services in real-world settings through the adoption of digital innovations. The evidence collected around the artifacts generated through this methodology contributes to a growing knowledge base on organisational improvement strategies, providing valuable lessons for practitioners and researchers alike. Overall, the enhanced DSRM framework offers a holistic and adaptable approach to digital health services design, with the potential to drive transformative change in both healthcare and management domains.

An Enhanced Participatory Action Research Methodology for Collaborative Evaluation and Planning for Digital Health Services

The proposed PAR Methodology for collaborative evaluation and planning for digital health services, represents a significant theoretical and methodological advancement in digital health service design. By engaging various agents, including patients, healthcare professionals, developers, and researchers, throughout the research process, the study ensured that the final product addressed diverse needs and preferences.

This collaborative approach fosters interdisciplinary co-creation, enabling the aggregation of different human agents' opinions and expertise. The flexibility inherent in the PAR methodology facilitates efficient collaboration, leading to the selection of features aligned with users' needs and priorities (Schlieter et al., 2022). Consequently, the technological component proposed, offers personalised care by providing valuable patient information to clinical teams for patient-centred medical decision-making. Moreover, the technological component's data infrastructure allows comprehensive data collection along the patient pathway, facilitating outcome assessment and intervention evaluation. The dynamic and iterative nature of the research process ensured simultaneous consideration of diverse topics, from design to execution, enhancing information exchange among agents. Practical implications of this approach include improved patient adherence, enhanced safety perceptions, and the potential for increased access to high-quality digital surgical follow-up services, particularly relevant in pandemic contexts where remote care is crucial.

Proposed methodology for studying Complex Adaptive Systems:

The proposed methodology for studying Complex Adaptive Systems represents a significant theoretical and methodological contribution to both BOR and the digital health research fields. In the BOR domain, this approach facilitated the examination of the roles, individual actions, and interactions of agents within real-world interventions. It enhanced our understanding of how agents create and use models as action-mediating artifacts to solve or structure problems (Franco et al., 2021).

Through dynamic evaluation, the study mapped complex interactions among agents over time, revealing the complementary and nonlinear sequencing of interventions during service digitalisation. Additionally, it shed light on how technology-related artifacts interact with human agents throughout the digitalisation process. Analysis of the methodologies used in each intervention unveiled common agent objectives and their evolution. In the realm of digital health research, this analysis has highlighted the complexity and adaptive nature of the digitalisation process within healthcare services, paving the way for new approaches to the design and evaluation of digital health interventions (Fahy & Williams, 2021).

8.3. Limitations

Proposed Digital Health Service Life Cycle Model:

The proposed digital health service life cycle model faces three limitations. Firstly, there is an inherent overlap in certain activities, such as seeking funding, across different phases. This overlap introduces ambiguity in execution and could benefit from clearer delineation to enhance efficiency and effectiveness. Secondly, the model lacks specificity regarding the type of evidence expected to be generated during the implementation and commercialisation phase, posing challenges for assessing intervention progress and effectiveness. Additionally, while the model aims to involve various agents throughout the phases, the methods for the implementation and commercialisation phase are not clearly defined, requiring further refinement and validation through empirical testing and agents' feedback.

DSR Methodology applied for digital health:

The enhanced DSR methodology also exhibits limitations. The iterative nature of the methodology may introduce variability in the experiences of the clinical team, potentially undermining result reliability. Furthermore, the small sample size limits robust statistical analysis, hindering claims regarding the clinical effectiveness of the RPM service. Close support provided to patients by the technical team and clinicians may mask negative experiences and outliers, complicating the assessment of the service's effectiveness. To address these limitations, a larger-scale clinical study was conducted to mitigate variability in experiences.

Proposed PAR Methodology for Collaborative Evaluation and Planning for Digital Health Services:

Despite its valuable contributions, the PAR approach employed in the study faces several limitations. The indirect involvement of patients in the research process due to COVID-19 restrictions limited their direct input, potentially impacting the platform’s design and usability. Additionally, the lack of observations on topics generating more or less agreement during meetings hinders a comprehensive analysis of power dynamics within the PAR team, potentially affecting decision-making processes. Furthermore, the generalisability of the digital health service’ technological component to other contexts may be limited, raising concerns about its broader applicability. Specific limitations of the technological component include its lack of integration with the hospital’s information system and the relatively small sample of patients testing each feature.

Proposed methodology to studying Complex Adaptive Systems:

The proposed methodology for studying Complex Adaptive Systems has two main limitations. Firstly, while theoretical arguments were supported with a case study analysis tailored to the study’s needs, a comprehensive disclosure of the case study from start to finish was lacking. The selective use of the case study limits the depth of insights provided, suggesting that a full analysis could offer more guidance to researchers conducting similar studies. Secondly, the focus was limited to a single context of digitalisation process, leaving open the possibility of alternative interactions in different contexts or when employing different methodologies.

CHAPTER 9 | Prospects for Future Research

Chapter 9 outlines potential avenues for future research.

9.1. Future Research

With a foundation in CST and action-oriented research, it is anticipated that this work will contribute with knowledge and motivation for future action-oriented research studies, promoting the accelerated transfer of knowledge to society and ensuring a positive impact on UHC.

In the realm of BOR, the findings presented in this thesis offer valuable insights into potential directions for future research. The preliminary results suggest that human agents involved in R&D projects often hold multiple roles and organisation affiliations. This realisation prompts researchers in stakeholder analysis to explore novel methods for defining stakeholder groups that dynamically evolve over time. By adopting such approaches, researchers can better analyse the preferences and goals of stakeholders throughout the intervention process, thus enhancing the effectiveness of stakeholder engagement strategies.

Secondly, there is an additional opportunity to leverage graph theory to model the interactions between human agents and artifacts within R&D projects for real-time decision-making. Building upon the findings presented in Chapter 7, future research should focus on constructing activity networks based on real-world data. This approach can provide stakeholders with a deeper understanding of the influence that individuals have within the network, facilitating more informed and timely decision-making processes. This insight will enable stakeholders to proactively identify and mitigate potential damages while maximising collaborative learning opportunities. By employing graph-theoretic techniques and Activity Theory (Ba et al., 2023; Beaman et al., 2018; Shafie, 2013; White et al., 2016), researchers can develop sophisticated models that capture the complexity of human-agent interactions, thereby facilitating more informed decision-making and enhancing the overall success of R&D endeavours.

In the field of digital health service life cycle models, future research should aim to explore and address broader challenges and opportunities. This includes investigating the scalability and adaptability of the proposed model across different healthcare settings and contexts, considering factors such as varying healthcare systems, cultural norms, and technological infrastructures, particularly in underserved populations. Additionally, there is a need to explore the potential integration of emerging technologies, such as decentralised technology, into the proposed model to enhance its effectiveness and relevance in an ever-evolving digital health landscape. Overall, continued research and refinement of digital health service life cycle models will be crucial for driving innovation, improving healthcare delivery, and ultimately advancing population health outcomes in the digital age.

Moreover, future research at the intersection of digital health and CST could explore how to address pressing environmental concerns and promote sustainability within the digital ecosystem. Recent work has highlighted the unsustainable trajectory of digital consumption and its implications for global greenhouse gas emissions, prompting the need to investigate strategies to promote digital sobriety and mitigate the environmental footprint of digital technologies (Itten et al., 2020). By adopting a CST approach, researchers could develop holistic frameworks that address systemic challenges and engage stakeholders across the digital ecosystem, including consumers, enterprises, vendors, and regulators. This research could contribute to the development of sustainable practices and policies that align digital transformation efforts in healthcare with environmental stewardship goals.

Lastly, insights from Subramoniam and colleagues' (2021) research on digital products and the circular economy shed light on how companies across diverse industrial sectors are leveraging existing data to drive remanufacturing and reverse supply chain systems. While the focus of this research primarily centred on automotive, telecom, and retail sectors, there exists vast potential to expand insights into the healthcare domain. As industries embrace new digital technologies, such as blockchain, the reverse supply chain and remanufacturing sector will witness increased importance, leading to faster product delivery, reduced costs, and environmentally friendly product offerings in the realm of digital health. Digitalising the product life cycle holds immense potential for offering competitive advantages and mitigating counterfeit products through enhanced traceability. Moreover, societal changes, such as consumer attitudes towards reused and remanufactured digital health products, play a crucial role in facilitating the transition to a circular economy. Research into the psychological dimensions of consumer behaviour and necessary technological advancements highlighted in digitalization trends are essential for driving this transition forward.

References

Aberdeen, T. (2013). Yin, R. K. (2009). Case study research: Design and methods (4th Ed.). Thousand Oaks, CA: Sage. *The Canadian Journal of Action Research*, *14*(1), 69–71. https://doi.org/10.33524/cjar.v14i1.73

ACSQHC. (2021). *National Safety and Quality Health Service Standards* (Second edition). Australian Commission on Safety and Quality in Health Care.

Adolph, C., Amano, K., Bang-Jensen, B., Fullman, N., & Wilkerson, J. (2020). Pandemic Politics: Timing State-Level Social Distancing Responses to COVID-19. *Journal of Health Politics, Policy and Law*, 8802162. https://doi.org/10.1215/03616878-8802162

Anderson, M., Mckee, M., & Mossialos, E. (2020). Developing a sustainable exit strategy for COVID-19: Health, economic and public policy implications. *Journal of the Royal Society of Medicine, 113*(5), 176–178. https://doi.org/10.1177/0141076820925229

Annis, T., Pleasants, S., Hultman, G., Lindemann, E., Thompson, J. A., Billecke, S., Badlani, S., & Melton, G. B. (2020). Rapid implementation of a COVID-19 remote patient monitoring program. *Journal of the American Medical Informatics Association*, *27*(8), 1326–1330. https://doi.org/10.1093/jamia/ocaa097

Azevedo, S., Rodrigues, T. C., & Londral, A. R. (2021). Domains and Methods Used to Assess Home Telemonitoring Scalability: Systematic Review. *JMIR mHealth and uHealth*, *9*(8), e29381. https://doi.org/10.2196/29381

Ba, C. T., Zignani, M., & Gaito, S. (2023). Characterizing growth in decentralized socio-economic networks through triadic closure-related network motifs. *Online Social Networks and Media, 37–38*, 100266. https://doi.org/10.1016/j.osnem.2023.100266

Baginski, B. N., Byrne, K. A., Vaz, D. G., Barber, R., Blackhurst, D., Tibbett, T. P., & Guichard, J. L. (2021). Development and implementation of a remote patient monitoring program for heart failure: A single-centre experience. *ESC Heart Failure*, *8*(2), 1349–1358. https://doi.org/10.1002/ehf2.13214

Bakalar, R. S. (2022). Telemedicine: Its Past, Present and Future. In J. M. Kiel, G. R. Kim, & M. J. Ball (Eds.), *Healthcare Information Management Systems* (pp. 149–160). Springer International Publishing. https://doi.org/10.1007/978-3-031-07912-2_9

Basole, R. C., & Rouse, W. B. (2008). Complexity of service value networks: Conceptualization and empirical investigation. *IBM Systems Journal*, *47*(1), 53–70. https://doi.org/10.1147/sj.471.0053

Beaman, L. A., BenYishay, A., Magruder, J., & Mobarak, A. M. (2018). Can Network Theory-Based Targeting Increase Technology Adoption? *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.3225815

Bellamy, M. A., & Basole, R. C. (2013). Network analysis of supply chain systems: A systematic review and future research. *Systems Engineering*, *16*(2), 235–249. https://doi.org/10.1002/sys.21238

Ben Charif, A., Zomahoun, H. T. V., LeBlanc, A., Langlois, L., Wolfenden, L., Yoong, S. L., Williams, C. M., Lépine, R., & Légaré, F. (2017). Effective strategies for scaling up evidence-based practices in primary care: A systematic review. *Implementation Science*, *12*(1), 139. https://doi.org/10.1186/s13012-017-0672-y

Bentley, M., Minstrell, M., Bucher, H., Morrissey, M., Robinson, A., & Stirling, C. (2014). A Case Study Evaluation Protocol to Assess Processes, Effectiveness and Impact of a Nurse Practitioner-Led Memory Clinic. *Health*, *06*(08), 748–756. https://doi.org/10.4236/health.2014.68096

Bhaskar, R. (2008). *A realist theory of science*. Routledge.

Bhaskar, R. (2009). *Scientific realism and human emancipation*. Routledge.

Bhattacharyya, O., Blumenthal, D., Stoddard, R., Mansell, L., Mossman, K., & Schneider, E. C. (2019). Redesigning care: Adapting new improvement methods to achieve person-centred care. *BMJ Quality & Safety*, *28*(3), 242–248. https://doi.org/10.1136/bmjqs-2018-008208

Black, A. D., Car, J., Pagliari, C., Anandan, C., Cresswell, K., Bokun, T., McKinstry, B., Procter, R., Majeed, A., & Sheikh, A. (2011). The Impact of eHealth on the Quality and Safety of Health Care: A Systematic Overview. *PLoS Medicine*, *8*(1), e1000387. https://doi.org/10.1371/journal.pmed.1000387

Blanchard, J., Rhoades, D., Nagykaldi, Z., Campbell, J., Cannady, T., Hopkins, M., Gibson, M., Lonewolf, H., & Doescher, M. (2022). Identifying Priorities and Strategies for Improving Colorectal Cancer Screening in Tribal Clinics. *Cancer Control*, *29*, 107327482211325. https://doi.org/10.1177/10732748221132516

Blandford, A., Gibbs, J., Newhouse, N., Perski, O., Singh, A., & Murray, E. (2018). Seven lessons for interdisciplinary research on interactive digital health interventions. *DIGITAL HEALTH*, *4*, 205520761877032. https://doi.org/10.1177/2055207618770325

Brzinsky-Fay, C. (2014). Graphical Representation of Transitions and Sequences. In P. Blanchard, F. Bühlmann, & J.-A. Gauthier (Eds.), *Advances in Sequence Analysis: Theory, Method, Applications* (Vol. 2, pp. 265–284). Springer International Publishing. https://doi.org/10.1007/978-3-319-04969-4_14

Buis, L. R., & Huh-Yoo, J. (2020). Common Shortcomings in Applying User-Centered Design for Digital Health. *IEEE Pervasive Computing*, *19*(3), 45–49. https://doi.org/10.1109/MPRV.2020.2997615

Burdette, R. (1926). Research for Teachers. *Burdett and Co, New York*.

Carter, P., Anderson, M., & Mossialos, E. (2020). Health system, public health, and economic implications of managing COVID-19 from a cardiovascular perspective. *European Heart Journal*, *41*(27), 2516–2518. https://doi.org/10.1093/eurheartj/ehaa342

Centro Hospitalar Lisboa Central. (2022). *Hospital de Santa Marta*. https://www.chlc.min-saude.pt/hospital-santa-marta/

Chesbrough, H. W., & Vanhaverbeke, W. (2018). Open Innovation and Public Policy in the EU with Implications for SMEs. In W. Vanhaverbeke, F. Frattini, N. Roijakkers, & M. Usman, *Researching Open Innovation in SMEs* (pp. 455–492). WORLD SCIENTIFIC. https://doi.org/10.1142/9789813230972_0015

Cilliers, P. (1998). *Complexity and postmodernism: Understanding complex systems*. Routledge.

Cirule, I., & Uvarova, I. (2022). Open Innovation and Determinants of Technology-Driven Sustainable Value Creation in Incubated Start-Ups. *Journal of Open Innovation: Technology, Market, and Complexity*, *8*(3), 162. https://doi.org/10.3390/joitmc8030162

Clegg, D., & Barker, R. (1994). *Fast-track: A RAD approach*. Addison-Wesley Pub. Co. ; Oracle.

Clemensen, J., Rothmann, M. J., Smith, A. C., Caffery, L. J., & Danbjorg, D. B. (2017). Participatory design methods in telemedicine research. *Journal of Telemedicine and Telecare*, *23*(9), 780–785. https://doi.org/10.1177/1357633X16686747

Coelho, P. N. M. P., Miranda, L. M. R. P. C., Barros, P. M. P., & Fragata, J. I. G. (2019). Quality of life after elective cardiac surgery in elderly patients. *Interactive CardioVascular and Thoracic Surgery*, *28*(2), 199–205. https://doi.org/10.1093/icvts/ivy235

Collins, J. M., & Dempsey, M. K. (2019). Healthcare innovation methodology: Codifying the process of translating knowledge into better healthcare products, services, and procedures. *Current Opinion in Biomedical Engineering*, *11*, 16–21. https://doi.org/10.1016/j.cobme.2019.09.003

Collins, J. M., Reizes, O., & Dempsey, M. K. (2016). Healthcare Commercialization Programs: Improving the Efficiency of Translating Healthcare Innovations From Academia Into Practice. *IEEE Journal of Translational Engineering in Health and Medicine*, *4*, 1–7. https://doi.org/10.1109/JTEHM.2016.2609915

Combi, C., Pozzani, G., & Pozzi, G. (2016). Telemedicine for Developing Countries. A Survey and Some Design Issues. *Applied Clinical Informatics*, *7*(4), 1025–1050. https://doi.org/10.4338/ACI-2016-06-R-0089

Cooke, A., Smith, D., & Booth, A. (2012). Beyond PICO: The SPIDER Tool for Qualitative Evidence Synthesis. *Qualitative Health Research*, *22*(10), 1435–1443. https://doi.org/10.1177/1049732312452938

Cooper, R. G. (2008). Perspective: The Stage-Gate ® Idea-to-Launch Process—Update, What's New, and NexGen Systems. *Journal of Product Innovation Management*, *25*(3), 213–232. https://doi.org/10.1111/j.1540-5885.2008.00296.x

Cota, M. P., Thomaschewski, J., Schrepp, M., & Gonçalves, R. (2014). Efficient Measurement of the User Experience. A Portuguese Version. *Procedia Computer Science*, *27*, 491–498. https://doi.org/10.1016/j.procs.2014.02.053

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: The new Medical Research Council guidance. *BMJ*, a1655. https://doi.org/10.1136/bmj.a1655

Crawford, A., & Serhal, E. (2020). Digital Health Equity and COVID-19: The Innovation Curve Cannot Reinforce the Social Gradient of Health. *Journal of Medical Internet Research*, *22*(6), e19361. https://doi.org/10.2196/19361

Crawford, T. C., Magruder, J. T., Grimm, J. C., Suarez-Pierre, A., Sciortino, C. M., Mandal, K., Zehr, K. J., Conte, J. V., Higgins, R. S., Cameron, D. E., & Whitman, G. J. (2017). Complications After Cardiac Operations: All Are Not Created Equal. *The Annals of Thoracic Surgery*, *103*(1), 32–40. https://doi.org/10.1016/j.athoracsur.2016.10.022

Cresswell, K. M., Bates, D. W., & Sheikh, A. (2013). Ten key considerations for the successful implementation and adoption of large-scale health information technology. *Journal of the*

American Medical Informatics Association: JAMIA, *20*(e1), e9–e13. https://doi.org/10.1136/amiajnl-2013-001684

Cummins, N., & Schuller, B. W. (2020). Five Crucial Challenges in Digital Health. *Frontiers in Digital Health*, *2*, 536203. https://doi.org/10.3389/fdgth.2020.536203

DeSanctis, G., & Poole, M. S. (1994). Capturing the Complexity in Advanced Technology Use: Adaptive Structuration Theory. *Organization Science*, *5*(2), 121–147. https://doi.org/10.1287/orsc.5.2.121

Devine, B. (2022). Assessing the Value of Remote Patient Monitoring Solutions in Addressing Challenges in Patient Care. *Value in Health*, *25*(6), 887–889. https://doi.org/10.1016/j.jval.2022.03.020

Di Stefano, G., Gambardella, A., & Verona, G. (2012). Technology push and demand pull perspectives in innovation studies: Current findings and future research directions. *Research Policy*, *41*(8), 1283–1295. https://doi.org/10.1016/j.respol.2012.03.021

Dias, P., Cardoso, M., Guede-Fernandez, F., Martins, A., & Londral, A. (2022). Remote Patient Monitoring Systems based on Conversational Agents for Health Data Collection: *Proceedings of the 15th International Joint Conference on Biomedical Engineering Systems and Technologies*, 812–820. https://doi.org/10.5220/0011011000003123

Dixon-Woods, M., Agarwal, S., Jones, D., Young, B., & Sutton, A. (2005). Synthesising qualitative and quantitative evidence: A review of possible methods. *Journal of Health Services Research & Policy*, *10*(1), 45–53. https://doi.org/10.1177/135581960501000110

Doraiswamy, S., Abraham, A., Mamtani, R., & Cheema, S. (2020). Use of Telehealth During the COVID-19 Pandemic: Scoping Review. *Journal of Medical Internet Research*, *22*(12), e24087. https://doi.org/10.2196/24087

Douglas, F. C., Gray, D. A., & van Teijlingen, E. R. (2010). Using a realist approach to evaluate smoking cessation interventions targeting pregnant women and young people. *BMC Health Services Research*, *10*(1), 49. https://doi.org/10.1186/1472-6963-10-49

Driggin, E., Madhavan, M. V., Bikdeli, B., Chuich, T., Laracy, J., Biondi-Zoccai, G., Brown, T. S., Der Nigoghossian, C., Zidar, D. A., Haythe, J., Brodie, D., Beckman, J. A., Kirtane, A. J., Stone, G. W., Krumholz, H. M., & Parikh, S. A. (2020). Cardiovascular Considerations for Patients, Health Care Workers, and Health Systems During the COVID-19 Pandemic. *Journal of the American College of Cardiology*, *75*(18), 2352–2371. https://doi.org/10.1016/j.jacc.2020.03.031

Drummond, M. (2015). *Methods for the economic evaluation of health care programmes* (Fourth edition). Oxford University Press.

Drummond, M., Griffin, A., & Tarricone, R. (2009). Economic Evaluation for Devices and Drugs—Same or Different? *Value in Health*, *12*(4), 402–404. https://doi.org/10.1111/j.1524-4733.2008.00476_1.x

Dugstad, J., Eide, T., Nilsen, E. R., & Eide, H. (2019). Towards successful digital transformation through co-creation: A longitudinal study of a four-year implementation of digital monitoring technology in residential care for persons with dementia. *BMC Health Services Research*, *19*(1), 366. https://doi.org/10.1186/s12913-019-4191-1

EasyHealth4Covid. (2021). *EasyHealth 4 Covid*. https://easyhealth4covid.vohcolab.org/

ECDC, E. U. (2020, May 20). *European Centre for Disease Prevention and Control An agency of the European Union*. https://www.ecdc.europa.eu/en/geographical-distribution-2019-ncov-cases

Efthymiou, C. A., & O'Regan, D. J. (2011). Postdischarge complications: What exactly happens when the patient goes home? *Interactive CardioVascular and Thoracic Surgery*, *12*(2), 130–134. https://doi.org/10.1510/icvts.2010.249474

Eisenmann, T., Ries, E., & Dillard, S. (2011). Hypothesis-driven entrepreneurship: The lean startup. *Harv Bus Sch Backgr Note, Case No. 812-095*. https://ssrn.com/abstract=2037237

Eldridge, S. M., Lancaster, G. A., Campbell, M. J., Thabane, L., Hopewell, S., Coleman, C. L., & Bond, C. M. (2016). Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework. *PLOS ONE*, *11*(3), e0150205. https://doi.org/10.1371/journal.pone.0150205

Engeström, Y. (2005). *Developmental work research: Expanding activity theory in practice*. Lehmanns Media.

EXPH, E. P. on effective ways of investing in H. (2018). *Assessing the impact of digital transformation of health services*. 10.2875/644722

EXPH, E. P. on effective ways of investing in H. (2019). *Defining value in "value-based healthcare."* https://doi.org/10.2875/35471

Fahy, N., & Williams, G. (2021). *Use of digital health tools in Europe—Before, during and after COVID-19* (Health Systems and Policy Analysis Policy Brief 42). WHO Regional Office for Europe.

Farias, F. A. C. de, Dagostini, C. M., Bicca, Y. de A., Falavigna, V. F., & Falavigna, A. (2020). Remote Patient Monitoring: A Systematic Review. *Telemedicine and E-Health*, *26*(5), 576–583. https://doi.org/10.1089/tmj.2019.0066

Farias, R., Sedeno, M., Beaucage, D., Drouin, I., Ouellet, I., Joubert, A., Abimaroun, R., Patel, M., Abou Rjeili, M., & Bourbeau, J. (2019). Innovating the treatment of COPD exacerbations: A phone interactive telesystem to increase COPD Action Plan adherence. *BMJ Open Respiratory Research*, *6*(1), e000379. https://doi.org/10.1136/bmjresp-2018-000379

Ferrua, M., Minvielle, E., Fourcade, A., Lalloué, B., Sicotte, C., Di Palma, M., & Mir, O. (2020). How to Design a Remote Patient Monitoring System? A French Case Study. *BMC Health Services Research*, *20*(1), 434. https://doi.org/10.1186/s12913-020-05293-4

Fisk, M., Livingstone, A., & Pit, S. W. (2020). Telehealth in the Context of COVID-19: Changing Perspectives in Australia, the United Kingdom, and the United States. *Journal of Medical Internet Research*, *22*(6), e19264. https://doi.org/10.2196/19264

Franco, L. A., Hämäläinen, R. P., Rouwette, E. A. J. A., & Leppänen, I. (2021). Taking stock of behavioural OR: A review of behavioural studies with an intervention focus. *European Journal of Operational Research*, *293*(2), 401–418. https://doi.org/10.1016/j.ejor.2020.11.031

Fraunhofer. (2022). *Fraunhofer Portugal*. www.fraunhofer.pt/en/about.html

Fraunhofer Portugal. (2023). *About Fraunhofer Portugal*. Associação Fraunhofer Portugal Research. https://www.fraunhofer.pt/en/about.html

Fundação para a Ciência e Tecnologia (FCT). (2022). *FCT Projects*. https://www.fct.pt/apoios/projectos/concursos/datascience/index. phtml.en

Gall, T., Vallet, F., & Yannou, B. (2022). How to visualise futures studies concepts: Revision of the futures cone. *Futures*, *143*, 103024. https://doi.org/10.1016/j.futures.2022.103024

Gheorguiu, B., & Ratchford, F. (2015). Scaling Up the Use of Remote Patient Monitoring in Canada. In G. Gillis, D. Newsham, & A. J. Maeder, *Global Telehealth 2015: Integrating Technology and Information for Better Healthcare*. IOS Press, Incorporated. http://public.ebookcentral.proquest.com/choice/publicfullrecord.aspx?p=5161911

Glaser, B. G., & Strauss, A. L. (2010). *The discovery of grounded theory: Strategies for qualitative research* (5. paperback print). Aldine Transaction.

Gooch, P., & Roudsari, A. (2011). Computerization of workflows, guidelines, and care pathways: A review of implementation challenges for process-oriented health information systems. *Journal of the American Medical Informatics Association*, *18*(6), 738–748. https://doi.org/10.1136/amiajnl-2010-000033

Gordon, W. J., Henderson, D., DeSharone, A., Fisher, H. N., Judge, J., Levine, D. M., MacLean, L., Sousa, D., Su, M. Y., & Boxer, R. (2020). Remote Patient Monitoring Program for Hospital

Discharged COVID-19 Patients. *Applied Clinical Informatics*, *11*(05), 792–801. https://doi.org/10.1055/s-0040-1721039

Graeber, D. (2001). *Toward an anthropological theory of value: The false coin of our own dreams* (1. ed). Palgrave.

Graeber, D. (2013). It is value that brings universes into being. *HAU: Journal of Ethnographic Theory*, *3*(2), 219–243. https://doi.org/10.14318/hau3.2.012

Granström, E., Wannheden, C., Brommels, M., Hvitfeldt, H., & Nyström, M. E. (2020). Digital tools as promoters for person-centered care practices in chronic care? Healthcare professionals' experiences from rheumatology care. *BMC Health Services Research*, *20*(1), 1108. https://doi.org/10.1186/s12913-020-05945-5

Gray, M. (2017). Population healthcare: Designing population-based systems. *Journal of the Royal Society of Medicine*, *110*(5), 183–187. https://doi.org/10.1177/0141076817703028

Grustam, A. S., Buyukkaramikli, N., Koymans, R., Vrijhoef, H. J. M., & Severens, J. L. (2019). Value of information analysis in telehealth for chronic heart failure management. *PloS One*, *14*(6), e0218083. https://doi.org/10.1371/journal.pone.0218083

Guo, C., Ashrafian, H., Ghafur, S., Fontana, G., Gardner, C., & Prime, M. (2020). Challenges for the evaluation of digital health solutions—A call for innovative evidence generation approaches. *Npj Digital Medicine*, *3*(1), 110. https://doi.org/10.1038/s41746-020-00314-2

Haby, M. M., Chapman, E., Clark, R., Barreto, J., Reveiz, L., & Lavis, J. N. (2016). What are the best methodologies for rapid reviews of the research evidence for evidence-informed decision making in health policy and practice: A rapid review. *Health Research Policy and Systems*, *14*(1), 83. https://doi.org/10.1186/s12961-016-0155-7

Hamilton, D. F., Lane, J. V., Gaston, P., Patton, J. T., MacDonald, D. J., Simpson, A. H. R. W., & Howie, C. R. (2014). Assessing treatment outcomes using a single question: The Net Promoter

Score. *The Bone & Joint Journal*, *96-B*(5), 622–628. https://doi.org/10.1302/0301-620X.96B5.32434

Hancock, D., Algozzine, B., & Lim, J. H. (2021). *Doing Case Study Research: A Practical Guide for Beginning Researchers 4th Edition*. Teachers College Press; 4th edition.

Hanley, J., Pinnock, H., Paterson, M., & McKinstry, B. (2018). Implementing telemonitoring in primary care: Learning from a large qualitative dataset gathered during a series of studies. *BMC Family Practice*, *19*(1), 118. https://doi.org/10.1186/s12875-018-0814-6

Hansen, D., Golbeck, A. L., Noblitt, V., Pinsonneault, J., & Christner, J. (2011). Cost factors in implementing telemonitoring programs in rural home health agencies. *Home Healthcare Nurse*, *29*(6), 375–382. https://doi.org/10.1097/NHH.0b013e31821b736f

Hayes, N. (Ed.). (1997). *Doing qualitative analysis in psychology*. Psychology Press.

Haynes, R. B., Taylor, D. W., & Sackett, D. L. (Eds.). (1979). *Compliance in health care*. Johns Hopkins University Press.

Heath, S., Fuller, A., & Johnston, B. (2009). Chasing shadows: Defining network boundaries in qualitative social network analysis. *Qualitative Research*, *9*(5), 645–661. https://doi.org/10.1177/1468794109343631

Herdman, M., Gudex, C., Lloyd, A., Janssen, Mf., Kind, P., Parkin, D., Bonsel, G., & Badia, X. (2011). Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of Life Research*, *20*(10), 1727–1736. https://doi.org/10.1007/s11136-011-9903-x

Hevner, March, Park, & Ram. (2004). Design Science in Information Systems Research. *MIS Quarterly*, *28*(1), 75. https://doi.org/10.2307/25148625

Hibbard, J. H., & Greene, J. (2013). What The Evidence Shows About Patient Activation: Better Health Outcomes And Care Experiences; Fewer Data On Costs. *Health Affairs*, *32*(2), 207–214. https://doi.org/10.1377/hlthaff.2012.1061

Hicks, L. L., Fleming, D. A., & Desaulnier, A. (2009). The application of remote monitoring to improve health outcomes to a rural area. *Telemedicine Journal and E-Health: The Official Journal of the American Telemedicine Association*, *15*(7), 664–671. https://doi.org/10.1089/tmj.2009.0009

Higgins, J. P. T., & Cochrane Collaboration (Eds.). (2020). *Cochrane handbook for systematic reviews of interventions* (Second edition). Wiley-Blackwell.

Holden, L. M. (2005). Complex adaptive systems: Concept analysis. *Journal of Advanced Nursing*, *52*(6), 651–657. https://doi.org/10.1111/j.1365-2648.2005.03638.x

Hospital Santa Marta. (2023). *Hospital Santa Marta – CH | Lisboa Central*. https://www.chlc.min-saude.pt/hospital-santa-marta/

Iakovleva, T., M. Oftedal, E., & Bessant, J. (2019). Responsible innovation in digital health. In T. Iakovleva, E. M. Oftedal, & J. Bessant (Eds.), *Responsible Innovation in Digital Health*. Edward Elgar Publishing. https://doi.org/10.4337/9781788975063.00008

Itten, R., Hischier, R., Andrae, A. S. G., Bieser, J. C. T., Cabernard, L., Falke, A., Ferreboeuf, H., Hilty, L. M., Keller, R. L., Lees-Perasso, E., Preist, C., & Stucki, M. (2020). Digital transformation—Life cycle assessment of digital services, multifunctional devices and cloud computing. *The International Journal of Life Cycle Assessment*, *25*(10), 2093–2098. https://doi.org/10.1007/s11367-020-01801-0

Jackson, M. C. (2001). Critical systems thinking and practice. *European Journal of Operational Research*, *128*(2), 233–244. https://doi.org/10.1016/S0377-2217(00)00067-9

Jani, A., Jungmann, S., & Gray, M. (2018). Shifting to triple value healthcare: Reflections from England. *Zeitschrift Für Evidenz, Fortbildung Und Qualität Im Gesundheitswesen*, *130*, 2–7. https://doi.org/10.1016/j.zefq.2018.01.002

Johannesson, P., & Perjons, E. (2021). A Method Framework for Design Science Research. In P. Johannesson & E. Perjons, *An Introduction to Design Science* (pp. 77–93). Springer International Publishing. https://doi.org/10.1007/978-3-030-78132-3_4

Johns, M. W. (1991). A new method for measuring daytime sleepiness: The Epworth sleepiness scale. *Sleep*, *14*(6), 540–545. https://doi.org/10.1093/sleep/14.6.540

Jones, P. W., Harding, G., Berry, P., Wiklund, I., Chen, W.-H., & Kline Leidy, N. (2009). Development and first validation of the COPD Assessment Test. *The European Respiratory Journal*, *34*(3), 648–654. https://doi.org/10.1183/09031936.00102509

Jovell, A. J., & Navarro-Rubio, M. D. (1995). Evaluation of scientific evidence. *Medicina Clinica*, *105*(19), 740–743.

Keahey, J. (2021). Sustainable Development and Participatory Action Research: A Systematic Review. *Systemic Practice and Action Research*, *34*(3), 291–306. https://doi.org/10.1007/s11213-020-09535-8

Keeney, R. L. (1996). Value-focused thinking: Identifying decision opportunities and creating alternatives. *European Journal of Operational Research*, *92*(3), 537–549. https://doi.org/10.1016/0377-2217(96)00004-5

Khangura, S., Konnyu, K., Cushman, R., Grimshaw, J., & Moher, D. (2012). Evidence summaries: The evolution of a rapid review approach. *Systematic Reviews*, *1*(1), 10. https://doi.org/10.1186/2046-4053-1-10

Khoury, H., Ragalie, W., Sanaiha, Y., Boutros, H., Rudasill, S., Shemin, R. J., & Benharash, P. (2020). Readmission After Surgical Aortic Valve Replacement in the United States. *The Annals of Thoracic Surgery*, *110*(3), 849–855. https://doi.org/10.1016/j.athoracsur.2019.11.058

Kidholm, K., Ekeland, A. G., Jensen, L. K., Rasmussen, J., Pedersen, C. D., Bowes, A., Flottorp, S. A., & Bech, M. (2012). A MODEL FOR ASSESSMENT OF TELEMEDICINE APPLICATIONS:

MAST. *International Journal of Technology Assessment in Health Care*, *28*(1), 44–51. https://doi.org/10.1017/S0266462311000638

Kowatsch, T., Otto, L., Harperink, S., Cotti, A., & Schlieter, H. (2019). A design and evaluation framework for digital health interventions. *It - Information Technology*, *61*(5–6), 253–263. https://doi.org/10.1515/itit-2019-0019

Krippendorff, K. (2013). *Content analysis: An introduction to its methodology* (3rd ed). SAGE.

Kruse, C. S. (2019). Writing a Systematic Review for Publication in a Health-Related Degree Program. *JMIR Research Protocols*, *8*(10), e15490. https://doi.org/10.2196/15490

Kvedar, J. C., & Fogel, A. L. (2017). Why Real-World Results Are So Challenging for Digital Health. *NEJM Catalyst*. https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0453

Lacasse, Y., Bureau, M.-P., & Sériès, F. (2004). A new standardised and self-administered quality of life questionnaire specific to obstructive sleep apnoea. *Thorax*, *59*(6), 494–499. https://doi.org/10.1136/thx.2003.011205

Lapão, L. V., Peyroteo, M., Maia, M., Seixas, J., Gregório, J., Mira da Silva, M., Heleno, B., & Correia, J. C. (2021). Implementation of Digital Monitoring Services During the COVID-19 Pandemic for Patients With Chronic Diseases: Design Science Approach. *Journal of Medical Internet Research*, *23*(8), e24181. https://doi.org/10.2196/24181

Lee, D. (2019). A model for designing healthcare service based on the patient experience. *International Journal of Healthcare Management*, *12*(3), 180–188. https://doi.org/10.1080/20479700.2017.1359956

Lemelin, A., Paré, G., Bernard, S., & Godbout, A. (2020). Demonstrated Cost-Effectiveness of a Telehomecare Program for Gestational Diabetes Mellitus Management. *Diabetes Technology & Therapeutics*, *22*(3), 195–202. https://doi.org/10.1089/dia.2019.0259

Lettice, F., Rogers, H., Yaghmaei, E., & Pawar, K. S. (2017). Responsible Research and Innovation Revisited: Aligning Product Development Processes with the Corporate Responsibility

Agenda. In A. Brem & E. Viardot (Eds.), *Revolution of Innovation Management* (pp. 247–269). Palgrave Macmillan UK. https://doi.org/10.1057/978-1-349-95123-9_9

Londral, A., Azevedo, S., Santos, J., & Coelho, P. (2021). CardioFollow.AI - A Digital Follow-up Service Expanded Beyond the Hospital Walls. *Health Management*, *21*(6).

Lugo, V. M., Garmendia, O., Suarez-Girón, M., Torres, M., Vázquez-Polo, F. J., Negrín, M. A., Moraleda, A., Roman, M., Puig, M., Ruiz, C., Egea, C., Masa, J. F., Farré, R., & Montserrat, J. M. (2019). Comprehensive management of obstructive sleep apnea by telemedicine: Clinical improvement and cost-effectiveness of a Virtual Sleep Unit. A randomized controlled trial. *PloS One*, *14*(10), e0224069. https://doi.org/10.1371/journal.pone.0224069

Maeder, A., Poultney, N., Morgan, G., & Lippiatt, R. (2015). Patient Compliance in Home-Based Self-Care Telehealth Projects. *Journal of Telemedicine and Telecare*, *21*(8), 439–442. https://doi.org/10.1177/1357633X15612382

Makhni, S., Atreja, A., Sheon, A., Van Winkle, B., Sharp, J., & Carpenter, N. (2017). The Broken Health Information Technology Innovation Pipeline: A Perspective from the NODE Health Consortium. *Digital Biomarkers*, 64–72. https://doi.org/10.1159/000479017

Maramba, I., Chatterjee, A., & Newman, C. (2019). Methods of usability testing in the development of eHealth applications: A scoping review. *International Journal of Medical Informatics*, *126*, 95–104. https://doi.org/10.1016/j.ijmedinf.2019.03.018

Mathews, S. C., McShea, M. J., Hanley, C. L., Ravitz, A., Labrique, A. B., & Cohen, A. B. (2019). Digital health: A path to validation. *Npj Digital Medicine*, *2*(1), 38. https://doi.org/10.1038/s41746-019-0111-3

McCoy, D., & Allotey, P. (2021). An Introduction to Health Systems. In Jo. M. Martins, I. Pathmanathan, D. T. Tan, S. C. Lim, & P. Allotey (Eds.), *Systems Thinking Analyses for Health Policy and Systems Development* (1st ed., pp. 3–16). Cambridge University Press. https://doi.org/10.1017/9781108954846.004

McElroy, I., Sareh, S., Zhu, A., Miranda, G., Wu, H., Nguyen, M., Shemin, R., & Benharash, P. (2016). Use of digital health kits to reduce readmission after cardiac surgery. *Journal of Surgical Research*, *204*(1), 1–7. https://doi.org/10.1016/j.jss.2016.04.028

Mehrotra, A., Ray, K., Brockmeyer, D. M., Barnett, M. L., & Bender, J. A. (2020). Rapidly converting to "virtual practices": Outpatient care in the era of Covid-19. *NEJM Catalyst Innovations in Care Delivery*, *1*(2).

Mengden, T., Vetter, H., Tislér, A., & Illyés, M. (2001). Tele-monitoring of home blood pressure: *Blood Pressure Monitoring*, *6*(4), 185–189. https://doi.org/10.1097/00126097-200108000-00004

Meystre, S. (2005). The Current State of Telemonitoring: A Comment on the Literature. *Telemedicine and E-Health*, *11*(1), 63–69. https://doi.org/10.1089/tmj.2005.11.63

Midgley, G. (1996). What Is This Thing Called CST? In R. L. Flood & N. R. A. Romm (Eds.), *Critical Systems Thinking* (pp. 11–24). Springer US. https://doi.org/10.1007/978-0-585-34651-9_1

Midgley, G. (2003). Science as Systemic Intervention: Some Implications of Systems Thinking and Complexity for the Philosophy of Science. *Systemic Practice and Action Research*, *16*(2), 77–97. https://doi.org/10.1023/A:1022833409353

Midgley, G. (2006). Systemic Intervention for Public Health. *American Journal of Public Health*, *96*(3), 466–472. https://doi.org/10.2105/AJPH.2005.067660

Midgley, G., Munlo, I., & Brown, M. (1998). The theory and practice of boundary critique: Developing housing services for older people. *Journal of the Operational Research Society*, *49*(5), 467–478. https://doi.org/10.1057/palgrave.jors.2600531

Milat, A. J., King, L., Bauman, A. E., & Redman, S. (2013). The concept of scalability: Increasing the scale and potential adoption of health promotion interventions into policy and practice. *Health Promotion International*, *28*(3), 285–298. https://doi.org/10.1093/heapro/dar097

Milat, A., Lee, K., Conte, K., Grunseit, A., Wolfenden, L., van Nassau, F., Orr, N., Sreeram, P., & Bauman, A. (2020). Intervention Scalability Assessment Tool: A decision support tool for health policy makers and implementers. *Health Research Policy and Systems*, *18*(1), 1. https://doi.org/10.1186/s12961-019-0494-2

Miller, D. (2008). The uses of value. *Geoforum*, *39*(3), 1122–1132. https://doi.org/10.1016/j.geoforum.2006.03.009

Miller, D., Costa, E., Haapio-Kirk, L., Haynes, N., Sinanan, J., McDonald, T., Nicolescu, R., Spyer, J., Venkatraman, S., & Wang, X. (2019). Contemporary Comparative Anthropology – The Why We Post Project. *Ethnos*, *84*(2), 283–300. https://doi.org/10.1080/00141844.2017.1397044

Mind Tools. (2022). *Cause and effect analysis: Identifying the likely causes of problems.* http://www.mindtools.com/pages/ article/newTMC˙03.htm

Mingers, J. (2000). The Contribution of Critical Realism as an Underpinning Philosophy for OR/MS and Systems. *The Journal of the Operational Research Society*, *51*(11), 1256. https://doi.org/10.2307/254211

Mingers, J. (2003). A classification of the philosophical assumptions of management science methods. *Journal of the Operational Research Society*, *54*(6), 559–570. https://doi.org/10.1057/palgrave.jors.2601436

Mingers, J. (2014). *Systems Thinking, Critical Realism and Philosophy: A Confluence of Ideas*. Taylor & Francis. https://books.google.pt/books?id=tcRwAwAAQBAJ

Mingers, J. (2015). Helping business schools engage with real problems: The contribution of critical realism and systems thinking. *European Journal of Operational Research*, *242*(1), 316–331. https://doi.org/10.1016/j.ejor.2014.10.058

Mingers, J., & Brocklesby, J. (1997). Multimethodology: Towards a framework for mixing methodologies. *Omega*, *25*(5), 489–509. https://doi.org/10.1016/S0305-0483(97)00018-2

Mingers, J., & Standing, C. (2020). A Framework for Validating Information Systems Research Based on a Pluralist Account of Truth and Correctness. *Journal of the Association for Information Systems*, 117–151. https://doi.org/10.17705/1jais.00594

Miranda, E. (2022). Moscow Rules: A Quantitative Exposé. In V. Stray, K.-J. Stol, M. Paasivaara, & P. Kruchten (Eds.), *Agile Processes in Software Engineering and Extreme Programming* (Vol. 445, pp. 19–34). Springer International Publishing. https://doi.org/10.1007/978-3-031-08169-9_2

Mogessie, Y. G., Ntacyabukura, B., Mengesha, D. T., Musa, M. B., Wangari, M.-C., Claude, N., Buntongyi, N., & Lucero-Prisno Iii, D. E. (2021). Digital health and COVID-19: Challenges of use and implementation in sub-Saharan Africa. *Pan African Medical Journal*, *38*. https://doi.org/10.11604/pamj.2021.38.240.27948

Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., & The PRISMA Group. (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Medicine*, *6*(7), e1000097. https://doi.org/10.1371/journal.pmed.1000097

Mollaei, N., Londral, A. R., Cepeda, C., Azevedo, S., Santos, J. P., Coelho, P., Fragata, J., & Gamboa, H. (2021). Length of Stay Prediction in Acute Intensive Care Unit in Cardiothoracic Surgery Patients. *2021 Seventh International Conference on Bio Signals, Images, and Instrumentation (ICBSII)*, 1–5. https://doi.org/10.1109/ICBSII51839.2021.9445145

Moncher, F. J., & Prinz, R. J. (1991). Treatment fidelity in outcome studies. *Clinical Psychology Review*, *11*(3), 247–266. https://doi.org/10.1016/0272-7358(91)90103-2

Mori Makoto, Angraal Suveen, Chaudhry Sarwat I., Suter Lisa G., Geirsson Arnar, Wallach Joshua D., & Krumholz Harlan M. (2019). Characterizing Patient-Centered Postoperative Recovery After Adult Cardiac Surgery: A Systematic Review. *Journal of the American Heart Association*, *8*(21), e013546. https://doi.org/10.1161/JAHA.119.013546

Morton, E., Barnes, S. J., & Michalak, E. E. (2020). Participatory digital health research: A new paradigm for mHealth tool development. *General Hospital Psychiatry*, *66*, 67–69. https://doi.org/10.1016/j.genhosppsych.2020.07.005

Mulgund, P., Sharman, R., Rifkin, D., & Marrazzo, S. (2021). Design, Development, and Evaluation of a Telemedicine Platform for Patients With Sleep Apnea (Ognomy): Design Science Research Approach. *JMIR Formative Research*, *5*(7), e26059. https://doi.org/10.2196/26059

Murray, E., Hekler, E. B., Andersson, G., Collins, L. M., Doherty, A., Hollis, C., Rivera, D. E., West, R., & Wyatt, J. C. (2016). Evaluating Digital Health Interventions. *American Journal of Preventive Medicine*, *51*(5), 843–851. https://doi.org/10.1016/j.amepre.2016.06.008

NEJM Catalyst. (2018). *What Is Lean Healthcare?* https://catalyst.nejm.org/doi/full/10.1056/CAT.18.0193

NOVA Medical School. (2022). *NOVA Medical School*. https://www.nms.unl.pt/pt-pt/nms

Nundy, S., Dick, J. J., Chou, C.-H., Nocon, R. S., Chin, M. H., & Peek, M. E. (2014). Mobile phone diabetes project led to improved glycemic control and net savings for Chicago plan participants. *Health Affairs (Project Hope)*, *33*(2), 265–272. https://doi.org/10.1377/hlthaff.2013.0589

Operational Research Society. (2023, March 18). https://www.theorsociety.com/about-or/

Padwal, R. S., So, H., Wood, P. W., Mcalister, F. A., Siddiqui, M., Norris, C. M., Jeerakathil, T., Stone, J., Valaire, S., Mann, B., Boulanger, P., & Klarenbach, S. W. (2019). Cost-effectiveness of home blood pressure telemonitoring and case management in the secondary prevention of cerebrovascular disease in Canada. *Journal of Clinical Hypertension (Greenwich, Conn.)*, *21*(2), 159–168. https://doi.org/10.1111/jch.13459

Palm, W., Webb, E., Hernández-Quevedo, C., Scarpetti, G., Lessof, S., Siciliani, L., & van Ginneken, E. (2021). Gaps in coverage and access in the European Union. *Health Policy*, *125*(3), 341–350. https://doi.org/10.1016/j.healthpol.2020.12.011

Pare, G., Jaana, M., & Sicotte, C. (2007). Systematic Review of Home Telemonitoring for Chronic Diseases: The Evidence Base. *Journal of the American Medical Informatics Association*, *14*(3), 269–277. https://doi.org/10.1197/jamia.M2270

Paré, G., Poba-Nzaou, P., Sicotte, C., Beaupré, A., Lefrançois, É., Nault, D., & Saint-Jules, D. (2013). Comparing the costs of home telemonitoring and usual care of chronic obstructive pulmonary disease patients: A randomized controlled trial. *European Research in Telemedicine / La Recherche Européenne En Télémédecine*, *2*(2), 35–47. https://doi.org/10.1016/j.eurtel.2013.05.001

Park, D. K., Jung, E.-Y., Park, R. W., Lee, Y. H., Hwang, H. J., Son, I. A., & Hu, M.-H. (2011). Telecare System for Cardiac Surgery Patients: Implementation and Effectiveness. *Healthcare Informatics Research*, *17*(2), 93. https://doi.org/10.4258/hir.2011.17.2.93

Parrish, J., Schachter, S., Dempsey, M., & Collins, J. (2015). Facilitating Translational Research. *Journal of Investigative Dermatology*, *135*(6), 1463–1465. https://doi.org/10.1038/jid.2015.5

Paté-Cornell, M. E., Rouse, W. B., & Vest, C. M. (Eds.). (2016). *Perspectives on complex global challenges: Education, energy, healthcare, security and resilience*. Wiley.

Peffers, K., Tuunanen, T., Rothenberger, M. A., & Chatterjee, S. (2007). A Design Science Research Methodology for Information Systems Research. *Journal of Management Information Systems*, *24*(3), 45–77. https://doi.org/10.2753/MIS0742-1222240302

Peirce, S. C., Hardisty, A. R., Preece, A. D., & Elwyn, G. (2011). Designing and implementing telemonitoring for early detection of deterioration in chronic disease: Defining the requirements. *Health Informatics Journal*, *17*(3), 173–190. https://doi.org/10.1177/1460458211409717

Pekmezaris, R., Mitzner, I., Pecinka, K. R., Nouryan, C. N., Lesser, M. L., Siegel, M., Swiderski, J. W., Moise, G., Younker, R., & Smolich, K. (2012). The Impact of Remote Patient Monitoring (Telehealth) upon Medicare Beneficiaries with Heart Failure. *Telemedicine and E-Health*, *18*(2), 101–108. https://doi.org/10.1089/tmj.2011.0095

Pekmezaris, R., Tortez, L., Williams, M., Patel, V., Makaryus, A., Zeltser, R., Sinvani, L., Wolf-Klein, G., Lester, J., Sison, C., Lesser, M., & Kozikowski, A. (2018). Home Telemonitoring In Heart

Failure: A Systematic Review And Meta-Analysis. *Health Affairs*, *37*(12), 1983–1989. https://doi.org/10.1377/hlthaff.2018.05087

Pham, Q., Wiljer, D., & Cafazzo, J. A. (2016). Beyond the Randomized Controlled Trial: A Review of Alternatives in mHealth Clinical Trial Methods. *JMIR mHealth and uHealth*, *4*(3), e107. https://doi.org/10.2196/mhealth.5720

Pine, G. (2009). *Teacher Action Research: Building Knowledge Democracies.* Sage.

Plsek, P. E., & Greenhalgh, T. (2001). Complexity science: The challenge of complexity in health care. *BMJ*, *323*(7313), 625–628. https://doi.org/10.1136/bmj.323.7313.625

Poole, M. S., & Van de Ven, A. H. (Eds.). (2021). *The Oxford handbook of organizational change and innovation*. Oxford University Press.

Porter, M. E., & Teisberg, E. O. (2006). *Redefining health care: Creating value-based competition on results*. Harvard Business School Press.

Porter, M. E., & Thomas, H. L. (2013). The Strategy That Will Fix Health Care. *Harvard Business Review 91, No. 10*, 50–70.

Pufahl, L., Zerbato, F., Weber, B., & Weber, I. (2022). BPMN in healthcare: Challenges and best practices. *Information Systems*, *107*, 102013. https://doi.org/10.1016/j.is.2022.102013

Reichheld, F. F. (2003). The one number you need to grow. *Harvard Business Review, 81*(12), 46–54, 124.

Ricciardi, W., Pita Barros, P., Bourek, A., Brouwer, W., Kelsey, T., Lehtonen, L., Expert Panel on Effective Ways of Investing in Health (EXPH), Anastasy, C., Barros, P., Barry, M., Bourek, A., Brouwer, W., De Maeseneer, J., Kringos, D., Lehtonen, L., McKee, M., Murauskiene, L., Nuti, S., Ricciardi, W., … Wild, C. (2019). How to govern the digital transformation of health services. *European Journal of Public Health*, *29*(Supplement_3), 7–12. https://doi.org/10.1093/eurpub/ckz165

Riley, J. P., Gabe, J. P., & Cowie, M. R. (2013). Does telemonitoring in heart failure empower patients for self-care? A qualitative study. *Journal of Clinical Nursing*, *22*(17–18), 2444–2455. https://doi.org/10.1111/j.1365-2702.2012.04294.x

Riley, W. T., Glasgow, R. E., Etheredge, L., & Abernethy, A. P. (2013). Rapid, responsive, relevant (R3) research: A call for a rapid learning health research enterprise. *Clinical and Translational Medicine*, *2*(1). https://doi.org/10.1186/2001-1326-2-10

Rouse, W. B. (2000). Managing Complexity: Disease Control as a Complex Adaptive System. *Information Knowledge Systems Management*, 143–165.

Rouse, W. B. (2008). Health care as a complex adaptive system: Implications for design and management. *Bridge-Washington-National Academy of Engineering-*, *38*(1), 17.

Rowland, S. P., Fitzgerald, J. E., Holme, T., Powell, J., & McGregor, A. (2020). What is the clinical value of mHealth for patients? *Npj Digital Medicine*, *3*(1), 4. https://doi.org/10.1038/s41746-019-0206-x

Sampson, S. E. (2010). The Unified Service Theory: A Paradigm for Service Science. In P. P. Maglio, C. A. Kieliszewski, & J. C. Spohrer (Eds.), *Handbook of Service Science* (pp. 107–131). Springer US. https://doi.org/10.1007/978-1-4419-1628-0_7

Sauro, J., & Lewis, J. R. (2012). Did We Meet or Exceed Our Goal? In *Quantifying the User Experience* (pp. 41–62). Elsevier. https://doi.org/10.1016/B978-0-12-384968-7.00004-7

Schlieter, H., Marsch, L. A., Whitehouse, D., Otto, L., Londral, A. R., Teepe, G. W., Benedict, M., Ollier, J., Ulmer, T., Gasser, N., Ultsch, S., Wollschlaeger, B., & Kowatsch, T. (2022). Scale-up of Digital Innovations in Health Care: Expert Commentary on Enablers and Barriers. *Journal of Medical Internet Research*, *24*(3), e24582. https://doi.org/10.2196/24582

Schrepp, M., Hinderks, A., & Thomaschewski, J. (2017). Design and Evaluation of a Short Version of the User Experience Questionnaire (UEQ-S). *International Journal of Interactive Multimedia and Artificial Intelligence*, *4*(6), 103. https://doi.org/10.9781/ijimai.2017.09.001

Selener, D. (1997). *Farmer-to-farmer extension: Lessons from the field*. IIRR.

Seto, E. (2008). Cost Comparison Between Telemonitoring and Usual Care of Heart Failure: A Systematic Review. *Telemedicine and E-Health*, *14*(7), 679–686. https://doi.org/10.1089/tmj.2007.0114

Shafie, T. (2013). A Multigraph Approach to Social Network Analysis. *Journal of Social Structure*, *16*.

Shaw, J., Agarwal, P., Desveaux, L., Palma, D. C., Stamenova, V., Jamieson, T., Yang, R., Bhatia, R. S., & Bhattacharyya, O. (2018). Beyond "implementation": Digital health innovation and service design. *Npj Digital Medicine*, *1*(1), 48. https://doi.org/10.1038/s41746-018-0059-8

Shortell, S. M. (2008). Health Care Reform Requires Accountable Care Systems. *JAMA*, *300*(1), 95. https://doi.org/10.1001/jama.300.1.95

Siefert, A. L., Cartiera, M. S., Khalid, A. N., Nantel, M. C., Loose, C. R., Schulam, P. G., Saltzman, W. M., & Dempsey, M. K. (2019). The Yale Center for Biomedical Innovation and Technology (CBIT): One Model to Accelerate Impact From Academic Health Care Innovation. *Academic Medicine*, *94*(4), 528–534. https://doi.org/10.1097/ACM.0000000000002542

Silva-Cardoso, J., Moreira, E., Lopes, I., Sousa, C., Leite, S., Campelo, M., Sousa, J. M., Fonseca, M., Harnevo, L., Farin, M., Azevedo, L. F., & Sousa, F. (2020). SmartBEAT: A Smartphone-Based Heart Failure Telemonitoring Solution. In J. Henriques, N. Neves, & P. de Carvalho (Eds.), *XV Mediterranean Conference on Medical and Biological Engineering and Computing – MEDICON 2019* (Vol. 76, pp. 1369–1376). Springer International Publishing. https://doi.org/10.1007/978-3-030-31635-8_167

Sittig, D. F., & Singh, H. (2015). A New Socio-technical Model for Studying Health Information Technology in Complex Adaptive Healthcare Systems. In V. L. Patel, T. G. Kannampallil, & D. R. Kaufman (Eds.), *Cognitive Informatics for Biomedicine* (pp. 59–80). Springer International Publishing. https://doi.org/10.1007/978-3-319-17272-9_4

Smith, A. C., Thomas, E., Snoswell, C. L., Haydon, H., Mehrotra, A., Clemensen, J., & Caffery, L. J. (2020). Telehealth for global emergencies: Implications for coronavirus disease 2019 (COVID-19). *Journal of Telemedicine and Telecare*, *26*(5), 309–313. https://doi.org/10.1177/1357633X20916567

Srivatana, V., Liu, F., Levine, D. M., & Kalloo, S. D. (2020). Early Use of Telehealth in Home Dialysis during the COVID-19 Pandemic in New York City. *Kidney360*, *1*(6), 524–526. https://doi.org/10.34067/KID.0001662020

Stilgoe, J., Owen, R., & Macnaghten, P. (2013). Developing a framework for responsible innovation. *Research Policy*, *42*(9), 1568–1580. https://doi.org/10.1016/j.respol.2013.05.008

Strode, S. W., Gustke, S., & Allen, A. (1999). Technical and clinical progress in telemedicine. *JAMA*, *281*(12), 1066–1068. https://doi.org/10.1001/jama.281.12.1066

Subramoniam, R., Sundin, E., Subramoniam, S., & Huisingh, D. (2021). Riding the Digital Product Life Cycle Waves towards a Circular Economy. *Sustainability*, *13*(16), 8960. https://doi.org/10.3390/su13168960

Sumberg, J., & Okali, C. (1988). Farmers, On-farm Research and the Development of New Technology. *Experimental Agriculture*, *24*(3), 333–342. https://doi.org/10.1017/S0014479700016185

Tagliente, I., Trieste, L., Solvoll, T., Murgia, F., & Bella, S. (2016). Telemonitoring in Cystic Fibrosis: A 4-year Assessment and Simulation for the Next 6 Years. *Interactive Journal of Medical Research*, *5*(2), e11. https://doi.org/10.2196/ijmr.5196

Tan, J., Wen, H. J., & Awad, N. (2005). Health care and services delivery systems as complex adaptive systems. *Communications of the ACM*, *48*(5), 36–44. https://doi.org/10.1145/1060710.1060737

Ulrich, W. (1987). Critical heuristics of social systems design. *European Journal of Operational Research*, *31*(3), 276–283. https://doi.org/10.1016/0377-2217(87)90036-1

University of Newcastle Library Guides. (n.d.). *University of Newcastle Library Guides—Research Methods*. Retrieved February 8, 2021, from https://libguides.newcastle.edu.au/researchmethods

Value for Health CoLAB. (2022). *Value for Health CoLAB*. https://vohcolab.org/about-us/

Value for Health CoLAB. (2023). *About us—Value for Health CoLAB*. https://vohcolab.org/about-us/

van Tol, L. S., Smaling, H. J. A., Groothuijse, J. M., Doornebosch, A. J., Janus, S. I. M., Zuidema, S. U., Caljouw, M. A. A., Achterberg, W. P., & de Waal, M. W. M. (2021). COVID-19 management in nursing homes by outbreak teams (MINUTES) — study description and data characteristics: A qualitative study. *BMJ Open*, *11*(11), e053235. https://doi.org/10.1136/bmjopen-2021-053235

Vegesna, A., Tran, M., Angelaccio, M., & Arcona, S. (2017). Remote Patient Monitoring via Non-Invasive Digital Technologies: A Systematic Review. *Telemedicine and E-Health*, *23*(1), 3–17. https://doi.org/10.1089/tmj.2016.0051

Velentgas, P., Dreyer, N., Nourjah, P., Smith, S., & Torchia, M. (n.d.). Chapter 6-Outcome definition and measurement. In *Developing a Protocol for Observational Comparative Effectiveness Research: A User's Guide.* Agency for Healthcare Research and Quality.

Vestergaard, A. S., Hansen, L., Sørensen, S. S., Jensen, M. B., & Ehlers, L. H. (2020). Is telehealthcare for heart failure patients cost-effective? An economic evaluation alongside the Danish TeleCare North heart failure trial. *BMJ Open*, *10*(1), e031670. https://doi.org/10.1136/bmjopen-2019-031670

Vodafone Portugal. (2023). *Vodafone—Quem somos*. https://www.vodafone.pt/a-vodafone/quem-somos.html

Walton, M. K., Powers, J. H., Hobart, J., Patrick, D., Marquis, P., Vamvakas, S., Isaac, M., Molsen, E., Cano, S., & Burke, L. B. (2015). Clinical Outcome Assessments: Conceptual Foundation—Report of the ISPOR Clinical Outcomes Assessment – Emerging Good Practices for Outcomes

Research Task Force. *Value in Health*, *18*(6), 741–752. https://doi.org/10.1016/j.jval.2015.08.006

Ware, J. E., Snyder, M. K., Wright, W. R., & Davies, A. R. (1983). Defining and measuring patient satisfaction with medical care. *Evaluation and Program Planning*, *6*(3–4), 247–263. https://doi.org/10.1016/0149-7189(83)90005-8

Ware, P., Dorai, M., Ross, H. J., Cafazzo, J. A., Laporte, A., Boodoo, C., & Seto, E. (2019). Patient Adherence to a Mobile Phone-Based Heart Failure Telemonitoring Program: A Longitudinal Mixed-Methods Study. *JMIR mHealth and uHealth*, *7*(2), e13259. https://doi.org/10.2196/13259

Ware, P., Ross, H. J., Cafazzo, J. A., Laporte, A., Gordon, K., & Seto, E. (2018). Evaluating the Implementation of a Mobile Phone-Based Telemonitoring Program: Longitudinal Study Guided by the Consolidated Framework for Implementation Research. *JMIR mHealth and uHealth*, *6*(7), e10768. https://doi.org/10.2196/10768

Wartofsky, M. W. (1979). *Models: Representation and the scientific understanding*. Reidel.

Wells, A., & Davies, M. I. (1994). The Thought Control Questionnaire: A measure of individual differences in the control of unwanted thoughts. *Behaviour Research and Therapy*, *32*(8), 871–878. https://doi.org/10.1016/0005-7967(94)90168-6

Werger, A. C., Breel, J., van Kuijk, S., Bulte, C. S. E., Koopman, S., Scheffer, G. J., Noordzij, P. G., in ‘t Veld, B. A., Wensing, C. G. C. L., Hollmann, M. W., Buhre, W., & de Korte-de Boer, D. (2022). Outcome in patients undergoing postponed elective surgery during the COVID-19 pandemic (TRACE II): Study protocol for a multicentre prospective observational study. *BMJ Open*, *12*(6), e060354. https://doi.org/10.1136/bmjopen-2021-060354

White, L., Burger, K., & Yearworth, M. (2016). Understanding behaviour in problem structuring methods interventions with activity theory. *European Journal of Operational Research*, *249*(3), 983–1004. https://doi.org/10.1016/j.ejor.2015.07.044

Whitehead, A. L., Julious, S. A., Cooper, C. L., & Campbell, M. J. (2016). Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Statistical Methods in Medical Research*, *25*(3), 1057–1073. https://doi.org/10.1177/0962280215588241

Whitten, P., & Buis, L. (2007). Private Payer Reimbursement for Telemedicine Services in The United States. *Telemedicine and E-Health*, *13*(1), 15–24. https://doi.org/10.1089/tmj.2006.0028

WHO (Ed.). (2006). *Working together for health*. World Health Organisation.

Wilson, K., Bell, C., Wilson, L., & Witteman, H. (2018). Agile research to complement agile development: A proposal for an mHealth research lifecycle. *Npj Digital Medicine*, *1*(1), 46. https://doi.org/10.1038/s41746-018-0053-1

Wolstenholme, E. (2020). System Dynamics Applications to Health and Social Care in the United Kingdom and Europe. In B. Dangerfield (Ed.), *System Dynamics* (pp. 229–252). Springer US. https://doi.org/10.1007/978-1-4939-8790-0_269

Wong, G., Greenhalgh, T., Westhorp, G., & Pawson, R. (2012). Realist methods in medical education research: What are they and what can they contribute?: Realist methods in medical education research. *Medical Education*, *46*(1), 89–96. https://doi.org/10.1111/j.1365-2923.2011.04045.x

Woolson, R. F. (2008). Wilcoxon Signed-Rank Test. In R. B. D'Agostino, L. Sullivan, & J. Massaro (Eds.), *Wiley Encyclopedia of Clinical Trials* (p. eoct979). John Wiley & Sons, Inc. https://doi.org/10.1002/9780471462422.eoct979

World Health Organization (WHO). (1948). *About World Health Organization. Constitution.* http://www.who.int/governance/eb/ constitution/en/

Yearworth, M., & White, L. (2014). The non-codified use of problem structuring methods and the need for a generic constitutive definition. *European Journal of Operational Research*, *237*(3), 932–945. https://doi.org/10.1016/j.ejor.2014.02.015

Yun, J. E., Park, J.-E., Park, H.-Y., Lee, H.-Y., & Park, D.-A. (2018). Comparative Effectiveness of Telemonitoring Versus Usual Care for Heart Failure: A Systematic Review and Meta-analysis. *Journal of Cardiac Failure*, *24*(1), 19–28. https://doi.org/10.1016/j.cardfail.2017.09.006

Zaliūnas, R., Benetis, R., Vanagas, G., Slapikas, R., & Vainoras, A. (2009). Implementation of international transtelephonic ECG platform for patients with ischemic heart disease. *Medicina (Kaunas, Lithuania)*, *45*(2), 104–110.

Zhang, M., Bao, Y., Lang, Y., Fu, S., Kimber, M., Levine, M., & Xie, F. (2021). What Is Value in Health and Healthcare? A Systematic Literature Review of Value Assessment Frameworks. *Value in Health*, S1098301521016442. https://doi.org/10.1016/j.jval.2021.07.005

Appendix A. Thesis' Glossary of Relevant Concepts and Terms

This appendix serves as a comprehensive glossary, offering definitions of pertinent concepts and terms utilized throughout the thesis. Each entry is ordered alphabetically for ease of reference and includes a clear definition accompanied by its respective source, ensuring clarity and credibility in the presentation of key terminology within the document.

Concept or Term	Definition	Source
Access to Healthcare	Ensuring that all individuals have the opportunity to receive the care they require, regardless of their socio-economic status or geographic location. It emphasises the need for healthcare services to be readily available and easily accessible to everyone, thereby bridging any gaps that may exist due to financial constraints or geographical barriers.	(EXPH, 2019)
Digital Health or Healthcare Intervention (DHI)	Encompass both research-based interventions and practical interventions in the field of digital health, regardless of the specific objective being pursued, be it pure research or practical intervention. In this thesis, the terms "digital health intervention" and "digital healthcare intervention" are used interchangeably.	Author's definition
Digital Health or Healthcare Service (DHS)	The result of the digitalisation of health services: new healthcare services that integrate ICT. In this thesis, the terms "digital health service" and "digital healthcare service" are used interchangeably.	(EXPH, 2018)
Digitalisation process of healthcare services	Process of redesigning and managing new health services through the integration of ICT.	(EXPH, 2018)
Efficiency in Healthcare	Maximise the value of available resources, making strategic decisions to optimize resource allocation and minimise waste. It ensures that healthcare resources are utilized effectively to achieve the greatest benefit for patients and communities.	(EXPH, 2019)
Equity in healthcare	Fairness in the distribution of resources, acknowledging that certain groups may face greater challenges in accessing care due to factors such as income disparities or systemic inequalities. It strives to level the playing field, ensuring that everyone has an equal opportunity to achieve optimal health outcomes.	(EXPH, 2019)
Health	Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.	(WHO, 1948)
Health care and Healthcare	Health care is the prevention, treatment and management of illness and injury, and the preservation of mental and physical wellbeing through the services offered by healthcare providers. Throughout this thesis, I have used the words "health care" when referring to a noun (for example, "the state of health care in Portugal") and "healthcare" when referring to an adjective (for example, the "healthcare system" or "healthcare service").	(ACSQHC, 2021)
Health Service or Healthcare Service	A separately constituted organisation that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care to patients. It can be in any location or setting, including pharmacies, clinics, outpatient facilities, hospitals, patients' homes, community and primary healthcare settings, practices, and clinicians' rooms. In this thesis, the terms "health service" and "healthcare service" are used interchangeably.	(ACSQHC, 2021)
Health System or Healthcare System	A health or healthcare system includes the resources, policies, processes, and procedures that are organised, integrated, regulated and administered to accomplish a stated goal. According to WHO, this goal is to promote, restore or maintain health. The health systems are also usually defined as	(ACSQHC, 2021) and

	country-level entities, encompassing both rural and urban areas, public and private systems of health provision. In this thesis, the terms "health system" and "healthcare system" are used interchangeably. While some authors may differentiate between these terms, this distinction falls outside the scope of the current study. Therefore, for the purposes of clarity and consistency within this document, both terms are employed synonymously to refer to the broader system encompassing health services, facilities, professionals, and resources.	(McCoy & Allotey, 2021)
Intervention	Purposeful action by an agent to create change.	(Midgley, 2000)
Method and technique (used interchangeably)	A specific activity that has a clear and well-defined purpose (e.g., building a simulation model or developing a rich picture in soft systems methodology).	(Mingers, 2003, p. 559)
Methodology	A structured set of methods or techniques to assist people in undertaking research or intervention.	(Mingers, 2003, p. 559)
Multimethodology	The use, within an intervention of a combination of methods and perhaps methodologies such as soft systems methodology.	(Mingers, 2003, p. 559)
Performance in Healthcare	Enhancing overall population health, responsiveness to community needs, and fairness in financial contributions. It entails measuring success not only by the quantity of care provided but also by its impact on improving health outcomes and reducing disparities.	(EXPH, 2019)
Process	Sequence of activities or events, each converting some inputs into some outputs, leading to an outcome.	(Franco et al., 2021; Sampson, 2010)
Productivity in healthcare	enhancing the effectiveness of healthcare delivery, leveraging advancements in technology and innovation to increase the output of healthcare services while maintaining or improving quality standards.	(EXPH, 2019)
Quality in Healthcare	provision of safe, effective, and patient-centred care, focusing on delivering outcomes that make a tangible difference in individuals' lives. It prioritizes evidence-based practices and continuous improvement to ensure that healthcare services meet the highest standards of excellence.	(EXPH, 2019)
Remote patient monitoring (RPM)	Non-invasive technologies to allow healthcare professionals, patients, and caregivers to record and collect patient health- and well-being-related data from a distance.	(Devine, 2022)
Service	Following the Unified Service Theory: Services are production processes wherein each customer supplies one or more input components for that customer's unit of production. With non-service processes, groups of customers may contribute ideas to the design of the product, but individual customers' only participation is to select, pay for, and consume the output.	(Sampson, 2010)
System	A collection of elements working together as parts of a complex whole whose behaviour is greater than the sum of the parts. The word system is often used to refer to complex phenomena existing in the world (such as financial systems, health systems, and computer systems), but the true meaning of systems refers more to an abstract or model of such phenomena existing only in a conceptual world we construct to think about systems.	(Wolstenholme, 2020)
Systemic Intervention	Purposeful action by an agent to create change in relation to reflection on boundaries.	(Midgley, 2000)

Appendix B. Chapter 4's Supplementary Material

B.1. Glossary of Research Methods and Scalability Assessment Domains

Glossary of research methods and scalability assessment domains used to systematically review the eligible studies in Chapter 4.

Concept	Description	Reference
Problem	Description of the problem being addressed, who it affects, what it involves, and how it is currently being addressed.	(Milat et al., 2020)
Intervention	Description of the proposed programme or intervention to address the problem.	(Milat et al., 2020)
Strategic/political context	Description of the strategic, political, or environmental contextual factors that potentially influence any intervention to be scaled up.	(Milat et al., 2020)
Evidence of Effectiveness	Level of evidence available to support the scale-up of the proposed intervention, such as scientific literature and other known evaluations of the intervention.	(Milat et al., 2020)
Intervention Costs & Benefits	Consideration of the known costs of the intervention delivery and any quantifiable benefits. This includes the results of any types of economic evaluation studies.	(Milat et al., 2020)
Fidelity & Adaptation	Description of the proposed changes to the intervention required for scale-up.	(Milat et al., 2020)
Reach & Acceptability	Description of the possible reach and acceptability of the intervention for the target population.	(Milat et al., 2020)
Delivery Setting & Workforce	Define the setting within which the intervention is delivered as well as the delivery workforce.	(Milat et al., 2020)
Implementation Infrastructure	Implementation infrastructure is required for scale- up.	(Milat et al., 2020)
Sustainability	Longer-term outcomes of the scale-up and how once scaled up, the intervention could be sustainable over the medium to longer term.	(Milat et al., 2020)
Clinical Outcomes Assessment	Clinical outcomes assessment refers to the evaluation of efficacy endpoints when developing a therapy for a disease or condition. The patient assessment used in an endpoint, is the measuring instrument that provides a rating or score (categorical or continuous) that is intended to represent some aspect of the patient's health status.	(Haynes et al., 1979)
Humanistic Outcomes Assessment	Humanistic outcomes assessment refers to the evaluation of outcomes of interest to patients, which are clinically meaningful with practical implications for disease recognition and management and that are based on a patient's unique perspective,	(Combi et al., 2016)

	e.g., patient-reported scales that indicate pain level, degree of functioning, etc. This category of outcomes involves measures of health-related quality of life (HRQoL) and patient-reported outcomes measurements, which include measures of HRQoL.	
Utilization Outcomes Assessment	Utilization outcomes measurement refers to the evaluation of measures of health resource utilization, such as number of inpatient or outpatient visits, total days of hospitalization in a given year, or number of days treated with antibiotics. These outcomes are often used as proxies for measuring cost.	(Combi et al., 2016)
Satisfaction Assessment	Assessment of patient' and healthcare - professionals' satisfaction with the health intervention.	-
Economic Evaluation	Economic evaluation involves a comparison between alternative strategies, considering both their costs and their benefits.	(Whitten & Buis, 2007)
Fidelity Assessment	Fidelity assessment refers to the confirmation that the manipulation of the independent variable occurred as planned to ensure that fair, powerful, and valid comparisons of replicable treatments can be made.	(Gheorguiu & Ratchford, 2015)
Feasibility Assessment	Feasibility assessment consists of determining whether an intervention should be adjusted to be relevant and sustainable through the identification of aspects requiring modification.	(Craig et al., 2008)
Adaptability Assessment	Proposed changes to the intervention required for scale-up.	(Milat et al., 2020)
Acceptability Assessment	Acceptability assessment refers to the evaluation of the level of satisfaction, suitability or attractiveness perceived by the programme delivers or recipients.	(Craig et al., 2008)
Adoption Assessment	Assessment of the number of adopters of the [30] proposed programme or intervention.	(Paré et al., 2013)
Compliance Assessment	Compliance assessment refers to the evaluation of the extent to which the patient follows the prescribed and dispensed regimen as intended by the prescriber and dispenser.	(Paré et al., 2013)
Penetration Assessment	Assessment of the level of integration of the [30] programme or intervention within the existing services.	(Paré et al., 2013)

B.2. Economic Evaluation Main Results

Main results of the economic evaluations conducted in each eligible study of Chapter 4 that addressed the domains of costs and benefits.

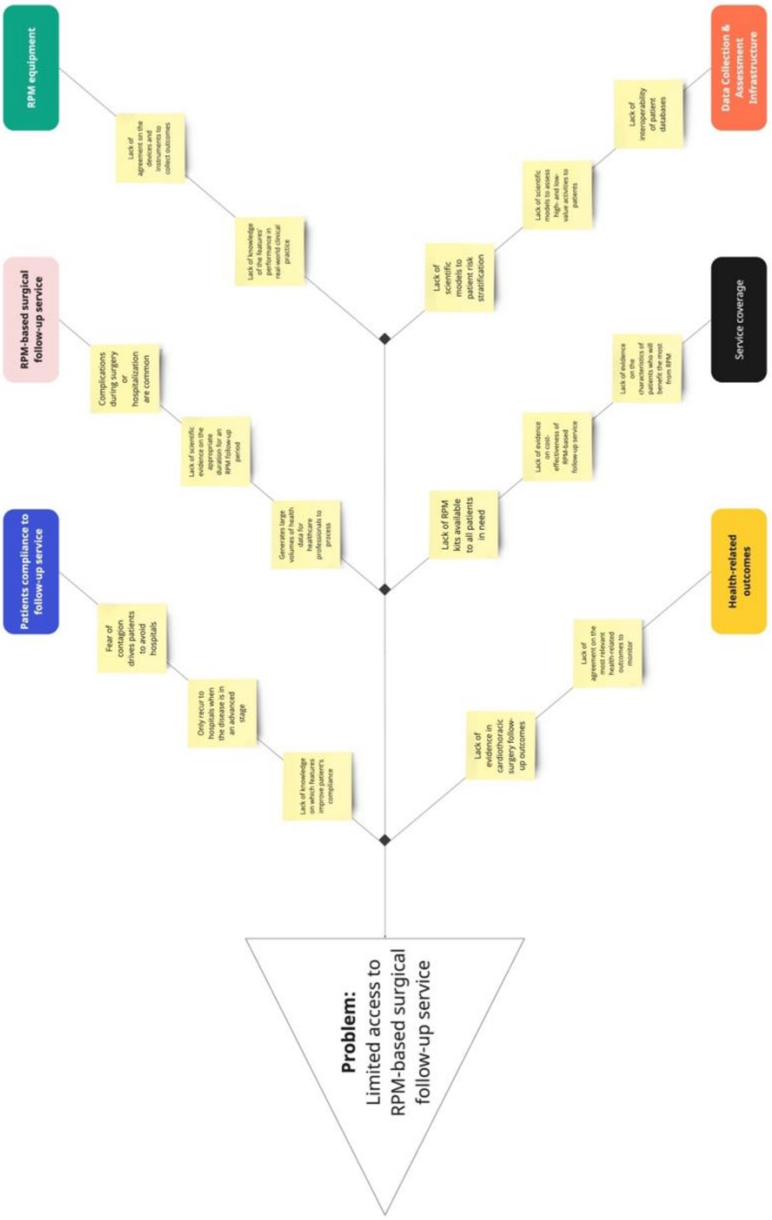
Study number, name	**Telemonitoring (n1); Control (n2)**	**Type of Analysis**	**Main Results**
2. Diabetes	74; 274	Cost Analysis	Improvements in glycaemic control (p = 0.01) and patients' satisfaction with overall care (p = 0.04). Telemonitoring reduced costs, yielding a net cost savings of 8.8%.
3. Cystic Fibrosis	29; 25	Cost Analysis; Costs-saving simulation	Potential saving of €40,397.00 per patient for 10 years, actualized at €36,802.97 for the follow-up of all patients enrolled.
4. Chronic heart failure	341;85	Value of Information Analysis	The cost of uncertainty regarding the decision on reimbursement of telehealth interventions for chronic heart failure patients is high in the Netherlands, and that future research is needed on the transition probabilities.
5. Obstructive sleep apnoea	94; 92	Cost- Effectiveness Analysis	The QSQ social interactions domain improved significantly more in the control group. The EQ-VAS improved more in the telemonitoring group. Total costs were lower in the telemonitoring group. Virtual Sleep Unit was cost-effective for a wide range of willingness to pay for QALYs.
6. Secondary prevention of cerebrovascular disease	228; 222	Cost-Utility Analysis	Telemonitoring resulted in an incremental 0.83 QALYs and cost savings of $1929 compared to control. Telemonitoring was the preferred treatment in 73% of simulations at a willingness to pay (WTP) of $0 per QALY, and 99% of the ICURs fall below a WTP threshold of $10 000 per QALY.
7. Heart failure	134; 140	Cost-Utility Analysis; Cost-Effectiveness Analysis	Telemonitoring provided a positive incremental NMB of £5164. The 1-year adjusted QALY difference between the telemonitoring solution and the usual care group was 0.0034 (95% CI: −0.0711 to 0.0780).

			The adjusted difference in costs was - £5096 (95% CI: −8736 to −1456) corresponding to a reduction in total healthcare costs by 35%.
8. Gestational Diabetes Mellitus	80; 81	Cost- Effectiveness Analysis	A decrease in medical visits by 56% ($p < 0.001$) in the telemonitoring group. No difference between the two groups in diabetes control or maternal and fetal complications. A 10-fold increase in nursing interventions in telemonitoring group. Satisfaction with care was high. Direct cost analysis revealed a savings of 16% in patients followed by telemonitoring.
9. Rural home health agencies	1513; 1573	Cost-Benefit Analysis	Average number of home health episodes per patient, the length of care, and the mean number of visits per episode was lower in the telemonitoring group. The total average cost/episode was lower in the control group.
10. Chronic obstructive pulmonary	60; 60	Cost- Minimization Analysis	Telemonitoring reduced the number of hospitalization days and the number of emergency room visits. Telemonitoring saved $1613 per patient per year compared to traditional care, representing a net gain of 14%.

Appendix C. Chapter 5’s Supplementary Material

C.1. Ishikawa Diagram

The Ishikawa diagram details the root causes and respective categories of the defined problem.



C.2. Content Analysis Coding Scheme for Minutes and Reports

TOPIC	FOCUS	INTERACTION	REACTION	OUTCOME	AGENT
Project Planning	Project presentation	Highlighted a conflict	All showed that they agreed with the statement	Generation of new feature	Researcher
Project Management	Problem definition	Shared a concern or fear	Most showed that they agreed with the statement	Adoption of new technological feature	Nurse (end-user)
Search	Objectives definition & results anticipation	Shared an opinion	Half of the participants showed that they agreed with the statement	Increased democratisation	Developer
Design	Roadmap definition	Shared an expectation	Almost no one showed that they agreed with the statement	Increased cost-effectiveness	Surgeon (end-user)
Development	Budget definition	Shared an experience	No one showed that they agreed with the statement	Better understanding on the part of researchers, of systems used by healthcare professionals/patients	
Execution & Implementation	Team definition	Solution-related question	No further discussion required	Better characterization and understanding the complex bio-physical and socio-economic constraints to sustainable software Development production and care service provision	
Evaluation & Assessment	Data Management Plan	Shared knowledge	Reaction not recorded	Development of technologies that cope with user needs	
		Solution-related problem		Improved research and extension system	
	Team changes	Shared an idea		Empowerment by improving healthcare professional's capacity for self-directed technology development and ability to adapt healthcare systems to changing conditions	
	Roadmap Execution	Selected an idea		No outcome is expected	
	Budget execution	Planned an action			

	Literature review	Generated knowledge			
	Benchmarking				
	Hospital Visits				
	Technological Solution Requirements				
	Data Analysis Framework Requirements				
	Data Storage and Protection Requirements				
	Literacy Activities Requirements				
	Study Protocol Writing				
	Software Development				
	Modelling and simulation				
	Data storage and protection development				
	Study Protocol Approval				
	Technology Trial				
	Data collection & processing				
	Data storage and protection testing				
	Literacy activities testing				
	Technology evaluation				
	Data analysis & interpretation				
	Data storage and protection evaluation				
	Literacy activities evaluation				
	Results communication & dissemination				

C.3. Semi-structured Interviews Coding Scheme

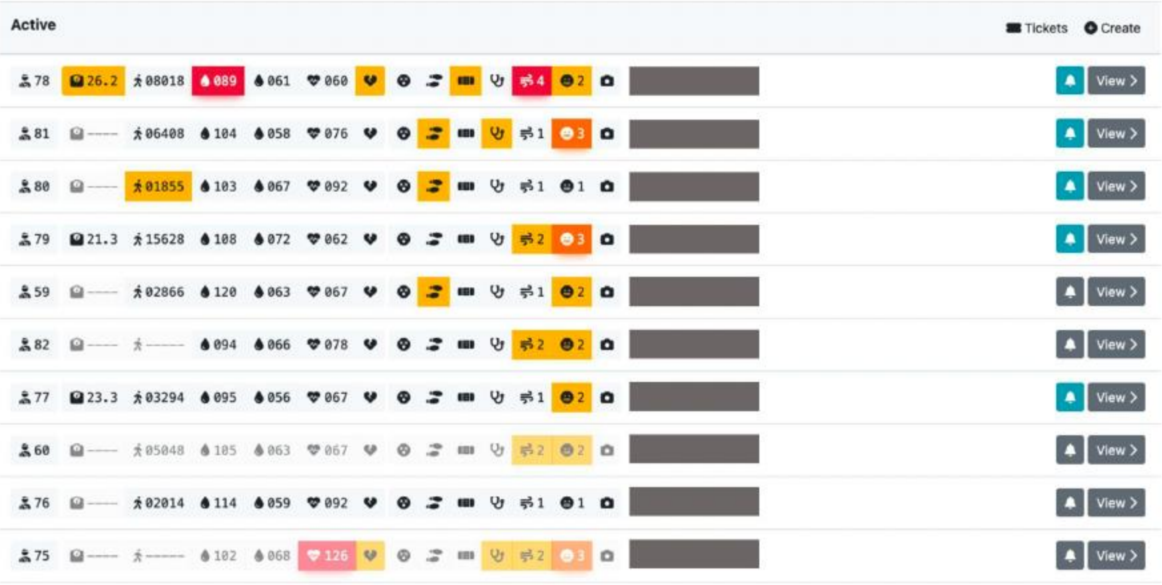
FEEDBACK ON EXISTING FEATURES	IMPROVEMENTS AND NEW IDEAS	GENERATED LEARNING	PROOF OF ACCEPTANCE	REFLECTIONS
Instructions	Telehealth video consultation	Learned how to read and control the outcomes measurements	Patient/Caregiver wants to use one or more IoT devices as much as they can	Reflection on the past
RPM period	Add a new patient-reported outcome measurement	Searched more about RPM-based service and learned about its impact	Patient and/or caregiver showed the desire to keep one or more IoT devices	Expectations for the future
Outcome collection using IoT devices	Outcome collection using voice-based message	Learned more about his/her health and how to improve habits	Patient/caregiver share that measuring the outcomes were part of his/her daily routine	Beliefs
Outcome collection using mobile app questionnaires	Give outcome analysis reports to patients and caregivers			Preferences
Outcome collection using smartphone camera	Other			Patient/Caregiver recommends the RPM service to other patients
Outcome collection using a chatbot				Patient/Caregiver reflects about the type of patients that should have access to RPM-based services
RPM-based therapy management				Patient/Caregiver reflects about the barriers to other patients to access RPM-based services
RPM-based therapy management using a chatbot				
Web-based RPM care management platform				
Role definition				
Surgical team alert email notification				
Outcome-based automated alerts				
Patient remote monitoring dynamic table				

C.4. Web Platform and Smartphone Application Description

The RPM solution includes one Android smartphone application connected to IoT devices and one web-based application.

1. **Web platform:**

The aforementioned features were integrated to create a new platform for RPM. This integration was made in a modular way, so the implemented features can be reused, and new ones can be added in the future. Below, some figures depict features of the proposed platform: a list of remotely monitored patients, medication list, monitoring action, list of photos of the wound, and outcomes analysis graphics. Figure C.4.1. depicts the RPM dynamic table feature, which consists of list of monitored patients and their respective outcomes. Each line has information regarding a patient. The first icon on the left has the patient ID. The following group of icons represent the last measured value of each outcome. If the value is outside of the normal range, the icon has a different colour than grey. This way, the surgical team can quickly assess the patients that need more attention. If the icon is faded, the represented value is not from that day. Behind the big grey the rectangle is the name of the patient. On the right side, it is possible to observe a bell icon that lights up if a monitoring action was taken during that day and a view button that leads to the detailed page of that patient.

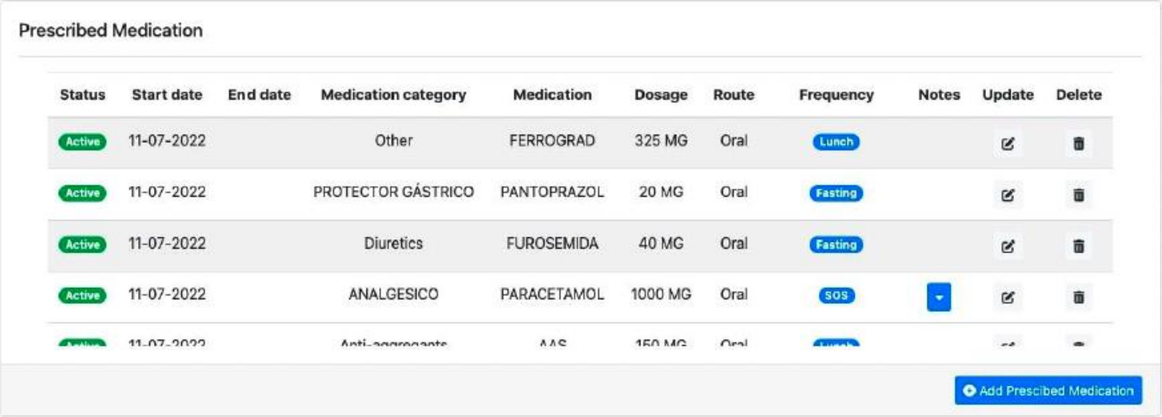


Active

78	26.2	08018	089	061	060	4	2	View >
81	——	06408	104	058	076	1	3	View >
80	——	01855	103	067	092	1	1	View >
79	21.3	15628	108	072	062	2	3	View >
59	——	02866	120	063	067	1	2	View >
82	——	——	094	066	078	2	2	View >
77	23.3	03294	095	056	067	1	2	View >
60	——	05048	105	063	067	2	2	View >
76	——	02014	114	059	092	1	1	View >
75	——	——	102	068	126	2	3	View >

Figure C.4.1. – RPM dynamic table feature.

Figure C.4.2. illustrates an example of the application of the RPM-based therapy management feature, which consists of a patient's medication list. In addition to information related to taking the medication and its type, it is also possible to access notes that have been added for both the patient and the clinical team. Also, the clinical team can manage each medication the patient takes.

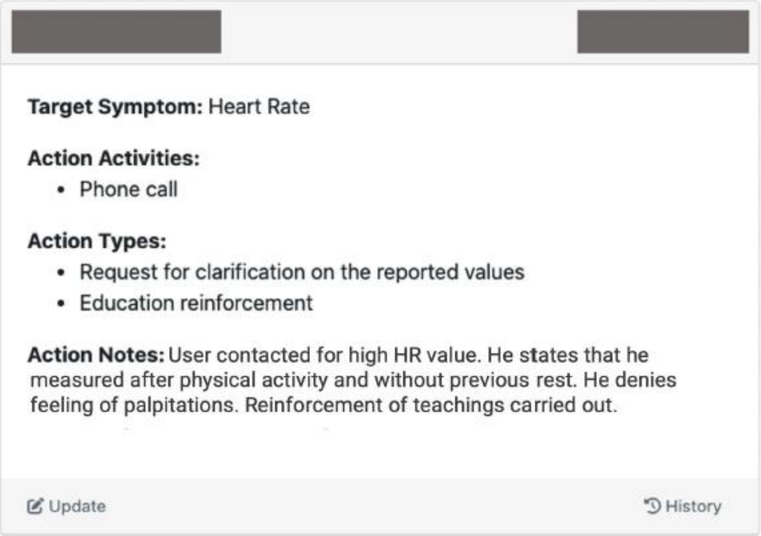


Prescribed Medication

Status	Start date	End date	Medication category	Medication	Dosage	Route	Frequency	Notes	Update	Delete
Active	11-07-2022		Other	FERROGRAD	325 MG	Oral	Lunch			
Active	11-07-2022		PROTECTOR GÁSTRICO	PANTOPRAZOL	20 MG	Oral	Fasting			
Active	11-07-2022		Diuretics	FUROSEMIDA	40 MG	Oral	Fasting			
Active	11-07-2022		ANALGESICO	PARACETAMOL	1000 MG	Oral	SOS	▾		
Active	11-07-2022		Anti-agregante	AAS	150 MG	Oral	Lunch			

Figure C.4.2. – RPM-based therapy management feature.

The feature related to RPM activities management and allocation of resources is illustrated in Figure C.4.3. Monitoring actions are displayed in a vertical timeline where at the top are the most recent. This figure can be divided into four elements: target symptom, action activities (such as phone calls or hospital appointments), action types (such as medication adjustment or health literacy reinforcement), and action notes. The first one is associated with the reported outcomes that lead to that action. The second one is related to the activity that was performed. The third one corresponds to what was done during the activity. The last one shows the notes the clinical team member wrote associated with that action. Creating well-adapted and detailed clinical actions is key to identifying the added value of different clinical actions within an RPM service.



[redacted] [redacted]

Target Symptom: Heart Rate

Action Activities:
- Phone call

Action Types:
- Request for clarification on the reported values
- Education reinforcement

Action Notes: User contacted for high HR value. He states that he measured after physical activity and without previous rest. He denies feeling of palpitations. Reinforcement of teachings carried out.

Figure C.4.3. – RPM activities management and resource allocation.

Figure C.4.4. shows the web platform User Interface (UI) that enables the visualization of PROMs evolution through time. The (A) part shows an example of the list of surgical wound pictures sent by the patient during the RPM period. The web platform allowed the surgical team to evaluate the picture regarding its quality and healing changes in the surgical wound. The (B) part shows an example of a graphic of the collected outcomes, where it is possible to check if the reported values are abnormal.

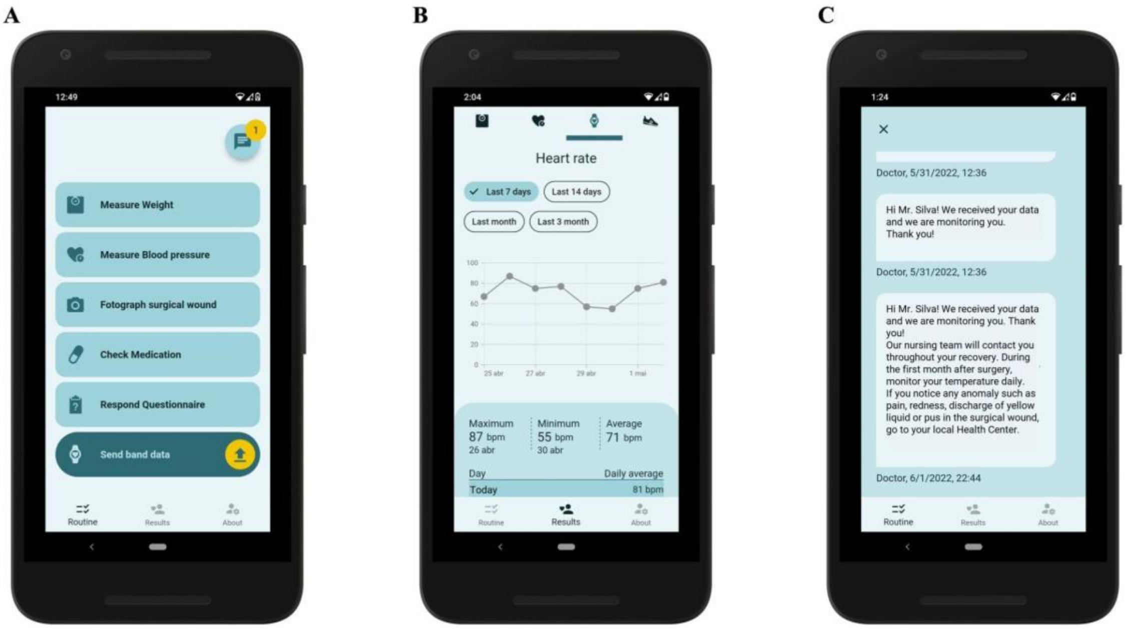
Figure C.4.4. – Web platform UI that enables the visualisation of PROMs evolution.

2. Mobile Application:

The smartphone app (Figure C.4.5.) is provided to the patient together with a set of IoT devices, which includes a weight scale (A\&D Medical UA-352BLE), a blood pressure monitor (A\&D Medical UA-651BLE), a smartwatch (Shenzhen E80), and a smartphone (Xiamoi Mi A2 Lite). The IoT kit allows the collection of the following measures: weight, diastolic and systolic blood pressure, heart rate at rest, heart rate irregularity, continuous heart rate, and steps. This health parameter collection is executed through the mobile app using Bluetooth.

Within the smartphone app, the patient can explore their health data history (B) and perform additional tasks relevant to the follow-up of these patients (A). These tasks include acquiring pictures, answering questionnaires for self-reported signs and symptoms, and accessing the daily medication plan. The patient is requested by the surgical team to perform the tasks at a specific pre-defined time. To promote engagement, the app allows patients to receive messages (C). These messages are received via the proposed web app. They can either be pre-defined automated messages, triggered according to the adherence and health specificities of each patient, or written by the clinical team on therapeutic recommendations.

To assure standardized interoperability, the smartphone app connects with FHIR based server. The FHIR incorporation allows a straightforward exchange of health data with multiple health information systems that integrate this standard.



Maximum 87 bpm 26 abr

Minimum 55 bpm 30 abr

Average 71 bpm

Day — Daily average

Today — 81 bpm

Doctor, 5/31/2022, 12:36

Hi Mr. Silva! We received your data and we are monitoring you.
Thank you!

Doctor, 5/31/2022, 12:36

Hi Mr. Silva! We received your data and we are monitoring you. Thank you!
Our nursing team will contact you throughout your recovery. During the first month after surgery, monitor your temperature daily.
If you notice any anomaly such as pain, redness, discharge of yellow liquid or pus in the surgical wound, go to your local Health Center.

Doctor, 6/1/2022, 22:44

Figure C.4.5. – Smartphone Application.

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Appendix D. Chapter 7's Supplementary Material

D.1. Digitalisation Process of the Cardiac Surgery Follow-Up Service Information Sources

The following table provides a detailed description of the information sources used to analyse the digitalisation process of the cardiac surgery follow-up service. DHI indicates Digital Health Intervention.

Information Source	Goal	Documentation record	Timing	Affected Agent
Patient demographic data (patient's sex, birthdate, nationality, and home residence)	To conduct a demographic characterisation of the DHI sample of patients (population's sex and age composition and distance to the hospital)	Hospital Electronic Health Records	2019 to 2023	Patients
Inpatient hospital data (surgical and post-operative data)	To conduct a baseline health status characterisation of the DHI sample of patients before joining the DHI (surgery type, surgery date, discharge date, patient status before joining the DHI, post-operative complications, risk of developing complications during the DHI)	Hospital Electronic Health Records	2019 to 2023	Patients
Individual sessions with patients to evaluate their digital health literacy, train them on how to use the DHI technology, and provide instructions on how to cope with the recovery period	To characterise each patient's perceptions of what to expect from the DHI (role, goals, interests, outcomes, fears, concerns, risks)	Observer notes	2019 to 2021	Patients
Patient daily IoT and mobile app utilization (number of replied questionnaires, pictures sent, and conducted measurements) and health-related data (blood pressure and heart rate, weight, number of steps, the occurrence of blackouts, perceived alterations in surgical wound healing, picture of the surgical wound, presence of palpitations, presence of edemas, presence of dyspnea, chest pain intensity level) collected during the DHI	To characterise each patient's pathway considering patient's activities and health status during the recovery period.	Patient remote monitoring (RPM) data collected using a mobile app connected to IoT devices and stored on a web-based RPM management platform	2019 to 2023	Patients
Nurses and surgeons daily web-based RPM management platform utilization data (registered accounts, number of actions, and notes) collected during the DHI	To characterise each patient's pathway considering surgeon and nurses' activities triggered by the RPM data during the recovery period and to characterise surgeons' and nurse engagement with the RPM platform.	Data collected and stored on a web-based RPM management platform	2019 to 2023	Patients; Nurses; Surgeons

Individual sessions with patients to receive feedback after the DHI has ended. In these sessions, patients filled out questionnaires with closed and open questions. Some of these sessions were video recorded	To characterise each patient's satisfaction, experience, and perceptions of what was the most important and most difficult during the DHI, and what should be improved for future patients joining the DHI.	Answers to System Usability Scale (SUS) questionnaire, User Experience Questionnaire (UEQ), and recovery period open questions, and video transcripts	2019 to 2023	Patients
Periodical nurse follow-up calls with each patient until 12 months after surgery to evaluate patient's status (Socioeconomic Status, Socio-Family Support, Pain, Lifestyle Behaviours, Medication, Overall Physical and Mental Health, Functioning, Surgical Scar, Health monitoring) and provide appropriate follow-up care (Periods: 3 days, 30 days, 3 months, 6 months, 12 months)	To characterise patient's status and patients and healthcare professional actions during the patient's recovery period until 12 months after surgery.	Hospital Internal Database: Responses to follow-up questionnaires 3 days, 30 days, 3 months, 6 months, 12 months after surgery	2019 to 2023	Patients; Nurses; Surgeons
Project meetings with surgeons, nurses, hospital administrative board members, developers, and researchers	To identify the roles, goals, expected outcomes, interests, fears, concerns, risks, interests, and decisions of each stakeholder involved and to understand what triggered stakeholders to change their behaviour during the DHI.	Meeting minutes	2019 to 2023	All
Project reports and funding research applications and evaluations	To review project information, including goals, main activities, and results, that stakeholders and funding bodies deem relevant for research and development funding.	Official reports and internal team documents	2019 to 2023	All agents involved in the DHI and the funding bodies.
Public dissemination of consolidated knowledge on the DHI	To reflect on the knowledge that stakeholders and the scientific community consider relevant for dissemination.	Published scientific papers	2019; 2021; 2022	All agents involved in the DHI and the worldwide scientific community.

D.2. Self-reported position and affiliation typology analysis

The self-reported position and affiliation typology analysis was conducted by characterising each human agent with two attributes: Self-reported position (layer 1) and affiliation (layer 2, 3, and 4).

Layer	**Description**
Layer 1	Social or professional positions in the organisation grouped by similar responsibilities
Layer 2	Organisations subunits such as Faculty Departments or R&D Units grouped by similar organisation structure of organic subunits
Layer 3	Organisations units such as Faculties, Business Units, Conferences, Journals grouped by similar organisation structure of organic units
Layer 4	Official organisations such as Universities, Publishers, Non-profit associations grouped by legal characterization and sector

The typology schema applied to each layer was generated after three rounds of classification and the analysis is provided in the following table.

Layer 1	**Total**	**%**	**Layer 2**	**Total**	**%**
B.Sc. Student	4	0.54%	Department Division of the Institute	1	0.14%
Business Developer	3	0.41%	Journal Section	1	0.14%
Cardiologist	1	0.14%	MCTES Associated Laboratory	1	0.14%
Caregiver RPM Patient	12	1.63%	Research and Education Office	1	0.14%
Caregiver RPM Patient as Citizen	12	1.63%	Organic Subunit of Business Development	6	0.81%
Clinical Area Administrator	1	0.14%	MCTES Research and Development Unit	33	4.48%
Clinical Area Director	1	0.14%	Organic Subunit of Research and Development	38	5.16%
Clinical Research Support Member	1	0.14%	Department of the Faculty	39	5.29%
Clinical Service Director	2	0.27%	nan	55	7.46%
Clinical Service Head Nurse	1	0.14%	City	264	35.82%
Conference Chairperson	18	2.44%	Clinical Service	298	40.43%
Data Protection Officer	1	0.14%	**Total**	**737**	**100.00%**
Developer	5	0.68%	**Layer 3**	**Total**	**%**
Directors Board Member	8	1.09%	Department of the Institute	1	0.14%
Editor-In-Chief	14	1.90%	Support Structure	3	0.41%
Ethics Commission President	1	0.14%	Business Unit	4	0.54%
Executive Board Member	6	0.81%	Journal	7	0.95%
Financial Area Director	1	0.14%	nan	3	0.41%
Funding Manager	1	0.14%	Governance Bodies	13	1.76%
Head of Research & Development (R&D) Group	6	0.81%	Organic Unit of Research and Development	16	2.17%
Investigator	46	6.24%	Conference/Workshop	18	2.44%
M.Sc. Student	12	1.63%	Research Center	29	3.93%
Marketing Director	1	0.14%	Faculty	73	9.91%
Nurse	24	3.26%	District	264	35.82%
Nurse Coordinator	1	0.14%	Clinical Structure	300	40.71%
Ph.D. Student	7	0.95%	Magazine	2	0.27%
Policy Consultant	1	0.14%	News web portal	2	0.27%
Professor	18	2.44%	Newspaper	1	0.14%
Research Intern	18	2.44%	Television	1	0.14%
RPM Patient	115	15.60%	**Total**	**737**	**100.00%**
RPM Patient as Citizen	115	15.60%	**Layer 4**	**Total**	**%**

SOC Patient	137	18.59%	Private Business Entity Providing Healthcare Services	2	0.27%
SOC Patient as Citizen	137	18.59%	Public Institute	1	0.14%
Surgeon	3	0.41%	Public Polytechnic Higher Education Institution	1	0.14%
Surgical Follow-up Nurse Manager	1	0.14%	Global Private Telecommunications Operator	6	0.81%
University Vice-Rector	1	0.14%	For-Profit Private Media Company	6	0.81%
Ward Nurse Manager	1	0.14%	For-Profit Private Publisher	7	0.95%
Total	**737**	**100.00%**	Collaborative Laboratory (CoLAB)	24	3.26%
			Non-Governmental Non-Profit Association	42	5.70%
			Public Higher Education Institution	79	10.72%
			Region NUTS II	264	35.82%
			Public Hospital Center	305	41.38%
			Total	**737**	**100.00%**

D.3. Contexts Characterisation

The aim of this appendix is to illustrate how the use of content analysis supported the contexts characterisation. Table 23 provided the coding scheme.

Three distinct temporal contexts were identified through the analysis of meeting notes, reports, interviews, and publications. The first context revolved around the design, development, and testing of a digital service for cardiac surgery follow-up care. The second context pertained to securing funding and planning a scaled-up technological roadmap for conducting a clinical study with a larger patient population. Finally, the third context entailed designing and implementing a clinical study involving 150 patients to ascertain which patient groups would derive greater benefits from the service, and how the healthcare team would manage the increased patient load. The first part of the summary of context 1 is provided to illustrate how the analysis was conducted.

Context 1 – The design, development, and testing of a digital service for cardiac surgery follow-up care:

Start date: February 2019 – Meeting note: Surgeons and nurses explained the need to continuously monitor the patients after hospital discharge. Analysis of existing data to characterise the patient pathway of patients submitted to cardiothoracic surgery from the moment of hospital registration to 1-year after 3-days post-surgery.

End date: January 2021 – Meeting note: Analysis of the results of the last group of patients under the digital health service.

Summary of Context 1-related Actions and Agents:

1. Surgeons and nurses (St. Marta Hospital) explained the issue of lack of reliable and continuous of information patients in the post-surgery period to researchers (VOH.CoLAB) (***challenge 1***): <*Surgeon*> "*The first month after surgery is the most critical one concerning post-surgery complications. We have a current practice monitoring patients. Nurses call patients 3-days after leaving the hospital and 30 days and also the patient comes to the hospital to a hospital appointment after these 30 days.*" <*Nurse*> *"When we call patients 3-days after leaving the hospital, we can understand some of the symptoms he is experiencing, but in a very subjective way. We ask him if he is monitoring blood pressure and weight lost, but we do not actually know if he is doing or doing it right. Without that is difficult to understand the symptoms (...). Some patients can explain you everything in detail, but most can't because they don't know how to do it, or they didn't monitor."* Surgeons and nurses believe that patient daily monitoring

in the first 30 days after surgery will help them evaluating the patient health status and avoid severe complications (***motivation 1***).

2. The researchers proposed the Design Science Research (DSR) Methodology to guide the project. Surgeons and nurses understood one of the main guiding principles: <Surgeon> "*Yes. I understand. Let's do it step by step and learning from it.*"
3. Researchers conducted four visits to the hospital to understand how surgeons and nurses worked in the standard of care (SOC) cardiac surgery follow-up service. In meetings they worked together in designing two models that helped illustrate how the SOC service operated. Researchers proposed to adopt the Business Process Notation (BPN) modelling approach to design the SoC patient care delivery process (the patient flow throughout the care delivery actions) – *as-is* process model (***mediating artifact 1***). Surgeons and nurses validated three versions until it was, in their perception, a comprehensive illustration of the service. Using ICHOM notation modelling of patient pathways (mapping data collection events on the patient journey under care), researchers, surgeons, and nurses defined the timestamps that they were collecting data from the patients (***mediating artifact 2***).
4. Throughout these four visits the following concerns were raised:
    i. How to engage patients to engage daily in self-monitoring their health status? (***challenge 2***)
    ii. Who should be the main relevant partners that could support the digitalisation of the service? (***challenge 3***)
5. To address these issues, researchers (VOH.CoLAB) proposed the following: 1) invite through the Advisory Board other researchers and developers (Fraunhofer) with previous work in digital cardiology follow-up service (mobile application and IoT devices to monitor the patients); and 2) conduct a short experiment with one patient and understand potential concerns. Researchers referred to this short experiment an "***iteration 0***" – concept commonly used in software development (***mediating artifact 3***). <Researcher> "*As we do not have funds to design a completely personalised service for this case, we could use pre-existing solutions. Fraunhofer has already worked with a Cardiology Department in Coimbra in monitoring patients remotely. We could see if the technological solution they have could work in this context. Well, at least we can understand if patients are willing to engage in this new way of surgery follow up.*"
6. Fraunhofer accepted to provide the mobile application, IoT devices (weight scale, blood pressure and heart rate monitor, steps tracker), and a data visualisation platform – technological solution (***mediating artifact 3***) but highlighted that did not have the resources to customise the

questions to patients in the mobile application in time – new collaboration started (***goal 1 achieved***) and minimal resource allocation (***constraint 1, source of control in the approach to approach the problem***).

7. Researchers (VOH.CoLAB) helped nurses and surgeons understand how the technology worked and surgeons decided to invite one patient to provide data for one week after surgery – technology and data flow architecture (***mediating artifact 4***). The patient accepted the invitation and after one week he had reported data every day. In the end of the week, a researcher (VOH.CoLAB) met with the patient and asked him to describe his experience: <*Patient*> *"I did what they (surgeons and nurses) told me to do. I didn't have any problem. This is very simple and helps them to know if I'm ok. I did everything as they told me."*
8. Both researchers and surgeons and nurses discuss the iteration and concluded that it worked as intended – patient engaged daily in self-monitoring their health status (***goal 2 achieved***) – **iteration 0 completed (From February 2019 to July 2019 – 4 months)**.
9. This motivated surgeons to think about conducting a study with more patients to understand the clinical relevance (***motivation 2***). In order to conduct a study with more patients, researchers (VOH.CoLAB) and surgeons and nurses highlighted the need of:
    a. More mobile phones and corresponding set of IoT devices (***challenge 4***)
    b. Mobile application questions customisation (***challenge 5***)
    c. Include an oximeter as an IoT device (***challenge 6***)
    d. Include the option for patients to send pictures of their surgical wounds (***challenge 7***)
    e. Data visualisation platform customisation to surgeons and nurses (***challenge 8***)
10. Researchers (VOH.CoLAB) asked Fraunhofer if they were willing to participate in a second iteration (iteration 1 – ***mediating artifact 2 changed***). Fraunhofer explained that they could provide 12 mobile phones and corresponding set of IoT devices and customise the mobile app questions to the case of cardiac surgery – collaboration maintained (***goal 3 achieved***). However, they did not have resources to include an oximeter (***challenge 6 remained***) and the capacity to develop a picture upload feature in the mobile app (***challenge 7 remained***) and customise the data visualisation platform (***challenge 8 remained***). Fraunhofer highlighted the need to have a partner that could provide the SIM cards to establish the communication (***challenge 9***).
11. Researchers (VOH.CoLAB) asked via the Advisory Board, one of his founding partners a telecom provider (Vodafone) with interest in developing new business models in digital healthcare to provide the SIM cards. Vodafone accepted to be part of the project and provide 12 SIM cards – new collaboration started (***goal 4 achieved***).

12. Researcher (VOH.CoLAB) along with surgeons designed the digital patient care delivery process – *to-be* process model (***mediating artifact 1 changed***) – to identify the digital health service main actions, the flow of information, and the resources involved in each action. Using ICHOM notation modelling of patient pathways, researchers, surgeons, and nurses also redesigned the new timestamps to collect data from the patients (***mediating artifact 2 changed***).
13. Researcher (VOH.CoLAB) along with surgeons and nurses designed a daily patient monitoring report to be sent by the researchers to the hospital team every day (***mediating artifact 5***).
14. Researchers (VOH.CoLAB) proposed to surgeons and nurses the option of patients sending the pictures via WhatsApp and they accepted since: <Surgeon> "*They already send me picture without me asking*". Researchers (VOH.CoLAB) became responsible to generate daily the reports manually and send them to nurses and surgeons (***mediating artifact 4 changed***).
15. Researchers (VOH.CoLAB) and surgeons prepared the project proposal to be approved by the ethical committee and the Hospital Board of Directors. It was approved.
16. Researchers (VOH.CoLAB) created a brochure with explanations to give with the kit to the patient. Nurses provided feedback in the brochure (***mediating artifact 6***).
17. Nurses and researchers (VOH.CoLab) delivered the kit at the hospital discharge appointment to the second patient, explained how to use it, and ask patients to repeat the task. After 30 days of remote monitoring, the patient was asked to share feedback in a semi-structured interview.