PAYING FOR HEALTHCARE INNOVATION

Sanne Allers

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Switching the focus from commercial value towards value for health and society

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Betalen voor zorginnovatie

Focus verleggen van commerciële waarde naar waarde voor gezondheid en maatschappij

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Cover design by Evelien Jagtman
Layout by Tiny Wouters
Printed by Ridderprint

ISBN: 978-94-6506-460-4

Financial support for this thesis was kindly provided by Medical Delta and Erasmus University Rotterdam.

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Thesis

to obtain the degree of Doctor from the
Erasmus University Rotterdam
by command of the
rector magnificus

Prof. dr. ir. A.J. Schuit

and in accordance with the decision of the Doctorate Board.

The public defence shall be held on

Friday 13 December 2024 at 13.00 hrs

by

Sanne Allers

born in Nieuwegein, The Netherlands.

Erasmus University Rotterdam

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De zeer oude zingt:

er is niet meer bij weinig
noch is er minder
nog is onzeker wat er was
wat wordt wordt willoos
eerst als het is is het ernst
het herinnert zich heilloos
en blijft ijlings

alles van waarde is weerloos
wordt van aanraakbaarheid rijk
en aan alles gelijk

als het hart van de tijd
als het hart van de tijd

Lucebert (1924-1994)

CONTENT

Chapter 1

General introduction

1.1 Background

To innovate means to introduce change (1). Looking at the world around us, it is evident that healthcare needs to keep changing to keep up with demands from society and to deal with pressing challenges. We see ageing populations with accumulating chronic diseases (2), increasingly empowered patients requesting personalised care (3,4), and an expanding focus on health(care) in domains beyond the healthcare sector (5). These developments urge healthcare professionals to change the way in which they are providing healthcare, engineers to create novel technologies, patients to be actively involved in their own care experiences, decisionmakers to adapt policies, and everyone to awaken the innovator within themselves.

The promise of innovation seems infinite, supported by ever-expanding inventions in science (6). In order to study this promise, it is important to define what we mean by innovation. Throughout the research performed for this dissertation, we characterize innovation as being *the design, invention, development and/or implementation of new or altered products, services, processes, systems, organizational structures, or business models for the purpose of significantly benefiting the individual, the group, or wider society* (7,8). Innovation can thus be seen as an expansive process of change, including all the steps necessary to induce change in many different forms with an ambition to change things for the better. We will dive a little deeper into these aspects of innovation below.

1.1.1 Different forms of innovation

Change can take many different forms, materializing as a new product, a new service, or a new governance model. Hence, innovation literature provides different ways to distinguish among innovations. An often used categorization is based on the type of innovation, distinguishing process from product innovations (7,9,10). Process innovations are defined in this dissertation as *a care service or process that is new or significantly improved with respect to its characteristics or intended outcomes and allows for a significant increase in the value delivered to one or more stakeholders.* Examples of such process innovations are novel treatments, changes in referral procedures of patients, or new professional roles in the healthcare workforce. On the other hand, a product innovation is characterized in this dissertation as *a good that is new or significantly improved with respect to its characteristics or intended uses and allows for a significant increase in the value delivered to one or more stakeholders.* Product innovations can be further subcategorized into devices, health information technologies (HIT) and pharmaceuticals (11). In this dissertation, we focus on medical devices and HIT tools, excluding pharmaceutical innovations because of their specific nature (e.g., patentability and lack of user-dependency) and regulations around market access setting them apart from other types of innovation (12,13). Examples of device innovations can be found in every day, low-risk products such as bandages and wheelchairs, as well as in complex, expensive, and potentially high-risk diagnostic and therapeutic technologies such as CT scanners or injectable chips. Examples of HIT tools include eHealth applications, administrative technologies, and decision support tools.

While we distinguish between products and processes, we acknowledge that the one is hardly ever present without the other. For example, when implementing an innovative product in healthcare, the care process around this product likely needs to change along. Innovative products often result in changes in the tasks professionals are required to perform and in the way in which a patient receives treatment. Thus, even though these categories of innovation form a useful framework for research, they are a simplification of a more complex reality.

1.1.2 To change things for the better

Regardless of the form of the innovation, its definition prescribes the presence of benefits for either the patient, provider, or society at large. In other words, innovations are changes that have the potential to add value to health or society (14). Value can be defined and interpreted in many ways. In the context of healthcare, a European panel of scientific experts proposed a broad interpretation of the meaning of value, consisting of four pillars: *personal value* (achieving personal goals), *technical value* (achieving the best possible outcomes), *allocative value* (achieving equitable distribution across all groups), and *societal value* (contribution to social participation and connectedness) (15). Each of these values, independently or combined, could result in valuable innovations as long as the innovation remains within the limits of available resources in terms of people, money and the environment (15).

During the course of this PhD-project, we came across many examples of innovation that add impressive value. One example is the heart-in-a-box, restarting donor hearts after they stopped beating and keeping them alive outside of the body (16). This technology has resulted in a 100 percent increase in available donor hearts, saving double the number of lives. Consequently, by the summer of 2023, the waiting lists in the Netherlands had stabilised (17). Another example is the introduction of new professionals called nurse specialists and physician assistants, with several thousands of nurses in all sectors of healthcare educated to assist medical specialists by being able to take over tasks in patient care (18). Not only has this led to an alleviation of the scarcity of care professionals, it also added career perspective and job satisfaction for these nurses. A change that could prove vital for a sustainable healthcare system in the future.

Nevertheless, there are also innovations of which the added value is questionable. An example is the widespread use of the Da Vinci Robot, an innovation allowing surgeons to perform surgery through a robot. Despite its potential for value, outcomes for patients have generally not improved while buying and using the devices have proven very expensive and polluting (19,20). Nevertheless, the innovation has spread quickly, with almost twenty hospitals in the Netherlands having purchased the robot (21). This shows that not all innovation in healthcare is likely to add value for health or society, an important but complicated fact to acknowledge in innovation research.

There is another type of value that can be produced by innovation, namely the potential for monetary profit (i.e., a high return on investment) for investors, owners or users of the innovation, which we term commercial value. However, given the large amounts of public resources distributed to support innovation to address the challenges facing our healthcare systems, the importance of adding value for health or society is particularly high (22–24).

1.1.3 The necessary steps

Many potentially valuable innovations are lost because they do not manage to successfully proceed from the initial idea to sustainable implementation in practice (25,26). This pathway from idea to practice is called the healthcare innovation process, commonly divided into separate phases. Many frameworks that focus on the entire innovation process present so-called stage-gate models, distinguishing successive phases (the stages) from initial idea to adoption in practice (27). Stage-gate models assume that in order to move from one phase to the next, barriers must be overcome (the gates). Based on an existing stage-gate model (28), we discern three phases: *development* (including activities such as identifying opportunities and creating a prototype), *translation* (including activities to prepare the prototype for market launch), and *implementation* (including activities for commercialization of the innovation through adoption, exploitation and expansion).

In the translation phase, we can find the 'valley of death'. The name refers to the many innovations that end at this point in the process, because they fail to mature sufficiently to reach sustainable implementation in practice (29). Moving from prototype to practice requires many vital steps to be taken, such as finding a sufficient number of users willing to adopt the innovation, meeting all the regulatory requirements, making financial agreements with one or more parties to pay for the innovation, and establishing a production process ready to produce the desired number of innovations. The complexity of these tasks and the resources needed result in a phase in the process where many potentially valuable innovations fail.

Even though the innovation process is often visualized in a linear way, innovation is much messier in reality. Innovations move iteratively between phases, incrementally improving as they go back and forward. As innovations are likely to get stuck somewhere in the process, managing all the steps to realize a successful innovation requires more than simply a good idea.

1.1.4 The role of payment

One of the factors potentially influencing innovations' progress is payment (30). For every step in the process and every form of innovation, both the amount and type of payment available could influence the direction the innovation will take (31). In this dissertation, we approach the amount of payment available for an innovation predominantly as an allocative question (i.e., which

innovations get access to a share of the scarce resources?) rather than an absolute question (i.e., how much resources are available in total?).

Regarding the type of payment available, we distinguish between *temporary funding* (such as research grants and subsidies) and *sustainable reimbursement* (such as insurance coverage). These types of payment have different characteristics, such as being closed- or open-ended, involving more or less strict evidence requirements, and even having different aims (i.e., stimulating knowledge development or stimulating affordable, accessible and high-quality care provision). It is therefore likely that these different types of payment play different roles in the innovation process. Moving through the innovation process, innovations will likely come across challenges and opportunities related to both types of payment.

Despite the insights described above, there is little evidence on the exact role that payment plays in the innovation process. In what phases, for which innovations, and how does payment play a facilitating or an impeding role? In order to facilitate valuable innovations to find their way through the process, it is vital that we strengthen our knowledge about the role of payment in innovation processes. Moreover, to support decisionmakers in facilitating valuable healthcare innovation, it is important to increase our understanding about possible solutions to overcome financial barriers and advance the impact of payment on innovation.

1.2 Central aim

Against this background, the central aim of this dissertation is to improve the understanding of the role of payment in healthcare innovation processes and explore promising solutions to improve the role of payment in enhancing innovation with high potential value for health or society. This translates in the following central research question:

What role does payment play in the healthcare innovation process and what are promising solutions to overcome financial barriers for the progress of potentially valuable innovations?

This central question will be answered by addressing five subquestions. Before discussing these subquestions, we will first outline the setting in which this study took place.

1.3 Study setting

Research into complex, multifaceted phenomena, such as the one forming the basis of this dissertation, is shaped by the context in which it is performed. Regarding our studies, four features stand out:

1.3.1 Broad perspective of the innovation field

In order to formulate a valid answer to the central research question, we adopt a broad perspective of the innovation field, both in terms of the phases of the innovation process looked at (from the initial idea spanning all the way to attempts at scale-up of implemented innovations) and the types of innovation studied (medical devices, HIT tools and process innovations). Healthcare innovations are often studied, yet the field is dominated by research focusing on single aspects of the innovation process or on specific payment mechanisms without taking into account the broader context (32). The broad perspective taken in this dissertation is likely better suited for understanding the different financial factors that may play a role throughout innovation processes and the interaction of payment with context.

1.3.2 Variation in research methods

In addition, to be able to answer our multifaceted research question from different perspectives, we adopt a variety of research methods in our studies. The methods include a systematic review of the scientific literature, qualitative case studies of healthcare innovations, and a Delphi study assessing the opinions of experts. Not only does this variation in research methods allow us to investigate different types of evidence, it also provides the opportunity for different kinds of stakeholders to have a voice in our research. Specifically, we consider the perspectives of innovators, payers, providers, managers, decisionmakers and scientists to formulate a comprehensive view on the matter.

1.3.3 Practice-oriented data collection

Furthermore, we apply a practice-oriented approach in our research. Experiences of innovators and other actors in healthcare innovation practice form the core of our data. Not only do we investigate these experiences in the various studies performed, throughout the course of the PhD-project many innovation events were attended. These events provided an opportunity to speak with people who were in the midst of innovation processes, which allowed us to get a feeling of the struggles experienced by the various stakeholders involved, offered inspiration and information about the latest developments in the field, and helped to assess the design of the methods and validity of the findings in the studies.

1.3.4 The Dutch healthcare innovation system

Finally, this dissertation mainly focuses on innovation in the context of the Dutch healthcare system. Specifically, the research was performed in the context of the Medical Delta association for healthcare innovation. This organisation brings together professionals from engineering, healthcare providers, and academics from different institutes in the South-Holland region to collaborate on creating technological solutions for sustainable healthcare (33). Motivated by the failure of many valuable innovations to find their way to practice, the research project 'from prototype to payment' was initiated by Medical Delta to investigate the reasons behind this. The central aim of this dissertation was derived from the experiences by participants of this association, and our research is part of a broader project studying various influences on healthcare innovation in the Netherlands.

The Dutch healthcare innovation context has several interesting characteristics that should be acknowledged as being part of the context in which our studies were conducted. The Netherlands is characterized by relatively limited private and public investment levels in research and development of innovation compared to other European countries (34–36). Despite this, the Netherlands is consistently ranked as an innovation leader both in Europe and worldwide, due to a strong knowledge economy, highly educated workforce and favourable infrastructure and regulatory climate (36,37). This suggests that conditions for healthcare innovation may be relatively favourable within the general Dutch context.

1.4 Research questions

Our central aim and study setting give rise to five research questions, to be answered in this dissertation. First, it is important to commence any research project by assembling and assessing the existing scientific knowledge. As stated before, the role of payment in healthcare innovation processes has often been studied, but a comprehensive overview of the evidence is missing. This leads us to the first research question:

Q1: What is already known in the scientific literature about the role of payment in healthcare innovation throughout the various phases of the healthcare innovation process?

To answer this research question, we perform a systematic review of the literature published between 2000 and 2022, narratively synthesizing articles discussing the influence of payment on healthcare innovation in OECD countries. Using the literature review for identifying specific gaps in the literature, we proceed to study innovation in practice with the aim to fill these gaps. Specifically, the review shows that most of the previous research is based on a narrow, de-contextualized view of innovation, highlighting the importance of studying innovation processes in their entirety including

relevant contextual influences. In addition, given their distinct characteristics it is important to pay attention to both product-type and process-type innovations in our research. This results in the following two research questions.

Q2: What financial influences do innovators encounter when developing, translating, and implementing innovative products in the Dutch healthcare system?

Q3: What financial influences do innovators encounter when developing, translating, and implementing innovative processes in the Dutch healthcare system?

To answer these research questions, we perform two sets of qualitative case studies of innovation processes in practice, from the perspective of the innovators themselves. The first set of case studies focuses on both medical devices and HIT tools. Through analysing four innovations emerging within academic institutes with high potential value for patients, we infer the facilitating and impeding effects of payment on product innovation. Additionally, we gain insight in the differences in influence of payment on medical devices compared with HIT tools. The second set of case studies focuses on four projects aiming to integrate care processes between different healthcare organisations. Through these case studies we obtain a better understanding of the role of payment in process innovations.

Subsequently, using our findings from the first three studies as a guide, we proceed to study those types of healthcare innovation that seem most severely impeded by financial barriers during specific phases of the innovation process. With these studies, we also aim to provide promising solutions to address the challenges in these phases of the innovation process. First, we examine attempts by innovators to scale up HIT tools after their initial local implementation. Second, we study medical devices in the translation phase, aiming to bridge the valley of death towards sustainable implementation. For the final study, we adopt a broader stakeholder perspective, not focusing solely on the experiences of the innovators. This leads to the final two research questions.

Q4: Which complexities do innovators encounter in the scale-up of innovative health information technologies in the Dutch healthcare system, and what are promising strategies to address these complexities?

Q5: Which financial barriers for innovative medical devices in the translation phase are perceived as most urgent by various stakeholders in the Dutch healthcare system, and which solutions do they deem most promising?

With regards to understanding the complexities encountered in attempts to scale-up HIT tools, we conduct a cross-disciplinary theoretical and empirical analysis of an exemplary innovative HIT tool. Specifically, we cooperate with researchers from another scientific discipline, involving the sociological and organisational perspectives to complement our economics and management perspectives on innovation. Through this combination of disciplines, we aim to determine what is overlooked in existing research and practice on innovation scale-up, identifying promising strategies to address the complexities of scale-up.

To answer the final research question, we conduct a Delphi study asking a large panel of experts involved in the process and payment of innovation to identify and rate which financial barriers they perceive as most urgent and which solutions they deem most promising. Based on the results of this study, decisionmakers can formulate broadly supported strategies to overcome financial barriers. Furthermore, this study also provides the opportunity for a variety of stakeholders to reflect on the role of payment in healthcare innovation.

1.5 Outline of the dissertation

This dissertation is structured as follows. In five chapters, we aim to answer our central research question. The systematic literature review in chapter 2 synthesizes the available scientific evidence about the role of payment throughout the various phases of the healthcare innovation process, both for product innovations and for process innovations. Chapters 3 and 4 then elaborate on the experiences of innovators in practice, with the former detailing the financial influences encountered during the progress of product innovations and the latter focusing on the financial influences for process innovations. Then, we turn our attention to two types of innovation in specific phases that seem most severely impeded by financial barriers. First, chapter 5 aims to shed light on the stagnation of innovative HIT tools in local implementation, providing insight into promising solutions for innovation scale-up. Subsequently, chapter 6 focuses on the financial barriers for innovative medical devices in the translation phase, known as the valley of death. This chapter searches for consensus among experts about the most urgent barriers to be solved and about the most promising solutions to bring innovative medical devices towards sustainable implementation in practice. Finally, chapter 7 summarizes and discusses the main findings and formulates implications for policy, practice, and research.

Most of the work presented in this dissertation has been performed independently by the author of this dissertation. Specifically, the author played a leading role in formulating the research questions, searching and studying relevant literature, setting up the studies, performing the empirical analyses, and interpreting and reporting the findings of the different chapters. Extensive feedback from promotors Erik Schut and Erik van Raaij and co-promotor Frank Eijkenaar has been incorporated in all chapters. Finally, co-author Chiara Carboni played an important role in the conception, design and execution of chapter 5, with feedback from co-author Rik Wehrens incorporated in chapter 5 as well.

Chapter 2

Paying for healthcare innovation: A systematic review of the influence of funding and reimbursement on innovation processes in healthcare

Under review

Abstract

Innovation is considered essential to the quality and sustainability of healthcare systems. However, the path from innovative idea to adopted reality is complex and fraught with barriers. The way in which healthcare innovations are financed is often mentioned as a major stumbling block, but a comprehensive overview of the role payment mechanisms play in innovation processes is lacking. To fill this knowledge gap, we conducted an extensive literature review, combining a systematic data search with textual narrative synthesis. We contextualize the literature on the role of funding and reimbursement in the process of healthcare innovation in relation to stage-gate models of innovation processes. This results in a 'financial fugle model' in which the role of funding and reimbursement is analyzed in three consecutive phases of the innovation process: development, translation, and implementation. From the review of 157 included articles, four key findings stand out: i) shortcomings in national reimbursement systems result in local fragmentation in the implementation of innovations; ii) lack of evidence on costs and benefits in financial decision-making may harm the development and implementation of potentially value-enhancing innovations; iii) more disruptive innovations encounter larger financial barriers; and iv) non-financial factors, including innovator characteristics and institutional support, are essential in overcoming financial barriers. Based on these key findings, we develop a research agenda for further investigation of the influence of payment mechanisms on the process of healthcare innovation.

2.1 Introduction

Every day, new ideas, technologies, methods, and procedures are developed to improve the functioning of healthcare systems (38). Some authors even regard innovation as *"the engine that drives the healthcare system"* (39). Prolonged life expectancy, improved quality of life, and increasingly efficient delivery of care have all been ascribed to the array of innovations that have occurred in healthcare during the past century (7). Unsurprisingly, innovation is often viewed as having a direct influence on the quality, affordability, accessibility, and hence, the future sustainability of healthcare systems (9,11). Concurrent to the focus on innovation as the route to improving the functioning of healthcare systems, those systems are also facing increasing pressure to balance financial sustainability with patient access to the best quality care (7). The importance of future sustainability has inspired critical attention to the management of healthcare innovations, specifically which innovations are developed and implemented, and which are not. Ideally, these should be the innovations with the potential to deliver value for society, providing health benefits while also keeping costs down. As summarized by Miller and Lehoux (40), there is a general imperative for health policy to take societal need and the actual use of innovation as the starting point, rather than producing more innovations *per se*.

For innovation to play this role, the right conditions with the right incentives must be in place. Despite a proliferation of ideas that could ultimately evolve into value-enhancing innovations, significant barriers often appear to prevent these ideas from becoming an adopted reality (41). Factors that are known to inhibit healthcare innovation processes include the inadequate measurement of health outcomes, regulatory burdens, communication failures, siloed delivery of care, and misaligned financial incentives (42). This paper focuses mainly on the last of these factors – financial incentives embedded in payment mechanisms and their promoting or impeding role in the management of innovation processes in healthcare.

Over the last two decades, there has been a considerable increase in scientific research activity into this topic and both the media and government publications frequently report on the influence of payment mechanisms on innovation in healthcare (31,43–45). However, systematic insight is lacking into the role specific payment mechanisms play, and the key financial issues innovators encounter in different phases of the innovation process. By combining systematic data search and extraction with a narrative synthesis, this paper provides a comprehensive overview of the role of payment mechanisms in healthcare innovation in the various phases of the innovation process. To our knowledge, such an overview does not yet exist. In addition, this review explicitly compares the role of payment mechanisms between product and process innovations in healthcare, which has also rarely been done in previous research. We believe these insights could help researchers, policymakers, and managers to develop and adopt effective payment mechanisms for valuable healthcare

innovation, thereby contributing to more sustainable healthcare systems. Based on the findings, we formulate a research agenda highlighting the most significant gaps in the literature.

2.2 Conceptual framework

We devised a conceptual framework of the healthcare innovation process to structure and analyze the literature. This framework is based on the following definition of innovation: *the design, invention, development and/or implementation of new or altered products, services, processes, systems, organizational structures, or business models with the purpose of significantly benefiting the individual, the group, or wider society* (7,8). This definition clearly emphasizes the different features an innovation may have as well as the various phases of an innovation process. We use both elements to construct our conceptual framework. First, we apply a common categorization of innovations for research purposes, namely the distinction between *product and process type innovations* (see Box 2.1) (7,9). Although we understand that product and process innovations rarely are completely separate entities in practice, the differences in tangibility and user dependency could result in a strongly diverging influence of payment mechanisms between these two categories of innovation. Therefore, the distinction between product and process innovations will explicitly be adopted in this review. Second, we distinguish between a *development, translation and implementation* phase in the innovation process (see Box 2.1). These phases are derived from stage-gate models, distinguishing successive phases (the stages) from idea to launch (46). Stage-gate models assume that to move from one phase to the next, barriers must be overcome (the gates). Henceforth it presents a useful framework to identify the crucial financial barriers in different phases of an innovation process. We combined the Fugle[1] stage-gate model developed by du Preez and Louw (28) with information on the role of payment mechanisms in the different phases. We acknowledge that in practice innovation processes are far from linear, but for the purpose of this research the Fugle stage-gate model presents a concise yet comprehensive overview to analyze the innovation pathway. Finally, we also distinguish two main categories of innovation payments: temporary payments (i.e., *funding*) and structural payments (i.e., *reimbursement*).

[1] Fugle is the fusion of a funnel and bugle, illustrating the convergent and divergent parts of the innovation process model (28).

***Box 2.1**. Definitions*

Innovation type
Product innovation – A physical good, such as a device or digital tool, which is new or has been significantly improved in terms of its characteristics or intended uses and allows for a significant increase in the value delivered to one or more stakeholders.
Process innovation – A care service or process, such as a treatment or referral procedure, which is new or has been significantly improved in terms of its characteristics or intended outcomes and allows for a significant increase in the value delivered to one or more stakeholders.

Process phase
Development – Identifying opportunities and creating a prototype.
Translation – Preparing projects for market launch, from prototype to commercialization in mainstream practice.
Implementation – Commercialization through adoption, exploitation, and expansion.

Payment mechanism type
Funding – Temporary investments and grants.
Reimbursement – Structural financial compensation.

2.3 Methods

Considering the quantity and heterogeneity of the literature on payment mechanisms in healthcare innovation, we have chosen to combine a systematic literature review with a narrative synthesis approach. We followed the systematic review guidelines of Bramer et al. (47,48), based on the Cochrane guidelines, to search for and select relevant literature. We then followed textual narrative guidelines to extract and synthesize data from the literature (49,50).

2.3.1 Eligibility criteria

We included both theoretical and empirical peer-reviewed scientific articles, including reviews and primary research published between January 2000 and March 2022, with a focus on the influence of payment mechanisms on the development and/or implementation of healthcare innovations. The articles had to be written in English and discuss findings from OECD countries. We chose to focus only on OECD countries because healthcare systems in non-OECD countries can be very different in terms of structure, access and, most importantly, financing.

We excluded articles that focused on pharmaceutical innovations because of their specific nature (e.g., patentability and lack of user-dependency) and regulations around market access. In addition, we excluded opinion papers, editorials, book chapters, conference proceedings and newsletter articles, as well as hypothetical studies about payment for individual innovations. Lastly, we excluded articles reporting on health technology assessments and economic evaluations for individual innovations as well as methodological considerations thereof.

2.3.2 Search strategy

We devised an Embase search string with the assistance of an information specialist, combining Boolean operators with appropriate Emtree and abstract or full-text search terms, based on *payment, incentive, innovation* and *healthcare*. Subsequently, we adapted this search string for other databases (see Appendix 2.a). Based on research by Bramer et al. (48) regarding the optimal sensitivity and specificity of systematic literature reviews in the field of healthcare research, the databases searched included Embase, Medline, Cochrane Central Register of Controlled Trials, Web of Science Core Collection and Google Scholar (200 top-ranked). In addition, we searched Econlit and ABI/INFORM, the main databases in the fields of economics and management studies which we considered essential fields of study for this review to the extent that they concern healthcare innovation. Furthermore, we screened the reference lists of all articles included.

We used EndNote X9 software to remove duplicates and manage the selection of studies. The articles were included in two consecutive steps: first we screened titles/abstracts, and then we screened the full text of potentially relevant articles. In order to ensure that the eligibility criteria were applied consistently across authors, we used a calibration process, separately for both steps. Two authors (SA and FE) independently reviewed the first twenty percent of titles/abstracts (ordered alphabetically by author) using intermediate calibration discussions at five, ten and fifteen percent, as well as the first five percent of the full texts of the articles selected after the titles/abstracts were screened. Discrepancies between the selections were resolved through discussions involving all the authors of this paper, after which SA screened the remainder of the titles/abstracts and full texts. Articles about which doubts remained after this process were discussed in meetings with all authors.

2.3.3 Data extraction and analysis

We used a standardized data extraction form (see Appendix 2.b) based on the specific aims of this study and forms used in similar reviews (50,51). This form allowed for the systematic extraction of descriptive information such as the year of publication, study setting, data and methodology, as well as key findings on financial and non-financial incentives (facilitators and barriers) for innovation.

We used textual narrative synthesis to extract and appraise data and then to synthesize our findings. This approach is particularly useful for reviewing heterogenous literature that includes many different types of evidence, study designs, and perspectives (50). The reviewer first divides the literature into relevant homogeneous groups based on a standard form of study characteristics, context, and findings. Next, the findings for each group are synthesized, after which the groups can be compared. Figure 2.1 provides a visual representation of the data extraction and synthesis process that we used.

We created six groups based on two categories we distinguished in the conceptual framework: innovation type (product or process) and process phase (development, translation, or implementation). For each type and phase, we combined the Fugle stage gate model of Du Preez and Louw with information on the role of payment mechanisms, resulting in two 'Financial Fugle Models'.

We synthesized the findings by creating a summary for each group (i.e., a combination of innovation type and process phase) using mind-maps and other visual structuring methods (49). Next, we analyzed the summaries within and between groups, highlighting differences and similarities in the payment mechanisms and incentives. This resulted in: i) two separate 'financial fugle models' for product and process innovations; ii) an evaluation of the existing evidence regarding the influence of payment mechanisms for each group; and iii) an agenda for future research based on knowledge gaps identified.

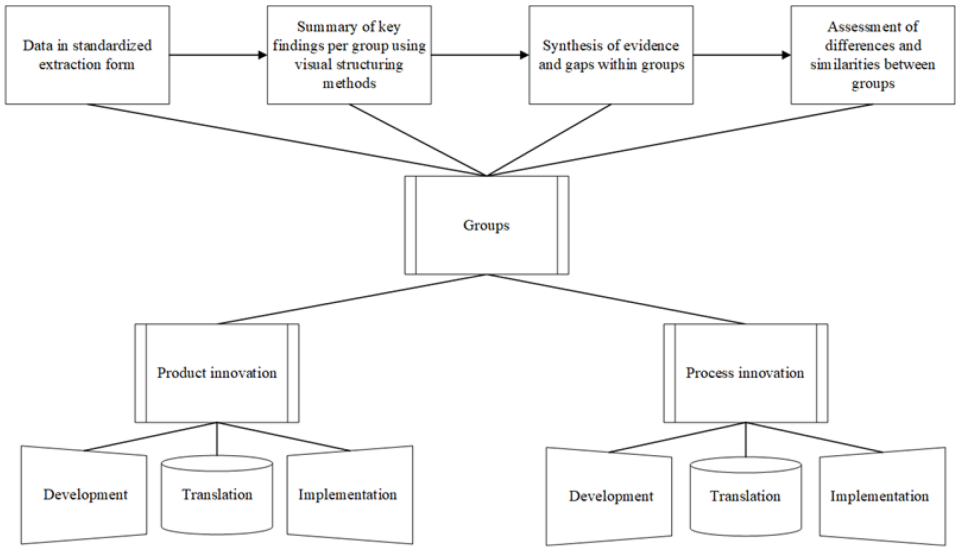

Figure 2.1. Process of data extraction and synthesis and categorization of homogenous groups.

2.4 Results

In total, 16,518 articles were identified in our systematic search, with 8,851 unique articles remaining after duplicates were removed. The screening of the titles and abstracts led to the removal of 8,345 articles, leaving 506 articles for full-text screening. Following this screening, 369 more articles were excluded based on the predefined criteria, a breakdown of which can be found in Figure 2.2.

Reference screening identified an additional 20 eligible articles, leading to a total of 157 articles for inclusion. These articles are listed in Appendix 2.c, in order of the groups they were categorized in.

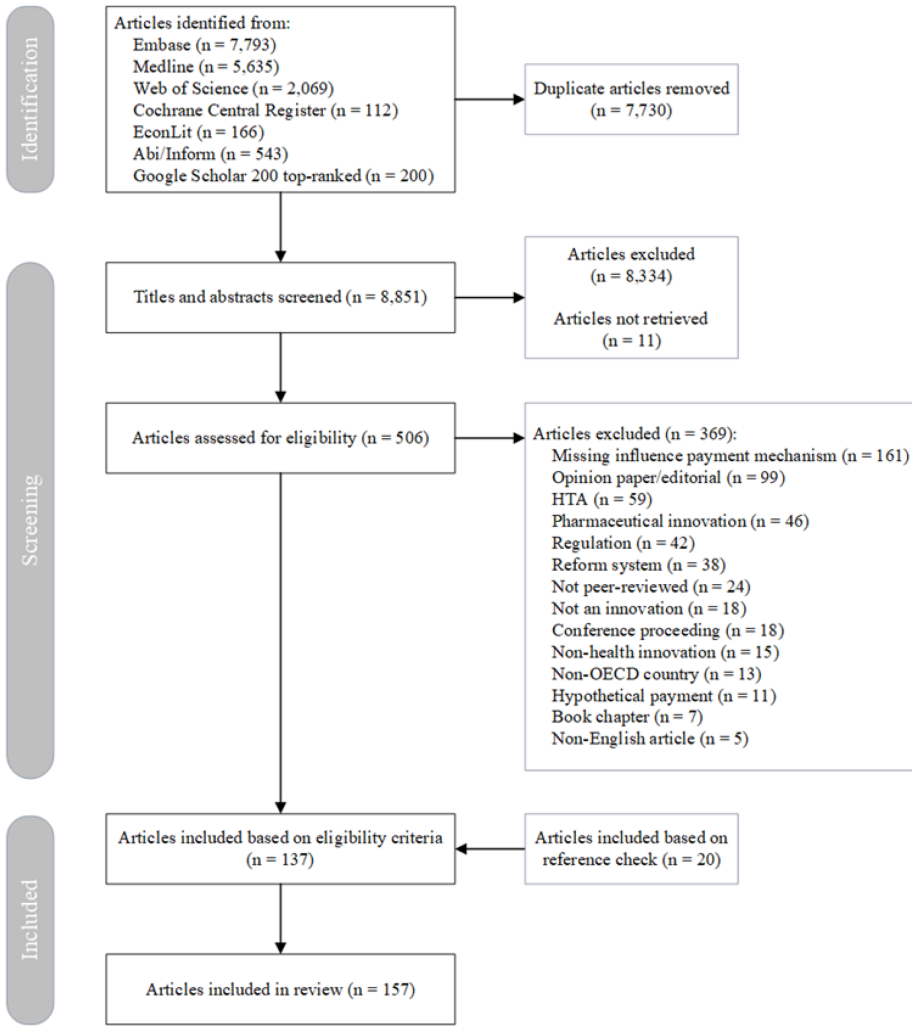

Figure 2.2. Flow diagram showing selection process for articles for systematic review.

As is customary in textual narrative synthesis, below we present our findings within and between groups. First, we distinguish between articles that relate to product innovations (54%, n=85) and process innovations (24%, n=38). The remaining articles (22%, n=34) were articles about both innovation types; their findings are discussed in both groups. Second, for both innovation types, we present findings on the development, translation, and implementation phase. Most research has focused on the implementation phase (74%, n=117).

2.4.1 Product innovations

The literature on financial incentives in relation to product innovations is extensive, with most studies focusing on the implementation phase (n=78) followed by the translation (n=30) and development (n=13) phases. As shown in Figure 2.3, several payment mechanisms were identified in these articles. We discuss the payment mechanisms and the associated financial incentives for each phase, identifying key issues as we move through the innovation process.

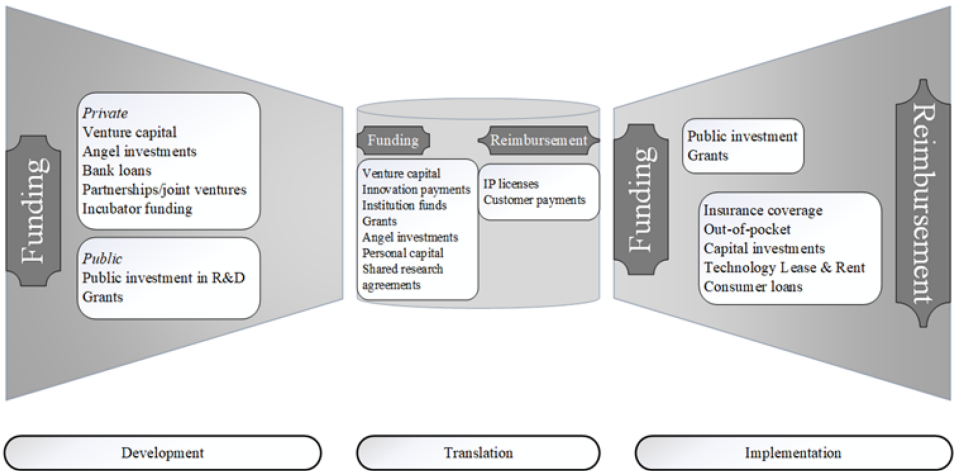

Figure 2.3. Financial Fugle Model for product innovation based on the process model of Du Preez and Louw

2.4.1.1 Development phase of product innovations

The development of innovative products is funded through both public and private capital. Public funding includes government R&D grants and subsidies, while private funding includes venture capital and angel investments. We will discuss public funding mechanisms first, as they mainly play a role in the earlier phases of the development phase. After that, we will discuss the most common form of capital in later-stage development, venture capital. Next, several alternative sources of private capital and expectations about future reimbursement will be highlighted. We conclude this section with the effect of public and private capital on the health and commercial value of innovations.

Public funding

Six studies examined the availability of public funding at the very beginning of the innovation process, the aim of which is to facilitate innovations that focus on health benefits. For example, in their study on governmental R&D funding, disease burden and the output of innovative products, Ward et al. (52) found a strong positive relationship between disease burden and the amount of

funding made available. In other words, most funding was spent on disease areas where innovation was needed most. Moreover, studies found that governments were prepared to fund innovative ideas long before private investors were willing to accept the risks of doing so. For example, in their survey of 37 US investment organizations for regenerative medical technologies Bertram et al. (53) found that public R&D grants are used mainly to fund innovation in the early seed stages. While private investors preferred projects where a return on investment could be expected within three years, government agencies were willing to wait five years or more. In addition to supporting innovation in seed stages, public funding was also found to be effective in increasing the number of innovative startups and innovative output (54). Although public seed-stage funding seems to be a factor that facilitates innovation, further funding is typically required in order to finalize the development of innovative products – funding that venture capitalists are able to provide. Consequently, Anderson et al. (55) concluded that including advisors from the private sector in public funding allocation boards is necessary to secure a balance of scientific merit with commercial viability of the product.

Venture capital

The majority of the studies (8 out of 13) look at venture capital: private equity investment that focuses on start-up companies, with profit sharing between investors and innovators. Venture capitalists finance the majority of development costs for many innovative products (especially in the later stages of the development phase), and their investment in healthcare has increased over the last two decades (56,57). For example, Lehoux et al. (58) found that the absolute levels of venture capital provided to Canadian technology-based life science companies more than doubled between 2001 and 2010. Studies also noted a shift in venture capital investment to the later stages of development, as innovations in these stages involve less risk and profits can be realized sooner (57,58).

Despite the opportunities that venture capital funding provides in turning an idea into a marketable commodity, authors questioned whether it has a beneficial impact on innovation in healthcare (57–59). This type of funding is often considered precarious, because it emphasizes commercial value over health value. For example, in a survey of venture capitalists in Canada, 85 percent of respondents indicated that they regard public health impact as 'not at all' or only 'somewhat' important (58). As Lehoux et al. (59) summarized: *"Overall, venture capital supports technologies that generate health gains by accident, not by design"* (p.514). In general, short-term profits for investors are prioritized over fundamental research that could result in significant health benefits (57,58). The focus on commercial value could, moreover, be a source of unrealistic return-on-investment requirements and time-to-market horizons (60). Innovators are forced to cede ownership and control, giving investors the opportunity to actively push products in a direction with better commercial prospects, potentially at the expense of health value gains.

It is important to note that research into the role of private venture capital has primarily been done in North America. However, one important exception is the study by Keppler et al. (61) who studied

European venture capital investments by conducting interviews with 39 experts from Germany, Switzerland, and Austria. Unlike the North American studies, they found that in these countries venture capitalists also play an important role in seed-stage development. They also found that in Europe venture capital investments in healthcare significantly declined since 2008.

Alternative funding mechanisms

Three studies looked at alternative funding mechanisms for the later stages of the development phase of innovative products, including partnerships, joint ventures, and incubator funds. Partnerships and joint ventures both aim to promote innovation by combining resources from different parties for a certain period of time. Grazier and Metzler (60) and Lettl et al. (62) both argued for increased use of partnerships and joint ventures involving medical start-ups and established healthcare providers and technology manufacturers to gain quick access to knowledge and capital. However, these funding mechanisms are not yet prevalent in healthcare, even though they have proven their effectiveness in other sectors (60).

Incubators are physical spaces "set up to assist in the growth and development of new enterprises" and provide increasing access to "vast resources for the transfer of knowledge and talent to commercial products and services" (63). Rotenstein et al. (64) presented empirical data on an incubator in Boston which has led to all kinds of innovations, discussing the features that may have contributed to its success. One of these features was that funding has been based on impact on healthcare practice, rather than on profit or commercial potential. The authors therefore argued that incubator funds can target innovations that would otherwise have lower chance of being funded under the prevailing venture capital model.

Expectations about future reimbursement

Regardless of the funding mechanism, five studies found that expectations about future reimbursement during the implementation phase play an important role in the availability of funding in the development phase (53,56,61,64,65). For example, based on their study of US investments in eHealth innovations after the introduction of reimbursement for such products, Lite et al. (56) found that funding levels of innovative eHealth products significantly increased due to better prospects of adoption in the implementation phase.

Conclusion on development of product innovations

In summary, both public and private capital seem to be needed for the development of innovative products and are more likely to be forthcoming if the prospects for future reimbursement are favorable. While public capital is concentrated mainly in the seed-stage of development, most venture capital funds are made available during later stages of product development. Investors of public capital are often willing to invest in innovative ideas that could provide health value

irrespective of their commercial value, venture capitalists seem primarily interested in the commercial value of innovations. Alternatives to venture capital were mentioned as a potential facilitator for innovations with health benefits, but the evidence on these alternatives remains limited and localized in nature.

2.4.1.2 Translation phase of product innovation

The translation phase of product innovation involves both funding and reimbursement mechanisms. Funding can include grants, venture capital and innovation payments. Reimbursement includes direct payments from customers and intellectual property licenses. We start this section with the results of studies that explain why many innovations are discontinued during this phase – a phenomenon that has become known as the 'valley of death' (6 out of 30 articles). We will then turn to a payment mechanism that has the potential to overcome this valley of death: public innovation payments (16 of 30). Finally, we will discuss literature on characteristics of innovators and institutional support that are needed to overcome financial barriers (8 of 30).

Valley of death and venture capital

At the start of the translation phase, the financial incentives of public and private capital are often misaligned. This is because products that have been developed with public funding are frequently unsuited to the interests of venture capitalists. According to Collins et al. (66), investments during the development phase, such as government-funded research without commercial potential, result in many innovative products ending up in the 'valley of death'. This term is often used to describe the translation phase: before and after the translation phase, large amounts of payment are made available, but during this phase many value-enhancing innovations lose momentum due to a lack of sufficient private (venture) capital.

There is also a misalignment between the needs of private investors in the translation phase and the public goals of the health system regarding reimbursement during the subsequent implementation phase (67,68). Sebastianski et al. (69), for example, concluded from their review of 15 years of literature and three case studies that *"while private companies need to act quickly to maximize profit, this is diametrically opposed to the public health system's mandate of ensuring resources are efficiently allocated"* (p.78). While private venture capitalists are interested in rapid progress towards structural reimbursement, public policies prioritize reducing cost pressures in the healthcare system and a critical assessment of which products are to be reimbursed.

In innovative areas where no reimbursement methods exist yet, it is very unlikely that venture capital funding for the translation phase of a product will be forthcoming. If this funding is provided, venture capitalists often require innovators to translate their prototype products into a more commercially profitable but less socially valuable form (61,67,68,70). As one respondent in a study of venture capital funds put it: *"investors who want to stay in healthcare will shift investments from*

life-saving products [...] to consumer pay cosmetic opportunities" (70). In other words, if product innovations do survive the 'valley of death' with investments from venture capitalists, they must have a certain profitable return on investment.

Innovation payments

To mitigate the risks of the translation phase and reduce dependency on venture capital, national governments have been introducing innovation payments since the early 2000s (71). Innovation payments are short-term instruments that aim to support innovations with the potential to provide health value, even in cases where the (clinical) evidence is not yet fully established. Studies performed in various countries found that innovation payments had a consistently positive effect on the adoption of innovative products in practice (72–77). Although such payments may seem to be a promising source of funding to supplement or replace private capital at first glance, all the studies also described significant issues in practice, including the fact that remarkably few products actually received innovation payments (71,78–80), as well as issues around the negotiations for obtaining sufficient amounts of payment (71,76,81), unclear requirements (78,80), differences in approvals between regions or hospitals (73,75,78,81–83), retractions due to safety concerns and conflicts of interest (77), concerns about the excessive implementation of innovations with only marginal benefits (84,85), and uncertainty about long-term reimbursement (71,76,78,83,86,87). As Sorenson et al. (81) concluded based on a survey in England: *"While a good concept in principle, only about one-third of respondents believed innovation payments were effective in meeting their aims in practice"* (p.168). To date, no country appears to have found the ideal mechanism by which to adequately support value-enhancing innovations through the translation phase.

Non-financial factors

The literature identifies many financial barriers to the translation of innovative products. As many authors note, the key to dealing with these issues can often be found in the characteristics of innovators and their network, and in their ability to convince key players to support and adopt the innovation (88). As Beaulieu et al. (89) concluded, based on twenty interviews with medical innovators in Canada: *"Bringing to light the new organization and associated product is primarily a political act. [...] Thus, being omnipresent and connected"* (p.1134, p.1139).

Several studies also highlighted the role of certain support structures in securing financing and creating innovative output in this phase. Specifically, while it is essential to build a strong business case and protect intellectual property (9), innovative ideas often come from professionals who rarely have the focus and skills required to develop a business case (90,91). This problem may be mitigated through the pooling of resources and knowledge in a larger network of academic institutions, hospitals and industry players. Such networks can be created by Technology Transfer Offices, which are also skilled in creating business cases, protecting intellectual property and managing conflicts of interest (92–94).

Conclusion on translation of product innovations

The translation phase is where public and private funding and reimbursement mechanisms come together, and the resulting misalignments mean that this phase is known as the 'valley of death' for many innovative products. Even though many different payment mechanisms are available, the diverging interests of public and private investors and the issues around innovation payments often prevent products from proceeding to the implementation phase. In addition, acquiring financial resources during this stage seems to depend heavily on the network, social skills and personal conviction of the individuals and parties involved.

2.4.1.3 Implementation phase of product innovations

Reimbursement methods – which can range from various types of insurance coverage to out-of-pocket consumer payments and capital investment by healthcare providers – play a major role in financing the implementation phase of innovative products. We will first discuss the role of the reimbursement methods used by payers and the role of evidence in reimbursement decisions. Then, we will move on to the role of capital investment and out of pocket payments, and we will conclude this section by discussing two important financial issues during the implementation phase.

Reimbursement methods

A large number of studies (27 out of 78) focus on the influence of insurance mechanisms on innovation. Many of those studies examined the role of payment for a care bundle around a diagnosis, such as a Diagnosis-Related Group (DRG), which is the dominant reimbursement method for hospital care in most OECD countries. These studies found that this method facilitated innovation more effectively than 'fixed' reimbursement methods (such as global budgets or salary payments), which do not link reimbursement to the volume or type of care provided (95–100). Cappellaro et al. (101), for example, found significantly higher implementation rates for innovative stents in Italian hospitals under DRG-reimbursement than in hospitals receiving global budgets. Castro et al. (102) found that DRG payments involve fewer incentives for innovation than fee-for-service payments (FFS; reimbursing providers for each individual activity rather than per bundle) thus supporting the notion that the more variable a reimbursement method is, the more rapidly innovations are implemented. However, Bodenheimer (103) found that while innovations might be implemented more rapidly under FFS, implementation levels in countries with more fixed reimbursement do tend to catch up eventually. Meanwhile, four studies showed that the implementation of innovative products in US hospitals was slowed down significantly by prospective capitation, which held back the numbers of innovative products implemented even over the longer term (104–107).

Several authors highlighted factors that influence the relative impact of variable versus fixed reimbursement methods on the implementation of innovations. These included different

reimbursement methods being applied simultaneously (97,108), differences in levels of insurance coverage (109), different features of innovations which make them more or less vulnerable for financial incentives (107,110), and different characteristics of professionals and hospitals (111). Another factor is the variation in the design and application of insurance mechanisms. Eight studies found important differences in the design, modification and application of DRG systems in the US and Europe, such as with regard to the frequency of updating DRG-codes (84,112), the incorporation of incremental improvements in healthcare products (12), the consistency of reimbursement updates across innovations (113), and the willingness of payers to cover innovative products (114–116). According to a large-scale survey conducted by Sorenson et al. (83), such differences determine whether DRG systems promote or hinder the uptake of innovations.

Evidence on costs and benefits

Ideally, decisions regarding the reimbursement of innovations are based on evidence about benefits and costs. However, eleven out of twelve studies on decision-making processes concluded that in practice such evidence is often unavailable or not taken into consideration. For example, in their survey covering fourteen countries Sorenson et al. (83) found that evidence on costs and/or effects was considered in two-thirds of decisions on innovation payments and in only one-third of decisions on DRG reimbursement. In another study, Gold et al. (117) reviewed the implementation processes for five innovative imaging devices in the US and found that although reimbursement coverage was essential to implementation, a positive decision on coverage was made years before evidence of any beneficial effect was published for several of the devices. In yet another study, Stafinski et al. (85) found that out of 31 national, provincial and institutional reimbursement processes studied, only two took account of social value. In cases where reimbursement processes do include criteria on cost-effectiveness, this evidence is difficult to establish for medical devices, especially when effects cannot be measured adequately prior to the launch of the product (13,118). What is more, due to relatively lenient market access requirements for many medical device innovations, the necessary data on effectiveness are frequently not yet collected when reimbursement decisions are being made, leading to significant delays in implementation (12,13,69,82,119).

The requirement for evidence in the implementation phase could come to play a greater role as alternative payment models, such as pay-for-performance and reference pricing, become more common. After conducting interviews with nine leading private insurers in the US, Long et al. (120) reported that all but one of the respondents observed that the use of outcome measures in reimbursement (i.e., pay-for-performance) increased provider sensitivity to the costs and benefits of innovative technologies. In addition, reference pricing (i.e., maximum reimbursement levels based on similar products with comparable effectiveness), even though it is still relatively uncommon, has been shown to contain costs while facilitating quality-enhancing innovations in five European countries (38,121).

Capital investment

Another issue identified in the literature is the upfront capital investment that hospitals are often required to make for new equipment. These costs are typically not included in reimbursement, and hospitals face significant pressure to balance their budget as well as demands from professionals or patients to implement a particular new technology (122,123). In order to strengthen the financial incentives to implement such capital-intensive innovations, Levaggi et al. (124) recommended a lump-sum payment to hospitals irrespective of the number of patients treated. However, this is rarely applied in practice, according to the authors. Another approach is the sharing of financial risk between the hospital and the technology supplier. The strategy of value-based procurement has been gaining attention as a promising approach to foster innovation. Value-based procurement entails establishing a long-term partnership between healthcare providers and technology suppliers which focuses on better outcomes for patients, hospitals and society; technology development; risk sharing; and cost reduction (125). This approach has been successful in facilitating the implementation of some innovations (126,127).

Out-of-pocket payments

Financial barriers increase when innovative products are not covered by insurance, meaning that consumers have to cover costs out of their own pockets. A prime example is assistive technology, a field of innovation in which insurance coverage is not always provided: people purchasing devices such as wheelchairs, hearing aids or insulin pumps routinely consider the costs as the main barrier to adoption (128–133). Nevertheless, the studies indicated that those who were least able to pay for assistive technologies were the most likely to receive support through public insurance or community loan programs. It seems, therefore, that financial barriers may be less of an issue for those patients who can least afford it. But this is not always the case: Calcoen et al. (134) found that in Belgium, where OOP payments are accepted for any innovative healthcare product, innovation tends to benefit patients who can afford to pay for it rather than the patients who need it most.

Disruptive innovations

An additional important financial barrier for healthcare innovations identified in the literature is the lack of compatibility with existing practices and reimbursement methods. Twenty-seven studies indicated that the influence of reimbursement on specific innovations differs according to the degree of 'disruptiveness' of innovations – defined as the extent to which innovations imply a deviation from existing healthcare practices and reimbursement codes. In short, the financial barriers are higher in the case of more disruptive innovations.

Most innovative products do not disrupt existing practices significantly. As Raab et al. (115) observed: "the overwhelming majority of new medical devices that come to market each year [...] fit within existing coding and payment categories or are similar to existing items for which coverage

determinations have already been made" (p.697). For example, nine studies found that drug-eluting stents (DES), which are an incremental innovation that improve on the bare-metal stents used previously (135), were implemented rapidly after being made available on the market, even though the exact rate differed between countries and even between patients within a single hospital, depending on the type and generosity of insurance coverage (96,101,109–111,136–139).

By contrast, sixteen studies examining various disruptive innovations in the fields of eHealth, prevention and personalized medicine showed that adequate reimbursement for these innovations is an issue under the dominant payment mechanisms (137–141). For example, Oderanti and Li (142) examined the implementation of eHealth in the UK and found that not a single eHealth application had achieved large-scale adoption or sustainable reimbursement. Existing eHealth initiatives are run by local champions and supported by state or institutional funding, due to a lack of a sustainable business case. Next to the small market sizes (142) and the high cost (143), it is the difference between "who pays" and "who benefits" that constitutes a barrier to reimbursement of eHealth innovations (144).

Several studies discussed the emergence of a new generation of diagnostic innovations known as personalized medicine. These innovations are particularly disruptive in terms of individualization of care, being incompatible with reimbursement systems based on standardized diagnosis and treatment (i.e., DRGs) (145–147).

Another feature of disruptiveness is a large time gap between the necessary investments and the benefits of innovations. Rao and Pietzsch (148) highlighted this issue with respect to monitoring devices in the US, which are characterized by delayed return-on-investment. Given that reimbursement methods are predominantly transaction-based, this poses a problem in practice. The authors showed that innovative monitoring devices were only eligible for reimbursement if they were paired with a care procedure that is already reimbursable or by finding a way to demonstrate direct cost-savings. Adding to the problem of delayed benefits is the 'long-run, short-run' efficiency paradox in healthcare resources (149). Even if innovations result in long-run cost savings or health benefits, inflexible labor and infrastructure often result in short-term losses following their implementation, forcing decision-makers to obstruct innovations that have the potential to lead to significant savings or benefits over the longer run.

Another example of innovations with delayed future benefits are prevention initiatives: "In a marketplace historically driven by a focus on acute care rather than prevention, identifying a payer or buyer for prevention services can be challenging" (150). Two US studies found that even if insurers can be persuaded to cover a contraceptive implant, the process of establishing new DRG-codes is so complex that these implants cannot be reimbursed, forming a barrier to implementation (151,152). Uncertainty seems to be the key word with respect to these types of innovation; care

providers, payers, and regulators have insufficient experience with such disruptive approaches to healthcare to embed these innovations properly.

Local versus national reimbursement

Another related problem identified in the literature is that many innovations are forced to rely on local reimbursement and implementation. Although some studies highlighted the importance of national reimbursement systems for product innovation, significant shortcomings were identified in the decision-making process for all the countries studied. Specifically, national reimbursement systems for innovation were found to be opaque, slow, inflexible, and arbitrary (11,38,96,106,153). As a result, innovators often try to obtain reimbursement at the local level. Concerns have been raised that local implementation may result in fragmentation. Even though the local reimbursement decision process is faster and has higher rates of coverage success, the result is that innovations are not implemented on a large scale (106,154). This could, in turn, lead to (increases in) disparities in access to the best quality healthcare (38,81,96,153,155,156).

The reliance on local reimbursement was also found to reduce attention for evidence of cost-effectiveness in reimbursement decisions (95,154,156). While decisions at the national level are more frequently based on this type of evidence, it tends to play a lesser role in local decisions. This raises the question of what these local decisions are based on instead; in this respect, respondents in multiple studies mentioned the receptiveness of local care providers, managers or budget holders to innovation and the support of key opinion leaders, in addition to innovators being able to convince these stakeholders (95,96,155,156).

Conclusion on implementation of product innovations

A general conclusion from the literature is that the more fixed a reimbursement method is, the more financial barriers there will be to the implementation of product innovations. These barriers are also larger for more disruptive innovations. Other major financial barriers are encountered by innovations that require high capital investment and innovations that are not covered by insurance. Finally, shortcomings in national reimbursement schemes often result in innovations being implemented locally on the basis of limited evidence around benefits and costs. This, in turn, reduces the chances of scaling up to the national level and can introduce or exacerbate disparities in access and quality within national healthcare systems.

2.4.2 Process innovations

Less research has been done into payment mechanisms and financial incentives for process innovations than for product innovations. Nevertheless, several interesting patterns can be identified. The share of research across the three process phases is similar to that of product innovations, with most articles focusing on the implementation phase (n=46), followed by the

translation (n=9) and development (n=5) phases. The payment mechanisms identified are included in the Financial Fugle Model for process innovation as shown in Figure 2.4.

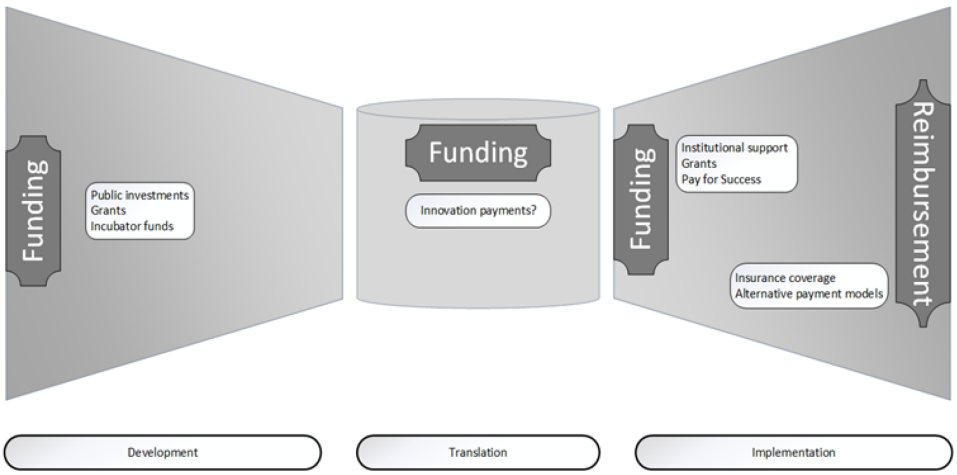

Figure 2.4. Financial Fugle Model for process innovation based on the process model of Du Preez and Louw

2.4.2.1 Development phase of process innovations

Scientific evidence on financial incentives for the development of process innovations is scarce. Only five articles discussing potential funding mechanisms were identified in this category. Examples of these mechanisms include local grants from medical institutions, governmental subsidies, and incubator funds. The only clear finding is that local grants seem to effectively facilitate the development of innovative processes, such as population health initiatives, prevention interventions, innovative treatments or integration of telemedicine in care delivery. Specific success factors reported are the availability of a large number of small grants (157), continuity of funding, the prioritization of research infrastructure rather than funds tied to a discrete project (158), and impact metrics based on care practice rather than profit or commercialization requirements (64). However, most development investments are linked to a for-profit business model (159), which makes it difficult for innovative processes without direct monetary revenues, such as integrated care and prevention, to attract funding.

As with product innovations, funding for the development of process innovations is determined by expectations about reimbursement in later phases. For instance, reference pricing may act as a financial facilitator for the development of innovative cost-reducing processes (160).

2.4.2.2 Translation phase of process innovations

No specific studies were identified on payment mechanisms specifically for process innovations in the translation phase. Nevertheless, eight articles on both product and process innovations provide two insights about the incentives during the translation phase of processes. First, two studies in fourteen different countries in Europe, North America, and Australia found that innovation payments are rarely obtained for process innovations (80,81). Second, five articles highlighted the lengthy process of translation, the lack of resources within hospitals, and the inability of academic developers to translate their research, which results in an important role for support structures specialized in commercialization of innovation (88,91–94). Moreover, as with product innovations, non-financial factors seem important in this phase. In particular, the motivation of medical professionals and the trust and collaboration between different parties in the project team is found to be essential to the success of innovative processes (66,88,92). As mentioned by Day-Duro et al. (88): *"Developing a culture of respect, valuing each individual and investing in people within each organisation were widely reported as drivers of success"* (p.478).

2.4.2.3 Implementation phase of process innovations

The 40 articles that discuss the implementation phase of process innovations show that implementation is financed by both funding and reimbursement mechanisms. In this section, we will first review the literature on reimbursement, and then discuss the studies on funding for innovative processes that do not succeed in acquiring structural reimbursement. Next, key findings from the literature on alternative payment models will be presented, and then financial incentives will be compared with non-financial factors.

Reimbursement methods

Twenty-four studies examined the influence of reimbursement methods on innovative services and treatments. A key finding is that higher coverage rates and lower patient copayments lead to more implementation of innovative treatments (161–163), although this relationship was not found in a study related to IVF treatments in Australia (164). In addition, systems with a purchaser-provider split appear to facilitate innovative services more than publicly integrated systems; this effect is larger in the case of a competition-based system (165).

Regarding innovative treatments in hospital care, specifically, the majority of studies focused on incentives in three dominant reimbursement methods. Each reimbursement method contains incentives to facilitate innovative treatments, yet they all come with critical disadvantages. First, FFS reimbursement is considered the most variable and facilitating method but also the cause of higher prices and the excessive implementation of new procedures in the US (103). Another US study found that FFS only facilitates complementary treatments, and not the substitution of existing care

with more efficient treatments (42). Innovations that replace less effective care processes are therefore unlikely to be implemented.

Second, DRG reimbursement could facilitate the implementation of innovative treatments in theory, but in practice it is associated with many barriers to innovation. Five studies concluded that it could take more than four years between market access approval and DRG reimbursement decisions, resulting in delayed payment and a financial void (83,84,86,166,167). Furthermore, in a study of ultrasound elastography in the US, Moreno et al. (168) found that DRG reimbursement codes are not automatically covered by insurers. This finding is confirmed by Dranove et al. (86) who also found that the adoption of innovative treatments increases ninefold if the code is promoted from provisional to permanent. Finally, Greenberg et al. (169) showed that after coverage of surgical laparoscopy was eventually provided by insurers in Israel, the additional equipment and/or human resources required to perform new procedures were not covered by higher DRG fees. Nevertheless, three studies found that innovative treatments were still implemented due to pressure from providers and patients, despite the insufficient DRG fees (166,168,169).

Lastly, several authors proposed a managed care approach with prospective capitation as the solution for balancing costs and quality in healthcare provision. According to the theory, managed care should be negatively associated with the implementation of expensive innovative processes (97,105,170,171). However, even cost-saving innovations have not always found their way into managed care hospitals (172). The budget pressures from prospective payments are presumed to be so strong that the initial investment required to change processes are too much of a risk for hospitals, highlighting the 'short-term, long-term' paradox, whereby long-term cost-savings are foregone due to the significant initial investment that is required (149). In one study on the implementation of MRI procedures in the US during the 1990s, the innovations that were impeded seemed to be less beneficial procedures, while the most advanced innovative procedures were adopted equally in managed care hospitals (170). A final finding is that prospective payment models may lose their inhibiting influence on the implementation of innovations over time (173), when FFS and DRG reimbursement methods are also present in the system (97), or when the number of hospitals tied to a managed care organization increases. The latter is because the enrollees in these managed care organizations are spread out between many hospitals, reducing their bargaining power to prevent the introduction of surplus innovation (171).

Funding for innovation processes without adequate reimbursement

In contrast to innovative treatments in hospital care, innovative processes in care delivery (e.g. integrated care) and public health (e.g. prevention initiatives) are found not to be facilitated by the existing reimbursement methods at all, which means they have to rely on other payment sources such as grant funding (150,174–179). As Thoumi et al. (180) stated, based on their literature review on the reform of diabetes care processes: *"There was a poor fit between the new models of care and*

many existing payment policies" (p.1494). However, grant funding is not a sustainable payment mechanism for such initiatives and appears to come with additional problems. One of these is the inability of funds to cover all costs associated with process changes. In their study on the widespread implementation of palliative care programs in the US, Kinderman et al. (181) found that 83 percent of locations experienced a budget shortfall, for example, and were compelled to attract additional funding, as well as continuing to rely on healthcare providers for in-kind support in terms of staffing.

Another consequence of reliance on grant funding in this phase is that promising process innovations tend to be locally financed, with scaling up being very difficult (153,166,179,180). Meit et al. (178) studied public health and prevention initiatives in the US and presented findings on the uneven distribution of funds across states. The reliance on grant funding not only prevents innovative processes from reaching certain regions, but also means that there is no clear pathway to sustainability for innovative public health and prevention interventions (180).

Alternative payment models

As a potential solution to the lack of adequate reimbursement methods for process innovations, seven studies examined alternative payment models (APMs) such as bundled or global capitation payments with risk-sharing, pay-for-performance and the Pay for Success initiative (182). Saulsberry and Peek (183) showed the potential of global capitation with shared savings for interventions focusing on the integration of social determinants in care delivery and Vaughn et al. (184) showed the positive effect of pay-for-performance incentives on the implementation of an initiative improving antibiotic use. In addition, Lluch (185) predicted that the introduction of bundled payments in several European countries will facilitate the implementation of tele-healthcare initiatives, while Christensen and Remler (186) argued for global capitation payments to facilitate IT-based forms of care provision. Contrarily, Gunter et al. (187) showed that implementing integrated diabetes care with interventions on social determinants in several US communities remained problematic under APMs, as organizations experienced difficulty accessing upfront payment to fund the initiative. Each community relied on additional funding for covering initial investments until shared savings were realized or performance metrics were reached and the reimbursement was provided. Finally, Iovan et al. (188) claimed that the Pay for Success programs launched in twenty different countries have led to the successful implementation of public health initiatives. Pay for Success programs facilitate social impact investing, enabling private investors to provide the capital required to implement public health interventions which the government will repay them for with interest if the interventions meet predefined health outcomes. Although these APMs seem promising for successfully implementing process innovations, the expected results have yet to be realized.

Non-financial factors

Financial incentives clearly have a significant impact on the implementation of process innovations. However, the results of six studies suggested that institutional and professional barriers, in addition to the essential role of finance, have a strong influence as well (166,175,176,181,189). Walston et al. (172) managed to quantitatively distinguish between the impact of financial factors and institutional factors on the implementation of medical process reengineering in over 2,300 hospitals in the US. They concluded that institutional pressures exert most influence on process innovations: *"A stable environment has been postulated to be a requirement for organizational experimentation, while uncertainty may impede innovation"* (p.213). Despite the consistent findings of these studies regarding financial and non-financial factors, Fleuren et al. (30) showed that all 57 studies included in their literature review on the determinants of implementation suffer from methodological flaws. Thus, according to these authors, all findings should be interpreted with caution. Nonetheless, it remains important to bear non-financial factors in mind when discussing solutions to financial barriers.

Conclusion on implementation of process innovations

In summary, the literature identifies many financial barriers during the implementation phase of process innovations, including the fact that existing reimbursement methods do not facilitate innovative treatments adequately, and public health and care delivery reforms are forced to rely on localized funding. Alternative payment models could help to stimulate the implementation of innovative processes, but they have yet to prove their potential. Despite the significant influence of financial incentives, ensuring successful implementation ultimately comes down to the individuals involved in a project and the institutional environment it is to be implemented in.

2.5 Discussion

2.5.1 Summary of main findings

By undertaking this review, we have aimed to provide an overview of the role of payment mechanisms in the healthcare innovation process. We analyzed 157 articles containing a wealth of information on this subject and synthesized this heterogeneous evidence using the narrative synthesis method. Four key findings stand out.

First, despite differences between countries in the design and availability of payment mechanisms, a discouraging pattern can be observed across all countries. Whether it is the highly privatized market of the US, the decentralized system of Italy, the managed competition system of the Netherlands, or the publicly integrated NHS of the UK, all countries struggle to provide a transparent, consistent, and efficient national system of reimbursement to support healthcare innovations move from

promising idea to value-enhancing reality. Innovation is often forced to take the path of locally or regionally fragmented implementation, rarely resulting in national scale-up. As a consequence, many people are deprived of the benefits of potentially value-enhancing innovations.

Second, another concerning finding is that the evidence requirements for funding and reimbursement are often ambiguous. Many innovations seem to be implemented without evidence on effects and costs being taken into account (190). Several studies suggest that this may be explained by a lack of harmonization between the results of health technology assessments (HTA) and reimbursement processes (191–194). Even if harmonization does take place, this often only applies to national reimbursement pathways (195), which tend not to be accessible to innovators. This is exacerbated by methodological issues around health technology assessments for medical devices and process innovations (196–199). All in all, our results suggest that existing payment mechanisms may not reward evidence-based innovations that appear to offer better quality at lower costs.

Third, all the financial barriers identified in this review are larger for more disruptive innovations. Such innovations are typically too innovative to fit in existing payment mechanisms, forcing innovations to rely on temporary funding rather than structural reimbursement. As pointed out, several types of innovation can be characterized as 'disruptive', including innovations in public health and prevention, integrated care, and personalized medicine.

Fourth, and finally, the literature also shows that overcoming financial barriers and successfully implementing product and process innovations in healthcare strongly depends on non-financial factors such as the social skills and network of the innovators and the presence of institutional support.

All in all, our findings suggest that current payment mechanisms typically do not incentivize innovations with potentially high societal value. From a societal point of view, the goal of payment mechanisms throughout the innovation pathway should be to stimulate healthcare innovations that add value. However, determining the value of an innovative product or process for society remains a complicated issue. For instance, more variable payment methods (e.g., fee-for-service) allow for innovations to be implemented more rapidly, but may also result in the adoption of costly innovations that have only marginal health benefits. By contrast, fixed reimbursement methods (e.g., global budgets) providers to focus primarily on cost-saving innovations, potentially disincentivizing the implementation of innovations with significant health benefits.

2.5.2 Research agenda

Based on our findings we provide seven recommendations for future research. To start, we identified that the literature on product innovations is much more extensive than the literature on process innovations and, regardless of the type of innovation, most papers focus on the implementation

phase. It is therefore not surprising that most financial issues were identified for product innovations in the implementation phase. However, this does not necessarily mean that the product innovators experience most financial problems and that these problems are concentrated around implementation. It could mean, for example, that the failure of product innovations that have struggled through the development and translation phases is simply more noticeable than all the potentially innovative ideas that fail to obtain seed funding or translational payments. Therefore, we firstly recommend researchers shift their focus to payment mechanisms in the earlier phases of innovation, especially the translation phase, because potential issues in these phases remain undiscovered. Secondly, the scarcity of literature suggests a large knowledge gap regarding the influence of payment mechanisms on healthcare process innovations.

Thirdly, additional research on the disconnect between the design of national reimbursement systems and the characteristics of product and process healthcare innovation is needed. Currently, most research on national decision-making focuses on pharmaceutical innovations, for which countries often already have consistent and transparent systems in place (86,200). Therefore, we recommend researchers to shift their focus to decision-making about national reimbursement of innovative devices and innovations in healthcare delivery processes to identify opportunities for improving chances of national implementation.

Fourthly, to strengthen evidence-based decision making for the reimbursement of product and process innovations we need to evaluate how appropriate evidence can be developed and used. Specifically, we need more knowledge about potential harmonization initiatives of HTA evidence and decision-making, and knowledge about novel methods for estimating appropriate cost-benefit ratios of innovative products and processes.

Fifthly, the for-profit business model of private payers in healthcare innovation emphasizes the need for alternative (payment) mechanisms to incentivize innovations specifically with a high potential for adding societal value. In our review we identified several initiatives combining the resourcefulness of private parties with the societal value aim of public parties, such as pay-for-performance and public-private partnerships. Initial findings regarding these initiatives are positive, but overall the evidence is still limited. Consequently, more research on mechanisms that try to combine the strengths of private and public parties could clarify their role and contribute to more value-enhancing innovation in healthcare.

Sixthly, while we established that both financial and non-financial factors play an important role in the healthcare innovation process, we cannot draw conclusions about their relative importance or the level of interaction between them. Although several studies in our review have attempted to assess the influence of both types of factors in parallel, only Walston et al. (172) established a dominant influence of non-financial factors whereas Fleuren et al. (30) and other authors were not

able to quantify the relative influence nor the interaction effects. More research is needed in order to prioritize on what factors initiatives aiming to incentivize value-enhancing innovations should focus.

Finally, perhaps most importantly, in order to be able to optimize payment mechanisms and incentives, it is essential to improve our ability to distinguish between innovations in terms of the value they are likely to bring to society. We recommend researchers to improve existing methods or develop new ones to assess the potential value of innovations for healthcare and society.

2.5.3 Strengths and limitations

The combination of a systematic search strategy and a narrative analysis of the literature has enabled us to conduct a literature review that is both comprehensive in terms of data collection and in-depth in terms of synthesis. By working with information specialists and designing our systematic search according to their guidelines, we have maximized both the sensitivity and specificity of our search. Additionally, the inclusiveness of our research question and the number of articles identified have resulted in a comprehensive overview of the role of payment mechanisms and incentives in this field.

Nevertheless, it is inherently difficult to compare and synthesize the literature without acknowledging all the relevant contextual factors. Although many studies seek to isolate the impact of financial incentives from other factors, the effect of exogenous factors can never be completely ruled out. For example, the specific design and context of similar payment mechanisms differs considerably between countries, which limits the possibility to derive generalizable conclusions about their role in innovation processes in different countries.

Moreover, for the purpose of this review, we have introduced and used our own definitions of key concepts based on desk research and by combining existing definitions. Although we believe these definitions to be distinctive and a recognizable representation of reality (and therefore useful for analysis and synthesis purposes), in practice they overlap. For example, product and process innovations often appear in parallel, and innovation processes are often characterized by iterative cycles in which different phases can apply simultaneously. In other words: our categorization in six groups according to innovation type and phase is a simplification of a more complex reality.

2.6 Conclusion

Innovation in healthcare, both in terms of innovative products as well as innovative processes, is considered key to the future of sustainable healthcare systems, but adequate financing to bring such innovations to healthcare practice is often a big challenge. This review has revealed many different funding and reimbursement mechanisms throughout the healthcare innovation process. In

reviewing these mechanisms in theory and in practice, three key issues are likely to obstruct the development and implementation of value-enhancing innovation in healthcare: flaws in national reimbursement systems hamper the implementation of innovations beyond the local level; insufficient use of evidence on benefits and costs complicates financial decision-making based on value; and the magnitude of the financial barriers experienced by innovators is directly linked to the disruptive nature of the innovation. Non-financial factors, including innovator characteristics and institutional support, are found to be essential in overcoming financial barriers. Based on our findings, we provide several suggestions for future research on payment mechanisms in healthcare innovation processes that could contribute to the sustainability of healthcare systems.

Appendix 2.a. Search strings per database

Embase

('funding'/mj/de OR 'investment'/mj/de OR 'purchasing'/mj/exp OR 'health insurance'/mj/exp OR 'hospital cost'/mj/exp OR 'health economics'/mj/exp OR 'economics'/mj/de OR 'cost'/mj/de OR 'financial management'/mj/de OR (fund* OR invest OR investment* OR investing* OR invested* OR purchas* OR commerciali* OR insuranc* OR incentiv* OR disincentiv* OR medicare* OR medicaid* OR reimburs* OR economic* OR financ* OR pay* OR cost*):ti,kw) AND ('invention'/mj/de OR 'technology'/mj/de OR 'biomedical technology assessment'/mj/de OR (invention* OR innovation* OR initiative* OR technology OR technologies OR technologics OR medtech* OR HTA):ti,kw) AND [English]/lim NOT ([Conference Abstract]/lim)

Medline

(*Capital Financing/ OR *Investments/ OR exp *Purchasing, Hospital/ OR exp *Insurance, Health/ OR exp *Costs and Cost Analysis/ OR exp *Economics, Medical/ OR *Economics/ OR *Financial Management/ OR (fund* OR invest OR investment* OR investing* OR invested* OR purchas* OR commerciali* OR insuranc* OR incentiv* OR disincentiv* OR medicare* OR medicaid* OR reimburs* OR economic* OR financ* OR pay* OR cost*).ti,kf) AND (*Inventions/ OR *Technology/ OR *Technology Assessment, Biomedical/ OR (invention* OR innovation* OR initiative* OR technology OR technologies OR technologics OR medtech* OR HTA).ti,kf) AND english.la. NOT (news OR congres* OR abstract* OR book* OR chapter* OR dissertation abstract*).pt.

Cochrane

((fund* OR invest OR investment* OR investing* OR invested* OR purchas* OR commerciali* OR insuranc* OR incentiv* OR disincentiv* OR medicare* OR medicaid* OR reimburs* OR economic* OR financ* OR pay* OR cost*):ti) AND ((invention* OR innovation* OR initiative* OR technology OR technologies OR technologics OR medtech* OR HTA):ti)

Web of Science (includes 3rd search element to focus on health and medical field)

TI=((fund* OR invest OR investment* OR investing* OR invested* OR purchas* OR commerciali* OR insuranc* OR incentiv* OR disincentiv* OR medicare* OR medicaid* OR reimburs* OR economic* OR financ* OR pay* OR cost*) AND (invention* OR innovation* OR initiative* OR technology OR technologies OR technologics OR medtech* OR HTA)) AND ALL=(health* OR medical OR hospital* OR clinic* OR nursing* OR diseas*) AND DT=(Article OR Review) AND LA=(English)

EconLit (only scholarly journals) (includes 3rd search element to focus on health and medical field)

TI((fund* OR invest OR investment* OR investing* OR invested* OR purchas* OR commerciali* OR insuranc* OR incentiv* OR disincentiv* OR medicare* OR medicaid* OR reimburs* OR economic* OR financ* OR pay* OR cost*) AND (invention* OR innovation* OR initiative* OR technology OR technologies OR technologics OR medtech* OR HTA)) AND AB,TI(health* OR medical OR hospital* OR clinic* OR nursing* OR diseas*) NOT PT (news OR comment* OR editorial* OR congres* OR abstract* OR book* OR chapter* OR dissertation abstract*) AND LA(english)

Abi/Inform (only scholarly journals) *(includes 3rd search* element to focus on health and medical field)

TI((fund* OR invest OR investment* OR investing* OR invested* OR purchas* OR commerciali* OR insuranc* OR incentiv* OR disincentiv* OR medicare* OR medicaid* OR reimburs* OR economic* OR financ* OR pay* OR cost*) AND (invention* OR innovation* OR initiative* OR technology OR technologies OR technologics OR medtech* OR HTA)) AND AB,TI(health* OR medical OR hospital* OR clinic* OR nursing* OR diseas*) NOT PT (news OR comment* OR editorial* OR congres* OR abstract* OR book* OR chapter* OR dissertation abstract*) AND LA(english)

Google Scholar

fund|funds|funding|investment|investments|investing|incentivize|incentivizing|disincentivize|disincentivizing|reimbursement|pay|cost|invention|inventions|innovation|HTA|health|healthcare|medical|hospital|clinic|clinical|nursing|disease|diseases

Appendix 2.b. Data extraction form

ID number	Author	Year	Journal	Title	Knowledge type	Methodology	*Methodology detailed (where possible verbatim)*	Country	Data sample	*Aims (where possible verbatim)*	Key finding(s)
1					*Theoretical* *Empirical* *Mixed*	*Qualitative* *Quantitative* *Mixed*					
…											
156											

Innovation category	*Innovation verbatim*	Process phase	*Process phase verbatim*	Payment category	*Payment verbatim*	Financial facilitators	Financial barriers	Other facilitators	Other barriers	*Key quotes*	My notes
Product *Process* *Other*		*Development* *Translation* *Implementation* *Other*		*Funding* *Reimbursement* *Other*							

Appendix 2.c. List of included articles, by innovation type and process phase

Product innovation, development phase

Anderson, B. J., Leonchuk, O., O'connor, A. C., Shaw, B. K., & Walsh, A. C. (2021). Insights from the evaluations of the NIH Centers for Accelerated Innovation and Research Evaluation and Commercialization Hubs programs. *Journal of Clinical and Translational Science*, *6*(1), 1–9. https://doi.org/10.1017/CTS.2021.878

Bertram, T. A., Tentoff, E., Johnson, P. C., Tawil, B., van Dyke, M., & Hellman, K. B. (2012). Hurdles in tissue engineering/regenerative medicine product commercialization: a pilot survey of governmental funding agencies and the financial industry. *Tissue Engineering. Part A*, *18*(21–22), 2187–2194. https://doi.org/10.1089/TEN.TEA.2012.0186

Halminen, O., Tenhunen, H., Heliste, A., & Seppala, T. (2019). Factors Affecting Venture Funding of Healthcare AI Companies. *Studies in Health Technology and Informatics, 262*, 268–271. https://doi.org/10.3233/SHTI190070

Lehoux, P., Miller, F. A., & Daudelin, G. (2016). How does venture capital operate in medical innovation? *BMJ Innovations*, *2*(3), 111–117. https://doi.org/10.1136/BMJINNOV-2015-000079

Lehoux, P., Miller, F. A., Daudelin, G., & Denis, J.-L. (2017). Providing Value to New Health Technology: The Early Contribution of Entrepreneurs, Investors, and Regulatory Agencies. *Int J Health Policy Manag, 6*(9), 509–518. https://doi.org/10.15171/ijhpm.2017.11

Lettl, C., Hienerth, C., & Gemuenden, H. G. (2008). Exploring how lead users develop radical Innovation: Opportunity recognition and exploitation in the field of medical equipment technology. *IEEE Transactions on Engineering Management*, *55*(2), 219–233. https://doi.org/10.1109/TEM.2008.919717

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Shau, D., Traub, B., Kadakia, R., Labib, S., & Bariteau, J. (2017). Health Policy: Ethics, Regulatory, and Financial Aspects of Innovation in Orthopedics: Introducing New Orthopedic Technology in the Current Health Care Environment. *Techniques in Orthopaedics, 32*(3), 167–172. https://doi.org/10.1097/BTO.0000000000000235

Product innovation, translation phase

Ackerly, D. C., Valverde, A. M., Diener, L. W., Dossary, K. L., & Schulman, K. A. (2008). Fueling Innovation in Medical Devices (and Beyond): Venture Capital in Health Care. *Health Affairs*, *28*(1), w68-75. https://doi.org/10.1377/HLTHAFF.28.1.W68

Beaulieu, M., & Lehoux, P. (2018). The emergence of health technology organizations among institutional healthcare and economic actors. *International Entrepreneurship and Management Journal, 15*(4), 1115–1151. https://doi.org/10.1007/S11365-018-0551-2

Clyde, A. T., Bockstedt, L., Farkas, J. A., & Jackson, C. (2008). Experience with medicare's new technology add-on payment program. *Health Affairs*, *27*(6), 1632–1641. https://doi.org/10.1377/hlthaff.27.6.1632

Ex, P., & Henschke, C. (2019). Changing payment instruments and the utilisation of new medical technologies. *European Journal of Health Economics*, *20*(7), 1029–1039. https://doi.org/10.1007/s10198-019-01056-z

Ex, P., Vogt, V., Busse, R., & Henschke, C. (2020). The reimbursement of new medical technologies in German inpatient care: What factors explain which hospitals receive innovation payments? *Health Economics, Policy and Law*, *15*(3), 355–369. https://doi.org/10.1017/S1744133110001024

Federici, C., Reckers-Droog, V., Ciani, O., Dams, F., Grigore, B., Kaló, Z., Kovács, S., Shatrov, K., Brouwer, W., & Drummond, M. (2021). Coverage with evidence development schemes for medical devices in Europe: characteristics and challenges. *European Journal of Health Economics*, *22*(8), 1253–1273. https://doi.org/10.1007/S10198-021-01334-9/TABLES/5

Isasi, R., Rahimzadeh, V., & Charlebois, K. (2016). Uncertainty and innovation: Understanding the role of cell-based manufacturing facilities in shaping regulatory and commercialization environments. *Applied & Translational Genomics*, *11*, 27–39. https://doi.org/10.1016/J.ATG.2016.11.001

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Keppler, S. B., Olaru, M., & Marin, G. (2015). Fostering Entrepreneurial Investment Decision in Medical Technology Ventures in a Changing Business Environment. *The AMFITEATRU ECONOMIC Journal*, *17*(38), 390–390.

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Lehoux, P., Miller, F. A., Daudelin, G., & Urbach, D. R. (2016). How venture capitalists decide which new medical technologies come to exist. *Science and Public Policy, 43*(3), 375–385. https://doi.org/10.1093/scipol/scv051

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Thompson, L.-J., Gilding, M., Spurling, T. H., Simpson, G., & Elsum, I. R. (2014). The paradox of public science and global business: CSIRO, commercialisation and the national system of innovation in Australia. *Innovation Organization & Management*, *13*(3), 327–340. https://doi.org/10.5172/IMPP.2011.13.3.327

Product innovation, translation & implementation phase

Henschke, C., Bäumler, M., Gaskins, M., & Busse, R. (2010). Coronary stents and the uptake of new medical devices in the German system of inpatient reimbursement. *Journal of Interventional Cardiology*, *23*(6), 546–553. https://doi.org/10.1111/J.1540-8183.2010.00592.X

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Hernandez, J., Machacz, S. F., & Robinson, J. C. (2015). US hospital payment adjustments for innovative technology lag behind those in Germany, France, and Japan. *Health Affairs*, *34*(2), 261–270. https://doi.org/10.1377/hlthaff.2014.1017

Martelli, N., & van den Brink, H. (2014). Special funding schemes for innovative medical devices in French hospitals: the pros and cons of two different approaches. *Health Policy (Amsterdam, Netherlands)*, *117*(1), 1–5. https://doi.org/10.1016/ J.HEALTHPOL.2014.04.007

Martelli, N., van den Brink, H., & Borget, I. (2016). New French Coverage with Evidence Development for Innovative Medical Devices: Improvements and Unresolved Issues. *Value in Health : The Journal of the International Society for Pharmacoeconomics and Outcomes Research*, *19*(1), 17–19. https://doi.org/10.1016/ J.JVAL.2015.10.006

Sebastianski, M., Juzwishin, D., Wolfaardt, U., Faulkner, G., Osiowy, K., Fenwick, P., & Ruptash, T. (2015). Innovation and commercialization in public health care systems: a review of challenges and opportunities in Canada. *Innovation and Entrepreneurship in Health*, *2*, 69–80. https://doi.org/10.2147/IEH.S60790

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Chapter 3

The long and winding road towards payment for healthcare innovation with high societal value but limited commercial value: A comparative case study of devices and health information technologies

Technology in Society, 2023; 75: 102405

Abstract

Innovation is widely recognized as an important means of tackling challenges that face healthcare systems. But innovation can only succeed in this role if financial conditions allow innovations with high societal value to be developed and implemented. This study is an in-depth examination of the role of payment mechanisms throughout the innovation process, from the perspective of innovators. We conducted a comparative case study of four innovation projects, two involving medical devices and two involving health information technologies, all of which originated from academic settings. Although financial factors were found to have impeded the progress of innovative products at every step in the innovation process, this effect appears to have been strongest during the implementation phase. The perceived commercial value of an innovative product was a key factor in obtaining sufficient payment. Innovative products with potentially significant societal value but limited commercial value are unlikely to become structurally embedded in practice, or to be scaled up beyond the local level. The study reveals four additional factors that affect progress through the healthcare innovation process: compatibility of the innovation with existing practice, and commitment, competences, and social capital of the innovator. We identify a number of lessons for policy and practice that we believe would increase the likelihood of innovations with potentially significant societal value to achieve widespread implementation. These lessons reflect three key issues identified in our research: i) shift the focus from commercial value towards societal value; ii) support dissemination of innovations beyond the local level; iii) help innovators to convey their valuable ideas.

3.1 Introduction

Healthcare innovation has a major impact on the quality, affordability and availability of care (7,9,201). For decades, policymakers and healthcare professionals have turned to innovative products – from robotic surgery tools to eHealth applications – to tackle the challenges faced by healthcare systems around the world. There are countless examples of innovations that support the work of healthcare providers, reduce the impact of disease on patients, and help put healthcare systems on a more sustainable footing.

However, innovation can only improve healthcare if the right conditions are in place to ensure that potentially valuable innovations end up being developed and implemented (159,202). Financial incentives in particular are known to play an important role in healthcare innovation processes. These incentives involve the influence that money has on behavior (e.g., the decision to take a novel idea and develop it into an innovative product), and they come about through the payment mechanisms that are used in healthcare systems. When it comes specifically to innovation, payment mechanisms can be subdivided into temporary funding and structural reimbursement schemes. Previous empirical work has shown that these payment mechanisms can have a significant influence on which innovations end up being developed (68) and implemented in practice (38,41,142,203).

The influence of payment mechanisms on innovation is of distinct concern in the context of healthcare (204). Given the large amounts of public resources distributed in healthcare systems to support innovation, the importance of adding societal value with positive impact for patients and society at large is particularly high (22–24). For this reason, payment mechanisms should be designed in such a way that they stimulate innovations with clear benefits for health and society, rather than providing monetary value (i.e., a high return on investment) for investors.

Despite the importance of innovation in healthcare, strikingly little research has acknowledged – let alone examined in detail – the complexities and contextual factors that are involved in payment mechanisms for innovations in healthcare. Based on a recent systematic review of the literature on the determinants of medical technology adoption, for example, Varabyova et al. (107) identify a lack of acknowledgement of the complexity of determinants. They emphasize that *"more detailed qualitative studies are needed to include the complexity of the surrounding settings into the analysis of determinants"* (p.240). Accordingly, Beaulieu and Lehoux qualitatively studied the process by which health technology innovators construct their firms to convince economic and health system actors of their idea, emphasizing the differentiation in health innovator's thinking and actions in response to (financial) pressures (205). Consequently, the authors recommend further research with regards to the actors who operate in the field between innovative industry and publicly funded healthcare systems. To better understand the influence of payment mechanisms on innovation in healthcare and the way in which the actors involved try to overcome the financial challenges that

they encounter in their efforts to provide value to health and society, a more detailed study of innovation processes is needed.

In addition to the knowledge gap outlined above, previous studies, including the systematic review by Varabyova et al. (107), appear to have neglected another aspect of healthcare innovation. The process of innovation commences long before an innovation is implemented in practice and starts with activities such as idea development and prototype testing. Since it is reasonable to assume that payment mechanisms must also be influential in these earlier stages, research that focuses on understanding the role of payment mechanisms should, ideally, consider their influence throughout the *entire* innovation process, including these earlier phases.

Based on a comparative case study of four innovation projects, this study is an in-depth examination of the role of payment mechanisms throughout the healthcare innovation process from the perspective of the innovator. Specifically, the objectives of this study are: i) to describe the innovation process around innovative healthcare products with high societal value but limited commercial value; ii) to identify how and to what extent innovators manage to secure funding and reimbursement for these innovations; and iii) to identify the perceived influence of payment mechanisms on the healthcare innovation process. Based on the results of this study, we will proceed to discuss the potential implications for policy and practice with respect to addressing financial challenges around healthcare product innovation.

3.2 Literature background

As mentioned, the importance of adding health and societal value through healthcare innovation is increasingly being acknowledged. Even though private investors and venture capitalists could play an important role in the early stages of innovation (206), once innovations become embedded in the practice of (largely) publicly financed healthcare systems, payment for the resulting healthcare products comes mainly from collective sources (207). This has spurred the recent scientific attention for *responsible innovation in health* (208), described as the responsibility innovation has for contributing to healthcare systems in terms of addressing collective needs and inequalities, responding to urgent health system challenges and making healthcare more sustainable (209). The literature on responsible innovation in health has focused mostly on different features that innovation should possess to qualify as being responsible (22), and on the role innovators and healthcare managers have in fostering such innovations (23). However, so far, research on responsible innovation has not been explicitly linked to insights from the field of payment mechanisms and incentives. Given the importance of healthcare innovation to bring value to society and the fact that payment mechanisms are known to influence behavior, we argue that payment mechanisms for healthcare innovation should primarily focus on the societal value of an innovation

rather than facilitating innovations with high commercial value only. This aim of innovation to provide societal value is even more imperative in the healthcare sector compared to more classical sectors of innovation (e.g., agriculture, automotive or telecommunication), where high commercial value can be accepted as sufficient grounds for payment because of the larger involvement of private money and the limited importance attached to solidarity.

To assess the extent to which payment mechanisms are successful in supporting healthcare innovations with high societal value, we study the innovation process from head to tail. In innovation research, innovation processes are commonly divided into separate phases. Many frameworks that focus on the entire innovation process present so-called stage-gate models, distinguishing successive phases (the stages) from initial idea to adoption in practice (27). Stage-gate models assume that in order to move from one phase to the next, barriers (such as payment hurdles) must be overcome (the gates). We discern three phases: development (including activities such as identifying opportunities and creating a prototype); translation (including activities to prepare the prototype for market launch); and implementation (including activities for commercialization of the innovation through adoption, exploitation, and expansion) (210). Although we acknowledge that in practice innovation processes are often iterative and messy, this provides a comprehensive yet simple framework for the purpose of structuring the findings of our research.

Previous literature has provided snapshot insights in specific payment mechanisms in specific stages of the innovation process. For example, whereas government subsidies are found to be effective in supporting early-stage R&D (53), venture capital funds provide the money to translate prototypes into certified products (68), transforming these innovations into more profitable commodities (60,70). Subsequently, research on later-stage implementation of innovations shows that payment mechanisms either facilitate or obstruct innovation, depending on the payment method (95,113,211) and the disruptiveness of the product relative to existing practices (141,144,150). Although the literature on the influence of specific payment mechanisms in specific stages of the innovation process is extensive, there is a lack of research on the influence of different payment mechanisms throughout the innovation process. In addition, research in this field has often ignored the existence of contextual factors, despite the findings of a recent systematic review that indicate the context co-determines whether payment incentives facilitate or obstruct an innovation (32).

The following section describes the data collection and methods used to analyze the selected innovation projects, and the setting in which these projects took place. Section 4 proceeds to describe the four projects, followed by our findings regarding the role of payment mechanisms throughout the innovation processes. Next, we identify five factors that impacted these innovation processes directly or indirectly by influencing payment allocation: commercial value, compatibility, commitment, competences, and social capital. Finally, we will discuss our main findings and formulate our conclusions for policy and practice.

3.3 Methodology

We conducted a comparative case study in order to identify the role of funding and reimbursement throughout the healthcare product innovation process (212). Case studies are an appropriate strategy for studying phenomena within complex and dynamic environments, especially where there may be strong interactions between influential factors (213,214). It is an appropriate method for an in-depth analysis of processes rather than exploring the influence of isolated (quantitative) variables (215). Our approach allowed for the holistic analysis of innovation processes and of the issues experienced in practice during those processes. It also allowed us to identify patterns across and between innovation projects, improving the generalizability of our findings while also leaving room to identify specific issues.

As explained in the introduction, innovation in healthcare ought to be developed and implemented with the goal of bringing value to patient, providers, and society at large. Therefore, the scope of this study is limited to innovations with the potential to bring health and societal value, in terms of improving wellbeing of the patient or the care provider, whilst keeping costs at a sustainable level (216). Hence, our study focuses on innovations with the potential to significantly change the provision of care and replace existing processes, i.e., radical innovations (217).

We focused on healthcare product innovations that originated from universities and university hospitals, because many innovations that prove valuable to society originate from the academic setting (204). To this end, the cases were selected in cooperation with the Medical Delta alliance, an initiative that supports the development of healthcare technology by bringing together innovators from academic institutions in the province of Zuid-Holland in the Netherlands. Over the past decade, the Dutch healthcare system has seen increasing activity in the field of healthcare product innovation and the Netherlands now ranks among the countries with the most innovative healthcare systems in the world (218,219). The Dutch system is organized according to the principles of regulated competition and universal coverage, with competing health insurers that are expected to act as prudent purchasers of healthcare on behalf of their enrollees (220). Competition among insurers is subject to government regulation in order to ensure affordability and accessibility, but is driven by a free choice of insurance plans among consumers (221). Insurers have a degree of flexibility regarding provider network and coverage of out-of-network spending, resulting in competition among care providers. Health insurance coverage for consumers is provided in three ways: i) a mandatory public insurance package for long-term care, ii) a mandatory basic health insurance package for curative care, and iii) a voluntary supplementary health insurance package covering additional services. Coverage for the two mandatory packages is determined by the government, while health insurers are free to decide on coverage in the supplementary package. Reimbursement for innovative healthcare products could be included in any of these three insurance packages.

Healthcare products are often placed in three categories: devices, health information technologies (HITs), and pharmaceuticals (222). We sampled cases from the first two categories: devices and HIT tools. Devices encompass a wide array of products ranging from low-risk, every-day products to complex, costly and potentially high-risk diagnostic and therapeutic technologies (222). HIT tools include information infrastructure products for the healthcare system, as well as administrative products or products that enable providers and patients to use IT infrastructure in clinical care (222). Specifically, four innovation projects were selected from the Medical Delta innovations: two medical devices and two HIT tools. This allowed us to compare our findings between these product categories, which we expected to differ significantly due to the particularities of software development versus hardware development, patentability and maturity of the field (223). The innovation process in the projects studied spanned the journey from idea generation to the development of hardware and software, and in three of the four cases also included actual implementation in healthcare practice. Apart from the type of product innovation and the phase in the innovation process, the selection of cases was based on the willingness and availability of the innovators to cooperate in the study. Given that each of these innovation projects took place within an academic setting, either a university or a university hospital, the project members spend their core time working on education, healthcare provision and research. This means that Medical Delta innovations are largely developed and implemented in the spare time of these innovators, and participating in a qualitative study represents a relatively significant burden for this specific stakeholder group.

Semi-structured interviews were held between June 2020 and April 2021 to find out about the four innovation projects in as much detail as possible. The interviews focused on particular characteristics of each project, such as the initial motivation for the project, the duration and continuity of the process, the stakeholders involved and their roles, financial barriers and facilitators, and any other important factors. The interviews were guided by a semi-structured topic list (see appendix 3.a). Respondents were sampled using the snowballing technique, starting with the project manager of each project and asking each consecutive respondent to suggest other individuals who had played an important role in the innovation process. The sampling of respondents continued until saturation was reached or until all the suggested individuals had been contacted. The occupational background of these individuals differed significantly between the four cases, depending on the nature of the project. In total, 20 interviews with 21 respondents were conducted (Table 3.1), with an average length of 69 minutes. Except for the first four interviews which were conducted face-to-face in the physical work environment of the respondent, all the other interviews were held online due to restrictions relating to the COVID-19 pandemic. Informed consent was obtained from all interviewees, and the interviews were audio-recorded. The project managers preferred the projects not to be identifiable, and therefore all identifiable details have been anonymized where possible or otherwise removed from the findings. Hereafter, the projects are referred to as project A, B, C and D.

Table 3.1. Respondents per case, by occupational background.

Case project	Occupational background during innovation project	Number of respondents
A	Researcher	4
	Medical professional	1
	Engineer	1
B	Researcher	3
	CEO of start-up	1
C	Researcher	1
	Medical professional	4
D	Researcher	1
	Medical professional	1
	Business development coordinator	1
	Sales department of hospital	2
	Health insurer	1

The interviews were transcribed verbatim by a professional transcription organization, after which all the transcripts were cross-checked with the audio file by the lead author. The resulting transcripts were sent to the respondents for a member check; five respondents made minor textual adjustments while the others agreed to the content of the transcripts. The transcripts were analyzed using Atlas.ti 9, following the qualitative coding guidelines from Corbin and Strauss (224). During the phase of open coding, sections of text were identified in which respondents spoke about how the project had advanced and the factors that had influenced the innovation process. A total of 36 different codes were assigned to the raw data, both deductively (i.e., codes derived from the topic list) and inductively (i.e., codes that emerged from the data). These codes were then grouped into generic themes in the axial coding phase, resulting in a code book with themes and the associated codes (see appendix 3.b). Finally, the results are discussed in the form of a narrative focusing specifically on the themes that related to the influence of payment mechanisms in the different phases of the innovation process. An overview of the research process is provided in Figure 3.1 .

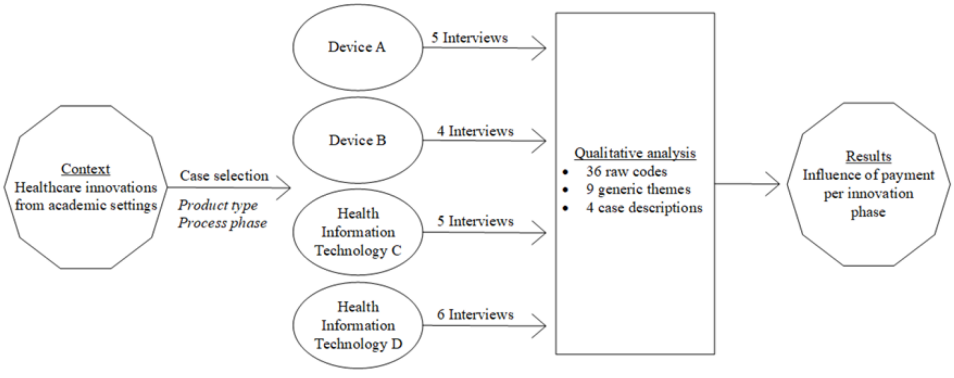


Figure 3.1. Research process using the case study methodology.

3.4 Results

This section will start with a description of the four cases. After the case descriptions, a cross-case analysis is presented, focusing on the role of payment mechanisms in the three phases of the innovation process, as well as the impact of contextual factors on the influence of payment mechanisms. An explicit comparison is made between the findings for the devices versus those for the HIT tools.

3.4.1 Description of the cases

Each case concerns an innovation project focusing on a technological solution for better healthcare. These include products for improved care at home, during rehabilitation or in the hospital. A summary of the case characteristics is presented in Table 3.2. Each of the cases originated in an academic setting (i.e., university or university hospital). In project C, the academic institution partnered with a private entity at the start of the process.

Table 3.2. Characteristics of each case project.

Project	A	B	C	D
Category	Device	Device	HIT	HIT
Context	Physical rehabilitation	Surgical training	Chronic disease management	Healthy lifestyle
Starting year	2005	2005	2017	2003
Initial motivation	Fundamental research findings	Fundamental research findings	Identified need in practice	Fundamental research findings
Initiator(s)	Engineer with academic background	Engineer with academic background	Medical specialist	Medical specialist
Current phase	Translation	Implementation	Implementation	Implementation
Current source of payment	Research funding	Revenue from user licenses	Research funding	Research funding & reimbursement from insurance coverage
Evidence of health benefits	Higher level of functional performance in users	Higher level of force and motion control by surgeons	Adoption of healthier behaviours and reduction in readmission rate	More healthy pregnancies

Projects A, B and D emerged from fundamental research findings, while project C was initiated in response to a need identified in practice. Regardless of the initial motivation, respondents reported fuzzy project boundaries at the start of all of the innovation projects (e.g., lack of clarity regarding the exact start date and which activities would or should be part of the innovation project) and a lack of clear direction for the innovation. This led to issues around planning and necessitated a dynamic and flexible attitude from project members. Representatives of three projects (B, C, D) explicitly

mentioned an iterative development and implementation process. Project A, which involved a device, currently remains in the translation phase, and strict patient safety regulations still need to be met before the device can be brought to market. As illustrated in Figure 3.2 the four cases can be positioned at different phases in the innovation process.

The projects are all ongoing and have been underway for between five years and twenty years. Most respondents from projects A, B and D indicated that it took about ten years before the initial idea was ready to be translated into a prototype technology. The development phase of these projects was experienced to have taken much longer than expected. Moreover, even the projects that have been actively working on implementation for five years (projects B and C) or ten years (project D) have not yet reached the level of adoption that the project members had envisioned. Finally, and importantly, conclusive evidence has been established for the added health benefits of each of these innovative products, if they were implemented in practice.

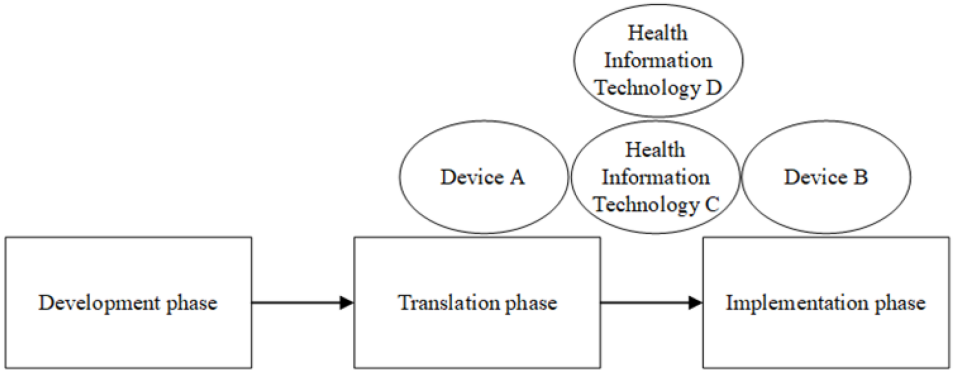


Figure 3.2. Case projects in different phases of the innovation process.

3.4.2 Role of payment mechanisms in the different phases

Payment mechanisms, in the form of funding or reimbursement, were perceived to have influenced each phase of the innovation process, affecting the planning, duration, and current status of the projects.

3.4.2.1 Development phase

Payment mechanisms in the development phase influenced all the projects in a similar way. In the case of every project, the granting of development funding, often in the form of a sizeable research grant, was cited as the reason why it was possible to initiate the project. Thereafter, the projects all relied on a multitude of funding sources, including public national and international funding

agencies, foundations, individuals with private wealth, employers, personal capital, and in-kind contributions. The respondents believed that most of this funding had been granted primarily to provide a continuous flow of money to 'keep academia functioning' and to test novel hypotheses, but not necessarily to ensure the actual implementation of that particular innovation. One respondent described this as 'soft money':

> *"It is a different kind of money: namely soft, scientific. Making sure that academic research continues, that is the primary motivation" (**B2**).*

The respondents also highlighted a distinction between earmarked and unearmarked funding. Unearmarked funding is awarded to people based on their past performance, but not tied to a specific research proposal. According to the respondents this facilitates innovation to a greater degree than earmarked funds. However, unearmarked funding is rare. Earmarked funding is provided on the basis of detailed project proposals, often indicating a specific budget for each resource such as materials, technician(s), principal investigator, and overhead costs. The main complaint made by the respondents about earmarked funding relates to what was described as *"by definition unrealistic proposals' (**A5**)* for funding applications. Earmarked funding forces the innovators to stick rigidly to the plans and deadlines in these proposals, even though the innovation process is often unpredictable and therefore unplannable, and therefore requires a more flexible approach. Furthermore, grants are increasingly awarded conditionally based on a clear plan for the commercialization of the results. Given the uncertainty about the direction that an innovation project may take during the development phase, the requirement for specific implementation plans with earmarked funding reduces the scope for responding flexibly to new and unexpected insights even further. On the other hand, four respondents (from projects B and C) said explicitly that funding is too often granted without any realistic plan for development and implementation, which leads to a waste of resources.

Reflecting on the criteria that were used in allocating research funding, respondents stated that a plan was required that reflected calls for proposals for funding, and that these generally focused on trending topics. Although respondents did not go so far as to state that the quality of a proposal was a secondary factor, they did find that securing funding was often a matter of good luck and opportune timing.

> *"Of course, you need to have a proposal that is strong in some way, but it is true that the acceptance rate is a percentage, and whenever you have percentages there is always some luck involved. I mean, there might be enough money for ten projects and you're the eleventh, and the reason why you're ranked eleventh and not tenth might just be bad luck" (**A3**).*

In addition, people who are renowned experts in a particular area and have previously succeeded in obtaining grants were perceived to be more likely to be awarded development funding for innovative products. Consequently, it is difficult for new researchers to secure grants and start a career without relying on these experts. Several respondents even referred to a sort of *'elite group' **(B2)*** and *'a like-knows-like network' **(A6)***. On the other hand, respondents also mentioned the importance of the experience of these people in navigating the world of development funding and establishing fruitful partnerships.

In general, most respondents acknowledged that it was possible to develop their innovation adequately using the funding received, although more funding could have improved the quality of the innovation and reduced stress on project members. Development grants often covered material costs and research hours. Other activities such as brainstorming with stakeholders from practice, communication within the network, or marketing the innovation were rarely included in earmarked funding, and project members invested a lot of their own time and resources into these additional tasks as a consequence. Respondents from projects A and B admitted they had sometimes been compelled to 'shuffle funding around' that had been granted for different projects in order to plug a funding gap creatively. On the other hand, as argued by two respondents from project C, finite funding can also function as a positive incentive, encouraging the more efficient use of limited resources.

Finally, respondents from projects A and B mentioned struggling with the high cost of the initial development of a device, while large-scale investment from private parties would only come at a later stage. The reasons for this were cited as the academic nature of the projects and the uncertainty of outcomes during the development phase.

> *"The actual design of the [device] is phenomenally expensive so until the design is finalized and there's some extra iteration to make it cheaper to manufacture, [...] then it's probably not going to hit the market immediately and there won't be any commercial pay-off" **(A4)**.*

Overall, the development phase seems to be a matter of persistently collecting relatively small amounts of development funding and incrementally improving prototypes for long enough to reach the level of technology readiness that is required for commercialization grants and investment from industry. However, as one respondent questioned:

> *"The question is: will you manage to achieve a concept, an idea that is mature enough to be worthy of a start-up? I think there's still a gap [in funding] there" **(D2)**.*

3.4.2.2 Translation phase

The respondents had a great deal to say about the translation phase, the phase between development and implementation, described by one respondent as *"the deepest valley between the idea and the actual market implementation" **(B2)***. But when asked about the availability of financial resources during the translation phase of the innovation project, respondents from all four projects argued that some funding can be found if you have the right idea and an extensive network.

> *"There really is money and there are always ways to get finance, as long as you have a good story and you have the capacity to push things along" **(D3)***.

Examples of financial resources gathered for the different projects in this phase included take-off grants from national agencies, personal capital or gifts from friends and family, and crowdfunding. An alternative is the early involvement of a health insurer that has agreed to cover the innovation on a trial basis. Another strategy perceived as relatively successful was the use of internal grants that are occasionally made available for early effectiveness trials. The combination of multiple innovative technologies in one start-up can also help, as funding gained for one technology can leave a surplus to cover the high costs of developing another.

In this phase, the payment mechanisms and financial issues associated with devices started to diverge significantly from those for HIT tools, primarily due to the different expenses involved. For the cases involving HIT, expenses were lower in this phase because of the absence of extensive regulatory processes and patents; the HIT tools (mostly software) could also be translated into implementation-ready technologies without the large-scale investment required for devices (with a large hardware component). Most of the investment in this phase was considered relatively small amounts of funding provided without too much emphasis on a guaranteed return and *"that have a very specific aim to make the world a little bit better through small projects of 50k or so" **(B2)***.

By contrast, severe financial barriers were experienced for the two innovative devices since these required extensive investment for large-scale commercial technological development and research into their effectiveness and safety. In addition, large amounts were needed to deal with an increasing number of stakeholders and regulatory procedures, as well as to maintain patents filed and to offset ongoing financial losses.

> *"So I mean, in the first five to seven years a spin-off company you lose money and you work your fingers to the bone, and you can only hope that eventually you will start making money" **(A5)***.

Although non-profit funding sustained innovative products during the first years of the translation phase, these funds were not enough to turn an innovative device into a marketable commodity, according to our respondents.

> *"In the beginning you still have those start-up grants, but in the medical field, product development takes quite a long time. Those start-up subsidies are usually very short-term, a couple of years, and then you need to stand on your own two feet. I think that's much too soon for many medical products" (**B1**).*

Moreover, translation funding increasingly requires co-investment from industry or other for-profit investors such as banks, private equity funds, venture capitalists, and large companies. One of the projects (B) succeeded in securing such investments in order to bring their innovative device closer to a market launch.

In order to secure the necessary investment, commercialization expertise and resources, it was very important for a private commercial organization to take over the innovation from the academic institution. However, in order for this step to take place, the innovation must be commercially attractive, i.e. it must offer a sufficient potential return on investment. This was framed as *"having a strong business case" (**B4**).*

Several features were mentioned with respect to a sufficiently strong business case. One of these features was the possibility of a patent to protect the innovative device from competitors, preferably a patent on the fundamental intellectual property that can be applied to many different products. This is potentially attractive to investors, because it means that profits from any technologies that emanate from the original concept will also revert to the patent owners. Other factors considered important were scalability and the expected time to implementation, each important for the commercial potential of the innovation. Many respondents expressed discontent with the medical sector regarding these factors because progress takes longer than expected. This means that scaling-up is difficult, earning back investment takes longer, production costs are high and there is a great deal of uncertainty around the whole process, especially finding enough funding to move to the implementation phase. Indeed, this sentiment led one respondent to state:

> *"If I had to do it all again, I wouldn't be so idealistic about wanting this on the market and available to specialists. If I simply wanted to earn money, I would look purely at the scalability. So, yes: where could I implement this outside of the medical field?" (**B2**).*

All in all, according to the respondents, the difficult circumstances in the medical sector during the translation phase often cause device start-ups to fail. To date, after almost twenty years, only one of the two devices studied here has reached the implementation phase. One respondent from the device project that has not yet managed to reach implementation, reflected as follows:

> *"A lot of my colleagues have left, either to their own start-up or to work in a start-up affiliated with the university, and unless you have a very good idea with good intellectual property protection, and you can bring it onto the market quite quickly, you're probably not going to get much investment and will probably fail before long" (**A4**).*

3.4.2.3 Implementation phase

The implementation phase involves market entry and was seen by the respondents as blending into, and sometimes overlapping with, the translation phase. The financial barriers in this phase were experienced as significant, as a result of which none of the innovations studied has been implemented on a sustainable footing so far. The main threat to implementation was said to be the lack of adequate structural financing, and the small number of potential payers. A major reason for this is that many innovations do not have the potential to earn large profits, even though they may have clear health benefits.

> *"That's the way things are in this world. Some things are really important and could really improve [outcomes] but they don't deliver direct hard cash, and so many people are not interested. And that means they do not have the right to exist" (**B2**).*

Respondents highlighted three specific issues in this regard. First, it takes a long time to gather enough evidence of health benefits for a device or HIT tool in order to convince healthcare providers and payers to adopt the innovation. Meanwhile, keeping the innovations on the market costs money, regardless of whether reimbursement is forthcoming.

Second, there is often great uncertainty regarding the appropriate payer. In theory, many parties might be expected to share the costs and also to reap the benefits of the innovation. These parties include insurers, consumers, healthcare providers, employers, research institutes, commercial organizations, municipalities, the national government, and foreign governments (all potential payers contacted by the respondents). In practice, however, innovators have often found themselves in a situation in which potential payers all point at each other when it comes to footing the bill, and the respondents have found it difficult to convince one to actually do so. This uncertainty has impeded the implementation of the HIT tools, in particular, with no preferred payer having been identified yet.

"Responsibility for [innovation] is shared between the municipality and the health insurers. [...] And then you end up with a 'who should pay?' debate that you can't resolve. What's more, as far as I know, we have not financed a single app purely from the Health Insurance Act. So you see that digital innovation and the way in which it relates to the basic benefit package, it still leads to questions" ***(D3)****.*

Both HIT projects remain (partly) dependent on short-term grants, turning them into 'never-ending projects' for the innovators involved. This issue is further complicated by the fact that the costs and the benefits often fall under different budgets and payers are not incentivized to contribute to costs if the benefits accrue to other parties.

Third, the respondents argued that unless innovation is financed by insurers or the government, the customer base in the medical sector is often very limited. Each of the three cases that have reached the start of the implementation phase (B, C and D) have involved discussions with insurers regarding supplementary insurance coverage. Only project D has managed to achieve inclusion in the supplementary package of one insurer; all the other efforts to secure reimbursement have been unsuccessful, with innovators encountering numerous rejections from insurers. One respondent representing the insurance company which has provided supplementary coverage for project D explained the reluctance of insurers to reimburse most innovative products as follows: insurers do want to embrace innovation, but only if the product is a good fit with their marketing strategy and increases their competitive advantage because no other insurance company will cover it. As this respondent noted:

"Well you know, if [a competing insurer] also covers [the innovation] as part of supplementary coverage, then it's no longer a unique selling point for us. [...] From a commercial point of view, we prefer it to be exclusively ours. I understand, of course, that's different for, well, the other side. But that's how it works for us" ***(D5)****.*

The three projects that have reached the implementation phase have all tried to persuade the government to include their innovations in the basic package and thereby achieve national coverage, but without success. In this context, the respondents expressed their frustration with the fact that innovation is subject to the whims of politics.

"If you look at the national government: I have been [...] invited to meet every successive Minister of Health. They have all assured me 'we consider prevention to be extremely important, we will put this on the agenda, and we will reimburse it'. It has never happened" ***(C2)****.*

Despite the many financial obstacles experienced by the innovators, one of the innovative device projects (B) has managed to acquire some level of reimbursement by licensing their product directly to potential users (i.e., healthcare providers). However, the number of users is currently thought too low to generate a sustainable stream of reimbursement. All three issues result in a situation in which the financial benefits of an innovation are at best uncertain, and at worst absent altogether, reducing the chances of any payer being willing to provide sustainable reimbursement.

According to the respondents, the strategy with the best chance of implementation and sustainable reimbursement for both devices and HIT innovations is to tie the innovation to existing care services that are already covered in the basic benefit package. This requires limited change on the part of healthcare professionals and payers, which reduces resistance, especially in the case of innovations that save money for the provider. If there are additional costs, respondents from the sales team of a healthcare provider explained that a large hospital can simply state they will provide care in an innovative way and increase the price of the relevant hospital product slightly (e.g., diagnostic related group).

> *"You know, if the medical specialist just says: we provide care in this particular way and that includes the app. [...] Technically, we can simply increase the prices by ten euros"* ***(D3)***.

However, to have an innovation implemented and reimbursed in this way, innovators must first convince healthcare providers to adopt the relevant innovation. Respondents from each of the projects studied in the implementation phase (B, C and D) have experienced what is called the 'not-invented-here' syndrome. Despite all the effort of innovators to disseminate their innovation to hospitals beyond those where project members were employed, they have rarely been successful. In the case of one of the devices, it has been adopted in several hospitals outside of the Netherlands, in addition to one Dutch hospital. But otherwise hospitals were not only reluctant to implement innovations that had been developed at rival hospitals, but there were also instances where there were financial disincentives to doing so. For example, hospitals can receive a prospective budget that does not vary according to the volume or quality of care provided. The respondents involved in one of the HIT innovations (C) were therefore unable to convince those hospitals to adopt their innovation, even though it provided a clear improvement in quality. As noted by a respondent involved in project C: *"maintaining the status quo is easier than changing healthcare processes"* ***(C1)*** and a higher-quality care provision would not result in a higher level of reimbursement. *"This really holds back innovation"* ***(C1)***.

3.4.3 Contextual factors influencing healthcare product innovation progress

The analysis of the four cases resulted in a complex narrative of the financial issues that occur at various stages in the innovation process. One factor was identified as causing many of these financial

issues: a (perceived) lack of commercial value of an innovation. The innovators involved in the cases analyzed emphasized that it was essential to be able to convince payers of the commercial value of their innovation with a strong business case in order to obtain financing in each of the three phases (Figure 3.3). A strong case for the health or societal value of the innovation is no substitute for a strong business case. This is summarized in our first proposition:

i) The stronger the business case for the innovation in terms of creating commercial value, the better the chance of securing funding and reimbursement.

Several contextual factors were said to have an important effect on an innovation's progress through the healthcare product innovation process, both indirectly via payment and directly (Figure 3.3). These factors are interdependent, as illustrated by the dotted box in the model, but below we will summarize them separately in the following four propositions:

ii) The higher the compatibility of an innovation with prevailing healthcare practices, the better the chances of securing funding and reimbursement, and the better the chance of making progress with the innovation.

iii) The greater the commitment of the people involved in the innovation project, the better the chances of securing funding and reimbursement, and the better the chance of making progress with the innovation.

iv) The more comprehensive and complementary the competences of the people involved in the innovation project, the better the chances of securing funding and reimbursement, and the better the chance of making progress with the innovation.

v) The greater the social capital of the people involved in the innovation project, the better the chances of securing funding and reimbursement, and the better the chance of making progress with the innovation.

We explain these last four factors – compatibility, commitment, competences and social capital – in more detail below.

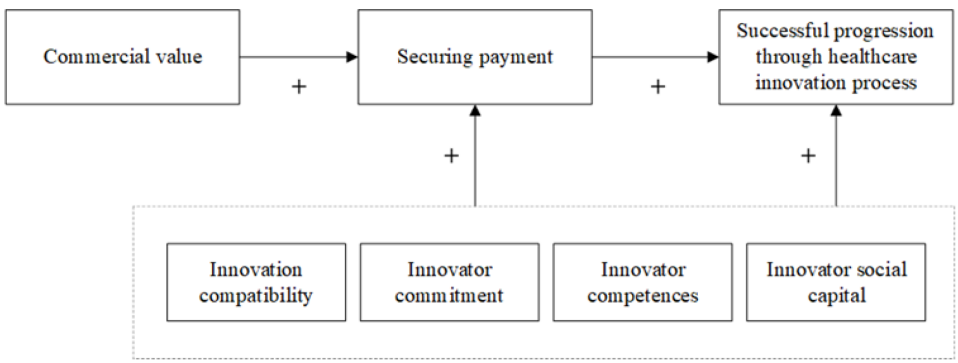


Figure 3.3. The direct and indirect effect of 5 C-factors on successful progression through the healthcare innovation process.

3.4.3.1 Compatibility with dominant practices

Existing healthcare practices and reimbursement options

The degree of compatibility of an innovation with existing healthcare practices and reimbursement options was mentioned as an important factor that influences the chances of both receiving payment and making progress with the innovation. For innovations that are incompatible with existing practices, it is more difficult to formulate a business case with a compelling narrative to convince potential payers, according to the respondents.

> *"Because it's not something that can be compared to existing products, there is still a lot of uncertainty, and I would guess a lot of business investors would not be super happy about gambling their money on an untested idea" (**A4**).*

Given the relative novelty of eHealth solutions, the HIT tools in our study were less compatible with prevailing practices than the devices in our study. As a result, finding sustainable reimbursement for a HIT tool being framed as a 'new way of delivering care' was perceived as an almost insurmountable challenge. The strategy of focusing on care practices that already exist and presenting the HIT tool as a blended care model – i.e., presenting the technology as an integral part of existing care rather than as an innovative replacement for it – was a more successful approach.

As well as convincing potential payers, an innovation also needs to be accepted by its users. For healthcare professionals it is important that it will not take much effort to adapt to *"the umpteenth innovation that no one really wants" (**C1**)*. Consequently, three out of four projects (A, C and D) stated that they had designed their innovation specifically as a complementary product.

> *"In many respects, it's already embedded. So it's better if you see it as something additional, providing it as a bolt-on solution. So you don't touch what is already there, and you just add something extra" (**C2**).*

Regulatory compatibility

Incompatibility with regulations was also cited as a negative influence on successfully bringing an innovation to market in three of the projects (A, C, D). For device project A, for example, it was increasingly strict medical certification required in Europe, as codified in the new Medical Devices Regulations which came into effect in 2021 (225), that was a difficult hurdle for innovations on the road to market access and implementation (226). Innovators spent a lot of time and resources on meeting those requirements, with no financial compensation coming in during that time. For project B, the regulations were much less strict because patients are not directly involved in the use of the device, and so this factor did not hold up the progress of the innovation.

For the HIT tools, conforming to existing regulations was perceived as reducing the chances of securing market access during the implementation phase. The system of healthcare reimbursements is perceived to be very complex due to the high levels of distrust between parties, which means that innovative products are subject to many bureaucratic rules.

Trending topics

The third aspect of dominant practice in healthcare that affects the innovation process is the compatibility of the innovation with trending topics in healthcare. In general, it was perceived that innovations that address trending topics with greater urgency are more likely to secure development funding. In other words, if an innovator is too early with an innovative idea, e.g., because there is no urgent need for it in practice, funding will not be made available. *"Timing is everything, and the sense of urgency"* ***(B2)***. Thus, many innovative ideas are dismissed because the timing is not (yet) right.

One respondent from project D argued that innovators are always 'ahead of their time', and this requires them to strike a difficult balance between innovation and the likelihood of securing funding.

> *"We look very far ahead with our ideas. We recognize their potential, but society is not ready for them yet. And that also applies to financing or other parties. That's innovation, you have to just believe in it sometimes"* ***(D1)***.

In addition to being important for development funding, new technologies should also be compatible with trending topics and urgent societal needs in order to secure structural reimbursement. The two HIT tools in this study focus on healthy lifestyle and prevention. These were generally perceived as relatively unimportant topics until a few years ago, and the eHealth innovation never received sufficient funding or achieved reimbursement.

> *"These days, the situation is completely different. Nowadays, prevention means 'we haven't figured out how to make it work yet, but we all know it's vital'. And it's very important to have that wind behind you"* ***(C2)***.

Nowadays, healthy lifestyle and prevention are increasingly perceived as a (shared) responsibility for all health insurers in the Netherlands. The COVID-19 pandemic significantly changed the healthcare landscape in this sense, creating a sense of urgency and societal support for digital healthcare provision, and strengthening the financial incentives for eHealth innovations. Specifically, respondents involved with one of the HIT tools (C) argued they would never have made it through the development and translation phase so quickly if the COVID-19 crisis had not highlighted the need for this eHealth technology. Nevertheless, even now, eHealth is still rarely included in the basic benefit package and the traditional payers (i.e., insurers and government)

remain reluctant to cover such innovative products. A complicating factor in this regard is the often lengthy development time that is required for innovations, with innovators having to look 10 to 15 years ahead and predict whether their innovation will ever become sufficiently accepted to receive reimbursement.

3.4.3.2 Commitment of the innovators

The degree of commitment of those involved in the innovation project team can also play a decisive role in the financial challenges of the innovation process.

> *"You can throw so much money in something, but if you don't have people who believe in a project, who enjoy working together, who are committed to working hard for each other and care about each other, I think you will get nowhere. If you lack the determination and the strength, it doesn't matter how much money you have. I think, in the end, the people make the difference" (**C5**).*

The individuals perceived as the most important are those at the core of the project teams, i.e., the innovators. These were the project leaders with the innovative ideas and the PhD students who had developed innovative products. Specifically, the commitment and conviction of project leaders was mentioned as a decisive factor in the innovation process. To underscore this, innovation projects were often seen as the 'life's work' of the project leaders. On the other hand, this dedication and conviction can also make them become so attached to their project that it is difficult for them to see the bigger picture. Two respondents (from projects A and D) mentioned that an external party was sometimes needed to make difficult decisions regarding the project.

3.4.3.3 Competences of the innovators

The competences available to the project team are another decisive factor. Depending on the background of the people who set up and led the innovation projects in this study (i.e., academic engineers and medical professionals), others with specific skill sets were also needed during the innovation process. For example, medical professionals found that they lacked knowledge regarding commercialization and business plans. Similarly, most of the engineers had limited knowledge of (or interest in) commercialization, regulatory aspects, and marketing, as well as limited experience of clinical practice.

> *"At the university, people are not used to thinking about that. That makes sense, but it does create a big gap between when something is finished at a university and when something is really finished at a company" (**A2**).*

Moreover, the initial innovators are often too busy with their regular work to spend enough time on the innovation. That means it is important to have a diverse team with a range of different

competences in order to successfully progress through the innovation process. This also helps the team to see their innovation as part of a 'bigger picture'.

In order to bring in the required competences, several external parties were mentioned by respondents as crucial additions to the device project teams: hardware development firms, organizations that coordinate large-scale funding, and healthcare providers to test the prototypes. For the HIT projects, stakeholders were mentioned in the fields of healthcare provision, commercial organizations and IT development.

> *"For an invention like this, so much depends on the right people getting together at the right time. It's almost a perfect storm that has to arise" (**D2**).*

Creating access to the right competences and resources at the right time was mentioned as crucial to making progress. Firstly, access to resources from the institutions where the innovators were employed was perceived as very important. Some departments were mentioned specifically as being able to provide such institutional support: the Technology Transfer Offices for the step from academia to business and intellectual property management; the hospital sales department for the framing of the business case and adapting the innovation to the reimbursement requirements of the health insurance system; and healthcare incubators for creating an atmosphere of innovation and bringing together different skills in one place. In addition, medical institutes provide a small market in which to start work on implementation, usually for research purposes. Ultimately, the institute's support for the innovator includes a willingness to offer the time to work on an innovative idea and in-kind support from colleagues.

Secondly, it is important to convince a commercial organization to take over the innovative product once it has been developed by an academic institution. Their role lies in ensuring that the regulations for market access are met and implementing the innovation in practice, ensuring a competitive advantage for the innovative product with their extensive resources. Furthermore, potential adopters are more likely to trust an innovative product if a well-known company's name is attached to it. Support from a commercial organization can therefore provide the resources for large-scale structural implementation.

3.4.3.4 Social capital of the innovators

The more influential the members of the innovators' network are and the more successful innovators are in persuading them to become involved, the better the financial prospects and progress of the innovation. In the projects that we studied, innovators built and maintained such networks not specifically linked to a project, but more as part of a strategic future investment in cooperation and fundamental trust. Although *"it all takes time and you are not exactly sure in advance if you will benefit from it" (**B4**)*, having a network of influential, trusted people is considered

crucial. As one respondent commented on the successful implementation and reimbursement of their innovative device:

> *"Acceptance from those around you is important for the implementation of your technology. To make that happen, you have to be able to discuss your ideas at the right level, get around the table with the right people. [...] Several times, an application of mine at the bank was taken care of and approved immediately. [...] They know who I am and what I'm doing, and that makes it easier to get through" (**B2**).*

Additionally, support from the medical professionals who are the target adopters of the innovative products was seen as essential. Gaining this support is highly dependent on the social capital of the innovators. Support therefore often starts with providers in their network, who know the innovators personally and are willing to give them a chance. It is not only medical professionals who regularly start with the question "who already uses it?"; health insurers also look at the support among medical professionals when considering whether to reimburse an innovation.

> *"The health insurers, in turn, will look at the medical specialists, because there's no way they are going to impose something on medical professionals. So in the marketing jargon, they look at the key opinion leaders" (**B4**).*

To date, none of the innovators we talked to had managed to convince a sufficient amount of people to adopt their innovation on a large scale: one of the innovative devices (project A) is not yet being used in practice; the other device (project B) is accommodated in a small start-up company; the two HIT tools (projects C and D) have only been implemented locally by healthcare providers that are part of the project team.

> *"In the meantime, the only thing you can do is make sure that the company keeps its head above water and the potential remains clear. The work to seduce the bigger players continues" (**B4**).*

3.5 Discussion

3.5.1 Summary and discussion of main findings

In this comparative case study of four product innovation projects, we have aimed to identify the role of payment mechanisms over three phases of the healthcare innovation process, for innovations with high societal value but limited commercial value. While financial factors impede the progress of innovative products at each step of the process, their influence appears most significant in the

implementation phase. Even though innovators sometimes find the acquisition of funding in the development phase exasperating, the overall perception is that sufficient funding can ultimately be secured to develop innovative devices and HIT tools. In the translation phase, the investment required for innovative devices is much higher than for innovative HIT tools. While the HIT tools analyzed in this study managed to make it through the translation phase with more limited 'soft' funding, the innovative devices had to present a convincing business case in order to bring in major private investment, translate their prototypes into marketable commodities and reach the implementation phase. Finally, now that the implementation phase has been reached, the innovative products in our study have not managed to secure structural reimbursement, preventing them from being used in practice beyond the local healthcare provider.

Studying these four innovation projects, we found that the perceived commercial value of an innovative product was a key factor in obtaining sufficient payment. This is consistent with previous work done by Lehoux et al. regarding the influence of venture capital funding and the active transformation of healthcare innovations into profitable products (58,67,159,200). In the four cases studied here, the commercial value has not yet been demonstrated convincingly enough to secure sustainable payment, despite evidence of significant health value. This bias in payment mechanisms towards innovations with a high perceived commercial value implies that an innovation with potentially significant health and societal value but low or uncertain commercial value would face two major obstacles. The first obstacle is the difficulty of putting a profitable business case on paper in order to reach the marketplace in the implementation phase. This proved essential for devices from the translation phase onwards, and for HIT tools from the implementation phase onwards. Building a strong enough business case was particularly difficult in the context of academic healthcare institutions, for instance, due to the lack of the necessary competences in this setting, uncertainty regarding the appropriate payer and the often narrow customer base. Previous studies have also identified the importance of a convincing business case in securing sustainable reimbursement and found that this is particularly difficult for more novel healthcare innovations such as HIT tools and prevention initiatives (141,144,150,227), but our study is the first to identify the persistent role of commercial value throughout the entire healthcare innovation process.

In our four cases, the lack of a commercially compelling business case was an important reason why the innovators failed to have their products included in the basic health insurance package; inclusion in supplementary insurance packages appeared to be primarily dependent on luck and a potential competitive advantage for the relevant insurer rather than societal value. An argument often deployed in favor of competition in healthcare systems is that it has a positive impact on innovation (228,229). In contrast, several studies suggest that competition may not always stimulate innovation (230–232), while most studies have produced inconclusive results and point out the need for further research (233,234). Our study shows that the influence of (regulated) competition on innovation is not necessarily a question of how much innovation occurs, but rather how much value the financed

innovation is generating for the benefit of society. Do innovative products end up enhancing the quality and efficiency of healthcare provision? Or do they merely serve to improve the competitive position of the insurer or healthcare provider?

The second obstacle arises once an innovator has successfully achieved reimbursement for sustainable implementation in local practice but is confronted with the next challenge of scaling up the innovation to the regional, national or international level. Due to fragmented payment mechanisms, which result from a competitive healthcare system and a persistent not-invented-here syndrome, innovations very rarely spread beyond local practice. This leads to practice variation and undermines the principle of equal access. Previous studies have highlighted the alarming effect of the fragmented and localized financing of innovations on transparency (153), efficiency (180), and accessibility (38,83).

The finding that perceived commercial value is much more important for obtaining payment than societal value is problematic in the healthcare sector, where innovation is largely financed from collective resources (216). These resources ought to be allocated with the societal objective to improve population health rather than making a profit. Figure 3.3 exposes a painful truth for the healthcare sector. While there are high expectations for innovation to contribute to tackling pressing challenges within the healthcare system, societal value is not the primary objective with which healthcare innovations tend to be financed. Consequently, innovations with the potential to fulfil (a part of) that societal promise are likely to encounter insurmountable financial barriers if they have no or limited commercial value.

We have identified four additional factors that determine the likelihood of securing payment and the successful progression through the healthcare innovation process: compatibility, commitment, competences, and social capital. These four factors are contextual in nature and, as such, should be *an integral part of the study object* in line with Varabyova et al.(107) Without sufficient compatibility, commitment, competences and social capital, even a product with a high level of commercial value is unlikely to make it through the innovation process. While the role of compatibility (235), commitment (88), competences (236) and social capital (237) have previously been studied in relation to healthcare innovation, to our knowledge their interdependent effect on the strength of the commercial business case and the chances of securing payment has never been highlighted before.

3.5.2 Implications for policy and practice

Our results have several important implications for how policy and healthcare practices could increase the chances for sustainable implementation of innovative products with potentially significant societal value but limited commercial value. These relate to major obstacles that we have identified in our research. First, from a societal perspective, it is imperative that the balance between

commercial value and societal value be redressed in favor of the latter. Accordingly, the incentives for developing innovations with potentially significant health and societal value should be increased. Two policy suggestions emerge from our analysis. First, increase the level and continuity of unearmarked public funding for innovations with potentially significant societal value, specifically for devices in the translation phase of the process. Subsequently, mitigate the bias towards commercial value that results from price-based competition in the healthcare system. This can be done by promoting value-based contracting in order to shift the focus of reimbursement away from volume-expansion or cost-reduction and towards societal benefits.

Second, the adoption and dissemination of innovations beyond the local level should be promoted. Specifically, the negative impact of lack of compatibility with prevailing practices and the not-invented-here syndrome should be addressed. For example, the inclusion of less compatible product innovations in the basic benefit packages of social health insurance schemes could be facilitated by revising the main admission criterion from 'customarily used in the profession' to 'innovative and providing potentially significant health and societal benefits'. In addition, the willingness to change in a cost-constrained healthcare system could be incentivized by offering financial leeway to insurers and providers to invest in innovative products – through public innovation payments for example. Furthermore, a more targeted approach to the not-invented-here syndrome could be taken by rewarding innovators specifically for disseminating their innovation or rewarding adopters for implementing an innovation from another institution. However, these recommendations should be contingent on the innovation creating sufficient societal value in terms of improved health outcomes and/or the more efficient use of resources. Clearly, innovations in healthcare should only be supported if they create genuine societal value and should not be disseminated beyond the target groups for which value has been demonstrated.

Third, it is important to help innovators to pursue innovative ideas with potentially significant value for society. Our results show that commitment, competences, and social capital are important in order for innovators to advance their innovation. Several steps could be taken in this regard, to help innovators succeed. For example, competences and networking opportunities for innovators could be improved by providing training on innovation and organizing dedicated events at academic healthcare institutions. Furthermore, commitment among innovators could be nurtured and the healthcare product innovation process made less daunting by implementing the policy recommendations above, and thereby creating a smoother pathway for future innovators.

3.5.3 Limitations

This study has at least three limitations. First, although we deliberately selected multiple projects from different product categories, it is difficult to draw definitive conclusions. We cannot state with absolute certainty that the experiences of the innovators in our cases are representative of innovator experiences more generally. Nevertheless, we believe that the patterns identified across multiple

settings, and confirmed by the wider literature, provide some useful insights for policy and practice. Second, this study analyzed innovation projects from the innovator's perspective. Subjectivity is inherent whenever experiences are studied, and the perspectives of other parties involved in the innovation process (e.g., healthcare managers, investors, insurers, government) would probably have yielded different experiences. Finally, we were only able to study the selected innovations because they had survived for so long; in other words, because they had managed to secure enough funding and reimbursement to sustain themselves. The opinions of respondents may therefore have been more positive and optimistic than those of innovators whose projects had ended (much) sooner in the process.

Finally, we have developed a conceptual framework based on an analysis of four healthcare innovation cases from an academic setting. It would seem reasonable to expect the (perceived) commercial value of an innovation to be even more crucial in a more commercial setting. Doubts about the commercial value of an innovation would probably lead to much earlier abandonment, and project durations of 1 5 years or more would probably be rare. The other factors – compatibility, commitment, competences, and social capital – are expected to also positively affect the success of innovative products in non-academic, more commercial contexts, but may be less important than commercial value. Nevertheless, in a more commercial context payers still need to be convinced by the business case, which is more likely if the innovation is compatible with prevailing practices, if the innovator team is highly committed, if the team has access to a wide range of complementary competences, and the social capital of the innovator team is strong.

3.6 Conclusion

In this comparative case study of four healthcare innovation projects, we have aimed to achieve a better understanding of the role of funding and reimbursement throughout the innovation process. We have highlighted the ways in which innovators try to overcome the financial challenges they face, and we have identified the key role of commercial value at every step of the process. A product that provides potentially significant health and societal value but is of less certain commercial value has a limited chance of becoming embedded in practice and scaling up beyond the local level. In addition, four factors have been identified as influencing the likelihood of securing payment and progressing through the innovation process: the compatibility of the innovation with prevailing healthcare practices, and the commitment, competences, and social capital of the innovator. Based on these factors and the financial challenges identified in the innovation process, we have formulated a number of lessons for policy and practice which would help innovations with potentially significant health and societal value to reach sustainable implementation.

Appendix 3.a. Semi-structured topic list

1) Introduction
   a. Personal introductions: interviewer and respondent
   b. Previous 'innovation' experience of respondent
   c. Short introduction to the innovation project (*all subsequent questions concern the experiences of the respondent with this particular innovation*)

2) Innovation process in general
   a. Would you be able to give a description of the innovation process? Including the start and the current state of the innovation? (Length, pauses, pace, phases, clearly defined or undefined)
   b. Would you describe the project to be under development or in implementation, and why?

3) Stakeholders
   a. Which (key) stakeholders are/have been involved in the process?
   b. At which moment(s) were these (key) stakeholder involved in the process?
   c. What is/was the role of the stakeholders?
   d. Which stakeholders were missing in the process?
   e. What would have been the added value of these stakeholders?

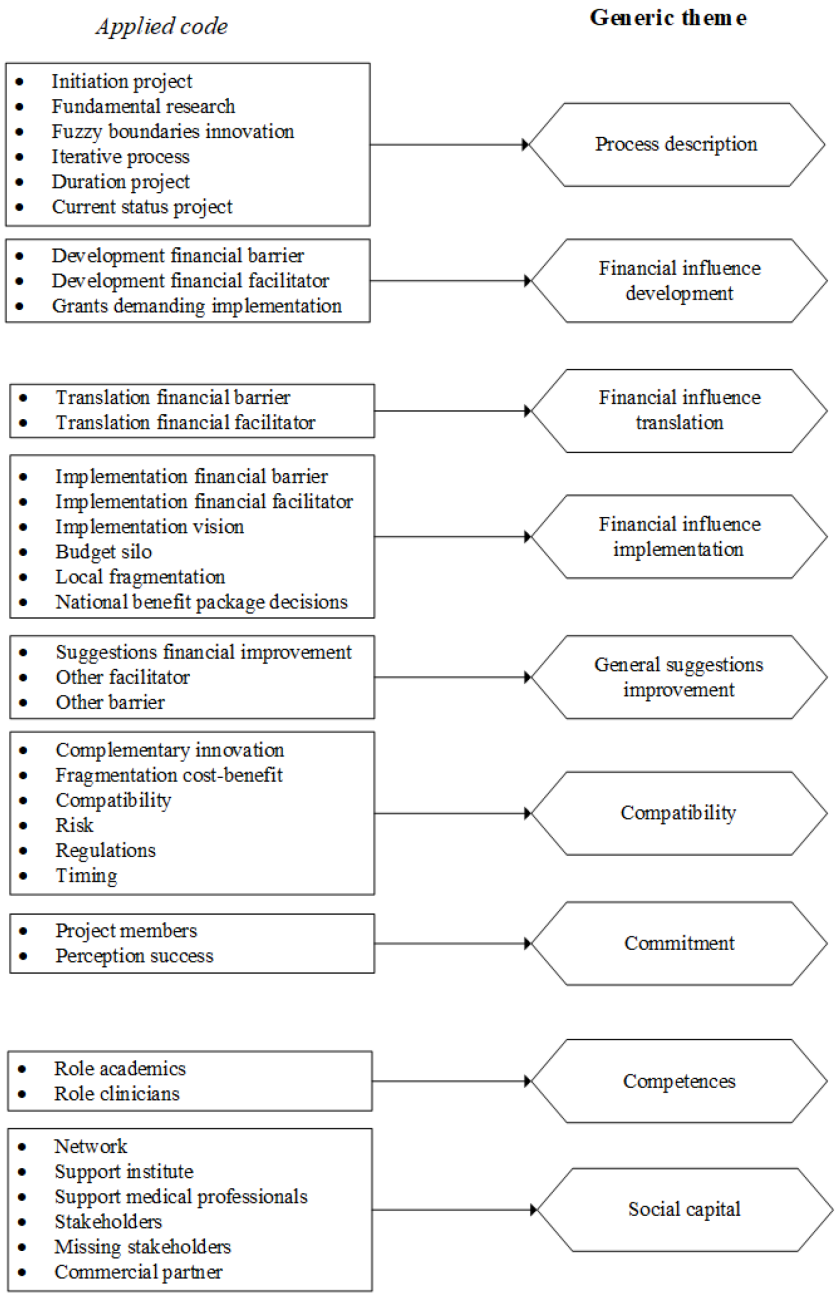
4) Successes and setbacks
   a. What are, in your opinion, the biggest successes in the progress of this innovation process?
   b. What are, in your opinion, the biggest setbacks in this innovation process?
   c. What is the ultimate goal to reach with this innovation for you? In other words, when will you see this innovation as a success?

5) Influence of payment mechanisms
   a. What types of payment has this project received so far?
      i. How would you describe the process of securing this payment?
   b. What types of payment has this project applied for, but not received?
      i. What were the most important reasons for this, in your opinion?
   c. What types of payment would you like to receive for this innovation in the future?
      i. Why? What would happen if you do not succeed in securing these types of payment?
   d. How would you describe the influence of payment on [successes mentioned]?
   e. How would you describe the influence of payment on [setbacks mentioned]?

6) Other relevant factors
   a. Which factors, besides financing, have had an important influence on [successes mentioned]?
   b. Which factors, besides financing, have had an important influence on [setbacks mentioned]?
   c. Would you consider these factors more or less influential during the process compared to the influence of financing?

7) Conclusion
   a. If you ever had the power to change the payment system for innovation in healthcare in the Netherlands, which change(s) would you most likely make?
   b. Any further questions or comments related to the interview?

Appendix 3.b. Codebook



Chapter 4

Aligning ambition and reality: A multiple case study into the synergistic influences of financial and other factors on the outcomes of integrated care projects

International Journal of Integrated Care, 2024; 24(3): 1–12

Abstract

While the benefits of integrated care are widely acknowledged, its implementation has proven difficult. Together with other factors, financial factors are known to influence progress towards care integration, but in-depth insight in their influence on the envisioned outcomes of integrated care projects is limited. We conducted a multiple case study of four integrated care projects in the Netherlands. The projects were purposely sampled to be representative of integrated care in its different forms. A total of 29 semi-structured interviews were held with project members, both medical and non-medical staff. In addition, 141 documents were analyzed, including scientific publications and minutes of meetings. Based on elaborate project descriptions we deduced the synergistic influences of financial and other factors on the outcomes of the projects. We found that financial factors have an important influence on integrated care projects, though this influence is neither deterministic nor isolated. This is because the likelihood of realizing a positive outcome is affected by the degree to which four key conditions are fulfilled: i) willingness to change, ii) alignment of interests and uniformity goal, iii) availability of resources to change, and iv) effectiveness of management of external actors. In conclusion, financial factors have an impact on the outcomes of integrated care projects but must be viewed in synergy with interrelated other factors. Crucial for realizing success in integrated care, a balance must be struck between the level of ambition set in a project and the reality of the prevailing key conditions.

4.1 Introduction

Healthcare systems worldwide are facing increasing threats to their sustainability, including rising costs, aging populations with complex multimorbidity, and staffing shortages. These developments have resulted in a growing call for innovations in healthcare provision to alleviate the burdens on the systems (238,239). Prominent innovations in healthcare provision involve strengthening collaboration among care providers, ensuring the right care is provided at the right place, and putting the patient at the center of care provision (240). In other words, these innovations focus on integrated care, which is defined by Leijten and colleagues (241) as *"structured efforts to provide coordinated, pro-active, person-centered, multidisciplinary care by two or more well-communicating and collaborating care providers either within or across sectors"* (p.13).

Even though the urgent need for integrated care provision is widely acknowledged, the implementation of integrated care has proven to be difficult. The persistent fragmentations in care delivery structures result from operational complexities, regulatory challenges, obstructive cultural differences, and misaligned payment structures (239,242). Regarding the latter, the misalignment of predominant payment structures with the general aim of integrated care can be found both in funding (e.g., temporary subsidies and grants) and in reimbursement (e.g., structural remuneration) mechanisms. Funding in the healthcare process innovation landscape has mainly focused on financing innovations with high commercial potential (e.g., innovative drugs and other medical products or treatments with a high expected financial return on investment), leaving integrated care projects without (sufficient) financial support (64,159,243). And traditional reimbursement mechanisms, in particular fee-for-service reimbursement, tend to emphasize volume over value of care, frustrate collaboration (244–247), and contribute to fragmented care provision (248). Nevertheless, as was concluded based on a study reviewing the different payment mechanisms for integrated care in Europe, *"there is limited evidence on the effects and effectiveness of financial incentives and other payment models in integrated care"* (249). This conclusion was echoed in a recent systematic literature review, showing that in-depth understanding of the exact role of payment mechanisms in the integration of care is still limited [publication forthcoming]. Specifically, though payment mechanisms have been identified as influencing the speed and fluency of integration processes in healthcare, little is known about their contribution to the eventual outcomes of care integration projects. More generally, as concluded by Auschra (242) based on the findings of a systematic literature review on barriers for the integration of care, *"empirical research should analyze how the existence of barriers to interorganizational collaborations affects the outcome of integrated care, as barriers do not necessarily prevent or terminate collaboration, but merely slow down collaborative processes"* (p.10).

In addition, when analyzing the influence of payment mechanisms on the outcomes of integrated care, it should be acknowledged that *"when analyzing barriers (either for research purposes or in order*

to overcome them), it seems helpful to assume that a barrier which is visible could be caused by one or several other barriers that are not obvious at first glance" (p.10) (242). Therefore, a context-sensitive perspective should be adopted in which the potential interrelated influences of financial and other factors are studied. While understudied, the synergy between payment and these other factors might very well explain why financial barriers sometimes seem to be the obvious factor impeding the successful implementation of integrated care, while in other instances they seem to play only a minor role in integrating care (250).

This study aims to address this knowledge gap by investigating the facilitating and/or inhibiting influence of payment mechanisms (both funding and reimbursement, henceforth referred to as 'financial factors') on the outcomes of integrated care projects in the Netherlands. The influence of these financial factors will be studied alongside the influence of other, potentially interrelated, non-financial factors. We define the outcomes of these projects as the extent to which the general goal of implementing integrated care and specific objectives set in care integration projects are achieved according to those involved.

The specific objective of this study is to establish the role of financial and interrelated factors in determining the outcomes of integrated care projects. Successively, we will i) describe the progress and outcomes of four projects attempting to integrate care processes in the Dutch healthcare system, ii) identify the factors contributing positively and negatively to the outcomes separately for each project, and iii) identify common patterns of influential factors across the projects, aiming to distill recommendations to facilitate positive outcomes of integrated care projects in practice.

4.2 Methods

We conducted a multiple case study of innovation projects aimed at realizing integrated care across and within provider tiers. The case study methodology allowed us to construct in-depth accounts of the progress of the projects, from the perspective of the project members involved.

4.2.1 Setting

The innovation projects focused on integrating care in the Netherlands. The provision of curative care in the Netherlands can roughly be divided in three tiers: a primary care tier with general practitioners acting as gatekeeper to higher tiers, a secondary care tier with general hospitals for basic care and top-clinical hospitals for more complex care, and a tertiary care tier for highly specialized care. The system for curative care is based on the principles of regulated competition with insurers and providers of care negotiating about reimbursement contracts. Ideally, this system incentivizes high quality care at the lowest possible costs (229,251). Provider reimbursement systems are largely volume-based, though there is much variation. In hospital care, for example, closed-ended cost-per-

case contracts (i.e. payments for diagnosis treatment combinations, which are similar to diagnosis related groups, under an expenditure cap) are most prevalent (252). Healthcare providers have some amount of freedom in their choice of treatment for each patient, facilitating efficiency in care provision (253). However, coordination of care across multiple providers is not typically incentivized.

The projects were selected from the portfolio of the BeterKeten organization. BeterKeten ("BetterChain" in English) is an organization with the aim to *"stimulate, facilitate, and initiate collaboration between healthcare organisations and healthcare professionals in the areas of patient care and scientific research in the Rotterdam-Rijnmond region. The ambition to provide the right care by the right professional at the right place is shaped by realizing collaborative projects and care networks via BeterKeten"* (254). For elaborate information on the strategies employed by this organization to govern the regional integration of care, see Van der Woerd et al. (255). BeterKeten was established in 2011, inspired to a great extent by the Boston model of healthcare (254). In this model, primary, secondary and tertiary care provision are completely integrated within a region in terms of protocols followed, information shared, IT facilities used, etc. The organization has several innovation managers supporting the initiation, acceleration and embedding of innovation projects by arranging project group meetings and providing administrative support, steering a project group towards actions and results, as well as sharing knowledge from their experience with earlier projects. The work performed by these innovation managers is financed by all hospitals related to the BeterKeten organization. Additional resources and knowledge, for example IT and legal expertise, are expected to be provided by the hospitals involved in the specific project; no other financial resources are made available by the organization. Project proposals are considered for support by BeterKeten if they aim to create value for patients, focus on streamlining a care pathway, and involve multiple care organizations in the region.

4.2.2 Case sampling

Over the past decade, more than 30 innovation projects have been initiated and supported by BeterKeten, each with the aim to improve quality of care through integration based on objectives formulated by medical professionals. All of these projects focus on cross-sectoral collaboration, involving multiple care organizations in the region. For this study, four projects currently in the implementation phase were purposively selected as diverse cases with the aim of being representative of integrated care in its different forms. Based on theory regarding the case study methodology, the diverse case selection technique is appropriate when sampling cases that represent different values of a predefined category (212). This way, the cases aim to represent the full variation present. For our study, following common classifications, the projects differ in the categories of direction (i.e., horizontal and/or vertical) (256) and level of integration (i.e., linkage, coordination or full integration) (257). Moreover, based on previous research and with assistance of the BeterKeten innovation managers, we specifically selected the cases such that they varied on the following five

dimensions: i) *the prevalence of the disease* that is focused on (i.e., high or low), ii) the *degree of change in care provision* aimed for (i.e., commonly accepted or innovative treatment), iii) the *number of care organizations* involved in the project group, iv) whether the envisioned integration is *crossing the borders of specialties*, and v) whether the envisioned integration is *crossing tiers in healthcare provision*. Table 4.1 describes the selected projects in terms of these dimensions. Based on the literature, we expected that these dimensions would be associated with the size of barriers a care integration project might face and the complexity of realizing a positive outcome: a) rare diseases are less attractive to spent resources on (258), b) more extensive process change disrupts existing practice to a greater extent (259), c) a larger number of parties involved increases the chances of conflicts of interests (242), and d) crossing the borders of organizations, specialties or tiers in healthcare provision means dealing with multiple, fragmented payment mechanisms, regulations and practices (257,260). In other words, it was expected that the variation in project dimensions would result in differences in (the size of) barriers faced in a project and the complexity of the ambition aimed for. In turn, this complexity was expected to influence the likelihood of successfully implementing integrated care in the projects.

Table 4.1. Dimensions of the different projects.

Project	A	B	C	D
Direction of integration	Vertical	Vertical	Horizontal	Horizontal
Level of integration	Coordination	Full integration	Full integration	Coordination
Prevalence of the disease	Low	High	High	High
Envisioned degree of change in care provision	Moderate (commonly accepted treatment)	High (innovative treatment)	High (innovative treatment)	Moderate (commonly accepted treatment)
Number of care organisations involved	Six	Seven	Three	Eight
Crossing specialties	No	Yes	Yes	No
Crossing tiers	Yes (secondary and tertiary care)	Yes (primary, secondary, and tertiary care)	No (secondary care only)	Yes (secondary and tertiary care)

4.2.3 Data collection

In order to identify financial, as well as other, factors contributing positively and negatively to the outcomes of the projects, we have constructed detailed accounts of the progress of each project towards realizing integrated care. To this end, we combined semi-structured interviews with document analysis. The interviews were performed with the members of the four project groups, mostly medical care providers (e.g., physicians and nurses) as well as support staff from non-medical departments of the hospitals if they had been involved in a project (e.g., IT, administrative and

project management staff). For recruiting respondents via email and telephone, an overview of the project members including contact details was provided to the researchers by the project leaders. This overview was checked with each individual respondent to ensure a complete account of the people involved. Inclusion of respondents was completed upon saturation or when all available project members had been included. In total 29 interviews were held between February and June 2022, with an average duration of 48 minutes. The interviews were audio-recorded, after informed consent was provided by all respondents. The respondents were asked to reconstruct the progress within the project, including their reflections on topics such as the initiation and the objectives of the project, the steps taken to reach those objectives, the achievements, and the financial and other factors that contributed positively and negatively to the outcomes (see appendix 4.a for the full topic list). Finally, a member check was performed with each respondent regarding the description of their project, which resulted in several textual changes. In addition, for the purpose of triangulation, documents were obtained from the internet, the interview respondents, and the innovation managers of BeterKeten. In total 141 documents were selected, including scientific publications on several of the projects' developments and clinical outcomes (n=7), minutes from meetings of the project groups (n=83), project and research proposals (n=26), integrated medical protocols and guidelines (n=12), questionnaires among care providers (n=6) and applications for payment (n=7).

4.2.4 Data analysis

The interviews were transcribed verbatim by a professional transcription organization, after which all the transcripts were cross-checked with the audio file by the lead author. The interview transcripts were coded inductively using Atlas.ti 9 (261). The coding guidelines for thematic analysis of Braun and Clarke (262) were followed, resulting in a codebook of 82 initial codes assigned to the raw data, grouped into nine generic themes such as the initial motivation, perception of achievements and barriers. Subsequently, a final analysis of the generic themes and coded data resulted in four theoretical dimensions, which will be elaborated on in the results section (see appendix 4.b for the codebook). Next, the document texts were coded deductively according to the nine generic themes obtained from the initial coding of the interview transcripts. The findings from the interviews were compared with the information in the documents, yielding corresponding insights.

Following this initial data analysis, elaborate project descriptions were created containing the storyline of each project, highlighting the various factors that played a role in the progress and influenced the outcomes of the projects. A summary of these descriptions per project is provided in appendix 4.c. Given a lack of formal project evaluations, project outcomes were assessed based on project members' statements and documentation regarding (non-)achievement of project objectives. Specifically, a positive outcome was evaluated in terms of the extent to which the project members perceived, and project documentation reported, the following as having been realized: 1) the specific project objectives as stated by the project members and/or formulated in project documentation,

and 2) the general goal of implementing integrated care (i.e., ranging from improved coordination between care providers to fully integrated care provision) (263).

It is important to note at this point that, for each project, the interview respondents also mentioned factors that had an influence on the (speed and/or fluency of the) progress of integration efforts but that – according to the respondents – did not determine the eventual outcomes of the project. Although these *process* factors were not the focus of our analysis, we do believe they provide relevant information for care integration projects, because they elucidate the context in which a project took place. Therefore, an overview of the identified process factors for each project can be found in appendix 4.d.

Based on the project descriptions, we analyzed i) whether the outcomes of the projects were positive, ii) which factors played an influential role in the outcomes of the projects, and iii) whether a relationship between financial factors and outcomes could be identified. Subsequently, a cross-case analysis was performed in which we compared the projects with more and less positive outcomes on the a priori defined project dimensions and the influential factors mentioned by the respondents. Because of our context-sensitive perspective, the analysis includes results on the synergy between the influence of financial factors with interrelated other factors. Finally, preliminary findings were discussed with the innovation managers of the BeterKeten organization to ensure validity and applicability of the results, which did not generate substantial alterations.

4.3 Results

This section first provides a short description of each of the four projects, including the initial motivation, objectives, finances, and achievements (Table 4.2). Next, section 4.3.2 presents an analysis of the financial and other factors that had a positive or negative influence on the project outcomes, followed by our cross-case analysis in section 4.3.3.

4.3.1 Project descriptions and outcomes

Project A is a collaboration project between care providers from secondary and tertiary care, focusing on treatment of a rare blood disease in children. The objectives of the project were to improve the knowledge of providers in the region concerning this rare disease, make clear agreements regarding the referral of these patients, document a care pathway for this disease and disseminate the protocol both regionally and nationally. The respondents were very positive about the outcomes and stated that *"we did not have to overcome major obstacles" **(A6)***. No specific funding was provided for the project, but according to the respondents neither was this needed. All in all, for this project the objectives were reached and the goal of integrating care was achieved to the level that was initially envisioned.

Table 4.2. Project descriptions.

Project	A	B	C	D
Care providers in project group	Two tertiary care and five secondary care providers treating children with a rare blood disease.	Two tertiary care providers, eight secondary care providers and two GPs treating allergies.	Two secondary care providers treating people experiencing dizziness.	One tertiary care and thirteen secondary care providers treating inflammatory bowel disease (IBD).
Initial motivation	High-risk patients combined with very limited knowledge in secondary care resulted in many phone calls to tertiary care.	An innovative treatment provided in secondary care could partly be given by GPs to achieve better quality for the patients and a cost reduction for society.	The disease is complex and requires multiple specialists, which resulted in patients traditionally falling through the cracks of the healthcare system.	There is a lot of regional variation in care provision, which was believed to have a negative impact on quality and/or costs of care.
Objectives	To improve the knowledge of providers in the region concerning this rare disease, make clear agreements regarding the referral of these patients, document a care pathway for this disease and disseminate the protocol both regionally and nationally.	To standardize the provision of the treatment amongst the different types of providers in secondary care involved in the treatment, educate GPs about the treatment, promote the transition of patients from secondary and tertiary to primary care for the continuation phase, and develop a shared EHR between the providers in all tiers.	To set up a multidisciplinary consultation hour, and to design clear triage and treatment protocols regarding the care pathway.	Overall: To increase transparency in care provision, share knowledge and expertise, to collaborate on scientific research and to improve patient information provision. Specific: To develop and implement a uniform care pathway in all hospitals in the region.
Ambition regarding level of integration	Low (alignment of care provision).	High (shared care provision).	High (shared care provision).	Low (alignment of care provision).
Process duration	One year and finalized.	Five years and finalized.	Five years and ongoing.	Four years and ongoing.

Table 4.2. (continued)

Project	A	B	C	D
Funding and changes in reimbursement	No funding and no changes in reimbursement were provided.	Private funding was provided to finance the shared EHR and a project manager, but the investments were finite. Furthermore, existing reimbursement fees were inadequate to cover the costs for providers, resulting in a financial conflict of interest.	Sufficient funding was provided by the hospitals to develop and implement the project. Reimbursement agreements (a registration code and adequate fee) were made with the insurer involved. Agreements about the distribution of reimbursement within hospitals have not yet been finalized.	Private funding was provided to finance a PhD candidate, who managed the project. There were no changes in reimbursement.
Achievements	• A regional care pathway. • A guideline in the national medical manual. • Regional education of providers. • Information provision at a national conference. • A reduced number of phone calls to tertiary care providers. • Improved referral of patients. • A positive experience to serve as foundation for future collaboration between these providers.	• A regional care pathway. • A shared EHR. • Regional education of providers. • Scientific publication. Not achieved: • Transition of patients to primary care. • Adequate reimbursement fees.	• Multidisciplinary consultation hour at a joint location. • A multidisciplinary meeting with additional medical specialists to discuss further treatment of multimorbid patients. • Integrated registration and reimbursement structures. • A website and other communication materials.	• Development and measurement of shared indicators. • Regional education of providers. • Multidisciplinary meetings with additional specialists. • Regional information provision for patients. • A website and other communication materials. • Scientific publications. • Development of a uniform regional care pathway.

Table 4.2. (continued)

Project	A	B	C	D
				• Adaptation of the IT-infrastructure to the care pathway. • Active dissemination of uniform care pathway. Not achieved: • Implementation of uniform care pathway in daily practice of all providers.
Outcome	Objectives and integration reached to the level envisioned.	Neither all objectives nor integration reached to the level envisioned.	Objectives and integration were reached beyond the level envisioned.	Objectives reached to a large extent, but integration not reached to the level envisioned.

Project B is a collaboration project between care providers in primary, secondary and tertiary care, focusing on an innovative treatment for allergies. The aims of this project were to standardize the provision of the treatment amongst the different specialties in secondary care involved in the treatment, educate general practitioners (GPs) in primary care about the treatment, promote the transition of patients from secondary and tertiary to primary care for the continuation phase, and develop a shared electronic health record (EHR) between care providers in all tiers. The respondents mainly spoke about setbacks the project endured. Eventually, the respondents were disappointed with the lack of uptake of the treatment among the GPs. Furthermore, the respondents mentioned significant financial barriers, both in terms of inadequate funding and reimbursement. Consequently, not all of the project's objectives were reached, and the goal of integrating care was not achieved to the initially envisioned level.

Project C is a collaboration project between care providers from two secondary and one tertiary care hospital, focusing on an innovative diagnostic method for people experiencing dizziness. The innovative approach proposed in this project consists of a lengthy, multidisciplinary consultation including different specialists in which the patient can be diagnosed timely and referred to the proper treatment. Accordingly, the objectives of this project were to set up a multidisciplinary consultation hour, and to design clear triage and treatment protocols regarding the care pathway. The initial lack of reimbursement for the providers could have caused severe financial barriers, but a financial conflict of interest was prevented through reaching a financial agreement between the insurers and healthcare providers. Also, a lot of funding and in-kind support were provided by the hospitals involved. Eventually, the respondents were very positive about the achievements: the objectives were reached above and beyond the initial vision of the project leads, and the goal of integrating care was achieved.

Project D involves a collaboration between care providers from secondary and tertiary care, focusing on aligning treatment for inflammatory bowel disease. The overall aims of the project were to increase transparency in care provision, to improve quality and efficiency of care through sharing knowledge and expertise, collaborating on scientific research and improving patient information provision. For the purpose of our study, we analyzed a single project within this larger integration collaboration. Specifically, the aim of the project is to develop and implement a uniform care pathway for treatment across the region. Apart from a general acknowledgement that a care pathway was developed, respondents' views regarding specific objectives of the project largely diverged. Eventually, most respondents expressed doubts about the benefits of the project, the scope of collaboration and standardization in practice, and the actual changes made in the care provided. Many respondents said they felt hesitant about strictly following a standardized care pathway thus they deviated from the pathway at their own discretion. Other respondents even admitted they decided not to follow the pathway at all. Moreover, the care pathway had been adapted to the wishes of every hospital, resulting in an absence of real standardization. Financial factors were not perceived

to have had a negative influence on the outcomes of this project. Sufficient funding was gathered to finance a PhD candidate, and reimbursement issues did not play a role since there were very little changes in care provision. Nevertheless, there are strong question marks about whether this project has integrated care sufficiently. Although the objective to develop and disseminate a uniform care pathway was realized, implementation in practice was only partially successful and most respondents stated that the goal of integrating care was not achieved to the level that was envisioned.

4.3.2 Factors influencing project outcomes

Respondents mentioned a broad range of financial and other factors that had a positive or negative impact on the outcomes of the projects. For project A, respondents stated that the rare blood disease in children and its treatment were especially suitable for designing a collaborative care pathway, because of three reasons: the manageable topic, the urgency of the problem, and the limited number of interests. As voiced by one respondent: *"Hematology is a niche area, and within it [the disease] is an even smaller area. So yeah, no one will have a problem with it. No board of directors will make a big deal out of it. So that helps" (**A2**)*. Furthermore, many factors were mentioned that illustrate a clear direction of the project group, a great devotion and sufficient resources to make change happen, and little dependency on people outside of the project group. Although several process factors, such as limited time, complicated the progress of the project, according to the respondents these factors did not determine the project's outcomes.

For project B, an innovative treatment provision for allergies, respondents mainly spoke about factors negatively impacting its progress and outcomes. A lack of direction, urgency, evidence, interest, as well as high levels of perceived risk and, eventually, absence of sufficient results were perceived to have harmed the participation of project members. As one respondent stated: *"In fact, I did not agree at all. And I still don't, based on considerations regarding quality of care" (**B2**)*. Moreover, several respondents mentioned conflicting interests due to the work and time required, and the impossibility of transferring payments in secondary care to providers in primary care. Furthermore, respondents mentioned that a lack of resources - including funding, input from medical specialists and project support - as well as the fragmentation of a large number of GPs upon whom the project depended, made it very difficult to convince the relevant actors in the region to participate in the transformation and succeed in reaching the objectives. Although several process factors that supported the project members in achieving some progress (e.g., the opportunity to obtain valuable knowledge about an innovative treatment) were also mentioned, eventually the project members were demotivated by the many setbacks and abandoned their efforts to integrate care.

For project C, the project group members, and specifically the medical specialists treating people experiencing severe dizziness, were devoted to reaching a uniform, urgent goal. The project started showing positive outcomes early in the process, strengthening the conviction that the project

members were on the right track. However, the need to overcome several process barriers in this project was also mentioned, including difficulties in making agreements due to the large number of interested parties involved, a lack of time, rigid regulations, and a lack of reimbursement. Yet, the project group was able to overcome these barriers because of the high level of pre-existing trust between the parties as well as access to support staff from the hospital who were able to figure out ways to arrange innovative administration codes and financial agreements with insurers. As one respondent argued: *"I think the main reason is the presence of mutual trust, which we created together in the years before this project" (**C2**)*. Furthermore, although the respondents mentioned a lack of interest from medical specialists outside of the project group, the project was not impeded by this barrier because it was not dependent on anyone outside the project group for realizing positive outcomes.

For project D several positive process factors were mentioned to have facilitated the project's progress, including the access to sufficient funding and in-kind resources. Despite these facilitating factors, the project does not seem to have reached the integration it aimed for in treating people with inflammatory bowel disease. Our analysis revealed two main reasons for this. First, a limited sense of urgency, a lack of direction, and a shortfall to formulate a univocal goal among the respondents were identified. Second, the respondents mentioned high levels of professional discretion and autonomy, and therefore differences in the way specialists provide this care. As described in one document: *"The manner in which the care pathway will practically be implemented may differ per hospital. [...] Because there are no strong arguments to direct this [treatment provision], the hospitals are free to decide for themselves" (document **D47**)*. These two factors resulted in care providers being hesitant to work with a standardized care pathway, especially those who were not part of the project group.

4.3.3 Key conditions for positive outcomes across projects

We expected beforehand that the project outcomes would be determined by the size of the barriers faced in a project, which from previous research were assumed to be associated with the project dimensions described in Table 4.1. These project dimensions were expected to influence the complexity of the ambition strived for, which in turn would determine the likelihood of realizing a positive project outcome. However, our cross-case analysis did not clearly reveal the expected relationships between the project dimensions (Table 4.1) and the extent to which the objectives and envisioned level of integration were realized (Table 4.2). In other words, the project outcomes do not seem to be solely or directly determined by the prevalence of the disease that is focused on, the degree of process change aimed for, the number of organizations involved, or whether the integration is envisioned to cross the borders of specialties or tiers in care provision, nor directly by the financial factors associated with these dimensions. However, as shown by our analysis this does not mean that the project dimensions are not related to the project outcome at all. Rather, as we illustrate in Figure 4.1, the facilitating or hindering role of the project complexity (shaped by the project dimensions) in determining outcomes appears to be influenced.

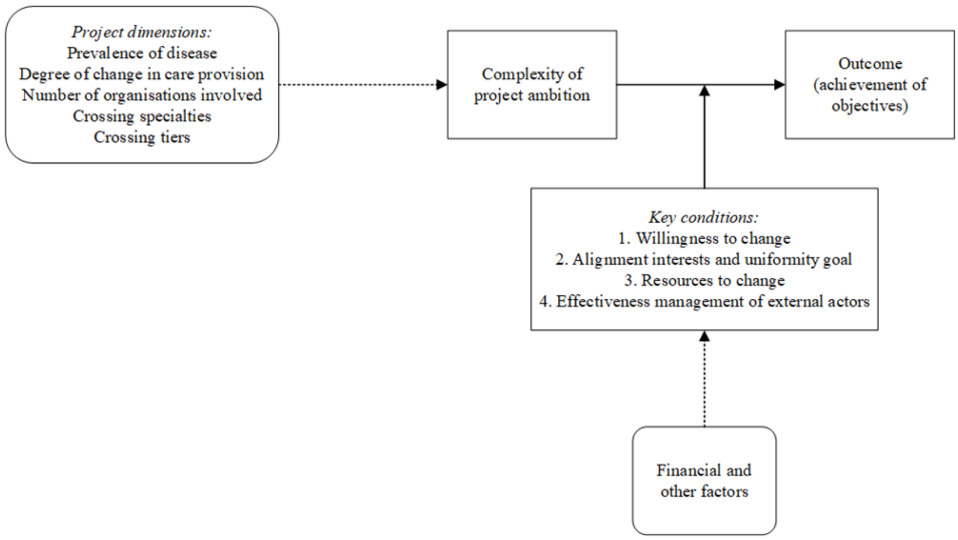


Figure 4.1. Framework on the influence of ambition and reality on the outcomes of integrated care projects.

When comparing the factors in the two projects that were evaluated more positively with the factors in the two projects that were evaluated less positively, a pattern emerges. The variety of influential factors, both financial and others (as can be seen in Table 4.3), are found to interrelate and can be grouped into four theoretical dimensions, henceforth called the four key conditions. This relationship of the various factors shaping the key conditions is visualized in Figure 4.1 with a dotted arrow. Specifically, the projects with a positive outcome are characterized by financial and other factors jointly shaping a high willingness to change, aligned interests and a univocal goal, and sufficient resources (financial, tangible, and personnel, such as dedicated medical leaders) to make the change happen. The projects with a less positive outcome were faced with a faltering willingness to change, conflicting interests diluting the objectives of different project members, and, for one project, a lack of resources. In addition, effectively managing dependency on external actors was found to be an important condition for realizing a positive outcome. In the context of this study, external actors refer to individuals who are not directly included in the project group but who are important for implementing the project. While the two projects that achieved their objectives only depended on the project members themselves, the other two projects also depended on care providers outside the project group. The data highlight the influence of these key conditions on the relationship between a more or less complex ambition and the eventual project outcome.

Table 4.3. Key conditions and associated factors (financial and other) influencing project outcomes.

Conditions	Project A – Outcome positive	Project B – Outcome negative	Project C – Outcome positive	Project D – Outcome negative
1. Project members willing to change	Yes • Interest in the topic. • Medical focus quality of care. • Initial lack of knowledge about treatment. • High urgency of problem due to risk of severe mistakes.	No • A lack of urgency. • A lack of interest. • A lack of evidence. • A lack of direction. • Project members demotivated by many setbacks and disappointing results.	Yes • Interest in the topic. • Medical focus quality of care. • High urgency of problem due to many patients without sufficient treatment. • Results in practice early in the progress.	No • A limited sense of urgency. • High levels of autonomy and differentiation in treatment provision.
2. Aligned interests and univocal goal	Yes • Singular aim. • Absence of conflicting financial interests. • Small niche of patients and limited number of referrals. • Non-specialty-transcending treatment. • Highly uniform structure of disease progression, manageable topic.	No • Doubts about medical or financial aim. • Conflicting interests due to the work and time involved. • Insufficient knowledge and high levels of perceived risk amongst GPs. • Professional GP guidelines advising against treatment. • Conflicting interests due to lack of sufficient reimbursement in both tiers.	Yes • Singular aim. • High level of trust between parties with a univocal goal, common ground to overcome differences. • Financial incentives not aligned, but no conflict of interests because parties reached an agreement.	No • Failure to formulate univocal goal.

Table 4.3. (continued)

Conditions	Project A – Outcome positive	Project B – Outcome negative	Project C – Outcome positive	Project D – Outcome negative
3. Resources to change	Yes • In-kind contribution from project leads and members. • Network of medical specialists. • Project support BeterKeten. • Time and culture to innovate in top-clinical hospitals.	No • A lack of sufficient funding to maintain the EPD. • A lack of sufficient funding to maintain a project manager.	Yes • In-kind contribution from project leads and members. • Network of medical specialists. • Project manager and support from top-clinical hospital. • Project support BeterKeten. • Joint clinic location with essential facilities. • A lot of media attention resulted in high demand innovative treatment.	Yes • Sufficient funding for a PhD researcher, acting as project manager. • In-kind contribution from project leads and members. • IT support staff from multiple hospitals. • Backing of prominent specialist academic hospital. • Project support BeterKeten.
4. Effective management of (dependency on) external actors	Yes • All medical specialists treating these patients were part of project group.	No • Fragmentation of a large number of GPs, upon whom the project depended.	Yes • All medical specialists and support staff needed were part of the project group.	No • Fragmentation of medical specialists, upon whom the project depended.

A respondent from project C, for example, stated that *"all things, such as IT, location, financing, can eventually be arranged [...] because the specialists that were involved had the will to change things"* (***C2***) whereas a respondent from project B stated *"the funds were gone, we had a mountain of issues to tackle, [...] if we wanted to make this a success we would need a large amount of money to hire someone to lead the project, who can convince and motivate practitioners to participate"* (***B1***). These quotes show not only the synergistic influence of financial and other factors, but also the mitigating effect that the key conditions have on solving complex issues to realize a positive outcome.

In summary, the project dimensions determine the complexity of the project ambition, which does impact the likelihood of realizing a positive outcome. However, as shown in our analysis, the impact of a given level of complexity on the likelihood of a realizing a positive outcome is influenced by the degree to which each of the four key conditions is fulfilled. The more facilitating financial and other factors are present in a project, the higher the degree of fulfillment of the key conditions. In that case, an exceedingly complex ambition can be turned into a positive outcome. Ultimately, to increase the likelihood of realizing a positive outcome in integrated care, the level of complexity of a project ambition needs to be aligned with the reality of the prevailing key conditions.

4.4 Discussion

We conducted a multiple case study of four integrated care projects to identify the influence of financial and other interrelated factors on the outcome of realizing integrated care in practice.

4.4.1 Key findings

Our analysis revealed three key findings. Firstly, although we could not confirm the expected direct relationship between financial factors and the likelihood of realizing a positive outcome (as suggested by previous literature), these factors do have an important influence on integrated care outcomes. There are financial factors influencing the degree to which key conditions for positive outcomes are fulfilled, affecting the likelihood of realizing a positive outcome. Although financial factors have an important influence on the outcomes of integrated care projects, this influence is neither deterministic (i.e., the influence can be mitigated or strengthened by the degree to which key conditions are fulfilled) nor isolated (i.e., the influence interrelates with the impact of other factors). This explains why, in practice, addressing financial barriers will not always result in the successful implementation of integrated care, and why persistent financial barriers will not always obstruct its implementation. Nevertheless, given that diminishing financial barriers will increase the likelihood of realizing integrated care, it is important to maintain ongoing efforts in devising better payment mechanisms such as bundled payment models for full disease pathways or integrated capitation payments (264).

Secondly, our multiple case study revealed four key conditions that influence the likelihood of realizing a positive outcome: willingness to change of medical and non-medical staff, alignment of interests and uniformity of goal, availability of resources to change and effectiveness management of external actors. Previous literature has identified the separate influences of these elements on the implementation of integrated care. For example, Whittle and Hewison (265) demonstrate that the willingness to change among medical professionals is vital for the implementation of any type of process change in healthcare. In addition, Mur-Veerman et al. (266) argue that, while a common tradition of innovation and collaboration among healthcare organizations is an essential condition for the willingness to integrate care, payment mechanisms in the Netherlands have failed to facilitate this condition. The importance of a shared vision, a shared narrative, and the formulation of specific goals was emphasized in previous publications as well with one study arguing for the importance of translating initial shared commitment into tangible action and timely results to prevent losing enthusiasm (267,268). Regarding the availability of resources to change, previous work has shown the importance of allocating sufficient funding, time, personnel and (medical) leadership committed to innovation in order to realize integrated care (269,270). Finally, the influence of effective stakeholder management through effective communication, coordination, collaboration and cooperation strategies, along with greater accountability among staff at all levels, has been identified by Burke et al. (271). Importantly, however, as our analysis shows, none of these conditions are deterministic. They need to be viewed in relation to one another, as well as in their alignment with the complexity of the ambitions aimed for. González-Ortiz et al. (272) concluded from their literature review on research about the dimensions of integrating care that the results of that research *"are mostly lists of key building blocks to integrated care, rather than frameworks supporting the process of implementation"* (p.10). We believe our findings do provide such a framework that can support the practice of integrating care, acknowledging the synergistic influences of financial and other factors. In section 4.4.2, we specify how to make these findings actionable in practice.

Thirdly, we find that project outcomes are eventually determined by the alignment of the degree of fulfilment of the key conditions to integrate care and the complexity of the project ambition. When the willingness to change is high, interests are aligned with a shared univocal goal, resources are available and all actors are on board, ambitions can be high and complex. To understand the implementation of integrated care, it is essential for future research to adopt a balanced perspective in which influencing factors are studied simultaneously to understand their joint impact on outcomes (242). Moreover, for integrated care to succeed, a similarly comprehensive perspective needs to be adopted in practice in which practitioners acknowledge the essential balance between ambition and reality.

4.4.2 Aligning ambition and reality

We propose a four-step iterative cycle to help succeed in aligning ambition and reality in practice (Figure 4.2). To start, the complexity of the ambition can be established by assessing the project dimensions, such as the ones explicated in Table 4.1 or other relevant dimensions. Second, the degree of fulfillment of the key conditions can be established by evaluating factors that may act as barriers or facilitators. Third, in case there is misalignment between the ambition and reality, project members can work on further fulfilling the conditions by resolving inhibiting factors and/or strengthening facilitating factors. Finally, in case the misalignment persists, the complexity of the ambition can be reduced by adapting the dimensions of the project. It is important to acknowledge the iterative and continuous nature of this alignment process. If conditions change or factors are adapted during the course of a project, the project dimensions and ambition should be adapted accordingly.

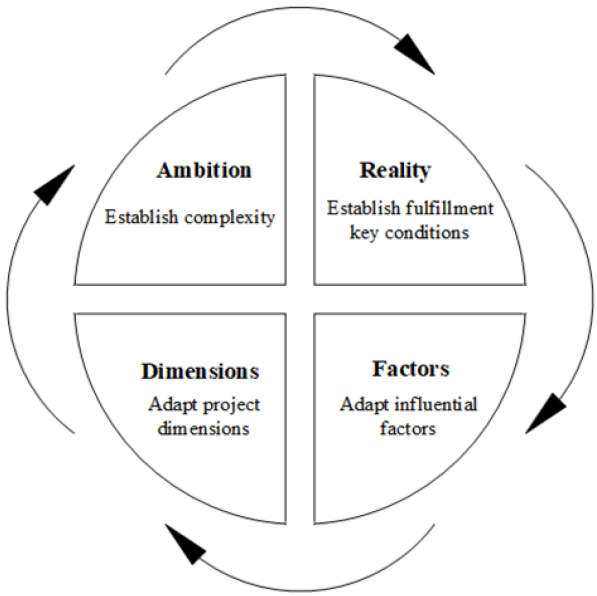


Figure 4.2. Aligning ambition and reality cycle.

4.4.3 Limitations

Although we believe that our findings apply broadly to integrated care projects in healthcare, we must consider the potential impact of the context in which these specific projects took place. All projects were embedded in the context of the BeterKeten organization. In addition to the project support provided at no additional costs, three characteristics of this context favor a positive outcome. First, in this context, medical professionals typically come up with the initial plan and take the lead in the development and implementation of the project. Previous research has shown the

indispensability of medical professionals with a high willingness to change when introducing process innovations (273). Our research builds on this conclusion by highlighting other conditions that need to be fulfilled to put these medical professionals in a position to make change happen. Second, the studied projects are all projects in which top-clinical secondary and/or tertiary hospitals played a role: care organizations with a mandate for research and development of innovation. This context has been shown to be a vital part of successful collaboration projects because the leaders in these organizations offer room for innovation and in-kind contributions from staff members (88). Third, each project aimed for integration of organizations in the same region. The physical proximity of the integrating parties is likely to affect the likelihood of positive outcomes, as this is positively related to a sense of cohesion and trust between the parties (274).

In addition to the potential impact of the specific BeterKeten context, there are several other potential limitations which are related to our study design. First, by studying projects in the implementation phase of integrated care, we did not examine factors that may inhibit or facilitate projects that are (still) in the development phase. Thus, our findings may suffer from survivorship bias. Second, another bias could result from the variation in the time between the end of the project and our moment of data collection. Some projects had very recently finished the project or were in the process of finishing up and were still very positive about the changes it would bring. Other projects had finished up a few years ago and could have been more negative because the change they initially envisioned was not realized in practice. Third, the reliance on self-evaluation of the respondents regarding the achievement of project objectives could have introduced bias in assessing the outcomes of the projects. However, we identified no contradictions in outcome evaluation between the interview data and (official) project documentation, diminishing the risk of recollection or self-evaluation bias. Finally, all projects encountered chance events that, according to the respondents, had an impact on the project outcomes. For example, the project manager in project B became ill and was not able to finish her work, and the establishment of a joint clinic in project C was advanced by the hospitals because their previous shared hospital location was closed. While such chance events will have had some impact on the progress in the projects, respondents stated it was the more generalizable factors, as depicted in Figure 4.1 , which eventually determined the project outcomes.

4.5. Concluding remarks

Financial factors have an important influence on the outcomes of integrated care projects, but this influence is neither deterministic (i.e., the influence can be mitigated or strengthened) nor isolated (i.e., the influence interrelates with other factors). In addition, a balance must be struck between the level of ambition set in a project and the reality of the prevailing key conditions. This balance should henceforth be adopted as a prime focus of both researchers and care integrators in creating a better understanding and realization of integrated care in practice.

Appendix 4.a. Semi-structured topic list

This topic list serves to facilitate semi-structured interviews. Depending on the specific role and knowledge of the respondent, certain aspects can be given more or less attention.

1) Introduction
   a. Personal introductions: interviewer and respondent
   b. Short introduction to the innovation project (*all subsequent questions concern the experiences of the respondent with this particular project*)

2) Process in general
   a. Would you be able to give a general description of the innovation process? Including the start and the current state of the innovation? (Initial motivation, duration, pace)

3) Objectives
   a. What are the objectives aimed for in this project?
   b. What is the ultimate goal of this project in your opinion? In other words, when do you think the project is a success?

4) Achievements
   a. Which achievements have been realized in the project?

5) Status of implementation integrated care
   a. Which professionals were informed about the integrated care pathway?
   b. Which professionals provide care according to the integrated care pathway? Do you provide care according to the integrated care pathway?
   c. Why do you/don't you provide care according to the integrated care pathway?
   d. Does the integrated care pathway align with your current/previous way of working? Does the pathway apply to the patients you treat?
   e. Which concerns do you have regarding the provision of care following the integrated care pathway?

6) Facilitating factors
   a. Which factors have had an important influence on the achievements realized in the project?

7) Barriers
   a. Which factors have been the largest barriers in developing and implementing the project?

8) Support
   a. What are things that helped you overcome these barriers, to the extent you managed to overcome them?

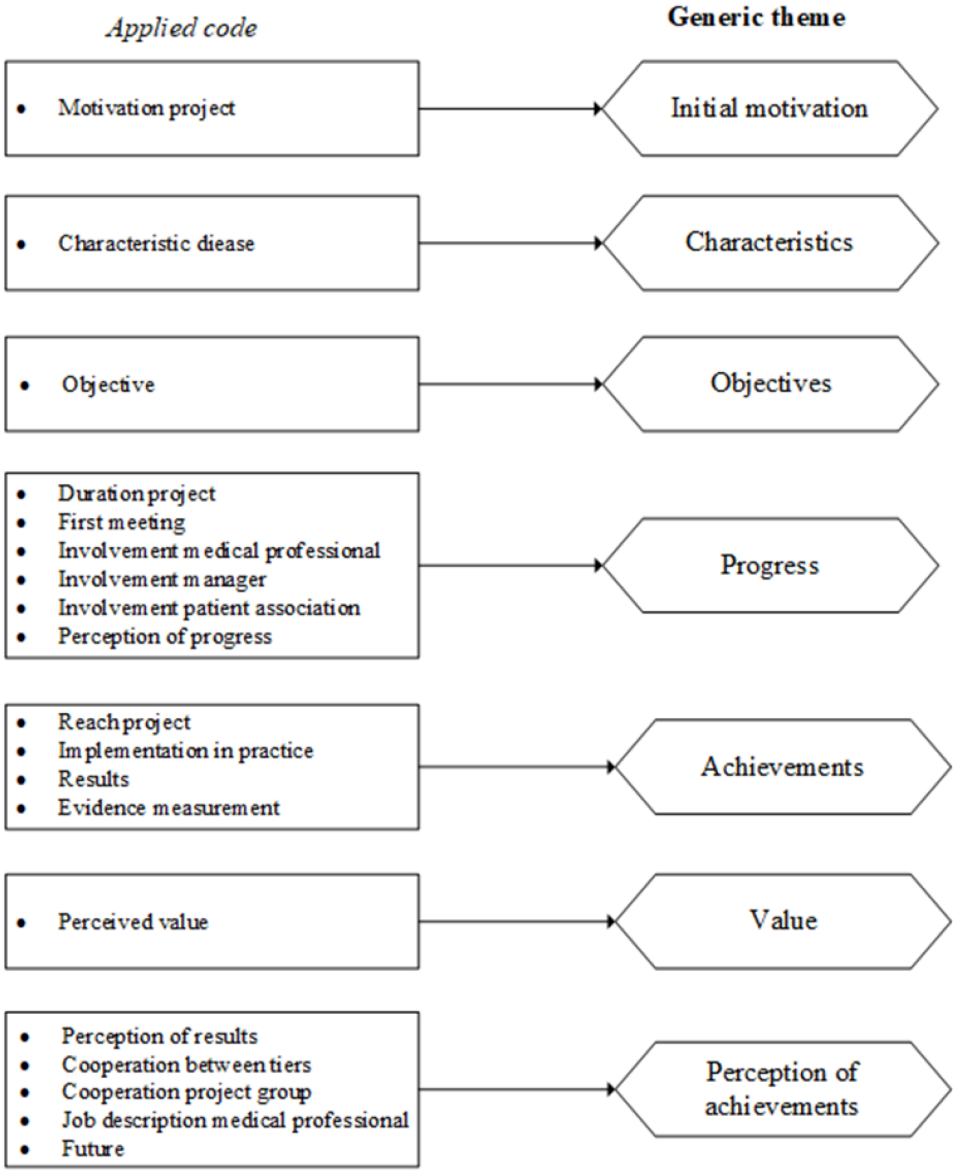
9) Finances
   a. Which forms of financing did this project receive?
      i. How would you describe the process of securing this financing?
   b. Which forms of financing did this project apply for, but not receive?
      i. What were the most important reasons for this, in your opinion?
   c. Which forms of financing would you like to receive for this project in the future?
      i. Why? What would happen if you do not succeed in securing these types of payment?
   d. How would you describe the influence of finances on the project?

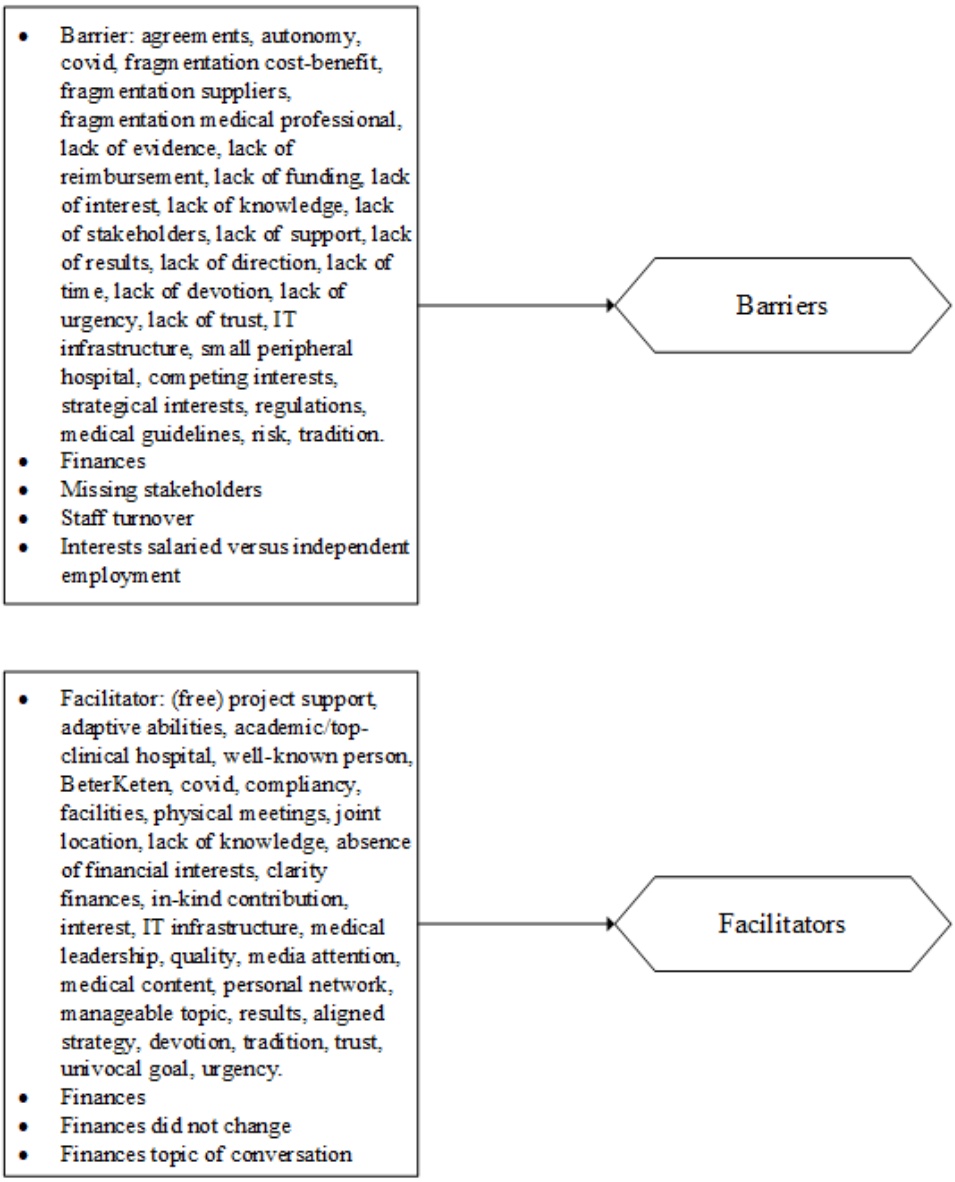
10) Stakeholders
   a. Which stakeholders are/were involved in the project?
      i. What is/was the role of these stakeholders?
   b. Are there any stakeholders you miss/ have missed in the project?
      i. What would be the additional value of these stakeholders?

11) Cooperation
   a. How was the cooperation between the different stakeholders?
   b. What was the impact of the project on the interaction between professionals within this organisation?
      i. What was the impact of the project on the interaction between doctors and nurses?
   c. What was the impact of the project on the interaction between professionals from different organisations?

12) Concluding remarks
   a. Any further questions or remarks related to the interview?

Appendix 4.b. Codebook




Barrier: agreements, autonomy, covid, fragmentation cost-benefit, fragmentation suppliers, fragmentation medical professional, lack of evidence, lack of reimbursement, lack of funding, lack of interest, lack of knowledge, lack of stakeholders, lack of support, lack of results, lack of direction, lack of time, lack of devotion, lack of urgency, lack of trust, IT infrastructure, small peripheral hospital, competing interests, strategical interests, regulations, medical guidelines, risk, tradition.
Finances
Missing stakeholders
Staff turnover
Interests salaried versus independent employment
Barriers
Facilitator: (free) project support, adaptive abilities, academic/top-clinical hospital, well-known person, BeterKeten, covid, compliancy, facilities, physical meetings, joint location, lack of knowledge, absence of financial interests, clarity finances, in-kind contribution, interest, IT infrastructure, medical leadership, quality, media attention, medical content, personal network, manageable topic, results, aligned strategy, devotion, tradition, trust, univocal goal, urgency.
Finances
Finances did not change
Finances topic of conversation
Facilitators

Appendix 4.c. Project descriptions and factors influencing the outcomes

1. Project description A

Project A is a collaboration project between care providers from secondary and tertiary care, focusing on treatment for a rare blood disease (immune thrombocytopenia) in children. The objectives of the project were to improve the knowledge of providers in the region concerning this rare disease, make clear agreements regarding the referral of these patients, document a care pathway for this disease and disseminate the protocol both regionally and nationally. The project group consisted of two providers from tertiary care and five providers from secondary care who met six times over the course of a year. Objectives reached in this project include a regional care pathway, also recorded as a guideline in the national medical manual, regional education of providers, information provision at a national conference, a reduced number of phone calls to tertiary care providers, and a positive experience to serve as foundation for future collaboration between these providers. The respondents were very positive about the outcomes, and stated *"we did not have to overcome major obstacles" (**A6**)*. All in all, this project showed how integrating care can be as easy as child's play: the objectives were reached, and the goal of integrating care was achieved to the level that was initially envisioned.

1.1 Description of financial factors project A

The project received no funding for development or implementation, apart from the resources of the BeterKeten organization, yet this was not perceived as harming the progress. The work done for the innovation project was perceived to be a part of the job description of medical professionals, even though it did require effort and time outside office hours. In terms of reimbursement, not a lot has changed in practice. Due to the small number of patients that were moved between providers, the low level of integration, and the involved providers being paid a fixed salary, conflicts of financial interests were absent. In contrast, the respondents felt the project produced feelings of clarity and security about finances. Secondary care providers gained the opportunity to treat patients for a longer period of time in addition to knowing exactly at what point tertiary care providers should refer patients back to them. Tertiary care providers were happy to spend their time only treating the most complex patients, given that they had their hands full with them anyways.

1.2 Analysis of influential factors within project A

In retrospect, the respondents stated that the disease and its treatment were especially suitable for designing a collaborative care pathway, because of three reasons. First, the highly uniform structure of the disease progression with only a few treatment options was easy to document. Second, the rarity of the disease combined with several very risky complications doubled the risk of severe mistakes and consequences. *"There is little experience in the peripheral hospitals: therefore, diagnosing these patients is difficult. The pediatricians in the academic hospital are only at the end of the line, and*

then it turns out there is a more serious issue" (document A4). "In case of a rare disease, for which experience is not quickly gained and at times fatal bleeding can occur, it is good to collaboratively document the treatment in a care pathway" (document A5). Third, the non-specialism-transcending treatment and very small niche of patients resulted in a limited number of involved parties and interests. *"Hematology is a niche area, and within it [ITP] is an even smaller area. So yeah, no one will have a problem with it. No board of directors will make a big deal out of it. So that helps" (**A2**).*

In addition to the manageable topic, the urgency of the problem, and the limited number of interests, we identified four factors that contributed to the achievements of this project. First, there was a willingness to change among the members of the project group. This willingness to change came from an interest in the topic, a medical focus on the quality of care provision, an initial lack of knowledge on the topic, and a general devotion to the project group as well as the urgency previously mentioned. Second, the willingness to change was directed towards the same goals. The respondents made note of a singular aim and an absence of any conflicting financial interests. The project was even perceived to clarify and better protect interests. Moreover, the number of patients was so small that the actual shift is relatively small, hence does not trigger large financial interests. *"Of course, it had to do with the fact that there are no shifts of large numbers of patients, there were no financial interests. And that's what makes it interesting for the medical specialists, the focus was very much on the medical content" (**A2**).* Third, the project had the resources to facilitate the change. These included the project support from BeterKeten, in-kind contribution from the project lead and project members who perceived this task as part of their job description, the network from the medical specialists, and the freedom to innovate in the involved top-clinical hospitals. Fourth, even though the respondents mentioned a lack of interest outside of the project group, the project was not impeded by this barrier because it did not need anyone outside the project group to participate in order to realize positive outcomes. On the other hand, several factors were mentioned to have complicated the progress of the project: a lack of time to schedule meetings, a lack of support in PR, and one project member being from a small peripheral hospital where innovation was facilitated less. Even though these factors might have impacted the process, they did not influence the eventual outcomes.

2. Project description B

Project B is a collaboration project between care providers in primary, secondary and tertiary care, focusing on an innovative treatment for allergies (immunotherapy). The treatment consists of two parts; the first, short-term initiation phase and the second, continuation phase which lasts for 3 to 5 years. At the start of the project, the treatment was used by different types of healthcare providers in secondary and tertiary care. However, it remained relatively unknown amongst general practitioners (GP) in primary care. Moreover, the continuation phase was in primary care perceived as being labor intensive, complex, and as having rare but very severe risks. In addition, the effectiveness was questioned by several respondents. The aims of this project were to standardize the provision of the

treatment amongst the different specialties in secondary care involved in the treatment, educate GPs in primary care about the treatment, promote the transition of patients from secondary and tertiary to primary care for the continuation phase, and develop a shared electronic health record (EHR) between care providers in all tiers. The project group consisted of eight providers from secondary care, two professors from tertiary care and two GPs, who met four to five times per year over the course of five years. The respondents mainly spoke about setbacks the project endured during these years: the project progressed for too long, the collaboration between care specialists from different tiers was arduous, and it proved difficult to recruit GPs to partake in the project group. Eventually, the respondents were disappointed with the lack of uptake of the treatment among the GPs. Moreover, several respondents mentioned the scope of the project kept broadening which made it even more difficult to successfully reach the objectives set. Consequently, not all of the project's objectives were reached, and the goal of integrating care was not achieved to the level that was envisioned.

2.1 Description of financial factors project B

The respondents mentioned significant financial barriers in the project, both inadequate funding and insufficient reimbursement were perceived to have played a role. The project received funding from private companies, with which to finance the development of the shared EHR and the appointment of a project manager. However, the funding was finite. After the funding was depleted, the maintenance costs of the EHR technology could no longer be financed and the work of the project manager was too intensive to be taken up by the providers themselves. The local hospitals, government and health insurers were contacted, yet none were prepared to invest in the integration project. Furthermore, the existing reimbursement fees for the treatment were not sufficient to cover the costs incurred for providing the treatment in secondary or tertiary care. Hence, moving part of the treatment to primary care could result in savings. *"So if you could organize it in a way that, well, those patients could go from the hospital to the GP. For the costs we make [and the reimbursement we receive], care can easily be arranged in primary healthcare. However, the transition of those finances is not easy to arrange"* ***(B1)***. In primary care, no reimbursement fee could be made available for providing the treatment and it was not possible to transfer money from the reimbursement available in secondary care to providers in primary care. *"Moving immunotherapy from secondary to primary care entails challenges in the area of reimbursement. The current fee for an extended consultation provides little incentive for the GP to take on this intensive task" (document B1).* These financial disincentives to take up the provision of the treatment resulted in suspicions from several project members regarding the underlying reasons for the project. On the one hand, respondents reported that the motivation to align and integrate care provision between medical professionals inspired the project. On the other hand, respondents mentioned that the actual motivation reason was likely to be financial.

2.2 Analysis of influential factors within project B

Four factors were identified to have hindered the project in reaching the objectives that were set. First, the willingness to change was not shared by all project members. Respondents mentioned a lack of direction, urgency, evidence, interest, and, eventually, results to have harmed the participation of project members. In addition, it was experienced to be difficult to arrange meetings due to a lack of time. Insufficient knowledge and high levels of perceived risk, combined with professional guidelines advising against the treatment, were said to reduce the willingness to change under GPs. *"Lack of specific knowledge regarding allergies in primary care and concerns regarding safety, turned out to be important obstacles in the past to shift patients for the continuation phase to the GP" (document B4). "In fact, I did not agree at all. And I still don't, based on considerations regarding quality" (**B2**).*

Second, the involved parties mentioned conflicting interests. The work, time and risks involved with the continuation phase resulted in some reluctance on the side of primary, secondary, and tertiary care providers to take up the treatment. *"How can I create support in my hospital [for this treatment]? It takes time and effort, for which we will not be reimbursed. Naturally, stakeholders are not very eager" (document B13).* Moreover, the innovative treatment would require the GPs to put in much effort to be educated about the procedure. An even more important source of conflicting interests was the financial disincentive, due to a lack of sufficient reimbursement for both tiers. The project members had approached both the national government as well as individual health insurers, to ask for financing of the integration. However, as one respondent argued, *"this condition does not have priority for payers" (**B1**)*, so no reimbursement was made available. The issue of contradicting financial incentives resulted in suspicions from several project members regarding the underlying reasons for the project and allergic reactions to the proposed integration plans.

Third, the project was impeded by a lack of resources, including funding, medical specialists, and project support, to realize change. The project received some funding from a pharmaceutical company to pay an IT company to create the shared EHR and finance the salary of a project manager. But, after all, the funding was finite, and after some time the project lost its resources. Maintenance costs for the app, as well as the rights to implement it, were taken over by the IT company. The work performed by the project manager was too much to be done by the medical specialists themselves. Missing this driving force significantly hurt the project. Respondents emphasized the negative influence of fragmentation between costs and benefits of healthcare innovation. According to one respondent, this kind of innovation is rarely financed upfront by the government or insurers, because the savings from the innovation should pay for the investments needed to realize change. However, as he explained the catch-22, "*without the savings there is no sufficient funding to realize those savings in the first place*" *(**B1**).*

Fourth, the fragmentation of a large number of GPs upon whom the project depended, made it very difficult to convince everyone in the region to participate in the transformation and succeed in reaching the objectives.

On the other hand, there were several factors that supported the project members in achieving some progress. First, the respondents positively recounted the project support from BeterKeten. Second, the general lack of knowledge on this innovative treatment created the opportunity to add something valuable. Third, the efforts and interest from the project lead and members of the project team were greatly valued by the respondents. Yet, eventually, the project support from BeterKeten ended, the project members were demotivated by the many setbacks, and they abandoned their efforts to integrate care.

3. Project description C

Project C is a collaboration project between care providers from two secondary care hospitals, focusing on an innovative diagnostic method for people experiencing dizziness. Despite the commonality of this disease, patients often fall through the cracks of the traditional healthcare system. The disease is complex, with high levels of multimorbidity, and setting a diagnosis requires a lengthy examination based on listening to the patient's life story. Traditionally, this required the patient visiting multiple hospital departments and a lot of deliberation between specialists. The innovative approach proposed in this project consists of a lengthy, multidisciplinary consultation including different specialists in which the patient can be diagnosed timely and referred to the proper treatment. A holistic approach towards the patient is key to this innovation. Accordingly, the aims of this project were to set up a multidisciplinary consultation hour, and to design clear triage and treatment protocols regarding the care pathway. The motivation for the project can be found in the personal interest of one of the project leads, who saw a similar innovative approach towards the disease in another region of the Netherlands. Hence, the start of this project was described by one of the respondents as *"a hobby that got out of hand"* ***(C5)***. The project had been ongoing for five years, and the project members had expanded from solely two secondary care providers to a group with support staff from project management, communication, administrative, and financial departments, and management of the hospitals. The respondents were very positive about the achievements, including a multidisciplinary consultation hour at a joint location, a multidisciplinary meeting with additional medical specialists to discuss further treatment of multimorbid patients, an integrated administration and reimbursement structure, a website and other communication materials. All in all, the respondents indicated that the project turned out to be a dazzling success: the objectives were reached above and beyond the initial vision of the project leads, and the goal of integrating care was achieved.

3.1 Description of financial factors project C

After the initial start of the multidisciplinary consultation by the care providers, the project was picked up by the hospitals' management. They decided to award the project the status of value-based healthcare project, in line with the hospitals' strategy, which made available support staff from the hospitals and investments from the innovation payments received from insurers. This way, minimal financial barriers were experienced for the development and implementation of the project. Contrarily, the most difficult part of the integration project was experienced to be agreeing on reimbursement arrangements for the present and the future sustainment of the project. Initially, costs were divided fifty-fifty between the two providers and the consults were registered as a regular consult with one medical specialist. However, the amount of reimbursement received for a regular consult did not cover the costs of the longer consultation with multiple specialists. In the absence of appropriate financial and administrative agreements between the two hospitals and with the insurers, a financial conflict of interest threatened the sustainability of the project. *"It is stated that the financial prospect must be established before the collaboration can commence" (document C16).* However, when the project gained access to support staff from the hospitals, there was a possibility to negotiate an agreement with the health insurers about a DRG-registration code and an appropriate reimbursement fee. Therefore, the financial conflict of interest was resolved and the project is currently sustainably implemented. For the future, however, the hospitals are bound by national agreement to zero growth in production. Agreeing on extra reimbursement for innovative treatments automatically results in fewer room to provide other, regular, treatments. *"The response given by insurers is always: 'It's fine if you want to perform more of this, but you have to look internally what you can do less'. It is kind of a waterbed effect" (**C2**).* The current limits on the number of patients that can be seen in the dizziness center have resulted in long waiting lists and a difficult choice for the hospitals about which treatments they will continue to provide. Moreover, the innovative treatment takes up a lot more time, resulting in fewer total patients treated hence lower income for the departments involved. Therefore, even though financial agreements have been made between the hospitals and insurers, agreements about the distribution of reimbursement within the hospitals had not been finalized yet. Nevertheless, all respondents were convinced this issue will be solved.

3.2 Analysis of influential factors within project C

Four factors have been identified to have added to the achievements of this project. First, the project group members, specifically the medical specialists, were devoted to change. They expressed an interest in the topic, praising the focus on improving quality of care provision and acknowledging the urgency of the problem. Moreover, the project started showing results in practice very early in the process, strengthening the conviction that the project members were on the right track. Second, the people involved in the project were aiming for a univocal goal and the respondents mentioned that the envisioned innovative treatment was reachable. Financial interests were eventually not

experienced to hinder the project substantially, because the specialists themselves stated to have no interest to get involved in financial discussions and the financial departments of the hospital managed to reach agreements with most of the parties involved. Finally, respondents mentioned that there was a high level of pre-existing trust in the hospitals and different departments wanting to reach the same goal, so the financial agreements that had not been reached yet were expected to follow soon. *"I think the main reason is the presence of mutual trust, which we created together in the years before this project. It is multifaceted: trust among the medical specialists, who really know each other very well which makes you believe that also on the content you will figure out a way, and trust between the financial departments. [...] You really notice if that trust is absent or very brittle, the smallest issue arises and you are immediately set a few steps back or the project comes to an end"* ***(C2)***. Despite potentially severe financial barriers along the way, the project managed to prevent a conflict of interest. Third, this project had abundant resources to make change happen. The resources started with the in-kind contributions of the project leaders and their network, followed by the project manager and (financial) support from a top-clinical hospital and eventually a joint clinic location with essential facilities. In addition, the media attention resulted in a high demand for this treatment, making it even more of a success. Fourth, even though the respondents mentioned a lack of interest from medical specialists outside of the project group, the project was not impeded by this barrier because it did not rely on anyone outside the project group to participate in order to realize positive outcomes.

On the other hand, there were some barriers to overcome in this project, including difficulties in making agreements due to the large number of interested parties involved, a lack of time, a lack of knowledge, rigid regulations, and a lack of reimbursement. Yet, the project group was able to overcome these barriers because of the high level of trust and devotion between the parties, and the access to support staff from the hospital who were able to figure out ways to arrange innovative administration codes and financial agreements with insurers.

4. Project description D

Project D is a collaboration project between care providers from secondary and tertiary care, focusing on pharmaceutical treatment with biologicals for inflammatory bowel disease (IBD). The aim of this project is to develop and implement a uniform care pathway for this treatment across the region. Apart from this general understanding, respondents' views diverged concerning the specific objectives of the project. Several respondents were convinced that there was potential to improve the quality of care by reducing regional variation in outcomes and costs. Or the quality of care could be improved by reducing within-hospital variation caused by different generations of specialists in hospitals who adhere to different treatment pathways. Other respondents simply stated that reaching uniformity in treatment was the goal in itself. Another motivation mentioned was to develop a minimal care pathway that prescribes a basic level of care all patients are entitled to. Contrarily, a motivation could have been to reduce the activities in the treatment to prevent

unnecessary care. A respondent mentioned the motivation for the project was to reduce costs and improve cost-effectiveness, because *"it's what we always have to focus on"* (D11). There were also respondents who stated the care pathway was developed for research reasons, in order to be better able to compare the effects of future innovations in the treatment. Finally, one of the project members argued there was no specific reason behind the project but *"the project just existed"* (D7).

The project group consisted of a PhD candidate, a medical specialist from tertiary care, thirteen providers (both medical specialists and nurses) from secondary care and IT support staff from the involved hospitals. The project had been active for four years, starting from the commencement of the PhD candidate, and achievements mentioned by the respondents included developing a uniform regional care pathway that potentially could help to reduce care activities; adaptation of the IT-infrastructure; and several scientific publications. Nonetheless, most respondents expressed doubts about the benefits of the project, the scope of collaboration and standardization in practice, and the actual changes made in the care provided. Many respondents felt a standardized care pathway was hard to swallow thus they deviated from the pathway at their own discretion. Other respondents even admitted they did not (consciously) follow the pathway at all. Moreover, the care pathway had been adapted to the wishes of every hospital, resulting in an absence of real standardization. As the objective was described in one of the ambition documents: *"Standardization of IBD care within the region with due observance of differentiation of the hospitals" (document D22). "The care pathway was adjusted to the local context as to not disrupt local processes" (document D2).* In conclusion, there are strong question marks whether this project has integrated care sufficiently. Thus, although the objective to develop and disseminate a uniform care pathway was realized in this project, implementation in practice was only partially successful and most respondents state that the goal was not achieved to the level that was envisioned.

4.1 Description of financial factors project D

The respondents described the effort they had to make to get sufficient funding for a PhD candidate, who could manage the project and study the results. The project team eventually managed to organize sufficient funding and the research project could start. Financial support was not required for other aspects of the project, the IT staff was on the payroll of the participating hospitals and the care providers stated that innovation of care was part of their responsibility as care provider. Furthermore, the project had no significant impact on reimbursement amounts because adjustments to the care provision were limited. In addition, most of the respondents perceived the financial aspect of the project as the responsibility of the financial departments.

4.2 Analysis of influential factors within project D

Three types of facilitating factors were identified. First, the project members had an interest in the topic from a medical perspective and they were positive about the opportunity to gain knowledge on a medical topic with limited evidence. Also, the proposed care pathway was perceived as

manageable and providers also praised its adaptability to each hospital. Second, respondents mentioned there were no conflicts of interest, because financial interests did not have an influence (no major changes in care provision hence no major changes in reimbursement amounts) and the respondents trusted the other project group members who they had been collaborating with for many years. Third, the project had access to resources to make change happen. These resources included the funding for a PhD researcher, who also acted as project manager, project support from BeterKeten, the project leaders and group members in-kind contribution, the possibility to use the available expertise of different departments of specialists of an academic center, and the IT support staff of the participating hospitals.

Despite these facilitating factors, the project does not seem to have reached their goal of persuading every care provider to work with a uniform pathway. The main factors identified as impeding this progress are twofold. First, a limited sense of urgency, a lack of direction, and a shortfall to formulate a univocal goal among the respondents were identified. Second, the respondents mentioned high levels of professional discretion and autonomy, and therefore differentiation in the manner in which individual medical specialists provide this care. As described in one document: *"The manner in which the care pathway will practically be implemented may differ per hospital. [...] Because there are no strong arguments to direct this [specific ways to provide the treatment], the hospitals are free to decide for themselves" (document D47)*. These two factors resulted in care providers being hesitant to work with a uniform care pathway, especially those who were not part of the project group. In addition, respondents also mentioned that other obstacles were a lack of time, smaller hospitals that are less able to support innovation, and rigid privacy regulations regarding data sharing.

Appendix 4.d. Influential process factors

Table 4.I. Influential factors (financial and other) influencing the progress of each project but not determining the eventual outcomes.

Project A	Project B	Project C	Project D
Barriers that were overcome • A lack of time to schedule meetings. • A lack of support in PR. • Small peripheral hospitals facilitating innovation less.	Facilitators that were not sufficient • General lack of knowledge about this innovative treatment created the opportunity to add something valuable. • In-kind contribution from the project lead and members of the project team. • Project support BeterKeten.	Barriers that were overcome • Difficulties making agreements due to many parties involved. • A lack of time to schedule meetings. • A lack of knowledge about the possibilities to embed innovations structurally. • Rigid regulations.	Facilitators that were not sufficient • General lack of evidence and guidelines created the opportunity to add something valuable. • Proposed integrated treatment perceived to be reachable. • Treatment adaptable to local circumstances. • Absence of financial or other interests, due to limited changes in care provision. • High level of trust between project members. • Sufficient resources for change.

Chapter 5

Understanding the complexities of the scale-up of eHealth innovation: A cross-disciplinary analysis and qualitative case study

Journal of Medical Internet Research, 2024; Forthcoming

Abstract

Innovative eHealth technologies are becoming increasingly common in healthcare systems worldwide, with researchers and policymakers advocating their scale-up within and across healthcare systems. Examples of successful scale-up remain extremely rare, however. Although this issue is widely acknowledged, we still have only a limited understanding of why scaling up eHealth technologies is so challenging. This study aims to contribute to a better understanding of the complexities innovators encounter when attempting to scale up eHealth technologies and their strategies for addressing these complexities. We performed a qualitative study investigating challenges and strategies around eHealth technology scale-up, drawing on both theoretical perspectives and the findings of an interview-based case study of a prominent remote patient monitoring (RPM) innovation in the Netherlands. We created a cross-disciplinary theoretical framework bringing together three perspectives on scale-up: a structural perspective (focusing on structural barriers and facilitators), an ecological perspective (focusing on local complexities), and a critical perspective (focusing on mutual adaptation between innovation and setting). We mobilised these perspectives to analyse how various stakeholders (n=14) experienced efforts to scale up RPM technology. Our study revealed two key insights: 1) the complexities and strategies associated with local eHealth scale-up are disconnected from those actors encounter at broader level scale-up; this translates into a simultaneous need for stability and malleability, which catches stakeholders in an impasse; and 2) pre-existing circumstances and associated path dependencies shape the complexities of the local context and facilitate or constrain opportunities for the scale-up of eHealth innovation. We conclude that the level at which scale-up is envisaged and pre-existing local circumstances – two factors whose importance is often neglected – contribute to an impasse in the scale-up of eHealth innovation at the broader level of scale.

5.1 Introduction

Innovative eHealth technologies, defined in this paper as tools that support the organisation and delivery of health services and information using the internet and related technologies (275), are becoming increasingly common in healthcare systems worldwide. These technologies have been discussed in the literature with careful enthusiasm, with studies often weighing challenges related to "privacy, liability, and costs" (276) against their potential to support patient-centred care, remote patient monitoring, and prevention (277–280). In addition, eHealth technologies have become increasingly central in policy debates, with policymakers consistently articulating high expectations around eHealth's role in healthcare's future sustainability.

The literature often singles out the fragmentation of the eHealth landscape as a potential hindrance (281 ,282). Such fragmentation is found to result in various problems, including non-dissemination of valuable innovations (1 80); inequalities resulting from a failure to reach patients who have the greatest needs (283) and/or who reside in specific areas (284); and generally unsustainable implementation, given that eHealth providers need to achieve a considerable level of coverage to become (economically) viable (1 41).

Scale-up is often proposed as a remedy in this context (285). For instance, policymakers have advocated replicating proven eHealth technologies within and across healthcare systems. In its global strategy 2020-2025, the World Health Organisation (WHO) recommends focusing on nationwide scaling of eHealth technologies, proposing that principles such as *scalability and replicability* should be at the heart of current efforts around eHealth development and implementation (286). Many national governments have also attempted to support the scale-up of eHealth technologies, emphasising that stakeholders should share and adopt best practices rather than reinvent the wheel (287,288).

Despite this dominant rhetoric, examples of successful eHealth technology scale-up are few (289). Widespread adoption is plagued by the "diffusion chasm", with a gap opening up between initial invention and successful market penetration (290). A recent literature review, for example, found that none of the eHealth technologies implemented in the United Kingdom managed to reach organisation-wide or large-scale adoption (1 42). Similarly, a publicly funded programme in the Netherlands aimed at introducing eHealth technologies nationwide (291) ultimately fell short of its goal, i.e., to counteract fragmentation and encourage further scale-up of local initiatives (292).

Although the poor scale-up of eHealth innovations is widely acknowledged (293), we still have only a limited understanding of why scaling up eHealth technologies is so challenging. So far, research has described the stagnation of eHealth implementation without articulating clear strategies to overcome it (294), (295). These studies focus on the local implementation of pilot eHealth

technologies and assume that this process has a clear beginning (i.e., the introduction of an innovation in a specific organisational setting) and an end (i.e., the innovation being structurally embedded in that specific organisational setting). What came before and what comes after is often left out of the picture. Thus, although researchers acknowledge the necessity of scale-up for sustainable eHealth innovation, they typically end up studying implementation issues as though they were separate from scale-up (296). This narrow approach does not contribute to our knowledge of what scaling up eHealth (and the complexities associated with it) entails or of promising strategies to facilitate scale-up.

This study seeks to address this knowledge gap by answering the question of what complexities are encountered when attempting to scale up an eHealth technology and what strategies are applied by stakeholders to deal with these complexities. We start by describing and combining insights from three existing theoretical perspectives on technology scale-up in and beyond healthcare. We then bring these insights to bear on eHealth by examining a case study of a Dutch eHealth technology that, despite being considered a success at the local level, encounters major (and common) challenges when being scaled up. By mobilising empirical insights stemming from the case analysis, our discussion contributes to existing theorisations of the complexities of scale-up, thus illuminating other dimensions of these difficulties as stakeholders experience them in practice.

5.2 Theoretical perspectives

5.2.1 Meaning of scale-up

While numerous, common definitions of scale-up in the literature fall into two categories. The first describes scale-up as *the replication* of an existing innovation in *"multiple geographic locations and contexts to maximise the number of people that an innovation reaches"* (297). Conversely, the second describes scale-up as *the gradual adaptation* an existing innovation undergoes as it becomes embedded in more and more dimensions of healthcare practice (i.e., covering more patients, involving more providers, or adding to the steps involved in care provision). Although they differ in how they regard the innovation itself, both definitions consider the core of scale-up to be an expansion of an innovation's *coverage*. Consistent with this, Spicer et al. (298) define scale-up as *"an increase in the coverage of health interventions that have been tested in pilot and experimental projects in order to benefit more people"* (p.31). This paper defines scale-up, in the broadest sense, as the steps taken to progressively expand the coverage of an existing innovation.

5.2.2 Theoretical perspectives on innovation scale-up

In this section, we offer a high-level discussion of a number of theoretical perspectives that various disciplines have developed to think through the complexities associated with innovation scale-up. The three cross-disciplinary perspectives we have selected are by no means an exhaustive list of the theoretical approaches to implementation and scale-up proposed in the literature. They do, however, mobilise a diversity of viewpoints and arguments that enable us to illuminate crucial aspects of the complexities of technology scale-up, giving us a generative heuristic framework for our analysis. Selected precisely by virtue of their differing approaches, the three perspectives synthesise a variety of middle-range theories stemming from conventional management scholarship, complex adaptive systems theory, and critical social science approaches respectively, but for brevity's sake we refer to them as a structural, an ecological, and a critical perspective. Although these labels might appear arbitrary, we argue that they emphasise crucial aspects of each perspective: a structural perspective's focus on high-level mechanisms and a somewhat immobile social world; an ecological perspective's emphasis on interactions of different (human) components of health systems; and a critical perspective's attempt to politicise scale-up as well as subvert its commonsense conceptualisations. In what follows, we first illustrate these perspectives' conceptualisations of the complexities around and solutions for enabling scale-up. Subsequently, we combine these theoretical perspectives to analyse a real-world eHealth innovation case.

Structural perspective

The structural perspective, particularly prominent in economic and management theories, foregrounds the role of structural system barriers in hindering scale-up beyond the local level, with the possibility of scale-up resting on the removal of these barriers. For instance, Wang et al., in their study of telehealth adoption in the United States (299), find that the medical-legal framework of healthcare delivery impedes the successful scale-up of telehealth. As they argue, *"policymakers must rethink and address the economic incentives and payment of telehealth services, the medical-legal issues surrounding virtual care, and the effects of increased competition across geographic areas and jurisdictions"* (p. 675). Similarly, Gijsbers et al.'s scoping review (300) concludes that *"successful upscaling of telemonitoring requires insight into its critical success factors, especially at an overarching national level. [...] A wide programme on change management, nationally or regionally coordinated, is key"* (p.1). In sum, the structural perspective proposes that system-wide innovation scale-up depends on overcoming all critical barriers, assuming that it is possible to adjust systems to remove such barriers.

Ecological perspective

The ecological perspective, rooted in organisation studies and health systems research, emphasises the local, interrelated factors that must be considered to scale an innovation locally and replicate it

in another setting. Greenhalgh and Papoutsi's (301) analysis of the different logics that challenge the dissemination of innovations exemplifies this perspective:

> *"Complexity can be hard to square with spread strategies that seek to replicate a "blueprint" innovation in a standardised way across widely different settings. The plan-do-study-act engine might work for small-scale improvement initiatives, but spreading and scaling up major innovations across a health system requires attention to the underlying logic of complex systems, which is ecological rather than mechanical." (p.2)*

In another study, Greenhalgh et al. argue that explaining the complexities of innovation in terms of barriers and facilitators does not sufficiently acknowledge the intricacies of the setting in which it is introduced. Studies that we group under the ecological perspective emphasise, for example, the importance of conducting sensemaking work among stakeholders before replicating an innovation (302). Others emphasise the need to acknowledge the dynamic relationship between different factors in a local setting (144), or argue that an innovation must fit in with the diverging institutional logics of all relevant stakeholders before they can accept it as part of their practice (303). In short, the human and technical characteristics of the local setting (e.g., belief systems of local providers, technical interoperability of adopted and pre-existing systems, stakeholders' clashing institutional logics) must be acknowledged and worked on before an innovation can be scaled from another context.[1] In other words, the ecological perspective postulates that a successful innovation scale-up requires work to adapt the local setting so that it will accommodate the innovation.

Critical perspective

A more critical perspective on scale-up has been formulated by authors active in the field of science and technology studies (STS). For instance, in their article on the politics of scaling, Pfotenhauer et al. describe scaling as a current *"obsession of innovation discourses and, with it, contemporary social, political and economic life at large"* (p.4) [306]. Critical reflections on scaling often build on Anna Tsing's definition of scalability as the ability of a system to *"expand without changing"* (304) and, according to Hanna and Park, without *"rethinking its constitutive elements"* (305). These authors shed a different light on the local uniformity that the ecological perspective posits as necessary for scaling up: adapting local systems generates tensions because it disregards the diverse ways in which people define problems and solutions, priorities, and values. As Pfotenhauer et al. argue, any narrative presenting scaling up as a smooth process is suspicious because it probably excludes certain perspectives (306). Hanna and Park argue that the very idea of scalability as replication entails that

[1] An example of a widely used theory applying this perspective is the RE-AIM framework, which fits in with a social-ecological perspective (351). It conceptualises the impact of innovative programmes as depending on the percentage and characteristics of the people who receive or are affected by the intervention. Eventually, its aim is for innovations *"to become a relatively stable, enduring part of the behavioral repertoire of an individual, organization or community."*

the work that sustains innovation needs to be something *"interchangeable, abstract and universal"* (305). Thus, in scaling-up discourse, the emphasis ends up being on standardisation of infrastructure, for instance, at the expense of more relational views that stress the inherently more unpredictable and therefore flexible work needed to maintain networks of humans and technologies. In other words, the critical perspective describes the need to examine innovations in their specific context of emergence, assuming that during implementation both the innovation and the local setting are reshaped in a work-intensive process of mutual adaptation, and that some type of local knowledge or practice is inevitably lost in this process. Unlike the ecological perspective, the critical perspective suggests that replicating a blueprint innovation in a new setting requires work to adapt not only the context but also the innovation itself.

Cross-disciplinary framework

Table 5.1 summarises the characteristics of the three perspectives on innovation scale-up. We have combined the three perspectives into a cross-disciplinary framework, with each one making a unique contribution.

The structural perspective advocates removal of systemic barriers and strengthening of facilitators, assuming that the changes required to stimulate scale-up can be pinpointed. This perspective contributes to our framework by focusing on the structural facilitators and barriers (e.g., regulatory, financial) that emerge in systems and that support or hinder innovation up-scaling.

The ecological perspective teaches us that conditions at the local level are complex and diverse; we cannot expect to know in advance what needs to be done for innovation to "work" in a specific setting. Local complexity must be considered before introducing an innovation in a new setting or to new users. This perspective assumes that the innovation itself remains largely unchanged in the process of scaling, and that it is crucial to convince users of its utility or value and to create a fitting context. This perspective contributes to our cross-disciplinary framework by highlighting aspects of the local context that are perceived to influence the past and future evolution of the innovation.

The critical perspective assumes that the process of organisational embedding transforms both the context and the innovation to such an extent that the very possibility of scaling a specific innovation needs to be questioned. This perspective does not suggest that scaling up is altogether impossible, but it does emphasise that the innovation itself changes continuously in local scale-up processes as it potentially loses or gains aspects while moving across localities. This perspective contributes to our framework by focusing on the possibility that the innovation itself must adapted during the scale-up process in response to the context to which it is being scaled.

Table 5.1. Summary of the three theoretical perspectives on innovation scale-up.

Perspective	Complexities of scale-up	Type of solution
Structural	Structural factors support or hinder successful scale-up of innovation	Remove structural barriers and strengthen structural facilitators
Ecological	Local context defines whether the innovation can be successfully scaled up	Prepare local contexts for the replication of an innovation
Critical	Innovations cannot be uniformly applied to different contexts and must adapt in response to changes in the context	Rethink scaling up beyond blueprint innovations; acknowledge the mutual transformation of local context and innovation as necessary

5.3 Methodology

We examined why it is so difficult to scale up eHealth technologies in actual practice by performing a qualitative case study of an eHealth technology in the Netherlands. We used the cross-disciplinary theoretical framework for innovation scale-up described above as an interpretative lens. We selected the case purposively because the media had portrayed it as a best-practice example of remote patient monitoring (RPM) in the Netherlands, with its developers and the care professionals involved advocating its wider-scale implementation.

5.3.1 Case description

The eHealth technology considered here consists of several measuring devices for physiological variables (e.g., weight, blood pressure, heart rate) and a smartphone app to enable RPM in a Dutch university medical centre. Patients perform the measurements at home according to a pre-determined schedule, after which the data are automatically sent to the care professionals at the hospital. This eHealth application is meant to encourage healthy behaviour in patients by showing them their progress and to allow care professionals to monitor their treatment more closely by sharing continuous health measures. In addition, it greatly reduces the need for outpatient visits. The cardiology department of a Dutch university medical centre initially implemented this innovation to monitor one specific group of patients and then attempted to extend it to other cardiology patient populations and other departments. Research framed the innovation as a local success: first, it showed that the health outcomes of patients using the innovation did not differ substantially from those of patients following standard face-to-face care trajectories; second, it showed that patient experience improved, that patients became more involved in their own care, and that care professionals had better insight into patients' health (references omitted to preserve anonymity).

5.3.2 Data collection

We performed 14 semi-structured interviews (average duration of 60 minutes) with professionals involved in the development, implementation and scaling of the innovation. All respondents provided informed consent, and interviews were audio-recorded and transcribed verbatim. The respondents included 2 researchers who developed the innovation, 4 healthcare professionals (nurses and doctors), 3 IT professionals, 2 project managers (cardiologists), 1 department manager, and 2 liaisons from a MedTech company. Potential respondents were identified through snowballing, starting with the current project lead, and recruited via email. Recruitment stopped when respondents started referring us to people we had already interviewed, thus indicating that we had consulted all the main actors involved in the case. Moreover, while different respondents may have been better or less well acquainted with particular aspects of the innovation's trajectory, the similarity between their views and arguments around scale-up indicated that we had reached analytical saturation.

Most of the interviews (12 out of 14) were conducted jointly by the first two authors (SA and CC) to ensure that the data collection reflected the cross-disciplinary perspectives at the heart of this study's design. The remaining two interviews were conducted by one or the other. One of the interviewers has a background in healthcare economics/management and the other in sociology/organisation science and also studies healthcare systems. The two interviewers jointly developed semi-structured topic lists and adapted them to the specific expertise of each respondent. Respondents were asked to reflect on such topics as how they experienced developing or using the innovation, difficulties encountered during its development or implementation, changes in care provision and infrastructure, interaction between stakeholders, and views on the future of the innovation.

5.3.3 Data analysis

We performed data analysis abductively, going back and forth between the insights from theory and the empirical data (307). This paper's focus on scale-up emerged organically as part of this abductive process. Indeed, we initially aimed to investigate what made the innovation a "successful" eHealth innovation. The respondents questioned this depiction of the innovation, however, as they did not perceive its development as finished. Scale-up emerged inductively from our interview data as a central theme in actors' attempts to make sense of what they were involved in and spurred the development of our cross-disciplinary theoretical framework. Using this framework, we analysed the narrative generated by the respondents as they reflected on the past and future evolution of this eHealth technology, including their views on scale-up. Our aim in combining and comparing the different perspectives was to gain a richer understanding of the scale-up of eHealth innovation. Based on the theoretical perspectives, we identified five themes and used these to code the interview transcripts deductively, making use of the qualitative analysis software Atlas.ti 23 (308). The first

two themes were related to the different meanings of scale-up (*gradual adaptation* within the same setting or *replication* in a new setting) and the nature of scale-up and its complexities (*barrier or facilitator* for the structural perspective, *complex local factor* for the ecological perspective, *mutual adaptation of innovation and context* for the critical perspective). Additionally, we highlighted parts of the interview transcripts that presented reflections beyond the insights of the theoretical framework and coded them inductively, following Braun et al.'s guidelines (262). This resulted in three additional themes: *process description*, *discourse on scale-up* and *discourse on the innovation*. Subsequently, using both the deductively and inductively coded interview fragments, we created a chronological narrative piecing together the respondents' perspectives. This narrative consists of three parts, which structure our results: the development and initial embedding of the innovation; its local organisational scale-up; and its broader cross-organisational scale-up.

5.4 Results

Regarding the scale-up of the eHealth innovation, we noted that the respondents' narrative distinguished between *local* organisational scale-up (instances where the innovation's scope was expanded to include more dimensions of care practice in the same organisation) and *broader* cross-organisational scale-up (replicating the innovation in a new organisation). We have therefore structured this section accordingly. First, we describe how stakeholders made sense of what happened during the initiation and embedding of the innovation. These early experiences demonstrate the importance of pre-existing circumstances for local scale-up. Then, we present respondents' reflections on the local scale-up and the complexities encountered during this process. Finally, we discuss respondents' current experiences and future ambitions for scaling up their innovation to other organisations.

5.4.1 Initiation and embedding of the original innovation

Initiation of the original innovation

The innovation project started around 2015 at the cardiology department of a Dutch university medical centre. As its initiators report, the project was driven by the will to innovate the practice of cardiology by moving part of care provision outside the hospital using RPM. However, as one of the respondents described, *"it wasn't like this happened suddenly. [...] The undercurrent was already there"* (ProjectManag1). Several respondents referred to this *"undercurrent"* to describe the facilitating circumstances in the department prior to the project's initiation. We discuss three of these pre-existing circumstances below: the maturity of the department's IT infrastructure, the highly standardised care pathway for (some) patients, and the facilitating workflow, culture and resources.

First, in the early 2000s, this department was one of the first in the country to develop and implement an electronic health record (EHR). The in-house EHR gave the department a tailored, flexible infrastructure into which RPM devices and data could be integrated. The department also had an internal team of dedicated IT professionals who supported staff in integrating the hardware and software and were available to continuously adapt the EHR structure and its data visualisation. As one respondent stated, *"that made it easier, let's say, to add more things to our own electronic patient record. That was in fact a reason [for the innovation's success]"* (DepartManag1).

Second, the RPM project built on another project that had introduced a care pathway protocol, thereby restructuring care provision for a patient group. As reported by one of the innovation's initiators, this standardised care pathway laid the groundwork for RPM: *"the idea [of reducing patients' visits to the clinic] came from the project that had already been running in the department for years"* (IT1). Introducing the care pathway protocol had brought up two important points for consideration: on the one hand, the numerous physical contact moments between medical professionals and patients and, on the other, the lack of data on these patients between hospital visits. Thus, besides providing clarity on disease progression, and a *"very well-defined care track"* (DepartManag1), this project also singled out points for improvement that could be addressed through RPM technologies.

Third, the RPM project's initiators also highlighted how the practice and culture of cardiology is highly technology-, data- and innovation-driven. The department prided itself on its early adoption of earlier innovative technologies such as pacemakers, and for being *"used to problems with patients with home monitoring devices"*. In turn, this meant that they *"already had a very fast technical back office to help patients with their problems"* (DepartManag1). The professional workflow and culture at the department therefore enabled a transition towards technological innovation. In addition, being part of a university medical centre allowed the department to invest in several PhD candidates whose research on protocolised care pathways, IT infrastructure, and the innovation itself supported the transformation.

Embedding of the original innovation

After the innovation's inception, embedding it required a lot of time, effort, and communication. Many issues emerged, ranging from technical (i.e., selecting appropriate monitoring devices and finding ways to integrate data from commercial devices into the EHR) to governance-related (i.e., negotiating issues of safety, financing and medical device regulation) and usability (i.e., educating patients and professionals about a new form of care provision and discussing it with them). The department needed to undergo further significant changes to embed the innovation. Below, we discuss examples of changes in professional tasks and roles, IT, and physical infrastructure.

First, the department's staff – in particular specialised nurses – had to adapt their tasks and knowledge infrastructure. Crucially, nurses became responsible for interpreting the incoming RPM data and for following up with appropriate actions. This new task required them to re-specialise to provide care based on data produced remotely by patients. Specifically, as one of them stated, nurses had to become *"aware that [a number] is just a number, [...] measured by the patient in the home setting, by a device of which I'm not sure how old or how reliable it is"* (Nurse1). This required them to view measurements as not always trustworthy, as numbers that offered guidance but could not be taken at face value. This new orientation stemmed from first-hand experiences on the job, and from sharing these experiences with their colleagues. Furthermore, the department created a new role: *"eHealth consultants"*, tasked with distributing the innovation to patients, instructing them in its use, and addressing technical questions. By hiring eHealth consultants, the department acknowledged the work needed to guide patients in their use of the innovation and formally integrated tasks previously conducted informally by PhDs into the organisational structure. These organisational changes resonate with the ecological perspective in our theoretical framework.

Second, embedding the innovation in the department also involved adapting the innovation itself, reflecting the critical perspective articulated above. For example, the IT department, in collaboration with local nurses, developed a new dashboard in the EHR to visualise incoming data; they also installed secured software to enable e-consultations with patients, and developed an app to give patients personalised instructions.

Third, the hospital's physical infrastructure was also adapted. Specifically, the department transformed a central space in the hospital into an office where patients could meet the eHealth consultants and discuss their questions. As explained by a cardiologist:

> *"At this point there also came a different kind of department that had a focus on the innovation only, so they make sure that the patient gets the devices, they make sure that everything is electronically connected the right way, that the data are coming in, they always call the patients within 2-3 weeks to make sure that everything is going well, that the data are coming in. So I think that was crucial."* (Doctor1)

All these infrastructural changes were financed through the departmental budget and temporary research grants. According to the respondents, this was possible only because the cardiology department had access to more financial resources than other departments in this and other hospitals. Moreover, the department was responsible for the care pathway of the patient target group from beginning to end, giving them the autonomy necessary to transform care provision. As explained by the external project manager, *"because it's only their department, that makes them really quick in making decisions and going forward"* (ProjectManag2).

Analysing the innovation's organisational embedding highlights the necessity of addressing structural financial and regulatory barriers early on, and the need for a flexible and continuously developing local infrastructure. In addition, the innovation itself changed in response to the requirements of the local setting. With regard to embedding, then, the respondents' narrative resonates with the structural, ecological and critical perspective.

5.4.2 Local scale-up of the innovation

We now turn to an analysis of the innovation's evolution from its initiation (2015) to the period of data collection (2022). This period saw a local scale-up in terms of (i) the patient population covered by the innovation, (ii) technical aspects of the innovation, and (iii) the number of departments using the innovation. Each of these expansions of coverage faced several complexities.

Some of these complexities relate to the ecological perspective. To begin with, local scale-up focused on replicating the innovation within the cardiology department to cover new patient groups. This had major consequences for the care professionals involved (again, nurses in particular). Patient numbers and data collection requirements increased, placing a significant burden on the department's care professionals, who perceived the amount of data generated by up to 400 patients daily as overwhelming. Moreover, scaling up to other patient populations increased uncertainty in nurses' daily tasks, leaving them unable to plan and putting them under more stress. As one respondent explained:

> *"If you have patients who are continuously doing these measurements at times that they find suitable, they contact you at unpredictable times with questions that can be emotional, that can be technical, they can be completely fine, but they can also be extremely ill, and you must adjust your actions as a medical professional accordingly. That type of unpredictability, when you don't know at the beginning of the day where it's going to end, that just introduces some stress."* (Doctor2)

Several nurses decided to *"evaluate critically how often they check those measurements, because it is such a huge investment of time and such a burden"* (Nurse2). Nurses started looking critically at the real benefits of the deluge of data they received, and began to wonder whether *"it could potentially be better to place the responsibility with the patients"* (Nurse2). As a result, patients were increasingly instructed to keep an eye on their own data and explicitly made responsible for contacting the hospital if they believed something was wrong.

Complexities described by respondents also resonate with the critical perspective, since the innovation had to be adapted based on the needs and possibilities of the local context. For instance, the project leads continuously added hardware (i.e., new measuring devices) to the innovation to provide more extensive data. As one of them explained,

> *"What we're trying to do is check whether there are more non-invasive devices that you can combine to make sure that you can see that the patient is developing heart failure again as soon as possible. So that's why we're continuously monitoring and checking, okay, what could we add that could possibly help us? Because now we only have the step counter and the weight scale and the blood pressure monitor, but maybe, just maybe, it will help us if we can look at the sleep monitor as well. Because there will be some data that we can combine."* (Doctor1)

Since new hardware and datapoints would further exacerbate the data issues experienced by nurses, the IT department, in collaboration with nurses, started developing an artificial intelligence (AI) model aimed at analysing the growing amount of patient data and flagging those patients in need of nurses' attention. Although the model had not been implemented yet, many of the respondents agreed that AI was necessary for the innovation to be workable in practice – even more so given the scaling-up ambitions.

All these add-ons made it difficult to draw clear boundaries around the innovation. In addition, the innovation increasingly became an unstable object for local stakeholders, which in turn complicated further scale-up plans. One doctor stated:

> *"The project has not been finalised yet. [...] So, I would say, in order for it to be implemented in other hospitals, you need to come to at least a sort of 1.0 solution in which you have a proper and clear description of the product service design, [but] we are still designing it as we go along."* (Doctor2)

Interestingly, despite not considering the innovation a finished product, local professionals still attempted to scale it to other departments, especially following strategic investments from the hospital. As the context of scale-up started to move away from the original department, the stakeholder strategies that had functioned in the local context began to fall short. Stakeholders attempted to generate a process of mutual adaptation between local context and innovation, replicating the continuous changes that the "original" innovation underwent at the cardiology department. Many respondents acknowledged, however, that it was inherently much more difficult to scale the innovation to other hospital departments. The factors impeding this resonate with the structural perspective, for example the limitations of the external IT infrastructure adopted in other departments, their tight budgets, and the lack of eHealth consultants and dedicated IT staff there. Respondents reported being able to work around some of these barriers, for instance by drawing on temporary grants and budgetary slack to compensate for the lack of structural reimbursement, and by postponing discussions around regulatory safety and liability. However, as one respondent explained:

> *"Everything we have done so far was a little bit in this department, a little bit in that department. We had different ways of presenting the data [from patients], we*

had different IT infrastructural routes; [...] the hospital picked five different departments and said, "every department gets some money for fifty patients per [RPM innovation], they get some money from a grant". [...] For now, the departments, they arrange the technical explanations to the patients themselves. But, if we get new [versions of the innovation addressing different conditions], you know – the workload is already quite high with the nurse practitioners... [...] In an ideal world, you would like to have an overall eHealth department that can do the support of all the [innovations in different departments]. I think that would be necessary if we were really scaling up the [innovation] within the [hospital]." (ProjectManag2)

To summarise, local scaling of the innovation within the organisation had its challenges, with respondents recounting organisational complexity, mutual adaptation of context and innovation, and structural barriers. Yet despite these complexities, we can conclude that local scale-up successfully extended the innovation's coverage to include more patients, more aspects of the care pathway, and more departments.

5.4.3 Broader scale-up of the innovation

At the time of our interviews, respondents considered their innovation as one that was still evolving with the gradual addition of new software, hardware, and patients. They also envisaged further replications of the innovation in departments and hospitals nationwide. Generally, they viewed broader scale-up attempts as inevitable. Although many respondents mentioned this as a concrete possibility in the (near) future, they were well aware of the associated complexities.

To begin with, respondents recognised the organisational complexity, arguing that local people and infrastructure cannot be ignored when trying to implement the innovation in another setting – a point clearly reminiscent of the ecological perspective in our framework. In terms of local people, for example, they referred to the attitude of healthcare professionals towards innovation and to the different ways in which patients interacted with it. One significant challenge, in their view, lay in convincing medical professionals and local managers to support and adopt RPM, a relatively new type of care provision, because *"at this moment [...] it's very difficult to prove that it's better than what we used to do"* (Doctor2). As one respondent reflected on the attempts to scale up more widely:

"If you start this, you start with the small groups who are believers, curious people. So, they are motivated to do it. The difficult part comes after that, when you have to scale up, introduce more people to this way of care. And then you find people who say "oh this is extra, I have to look at all the data, I don't have time for that!" We have to explain to them that this is part of our journey." (ProjectMan1)

In terms of local infrastructure, respondents expected issues to arise around the local IT systems and the funds available to invest in all the necessary adaptations:

"The other thing is, let's say in terms of the cost structure, if we want to bring this to other hospitals, you also have to think about a lot of logistics. So, the innovation requires centres. [Hospital] has created an office, where you can go and get your stuff as a patient. All that is taken care of. It's not so easy to replicate that in other places [...] with minimal costs. And there are also hidden costs. For example, let's say, the personnel costs are not calculated by [hospital]." (Liaison1)

The farther away the innovation moves from the epicentre of its origin, the more difficult it seemingly becomes to get the innovation embedded in the organisational setting:

"The difficulty we have is that the infrastructure of the innovation is now really incorporated in the [hospital] infrastructure. So, if we want to expand to other hospitals, we need to get to a plug-and-play solution, that you get the app with a dashboard that you can connect into as a hospital. To connect them with the [hospital] infrastructure, that is also a step that needs to be made." (ProjectManag2)

Thus, respondents emphasised the necessity of a plug-and-play innovation to resolve issues on a broader level – a solution that reflects the structural perspective discussed earlier in this paper. Respondents struggled to articulate viable strategies for overcoming these systemic barriers, however, as the following quote illustrates:

"In the short term the business plan behind mobile health technology is bankruptcy. It just means bankruptcy for a classical hospital, so to say. So, there are a lot of hurdles that must either be taken or ignored in order to make this a success." (Doctor2)

Unresolved structural barriers mentioned ranged from healthcare providers not being reimbursed, or not enough, for saving patients unnecessary visits to the hospital; health insurers having to choose from among a growing number of potential eHealth innovations; and the lack of resources for insurers with the largest market share in a region, who would be expected to take the lead in investing in innovations. As one respondent summarised, *"it has nothing to do with the technology, it's purely a cost versus revenue issue. [...] that's what makes it difficult to bring this to other organisations"* (Liaison1).

In addition to financial issues, participants recognised structural barriers to broader scale-up of eHealth innovations in regulatory and quality constraints; in the fragmentation in IT systems used throughout the country; in hospitals' perceived risk aversion when it comes to investing in innovations; in the absence of a suitable hospital infrastructure and new professional roles

supporting eHealth care provision; and in the environmental unsustainability of data storage and single-use medical devices. Nevertheless, respondents did emphasise that they expected these issues to be resolved over time:

> *"Like I said, there is hope, we just need to accept that the way we organise our health insurance system is not going to help us implement digital solutions. There is enough awareness, so I guess at some point in time we will come up with a solution, but it's going to take time."* (Doctor2)

Moreover, respondents considered several strategies for dealing with the structural complexities:

> *"We are working on the general issues, for instance liability, ethics, data ownership. We organise meetings with all the (national) institutes that are responsible, we convene. Because everybody needs the same answers. They have the same questions at least."* (ProjectManag1)

In addition, they recounted that collaborations with private companies had been considered to support broader scale-up, often framed as *"commercialisation"* (Researcher2). In this scenario, selling the innovation to an independent organisation would allow them to outsource legal liability and the development of an independent IT infrastructure. The strategies respondents described to address structural barriers in reimbursement and regulatory systems, however, all assumed that the innovation was a finished product. For the insurer to provide a reimbursement code, authorities to provide certification, or a private company to sell the innovation, there needed to be agreement on a stable and finalised innovation.

While some respondents described the innovation as always boiling down to *"the same object"* (IT2) regardless of setting, others held the view it could not simply be considered *"a thing"* that was reproducible across settings. Consistent with the critical perspective identified above, these respondents claimed that every instantiation of the innovation would in fact amount to another entity altogether, because the innovation had to shed some features and acquire new ones in order to work locally. This narrative problematised the depiction of the innovation as a stable technological object:

"[Although] there is one message and one goal, [...] the [innovation] has been expanded from that original one. [...] See, you see an [innovation]. But it is the whole idea behind it, it's the concept. It's not a technology, it's a concept. That can be difficult to explain." (ProjectMan1)

These "critical" respondents questioned what constituted the core of the innovation. Was it a form of care provision at home with the involvement of remote technology? A preventative intervention to keep patients out of the hospital? Or nothing more than a concept, an idea about the values of contemporary healthcare? These reflections – i.e., which of the core features of the innovation had to be replicated for the replication to count as scale-up – have important implications for how we appreciate the complexities of broader scale-up. As one respondent put it:

"Nobody cares about the devices. How are you selling something that is a way of working right? How are you selling change management? [...] Maybe the [innovation] is more like a consultancy service that you buy as a hospital." (Liaison1)

In summary, in trying to make sense of the complexities of broader scale-up, our respondents were caught up in a paradox. On the one hand, they considered the innovation a clearly demarcated product subject to financial and regulatory issues. On the other hand, they also acknowledged that it needed to be malleable to deal with the complexities of transitioning to another context. In our discussion, we reflect on this tension and draw lessons from it for both theory and practice.

5.5 Discussion

To dissect the complexities involved in scaling up eHealth innovations, we have combined different theoretical perspectives to make sense of the narrative constructed by stakeholders involved in the scale-up of an innovative eHealth technology. Based on insights from different fields of literature, we have (in brief) identified a structural perspective focusing on systemic barriers and facilitators, an ecological perspective focusing on local organisational complexity, and a critical perspective focusing on mutual adaptation of context and innovation. The three perspectives provide complementary explanations for the complexities perceived in the scale-up of eHealth innovation. The structural perspective, for example, aligned with respondents' observations regarding flawed reimbursement systems and fragmented IT infrastructures within and between Dutch hospitals. The ecological perspective resonated with respondents' reflections on the importance of convincing medical professionals of the innovation's value, as well as on the reconfiguration of nurses' tasks and the establishment of a central eHealth office to improve workflow. The critical perspective was

consistent with respondents acknowledging the ongoing evolution and adaptation of the innovation, for example with the addition of novel monitoring devices and AI-powered software.

Our analysis thus shows the importance of adopting a cross-disciplinary perspective when examining eHealth scale-up and its associated complexities. Whereas the structural perspective tends to overlook the flexibility and malleability necessary for scaling innovation to another organisational context, the ecological and critical perspectives fail to connect local experiences with the stability perceived to be required of the innovation to reach upscaling at broader levels. Below, we elaborate on two distinct insights that emerged from this combination of perspectives and discuss their implications for researchers, practitioners and policymakers.

5.5.1 Differing strategies for scale-up at different levels of scale

While the respondents' narratives bore traces of each of the three perspectives, the strategies they used to deal with scale-related complexities differed considerably depending on the level (i.e., local versus interorganisational). When discussing *local scale-up*, the respondents stated that they worked on changing the context, adapting practices and infrastructure to embed the innovation, and reconfiguring the innovation itself. In this sense, the flexibility of organisation and innovation was crucial. Although respondents mentioned several structural barriers as having affected the progress of the innovation (e.g., the lack of reimbursement agreements with health insurers), they did not resolve them formally but rather worked around them informally.

In contrast, when reflecting on the plans for *broader scale-up*, respondents questioned the strategy of informality and flexibility. When it came to scaling the innovation to other organisations, respondents emphasised the need to find formal solutions to systemic barriers, such as national reimbursement arrangements, an integrated IT network, and national regulatory and liability agreements. Moreover, to realise this, the innovation itself had to cease being malleable and become a stable "product". The view of innovation as a formalised, stable entity stems from the structural perspective, which assumes that the innovation is a thing embedded in formal structures. In contrast, the critical perspective emphasises how scaling an innovation to another context entails changing what the innovation *is*. The idea that the innovation never becomes a stable entity amenable to replication does not align with the perceived necessity of turning it into a clearly demarcated product. This tension has critical implications for the solutions respondents envisage for dealing with complexities at a broader level of scale-up: proposing concrete solutions to overcome systemic barriers assumes that the innovation can achieve a state of closure, and that is not what the respondents experienced.

To summarise, our analysis revealed a tension between two different conceptions of eHealth innovation: as something that is malleable *and* entangled in an organisation, and as a stable product that can be replicated across contexts without changing. This tension results in an impasse in

developing strategies to overcome the complexities involved in broader level scale-up, with respondents being incentivised to keep the innovation malleable and fixed at the same time.

5.5.2 Importance of path dependencies

In addition to the important role of the level of scale, we identified another aspect that is often overlooked in understanding the complexities of scaling up eHealth innovation. Prior research has often advocated establishing the infrastructure needed for local scale-up without *acknowledging the influence of what already exists*. Although the ecological perspective emphasises the need to adapt the local setting, what is missing from this view are the path dependencies stemming from previous decisions. Defined by Mahoney as *"those historical sequences in which contingent events set into motion institutional patterns or even chains that have deterministic properties"* (p.507), path dependencies refer to how current events depend at least in part on a chain of prior events (309). When translating this to innovation scale-up, it becomes clear that success is predicated not only on present and future actions, but also on how past choices have shaped organisational structures. It is unlikely that all local circumstances can be adapted to accommodate an existing innovation; some are likely to complicate eHealth scaling. An example can be found in the discussion surrounding the pre-existing IT infrastructure of the cardiology department where the RPM innovation originated. The presence of an in-house EHR allowed for a tailored, flexible infrastructure into which the innovation's devices and data could be integrated, something that would have been much more difficult in a commercial platform. However, the use of such platforms is the prevailing reality in most hospitals in the Netherlands.

In sum, pre-existing local circumstances can significantly shape eHealth innovations' initiation and scale-up, and the associated path dependencies should be taken into account when attempting eHealth scale-up both locally and more broadly.

5.5.3 Recommendations for practice and policy

Our findings offer several lessons for practice and policy. First, the challenges faced by actors at the local and broader level are likely to differ greatly. Actors at the local level are likely to face complexities related to the continuous adaptation of both the organisational infrastructure and the innovation itself. Even so, there is little sense of urgency at this level about addressing structural barriers formally and systematically. In contrast, actors at the broader level need to deal with the tension between the limitations imposed by structural systems and the requirement of local flexibility. To do this, decision-makers must, first and foremost, acknowledge this tension and the confusion that is likely to result regarding the strategies that actors pursue in their attempts to scale up broadly.

The second lesson, related to the previous point, is that flexibility should be incorporated into system-wide structures that govern eHealth innovation (including IT infrastructures, regulations, and reimbursement mechanisms). Specifically, this would mean creating opportunities for local adaptation work, facilitating ingenuity in local contexts. While fostering such "facilitating space" will not remove all complexity, it will help actors deal with complexity by giving them a certain amount of leeway to tailor and adapt to the requirements of specific local contexts. This complexity includes the path dependencies imposed by pre-existing circumstances that define the opportunities for scaling up specific innovations.

That is why actors should be aware that, when adopting a scaled-up innovation, they will likely need to adapt the innovation itself as well as the local context. At the policy level, such awareness should be made part of reimbursement and regulatory structures. For decision-makers, this means not expecting a *"plug-and-play"* model of scale-up where innovation is simply replicated; rather, they must set aside the time and financial and human resources necessary for adaptation at the local level.

5.5.4 Recommendations for research

Our analysis leads us to make three recommendations for future research. First, despite discussing scale-up at length, existing literature lacks a conceptual vocabulary for studying the concept of scale itself, including its implications for the complexities stakeholders face and the strategies they use. There is almost no research addressing the phenomenon of scale in innovation scale-up, the notable exception being a study of strategies addressing scale-up complexities at different levels of scale in the energy sector (310). Future research on healthcare innovation scale-up should thus acknowledge the concept of scale itself (that is, the level at which scale-up is attempted) as a crucial factor in determining actors' strategies.

Second, research should focus on whether and how actors involved in different types of innovations may experience complexities at different levels of scale. The RPM innovation studied in this paper is only one of many types of eHealth innovation, each with specific characteristics that may affect the process of scaling. Others could, for example, have more stable or more malleable aspects and come up against more or fewer unresolved systemic barriers. More research is needed to further our understanding of these complexities and identify a broader set of action repertoires to deal with them.

Third, this study adopted a cross-disciplinary perspective, applying a generative heuristic framework to highlight the various complexities stakeholders encounter in the scale-up of eHealth innovations through a high-level discussion. Consequently, our findings leave considerable scope for research on more specific aspects of these complexities. One potentially relevant direction for research could be the interaction of humans with technologies, the novel challenges emerging from this interaction in

care processes (311), and the ways in which this interaction and the related challenges may differ based on the scale attempted.

5.5.5 Limitations

Our study has several limitations. First, for reasons of unavailability and privacy protection, we were unable to include the perspectives of all stakeholders currently involved in the RPM innovation project. Specifically, we did not include the perspectives of eHealth consultants, patients, and stakeholders in other departments outside of the original cardiology setting. Stakeholders in departments attempting to scale the innovation could have provided additional insights into the complexities of scale-up. We were also unable to speak to the nurses directly involved in the original version of the innovation owing to the work pressure they were experiencing. We did, however, talk to their colleague nurses, who witnessed how the workload associated with the innovation proved demotivating for several nurses.

Second, several biases could have emerged from the interview-based nature of the case study. Specifically, both the retrospective (recall bias, potentially misremembering events in the past) and prospective (declinism, the tendency to perceive the future more negatively than the past) nature of the respondents' reflections might have shaped our findings. We cannot preclude the possibility that we missed relevant aspects, as we were unable to observe the innovation's development as it happened. However, the interviews did allow us to piece together a longitudinal narrative spanning a much longer time period than any direct observations would have allowed. Moreover, we did reach analytical saturation based on our interviews, insofar as respondents presented similar views on scale-up across interviews, strengthening our confidence in the validity of our conclusions.

5.6 Conclusion

This study addressed why scaling up innovative eHealth technologies is so challenging in practice. For this purpose, we brought together three theoretical perspectives on the complexities of innovation scale-up from different fields of literature. We used these perspectives to make sense of the narrative produced by stakeholders involved in the scale-up of an RPM-based eHealth technology, which was presented as a local success but came up against challenges in broader scale-up attempts. Each of these perspectives highlights different but equally pertinent aspects of scale-up complexities and strategies for addressing them. Two key insights emerged from this cross-disciplinary analysis. First, we found that the level at which scale-up is pursued plays an important, yet so far neglected, role. Contextual complexities were overcome at the local level and systemic barriers informally worked around. By contrast, at a broader level tension emerged between the need for stability on the one hand and malleability on the other, leading to an impasse in the scale-up of the eHealth innovation. Second, our study has emphasised the role of path dependencies, namely in

terms of pre-existing organisational structures and technological infrastructure, in facilitating and constraining scale-up processes. The path dependencies in local contexts play an important role in shaping the complexities that actors face. Researchers, policymakers and stakeholder practitioners need to acknowledge and account for the crucial role that level of scale and path dependencies play in shaping the complexities involved in scaling up eHealth innovation. Such projects might enjoy greater success by rethinking structural systems to allow for malleability in the innovation, giving it the necessary leeway to align with the requirements of specific local contexts.

Chapter 6

Translating innovative medical devices from prototype to practice: A Delphi study of urgent financial barriers and promising solutions

Under review

Abstract

Financial barriers are widely perceived as a major obstacle for translating innovative medical devices from prototype to practice. However, a clear overview of relevant financial barriers, their perceived urgency, and promising solutions is lacking. Therefore, this study aims to identify and prioritize the multitude of barriers and solutions from the perspective of various stakeholders involved in the development and financing of innovative medical devices. We performed a Delphi study with three consecutive questionnaires sent to 72 experts from five stakeholder groups in the Netherlands: innovators, (social) venture capital investors, health insurers, healthcare providers, and (semi)governmental agencies. The response rate was 71 % in the first round and decreased to 46% in the third round, with each stakeholder group being well-represented. We identified 33 distinctive barriers and 183 associated solutions. Although respondents assigned a consistently high priority to each of these barriers, eight barriers stand out in terms of high priority and degree of consensus. In addition, 22 solutions were considered most promising to solve these barriers. For both the barriers and the solutions, differences in the degree of consensus were larger within than between stakeholder groups.

6.1 Introduction

Healthcare innovation is widely regarded as a promising strategy to deal with the challenges faced by healthcare systems worldwide (312,313). However, the process of healthcare innovation can be severely impeded by financial barriers. This is especially the case when translating innovative medical devices – ranging from every-day products to complex and costly diagnostic and therapeutic technologies – from prototype to practice (314). In this translation phase many innovative ideas do not manage to mature sufficiently to reach sustainable implementation. Therefore, this phase is aptly characterized as the 'valley of death' (29) in which many technological innovations fail (315).

Previous research has found ample evidence for the existence of this valley of death and identified several challenges, which tend to be financial in nature (316). This research often points towards a general lack of funding to support startups in commercializing a novel technology. Several studies have also provided potential solutions for overcoming these challenges, including better innovation management (317), support from innovation incubators (318), and financial support in the form of public coverage-with-evidence development schemes (319) and temporary innovation payments (81). Importantly, however, these studies typically have a narrow focus describing only a general financial issue or a single potential solution. As a result, insight remains lacking into (i) the multitude of financial barriers at play at the translation phase of the innovation process and (ii) possible solutions to these barriers in order to bridge the valley of death.

In this respect, it is important to acknowledge that various stakeholders involved in the development and financing of innovative medical devices may experience different barriers. Additionally, given that it is unlikely that these barriers can be addressed all at once, it is useful to prioritize them based on the urgency with which they ought to be addressed according to the stakeholders involved. In turn, the focus should be on solutions that seem most suitable to address the prioritized barriers. However, such an explicit link between urgent barriers and promising solutions as experienced by different stakeholder groups is currently missing in the literature. Consequently, decision-makers are expected to address barriers without being fully informed about their perceived importance and about how to deal with them effectively.

This study aims to provide a comprehensive overview of financial and related barriers influencing the translation of innovative medical devices from prototype to practice, as well as to identify the priority assigned to these barriers by different stakeholders. In addition, we aim to identify solutions that are perceived to be particularly suitable to address the identified high-priority barriers. In doing so, we contribute to the scientific and policy debate about facilitating the translation of valuable innovative devices to healthcare practice.

6.2 Methods

To gain insight in stakeholders' views on financial barriers and related promising solutions, we performed a Delphi study with the following characteristics (320): respondents being experts on the topic at hand; three questionnaire rounds in which information was collected, analysed, and fed back to respondents in subsequent rounds; the opportunity for respondents to revise their responses; and respondent anonymity (321). We were specifically interested in the priority assigned to the identified barriers and the perceived suitability of the suggested solutions to address those barriers. In addition, we were interested in the degree to which consensus could be reached on these barriers and solutions and differences therein between and within various stakeholder groups. Our focus was on innovative medical devices with high potential societal value (i.e., with clear benefits for patients, healthcare professionals, and/or society). We restricted our study to innovative medical devices for curative somatic care (i.e., primary, secondary, and rehabilitation care) in the context of the Dutch healthcare system, which operates as a decentralized healthcare system with universal social health insurance carried out by multiple competing health insurers (220).

6.2.1 Expert sampling

We sampled innovation experts from five stakeholder groups: innovators, (social) venture capital investors, health insurers, healthcare providers, and (semi)governmental agencies. These stakeholder groups all have an important role with regards to financing of healthcare innovation. We applied three recruitment strategies. The first strategy involved using the authors' networks to make targeted requests by email for participation. The second strategy focused on approaching representative organisations of the stakeholders (e.g., the Dutch association of health insurers), sending out open calls by email for participation. In addition, snowballing was used by asking recruited experts to suggest additional experts. A total of 72 experts agreed to participate (10-15 experts per stakeholder group).

6.2.2 Data collection and analysis

Three consecutive questionnaires were sent to all experts (Figure 6.1). A respondent information sheet was provided at the start of each questionnaire and informed consent was requested before respondents could proceed to the questions. Additionally, a description was provided to respondents with regards to the study focus as explained above (see appendix 6.a). This description could be downloaded by the respondents and remain visible while answering questions. The questionnaires were anonymous, but there was a voluntary option for respondents to fill in their names at the end of the questionnaire to allow for clarifying questions by the researchers in case of unclear answers. Other data collected in each round included the stakeholder group respondents belonged to and relevant job information (i.e., function title and number of years on the job). Below,

we provide an overview of the collected data and the analyses performed for each questionnaire round.

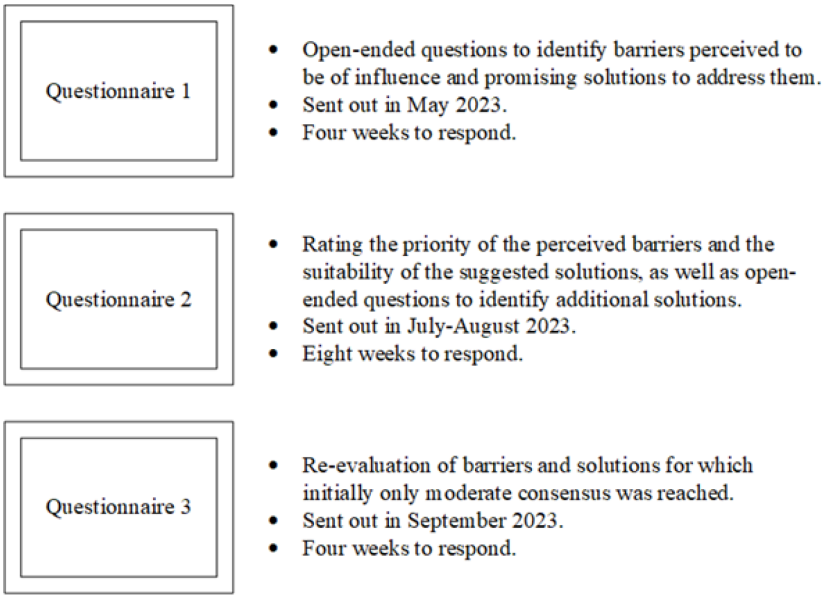


Figure 6.1. Focus and timeline of consecutive questionnaires.

First questionnaire

The first questionnaire collected respondents' views on urgent financial barriers and promising solutions. Using open-ended questions, respondents were asked to provide a maximum of five barriers and three solutions for each barrier, as well as a maximum of five solutions that could not be directly related to a specific barrier. Each answer had a word limit of 500 characters.

The questionnaire was pilot tested among five professionals in the field, recruited through the personal network of the authors. Following their recommendations, several changes were made to the visualisation and phrasing of questions before sending the questionnaire to the respondents. The questionnaire was accessible for four weeks, with reminders at two weeks, one week and one day before the deadline. The expected duration of completing this questionnaire was 15 minutes. Two authors jointly analysed the responses, which included a process of reading, merging, clarifying, and shortening the answers into a comprehensive overview of distinct barriers and associated solutions.

Second questionnaire

The second questionnaire collected insights on the priority assigned by respondents to the identified barriers and on the suitability of the suggested solutions. The information collected from the first questionnaire was presented to the respondents in the form of a list of barriers with associated solutions. Specifically, the respondents were first shown the full list of barriers and asked to prioritize each of them. Next, separately for each barrier, the respondents were asked to rate the suitability of the solutions suggested in questionnaire 1 . Respondents were asked to rate the barriers and solutions on a 7-point scale ranging from 'very low priority /highly unsuitable' (1) to 'very high priority/highly suitable' (7). In addition, for each barrier, respondents had the opportunity to mention additional solutions that were not suggested before. This option was implemented to ensure respondents could provide promising solutions for barriers they had not thought of themselves in the first questionnaire.

Questionnaire 2 was pilot tested among three professionals in the field. Following their recommendations, changes were made in the phrasing of questions and the length of the questionnaire. After these changes, the expected duration of completing this questionnaire was 45 minutes. The questionnaire was initially accessible for four weeks, but this period was extended to eight weeks to increase the response rate among two stakeholder groups (respondents from these stakeholder groups were sent an additional request to complete the questionnaire). Respondents were assigned to stakeholder groups based on self-identification and the information provided about their job.

To measure the rating of and consensus on the barriers and solutions, we calculated the following descriptive statistics: median, interquartile range (IQR), 25th and 75th percentiles, range, percentage of respondents providing a rating of at least moderate priority/suitability (i.e., rating 5 , 6 or 7), and the percentage of respondents providing a rating of at least a high priority/suitability (i.e., rating 6 or 7). A (moderately) high priority/suitability was defined as a median rating of 5 or higher. To determine consensus on priority and suitability, we initially opted for a categorisation based on the median and IQR, as is common in Delphi studies (322). However, as the ratings were found to be highly skewed to the left making the IQR less informative, we instead determined the degree of consensus based on the median and the 25th and 75th percentiles (Table 6.1).

In addition to descriptive statistics on overall rating and consensus, separately for the barriers and solutions we used the Kruskal Wallis test to assess whether there were statistically significant differences (alpha=0.05) between the median ratings of the five stakeholder groups. Finally, qualitative analysis was performed on the responses to the open-ended question for additional solutions per barrier, similar to the analysis of the responses from questionnaire 1 .

Table 6.1. Categorisation of consensus on the assigned priority of barriers and suitability of solutions.

	Description	*Cutoff points**	*Implication after round 2*
High consensus	High consensus about the priority / suitability being (moderately) high: *Entire IQR is concentrated on the higher side of the scale.*	Median ≥5 and 25th percentile ≥5	Accepted as barrier / solution with high consensus on (moderately) high priority / suitability.
Moderate consensus	Moderate consensus about the priority / suitability being (moderately) high: *IQR is concentrated on the higher side of the scale but includes the neutral rating of 4.*	Median ≥5 and 25th percentile 4	Re-evaluated in third questionnaire.
Low consensus	Low consensus about the priority / suitability being (moderately) high: *IQR is spread along the lower and higher sides of the scale.*	Median ≥4 and 25th percentile ≤3	Discarded as barrier / solution with consensus on (moderately) high priority / suitability.

* The categorization focuses on median ratings of 4 and higher, because our data do not include barriers or solutions with lower median ratings. In future research, this categorization can easily be adapted to include the categorization of consensus on lower median ratings.

Third questionnaire

The third questionnaire aimed to measure the stability of the responses on barriers and solutions for which moderate consensus was reached after the second questionnaire. Respondents were shown the list of barriers with moderate consensus, along with the overall median rating and 25th and 75th percentiles based on the responses from all respondents of questionnaire 2 (Figure 6.2). The respondents were asked to again rate the priority of each of these barriers. Similarly, the respondents were shown the moderate-consensus solutions for each barrier for which moderate or high consensus was reached in questionnaire 2, as these were the barriers that could potentially be prioritized. Again, information about the overall median and 25th and 75th percentiles was visible for each solution. Furthermore, the respondents were asked to rate the solutions that were additionally suggested in the second questionnaire on suitability to solve the associated barrier. The questionnaire was accessible for four weeks, with reminders at two weeks, one week and one day before the deadline. The expected duration of completing this questionnaire was 20 minutes.

For the final categorisation of respondents into stakeholder groups we again combined the self-identification with the job description provided. The same descriptive statistical analyses were performed as for the second questionnaire. Additionally, we analysed the stability or convergence in consensus between the second and third questionnaire. Although the samples were dependent, we were not able to pair responses as responses were anonymous. Therefore, we applied the Mann Whitney U-test for independent samples (alpha=0.05). For each barrier and solution included in both the second and third questionnaire we tested for statistically significant changes in response, both overall and within the different stakeholder groups.

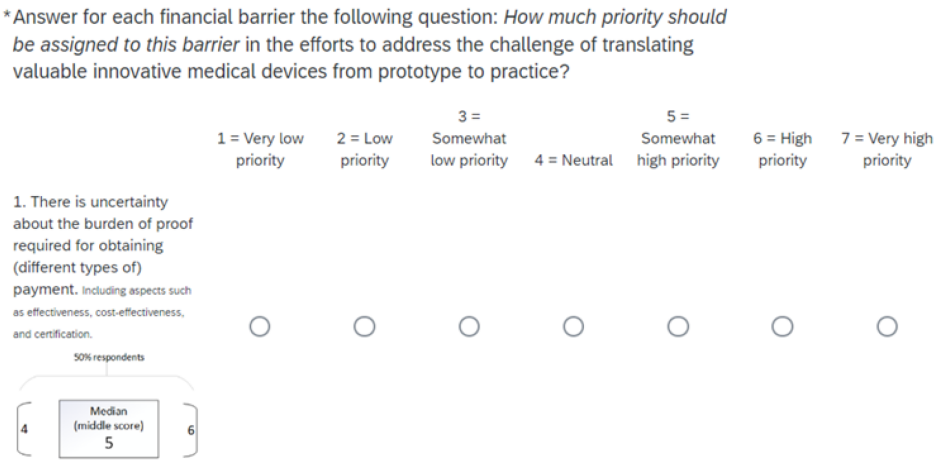


Figure 6.2. Excerpt from questionnaire 3 including the visualisation of the median and interquartile range of the general response from questionnaire 2.

6.2.3 Sensitivity analysis

Finally, we performed a sensitivity analysis for our results on the degree of consensus between respondents. As described above, we opted for a consensus categorization based on the median rating and the 25th and 75th percentiles. However, other commonly used measures of consensus in Delphi studies are based on the IQR or on a certain percentage of respondents providing a high rating. We compare our findings with results based on those alternative measures to assess the sensitivity of our findings to the choice of consensus measure.

6.3 Results

6.3.1 Response rates

The three questionnaires were sent out consecutively to all 72 experts. In total, 51 respondents (71 %) completed the first questionnaire, 44 (61 %) the second questionnaire, and 33 (46%) the third questionnaire. As can be seen in Table 6.2, each stakeholder group is well-represented in each round, except for the relative underrepresentation of venture capital investors in round 1 .

Table 6.2. Number of respondents (%) in each questionnaire round, by stakeholder group.

Stakeholder group	*Questionnaire 1**	*Questionnaire 2*	*Questionnaire 3*
Innovator	7 (14)	7 (16)	5 (15)
(Social) venture capital investor	4 (8)	8 (18)	5 (15)
Healthcare provider	11 (22)	9 (20)	6 (18)
Health insurer	14 (27)	11 (25)	7 (21)
(Semi-)government	10 (20)	9 (20)	10 (30)

*For 5 respondents, information about the stakeholder group was missing.

6.3.2 Barriers

Overall response

In round 1, the respondents described a total of 133 barriers for financing the translation of innovative medical devices to practice. Due to considerable overlap, these could be categorized into 33 distinctive barriers (Table 6.3). In subsequent rounds, the respondents were asked to rate these 33 barriers on their priority. Only two barriers (i.e., earmarked funding and a like-knows-like network; number 14 and 33) were assigned a neutral priority (i.e., score 4) with high consensus. In addition, high consensus was reached in round 2 on four barriers that should be assigned a (moderately) high priority (number 3, 8, 16 and 19). These prioritized barriers refer to financial challenges related to (i) difficulties in demonstrating cost-effectiveness, (ii) a lacking business case of prevention, (iii) required changes in related (care) processes remaining unpaid for, and (iv) a wrong-pocket problem (i.e., the benefits accruing to others than those investing in the innovation).

For 13 barriers, moderate consensus on assigned priority was reached in round 2. These barriers were re-evaluated in round 3, which resulted in consensus on a (moderately) high priority for four additional barriers (number 1, 13, 21, 30). These barriers concern challenges associated with (i) uncertainty about the required burden of proof, (ii) poorly aligned objectives of temporary funding and structural reimbursement, (iii) compartmentalized payment systems and healthcare provision, and (iv) higher total spending due to the lack of discontinuation of existing, low-value care.

In sum, after round 3 high consensus was reached about the assigned priority for 10 of the 33 identified barriers: eight with a (moderately) high priority and two with a neutral priority.

Table 6.3. Overview of 33 identified barriers with median[I], 25th and 75th percentiles, and degree of consensus on priority after questionnaire round 2 and 3[II].

Barriers[III]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
1. There is uncertainty about the burden of proof required for obtaining (different types of) payment, including aspects such as effectiveness, cost-effectiveness, and certification.	6	5-6	Moderate	High
2. It is challenging to demonstrate, in the translation phase, that an innovation meets current standards of science and practice. Burden of proof as a prerequisite for payment.	5	4-6	Moderate	Moderate
3. It is challenging to sufficiently demonstrate the cost-effectiveness/efficiency of an innovation in the translation phase. Burden of proof as a prerequisite for payment.	5	5-6	High	n/a
4. It is challenging to sufficiently demonstrate the possibilities for scaling up an innovation in the translation phase. Burden of proof as a prerequisite for payment.	4	3-5	Low	n/a
5 Unlike, for example, for new pharmaceuticals, the added value of a medical device must be demonstrated repeatedly at various healthcare providers.	5	3-6	Low	n/a
6. Unlike, for example, for new pharmaceuticals, the added value of a medical device must be demonstrated repeatedly to governments and payers in different European countries.	5	4-6	Moderate	Moderate
7. There is uncertainty about the benefits of financing innovative medical devices (return-on-investment). It is difficult to formulate a positive business case.	5	4-6	Moderate	Moderate
8. Preventative medical devices have no business case within the cure sector.	6	5-7	High	n/a

Table 6.3. (continued)

Barriers[III]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
9. Uncertainty regarding possibilities for financing innovation in the Dutch healthcare market.	5	3-6	Low	n/a
10. Fragmented payments from investors and grant providers. The large number of funds and grants as well as the fragmentation between different project phases.	5	4-6	Moderate	Moderate
11. Lack of uniformity in reimbursement by different health insurers. No uniformity in reimbursement conditions nor any coordination of reimbursement practices amongst insurers.	5	4-6	Moderate	Moderate
12. Dependency on temporary grants and investments due to the limited willingness of health insurers to pay for the translation phase.	4	3-6	Low	n/a
13. The objectives of temporary funding (subsidies) versus structural reimbursement (insurance contracts and basic benefit package) are not aligned.	5	5-6	Moderate	High
14. Too much of the temporary financing is earmarked money.	4	4-4	High (but low priority)	n/a
15. Interest among various parties (healthcare providers, health insurers, and suppliers) to maintain the status quo, due to the time, costs, loss of revenue, and efforts that are associated with change.	5	3-6	Low	n/a
16. The process surrounding an innovative medical device, such as the workflow or care pathway, must change along with the device and the necessary money, time, and efforts for this are often not paid for.	6	5-7	High	n/a
17. Lack of healthcare personnel (time) to work on innovation. Workforce scarcity.	5	4-6	Moderate	Moderate

Table 6.3. (continued)

Barriers[III]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
18. The not-invented-here syndrome among healthcare providers: unwillingness to invest in an innovation developed elsewhere.	5	3-6	Low	n/a
19. Fragmentation of costs and benefits, resulting in one party paying for the innovation while another party benefits: the wrong-pocket problem.	6	5-7	High	n/a
20. Fragmentation of costs and benefits over time, causing the costs that need to be incurred to precede the benefits by far.	5	3-6	Moderate	Low
21. Payment for and provision of healthcare are compartmentalized (siloed); it is difficult to obtain payment for innovations falling under multiple compartments.	6	5-6	Moderate	High
22. Innovation is financially costly for healthcare providers, while the available resources from healthcare providers to pay for innovation are limited.	5	3-6	Low	n/a
23. The large-scale production of innovative medical devices is costly for the innovator.	4	2-5	Low	n/a
24. Insufficiently clear vision and/or proactive policy in the field of healthcare innovation from the government.	5	3-6	Low	n/a
25. EU legislation in relation to competition policy makes it difficult for governments to pay for and steer innovation.	4	3-5	Low	n/a
26. The high level of detail and prescriptive nature of laws and regulations about healthcare at the national level limits opportunities for financing innovation.	5	3-5	Low	n/a
27. Limited transparency about the actual cost price of an innovation, and therefore what the pricing should be based on.	4	3-5	Low	n/a

Table 6.3. (continued)

Barriers[III]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
28. The high costs and lengthy processes involved in meeting all the prerequisites regarding regulations and certification before health insurers are willing or able to proceed with payment.	5	4-6	Moderate	Moderate
29. The large number of innovations being developed makes it difficult for payers to choose what and how much to finance.	4	2-5	Low	n/a
30. Innovation often makes healthcare more expensive, also due to the lack of discontinuation of payment for existing, low-value care.	6	5-6	Moderate	High
31. Innovations rarely add value in terms of ecological sustainability, affordability, or personnel sustainability.	4	2-6	Low	n/a
32. Lack of collaboration between the world of innovation and healthcare practice, resulting in innovation being driven by a (technology) push rather than a (problem) pull.	5	4-7	Moderate	Moderate
33. The world of healthcare innovation is dominated by a like-knows-like network. For instance, in the drafting of calls for grant applications, allocation of grants, and decisions regarding policy.	4	3-4	High (but low priority)	n/a

I. Respondents were asked to rate the barriers on a 7-point scale from very low priority barrier (1) to very high priority barrier (7), with (4) being a neutral option.

II. Degree of consensus was categorized as low, moderate or high based on the median and the 25th and 75th percentiles (see Table 6.1).

III. Barriers in bold were assigned (moderately) high priority with high consensus in round 2 or 3.

n/a. not/applicable; In case a barrier was assigned a level of priority with high consensus immediately in round 2, it was excluded from re-evaluation in round 3.

Differences in consensus on barriers between and within stakeholder groups

For all stakeholder groups, the majority of barriers received a median rating of (moderately) high priority (19 to 24 out of 33, data not shown). Statistical testing showed barely any significant differences between the median ratings of the groups; only two barriers were assigned a significantly different rating between stakeholder groups (number 5, 25). This suggests overall limited variation between stakeholder groups in consensus on the priority assigned to the barriers (Table 6.4).

Variation in the degree of consensus was larger within stakeholder groups. Respondents working at (semi)governmental agencies showed the highest within-group variation, with 16 out of 33 barriers rated with a low degree of consensus (Table 6.4). The other groups also reached low consensus on around a third of the barriers. When focusing on the eight prioritized barriers (in bold in Table 6.4), a high consensus was reached within at least three stakeholder groups for each of these barriers, However, only for one of these eight barriers (number 16) high consensus was reached within all five groups.

Stability between questionnaire rounds

The third questionnaire again included the 13 barriers for which moderate consensus was reached in round 2. While this resulted in high consensus on a (moderately) high priority for four additional barriers, statistical testing showed high levels of stability in responses rather than convergence of opinion, both overall and within stakeholder groups; for only one barrier (number 30) respondents from the stakeholder group of health insurers assigned a significantly higher median rating with a lower variance in round 3 compared with round 2.

6.3.3 Solutions

Overall response

The first round yielded 191 suggestions for solutions, which we could categorize into 166 distinct solutions (see supplement A, provided at the end of this dissertation, for a full overview). In the second round, respondents had the opportunity to provide solutions for barriers they had not thought of themselves, resulting in 17 additional solutions. The solutions differed substantially in terms of the stakeholder group considered responsible for executing the solution. For example, solutions focused on taking timely action by innovators (e.g., number A.6); co-creating and validating innovation by providers (e.g., A.12); bringing funding by investors more in line with reimbursement possibilities (e.g., A.82); increasing innovation support by insurers (e.g., A.68); and creating facilitating regulations by the government (e.g., A.51).

Table 6.4. Degree of consensus[I] on assigned priority for 33 barriers, by stakeholder group.

Barriers[II]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
1. There is uncertainty about the burden of proof required for obtaining (different types of) payment, including aspects such as effectiveness, cost-effectiveness, and certification.	High	High	Low	High	High
2. It is challenging to demonstrate, in the translation phase, that an innovation meets current standards of science and practice. Burden of proof as a prerequisite for payment.	Moderate	Moderate	Low	High	Low
3. It is challenging to sufficiently demonstrate the cost-effectiveness/efficiency of an innovation in the translation phase. Burden of proof as a prerequisite for payment.	High	High	High	Moderate	Low
4. It is challenging to sufficiently demonstrate the possibilities for scaling up an innovation in the translation phase. Burden of proof as a prerequisite for payment.	Low	Moderate	Low	Moderate	Moderate
5. Unlike, for example, for new pharmaceuticals, the added value of a medical device must be demonstrated repeatedly at various healthcare providers.	Low	High	Low	Moderate	Low
6. Unlike, for example, for new pharmaceuticals, the added value of a medical device must be demonstrated repeatedly to governments and payers in different European countries.	Low	Moderate	Low	Moderate	Low
7. There is uncertainty about the benefits of financing innovative medical devices (return-on-investment). It is difficult to formulate a positive business case.	High	High	Moderate	High	Low
8. Preventative medical devices have no business case within the cure sector.	High	Moderate	High	High	High
9. Uncertainty regarding possibilities for financing innovation in the Dutch healthcare market.	Low	Low	High	Low	Moderate

Table 6.4. (continued)

Barriers[II]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
10. Fragmented payments from investors and grant providers. The large number of funds and grants as well as the fragmentation between different project phases.	Low	Moderate	High	High	High
11. Lack of uniformity in reimbursement by different health insurers. No uniformity in reimbursement conditions nor any coordination of reimbursement practices amongst insurers.	High	Moderate	High	Low	Moderate
12. Dependency on temporary grants and investments due to the limited willingness of health insurers to pay for the translation phase.	Low	Moderate	Moderate	Low	Low
13. The objectives of temporary funding (subsidies) versus structural reimbursement (insurance contracts and basic benefit package) are not aligned.	Low	High	High	High	Moderate
14. Too much of the temporary financing is earmarked money.	High (low priority)	Low	Moderate	High (low priority)	Low
15. Interest among various parties (healthcare providers, health insurers, and suppliers) to maintain the status quo due to the time, costs, loss of revenue, and efforts that are associated with change.	High	Low	Low	Low	Moderate
16. The process surrounding a medical device, such as the workflow or care pathway, must change along with the device and the necessary money, time, and efforts for this are often not paid for.	High	High	High	High	High
17. Lack of healthcare personnel (time) to work on innovation. Workforce scarcity.	High	High	High	Moderate	Low
18. The not-invented-here syndrome among healthcare providers: unwillingness to invest in an innovation developed elsewhere.	Moderate	Low	Low	Low	Moderate

Table 6.4. (continued)

Barriers[II]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
19. Fragmentation of costs and benefits, resulting in one party paying for the innovation while another party benefits: the wrong-pocket problem.	Low	High	High	Moderate	High
20. Fragmentation of costs and benefits over time, causing the costs that need to be incurred to precede the benefits by far.	Low	Moderate	Low	Low	Low
21. Payment for and provision of healthcare are compartmentalized (siloed); it is difficult to obtain payment for innovations falling under multiple compartments.	High	Moderate	Low	High	High
22. Innovation is financially costly for healthcare providers, while the available resources from healthcare providers to pay for innovation are limited.	Low	Low	High	Low	Low
23. The large-scale production of innovative medical devices is costly for the innovator.	Low	Low	Moderate	High (low priority)	High (low priority)
24. Insufficiently clear vision and/or proactive policy in the field of healthcare innovation from the government.	Moderate	Moderate	Moderate	Low	Low
25. EU legislation in relation to competition policy makes it difficult for governments to pay for and steer innovation.	Moderate	Low	Moderate	Low	High (low priority)
26. The high level of detail and prescriptive nature of laws and regulations about healthcare at the national level limits opportunities for financing innovation.	Moderate	Low	High	Low	Low
27. Limited transparency about the actual cost price of an innovation, and therefore what the pricing should be based on.	High (low priority)	Low	Low	Moderate	Low
28. The high costs and lengthy processes involved in meeting all the prerequisites regarding regulations and certification before health insurers are willing or able to proceed with payment.	Moderate	High	Moderate	Moderate	Low

Table 6.4. (continued)

Barriers[II]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
29. The large number of innovations being developed makes it difficult for payers to choose what and how much to finance.	Moderate	Low	Low	Low	Low
30. Innovation often makes healthcare more expensive, also due to the lack of discontinuation of payment for existing, low-value care.	Low	High	High	High	High
31. Innovations rarely add value in terms of ecological sustainability, affordability, or personnel sustainability.	Low	Low	Low	Low	Moderate
32. Lack of collaboration between the world of innovation and healthcare practice, resulting in innovation being driven by a (technology) push rather than a (problem) pull.	Moderate	High	Low	Moderate	High
33. The world of healthcare innovation is dominated by a like-knows-like network. For instance, in the drafting of calls for grant applications, allocation of grants, and decisions regarding policies.	Low	High (low priority)	Low	High (low priority)	Low

I. Degree of consensus was categorized as low, moderate or high based on the median and the 25th and 75th percentiles (see Table 6.1).
II. Barriers in bold were assigned (moderately) high priority with high consensus in round 2 or 3.

Respondents rated the 183 solutions on their suitability for solving associated barriers. Most solutions, 156 out of 183, received a median rating of at least moderately suitable (i.e., 5 or higher). Only one solution was rated as being moderately unsuitable with a median rating of 3: mandating insurers to reimburse a fixed number of innovations per year (A.76).

Additionally, for 26 of the 33 barriers, high consensus was reached on at least one solution being considered (very) suitable. This suggests that for almost every barrier identified, there is broad support for at least one way to address it. Nevertheless, for the majority of solutions offered (100 out of 183) only low or moderate consensus was reached about their suitability. Particular dissensus was found for seven solutions with an IQR of 4 (supplement A: number 67, 80, 83, 137, 151, 172, 179). These solutions include replacing the multiple competing insurers by one national insurer; establishing a national innovation team to assess the appropriateness and sustainability of proposed innovations; nationally mandated funding levels or reimbursement fees for innovative devices; requiring certainty of structural reimbursement before providing temporary funding; and requiring regulatory approval before seeking reimbursement from insurers.

In contrast, regarding the eight prioritized barriers there was a high degree of consensus on 22 out of 38 solutions being (very) suitable (Table 6.5, in bold).

Differences in consensus on solutions between and within stakeholder groups

All stakeholder groups provided a median rating of at least moderately suitable for most solutions (144 to 166 out of 183, data not shown). Differences were statistically significant for only 14 solutions, suggesting high between-group consensus on the suitability of solutions.

While higher for the solutions than for the barriers (see supplement B, provided at the end of this dissertation), within all groups consensus on suitability was moderate or low for the majority of solutions. Across the five groups, a high consensus was reached for 89 (providers) to 66 (innovators) of the 183 solutions.

In contrast, when looking specifically at the 22 solutions with a high consensus on being (very) suitable for addressing the eight prioritized barriers (Table 6.5), within-group consensus was high. Nineteen of these solutions were deemed (very) suitable with high consensus by at least three stakeholder groups, and four solutions (number 13, 22, 34 and 36 in Table 6.5) even by all five stakeholder groups. These solutions focused on (i) allowing evidence from practice to count as sufficient proof of cost-effectiveness; (ii) developing innovations within the context for which they are intended; (iii) actively phasing out and devaluating low-value forms of care; and (iv) creating guidelines for the removal of low-value forms of care during the development of an innovation.

Table 6.5. Overview of suggested solutions to address the eight barriers that were assigned (moderately) high priority with high consensus, with median[I], 25th and 75th percentiles and degree of consensus on suitability in round 2 and 3[II].

Solutions[III]	*Median*	*25th - 75th percentiles*	*Degree of consensus on suitability after round 2*	*Degree of consensus on suitability after round 3*
Barrier 1: There is uncertainty about the burden of proof required for obtaining (different types of) payment.				
1. Involve the parties responsible for structural reimbursement at an early stage.	6	5-7	High	n/a
2. Allow exceptions to the burden of proof if users are open to it, but clearly communicate about the risks and responsibilities involved.	4	3-6	Low	n/a
3. Focus on the progress of evidence-based innovations by accepting them for reimbursement without competition.	6	3-6	Moderate	Low
4. Ensure that payers reach consensus on the goals and prerequisites of innovation payment among themselves.	6	5-6	n/a	High
5. Create an accessible, clear, and especially unambiguous overview of the required burden of proof, for example, per type of innovation.	6	5-7	n/a	High
6. As an innovator, inform yourself better and at an earlier stage about the burden of proof for financing.	6	5-7	n/a	High
Barrier 3: It is challenging to sufficiently demonstrate the cost-effectiveness/efficiency of an innovation in the translation phase.				
7. Allow the innovation to be conditionally reimbursed by the insurer until cost-effectiveness has been demonstrated.	6	4-6	Moderate	Moderate
8. In the context of basic benefit package management, assess whether the test on cost-effectiveness is proportional, and refrain from using it in case of disproportionality.	5	4-6	Moderate	Moderate

Table 6.5. (continued)

Solutions[III]	*Median*	*25th - 75th percentiles*	*Degree of consensus on suitability after round 2*	*Degree of consensus on suitability after round 3*
9. Allow exceptions for the application of an innovation at the request of users before cost-effectiveness is proven, but clearly communicate about the risks and responsibilities involved.	5	3-5	Low	n/a
10. Involve the parties responsible for structural reimbursement at an early stage.	6	5-7	High	n/a
11. Allocate more funds for scientific research on cost-effectiveness.	5	3-6	Moderate	Low
12. Focus on large RCT trials and allocate funding for them.	4	3-5	Low	n/a
13. Allow alternative forms of burden of proof; instead of an RCT, a trial period in which evidence can be collected in practice.	6	5-7	High	n/a
14. Allocate small subsidies to healthcare organizations for testing innovations, with the obligation to share the data with the supplier of the device.	6	5-6	High	n/a
15. Educate healthcare providers better in testing innovations to reduce the loss of time and money.	5	5-6	High	n/a
16. Pay for multi-centre implementation trajectories, thereby reducing the costs of reimbursement per centre.	6	4-6	n/a	Moderate
Barrier 8: Preventative medical devices have no business case within the cure sector.				
17. Expand the basic benefit package of the Health Insurance Act (Zvw) with preventative innovations.	6	5-6	High	n/a
18. Completely put the responsibility of payment for preventative innovation under the Social Support Act (WMO).	4	4-6	n/a	Moderate
19. Improve the validation of preventative innovations.	5	4-6	n/a	Moderate

Table 6.5. (continued)

Solutions[III]	*Median*	*25th - 75th percentiles*	*Degree of consensus on suitability after round 2*	*Degree of consensus on suitability after round 3*
Barrier 13: The objectives of temporary funding (subsidies) versus structural reimbursement (insurance contracts and basic benefit package) are not aligned.				
20. Align the objectives of temporary funding more closely with the objectives of structural reimbursement.	6	5-6	High	n/a
21. Provide temporary funding only when there is already some level of certainty of structural reimbursement.	5	2-6	n/a	Low
Barrier 16: The process surrounding a medical device must change along with the device and the necessary money, time, and efforts for this are often not paid for.				
22. Innovate and validate in the context for which the innovation is intended.	6	6-7	High	n/a
23. Involve specifically those users who are not the innovative pioneers.	5	5-6	High	n/a
24. Coach innovators early on in achieving change and impact, based on existing theories.	6	4-6	Moderate	Moderate
25. Consider not only the TRL (technology readiness levels) but also the SRL (society readiness levels) when assessing an innovation for payment.	6	5-6	High	n/a
26. Finance the communication and meetings between innovator and user which are necessary for the co-creation of an innovation.	6	5-7	High	n/a
27. Start with the necessary changes in care processes, and only then consider which (innovative) medical devices can be used in those changed processes.	5	4-6	n/a	Moderate

Table 6.5. (continued)

Solutions[III]	*Median*	*25th - 75th percentiles*	*Degree of consensus on suitability after round 2*	*Degree of consensus on suitability after round 3*
Barrier 19: Fragmentation of costs and benefits, resulting in one party paying for the innovation while another party benefits (wrong pocket problem).				
28. Implement sector and domain-crossing reimbursement codes.	6	5-6	Moderate	High
29. Implement shared savings structures.	6	5-7	High	n/a
30. Establish pathway innovation teams with the mandate to shift reimbursement within the care pathway.	6	5-6	Moderate	High
Barrier 21: Payment for and provision of healthcare are compartmentalized (siloed); it is difficult to obtain payment for innovations falling under multiple compartments.				
31. Implement sector and domain-crossing reimbursement codes.	6	5-6	Moderate	High
32. Implement integrated care pathway reimbursement.	6	5-7	High	n/a
33. Implement regional reimbursement.	5	3-6	Moderate	Low
Barrier 30: Innovation often makes healthcare more expensive, also due to the lack of discontinuation of payment for existing, low-value care.				
34. Actively phase out low-value forms of care (including the use of certain medical devices) and make them financially less attractive.	6	6-7	High	n/a
35. Implement outcome-based financing, based on comprehensive data on what works and for whom.	6	5-7	High	n/a
36. During the development of innovative medical devices, proactively consider and create guidelines for removing low-value forms of care.	6	5-7	High	n/a
37. Increase the focus on the care pathway surrounding an innovative medical device, and not only for the pilot organization's care pathway.	6	5-7	High	n/a

Table 6.5. (continued)

Solutions[III]	*Median*	*25th - 75th percentiles*	*Degree of consensus on suitability after round 2*	*Degree of consensus on suitability after round 3*
38.Systematically conduct evaluation research on medical devices within the basic benefit package to determine whether they still provide added value and should continue to be reimbursed.	6	5-7	High	n/a

n/a. not/applicable; In round 2: This solution was offered as an additional solution in round 2, hence was not evaluated on its suitability in this round. In round 3: In case a solution was assigned a level of suitability with high consensus immediately in round 2, it was excluded from re-evaluation in round 3.

Stability between questionnaire rounds

In round 3, respondents rated solutions for which moderate consensus was reached in round 2 and that were offered as a solution to a barrier that would potentially be prioritized (i.e., moderate or high consensus after round 2). This resulted in 31 solutions being re-evaluated. Compared with round 2, a high consensus was reached on the suitability of six additional solutions. Nevertheless, statistical testing showed a high degree of stability in responses; for only one solution (number 8 in Table 6.5) the healthcare providers gave a significantly higher median rating with lower variance in round 3 compared with round 2.

6.3.4 Sensitivity analysis

We assessed the sensitivity of our results for the way in which consensus is measured (see supplement C, provided at the end of this dissertation). In this study, consensus was measured using the median rating and the 25th and 75th percentiles. However, two other indicators often used in previous Delphi studies are (i) IQR <2 on a 7-point scale, and (ii) a minimum percentage of respondents above a certain threshold (e.g., ≥5 on a 7-point scale) (320). When applying the first alternative indicator to our own data, two of the eight prioritized barriers are not identified as such while one additional barrier is assigned a high priority with high consensus. When applying the second alternative indicator with at least 75% of respondents giving a rating 5 or higher, one of our eight prioritized barriers is not identified with no additional barriers. However, when 80% is used as cutoff instead, four of our prioritized barriers would not be identified as such with high consensus.

6.4 Discussion

6.4.1 Key findings

This Delphi study focused on identifying and prioritizing the multitude of financial barriers hindering the translation of innovative medical devices from prototype to implementation in practice, as well as promising solutions to address these barriers. Respondents recruited from all relevant stakeholder groups experienced many distinctive barriers, for which they mentioned many potential solutions. This not only shows the diverse nature of the financial challenges in the translation phase of the innovation process (encompassing both purely financial issues as well as related issues of a more procedural and governance nature), but also the shared responsibility of stakeholders to jointly address this challenge. In addition, the majority of the identified barriers and solutions were assigned a high priority and suitability, emphasizing the importance of taking (almost) every barrier and solution seriously.

Nevertheless, eight barriers stand out as having been assigned a high priority with a high degree of consensus overall (summarized in Box 6.1), though except for one of these barriers consensus was

not unanimous across all five stakeholder groups. Efforts to support innovative medical devices throughout the translation phase should therefore at least focus on addressing these barriers. Although these barriers were also identified separately in previous research (13,69,118,150,323), our results show that collectively these barriers are perceived as a major obstacle in practice.

Box 6.1. Prioritized financial barriers in the translation phase of innovative medical devices (in no particular order).

a. It is challenging to sufficiently demonstrate the cost-effectiveness/efficiency of an innovation in the translation phase: burden of proof as a prerequisite for payment.
b. Preventative medical devices have no business model within the cure sector.
c. The process surrounding a medical device, such as the workflow or care pathway, must change along and the necessary money, time, and effort for this are often not paid for.
d. Fragmentation of costs and benefits, resulting in one party paying for the innovation while another party benefits: the wrong-pocket problem.
e. Uncertainty about the burden of proof required for obtaining (different types of) payment, including aspects such as effectiveness, cost-effectiveness, and certification.
f. The objectives of temporary funding (subsidies) versus structural reimbursement (insurance contracts and basic benefit package) are not aligned.
g. Payment for and provision of healthcare are compartmentalized (siloed); it is difficult to obtain payment for innovations falling under multiple compartments.
h. Innovation often makes healthcare more expensive, also due to the lack of discontinuation of payment for existing, low-value care.

For the eight prioritized barriers, 22 solutions were considered suitable with high consensus. These solutions involve various strategies, including transparent and timely communication between innovators and regulatory and financial bodies; introducing alternative payment methods; and increasing attention for discontinuation of low-value forms of care. In line with the nature of the barriers, these solutions involve both improved financial mechanisms as well as improved innovation governance. Only one barrier was assigned a high priority with high consensus by all stakeholder groups and therefore seems a good starting point for improvement efforts: the lack of payment for required changes in the workflow to effectively implement and use an innovative medical device in practice. Three solutions were consistently perceived to be very suitable to address this barrier: (i) develop and validate the value of the innovation directly within the context for which the innovation is intended; (ii) consider not only technology readiness levels but also society readiness levels when financing an innovation, and (iii) finance the process of co-creating an innovation by innovator and user.

When evaluating the degrees of consensus between and within stakeholder groups, we identified high degrees of consensus between the groups but lower degrees of consensus within the groups. This suggests that individual respondents differ quite significantly in their opinion on the ratings of barriers and associated solutions, while the average opinion evens out similarly in every group. Consequently, despite overall agreement on the prioritized barriers and related solutions, attention

should be paid to potential disagreement within stakeholder groups. Nevertheless, for the eight barriers with the highest assigned priority and the accompanying solutions, the within-group consensus was high for the majority of stakeholder groups, which means that for these barriers and solutions the disagreement within stakeholder groups is limited.

We identified particular dissensus among respondents for seven solutions involving a major reform of the healthcare system, such as replacing multiple competing insurers by a single payer, introducing innovation governance on a national level, and imposing strict regulatory requirements before proceeding with reimbursement. Respondents thus seem particularly divided on the desirability of moving away from the current decentralized multi-payer system towards a more centrally governed system of healthcare innovation financing.

6.4.2 Implications for policy, practice, and research

The overview of prioritized barriers and promising solutions provided by this study can be used by stakeholders in practice to devise more targeted strategies to facilitate innovative medical devices in bridging the valley of death. Most importantly, this study highlighted the importance of viewing innovative medical devices as part of a broader care pathway. Changing care processes to embed innovative technologies requires not only effective change management within the targeted context (324), but also sufficient resources (30). Healthcare professionals and end-users should be involved early in the innovation process, and processes of co-creation and user validation should be actively supported within the envisioned implementation context.

Other implications relate to the importance assigned to transparent and timely communication, alternative payment models, discontinuing low-value care, and radical system changes. First, suggested solutions focus on the importance of communication between innovator and end-users for co-creation of the innovation, between innovator and insurers for clarity about requirements for payment, and between innovator and government for a clear overview of financing opportunities. Taken together, it is thus advisable for innovators to engage with all stakeholders early in the development phase to decide on the best approach to develop and test their device. Second, alternative payment models such as bundled payments and shared savings arrangements are being regarded as promising tools for stimulating value-based care (245,325). However, for a variety of reasons the design, implementation and upscaling of such models has proven difficult in practice (326,327). In this respect, stakeholders should take into account the lessons of recent payment reform initiatives, for example related to governmental stewardship, garnering mutual trust and active stakeholder engagement (328). Third and related to the previous point, the disconcerting continuation of payment for low-value care in addition to the innovation has been receiving increasing attention (329), in line with growing concerns about the economic and environmental sustainability of healthcare systems (330). Disincentivizing low-value care and actively communicating its undesirability to healthcare professionals will provide more room for valuable

innovation in healthcare. Finally, our findings suggest that radical systemic changes are unlikely to be successful in overcoming the identified barriers (at least in the short run) because of clear dissensus and limited support among stakeholders and the many unproductive discussions that can be expected as a result.

This study also has an implication for future Delphi studies, related to the measurement of consensus. Previous systematic reviews on Delphi studies demonstrated large variation in indicators and cutoff points used to define consensus, and the lack of sensitivity analyses applied in these studies (320). In view of our results, we argue that for skewed data our consensus indicator based on the 25^{th} and 75^{th} percentiles is preferred over indicators using the IQR. Specifically, our indicator is more sensitive to detect concepts that are actually highly rated when data is skewed to the left, and more reliable with respect to concepts that are actually lower rated when data is skewed to the right. In addition, we have shown that when using an indicator based on a minimum percentage of respondents giving some rating, the consensus measurement is strongly dependent on the cutoff percentage chosen. Future Delphi studies should carefully consider which consensus indicator to use, especially when data are skewed.

6.4.3 Limitations

Our study has several limitations. First, the qualitative analysis of the suggested barriers and solutions might have introduced bias in the results as this process included the interpretation, rephrasing, and categorization of responses. We tried to mitigate this bias by involving two authors and preserving the original wording as much as possible. Second, the length of the second and third questionnaire might have contributed to the lower response rates compared with the first questionnaire. Nevertheless, the absolute number of respondents in each round is higher than in other Delphi studies in this field (30,331,332). Additionally, the high stability in respondents' answers can be seen as a sign of saturation in the true opinion of experts, although the lack of significant differences between questionnaire rounds could also be related to the limited sample size. Finally, the additional 17 solutions offered in the second questionnaire round were only evaluated once, and almost all these solutions ultimately reached only moderate consensus. However, since a fourth questionnaire to re-evaluate these additional solutions would likely have resulted in survey fatigue and a low response rate, this idea was not implemented.

6.5 Conclusion

The valley of death has long been regarded as a major obstacle preventing innovative medical devices from being successfully implemented in healthcare practice. Despite this, a comprehensive understanding of the multitude of financial barriers, their perceived urgency, and promising solutions to address these barriers was missing. This Delphi study has identified and prioritized a

diverse set of financial and related challenges, highlighting the shared responsibility of all stakeholders to address these challenges through improved financial mechanisms and innovation governance. Among eight identified prioritized barriers, one stands out because it was assigned a high priority across all five stakeholder groups: the lack of payment for required changes in the workflow or care pathway due to the implementation and use of the innovative medical device. A promising solution to this barrier is to approach innovation as a financially supported process of co-creation and validation, with active early involvement of care professionals and users within the envisioned context of implementation.

Appendix 6.a. Description study focus

This questionnaire includes questions about the payment for innovative medical devices when these innovations are translated from a working prototype to being ready for implementation in regular healthcare practice. When answering these questions, please consider innovations with the following characteristics:

I. Innovative **medical devices**.

- These are products used in the prevention, diagnosis, treatment, or support of a disease or disability. The focus is on devices (such as surgical robots, smart patches, or implants) and specifically not on eHealth apps or pharmaceuticals.

II. Innovations in **curative somatic care**.

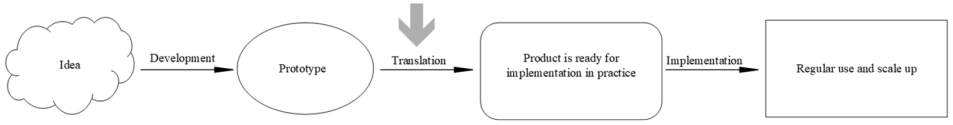
- This includes primary care, specialized medical care, medical rehabilitation, and physiotherapy.

III. Innovations with **high added value for healthcare** (higher quality and/or cost savings) but with **low potential for commercial value**.

- These are products where the potential for return on investment and profit is low or unclear.

IV. Innovations in the **translation phase**.

- These are products that have progressed to a clinically proven prototype and are attempting to transition to readiness for implementation in regular healthcare practice (Technology Readiness Level 7-8-9).



Finally, this study focuses on the **payment** for innovations and related healthcare. This includes **temporary funding structures as well as structural reimbursement systems**.

Chapter 7

General conclusions and discussion

7.1 Introduction

The central aim of this dissertation was to dive deep into the role that payment plays throughout the healthcare innovation process, to understand the facilitating and impeding influences different payment mechanisms have, and to investigate how to overcome severe financial barriers. In this chapter we will begin by offering a summary of the main findings, addressing the research questions that were posed in the introduction of this dissertation. We then proceed to discuss the overall conclusions drawn from these findings and elaborate on their implications for policy and practice and for future research. Finally, this dissertation will be completed with some closing words.

7.2 Summary of the main findings

Chapters 2 to 6 focused on understanding the role of payment throughout the innovation process, with chapters 5 and 6 also specifically highlighting the direction of promising solutions to overcome some of the most severe financial barriers. Five research questions were formulated, each of which was addressed in the respective consecutive chapters.

Q1: What is already known in the scientific literature about the role of payment in healthcare innovation throughout the various phases of the healthcare innovation process?

We performed a systematic review of the literature in chapter 2, on the role of payment mechanisms in OECD countries in innovation processes. Published between 2000 and 2022, 157 articles were included and narratively synthesized according to the type of innovation (product or process) and the phase of the innovation process (development, translation and implementation). We analysed the studies for the type of payment that was provided, its role in healthcare innovation, the main barriers and facilitators identified in the research and any other relevant findings.

We found that fewer studies were performed on the development and translation phases of innovation than on the implementation phase, and fewer studies on the role of payment in process innovations than in product innovations. However, the four main patterns we identified from the literature with regards to the role of payment apply to both types of innovation. First, we identified insufficient use of evidence on benefits and costs of innovation in financial decision-making, which may harm the development and implementation of potentially valuable innovations. Moreover, such decisions are influenced by the public or private origin of the payments. Whereas the former aims to increase health or societal value, the latter has a predominant focus on generating commercial value through innovation. Second, disruptive innovations do not fit well in existing, dominant payment mechanisms and care provision practices. Both the vested interests associated with existing

practices and uncertainties about the how-question hinder the implementation of disruptive innovations. Third, there is a lack of nationwide implementation and structural reimbursement opportunities for innovation, causing many innovations to remain stuck in local fragmentation based on temporary payments. Fourth, literature indicated the importance of viewing the role of financial factors in relation to other, non-financial factors. Thus, the type and amount of payment are not isolated determinants of the progress of healthcare innovations.

Finally, we also identified that most extant literature was missing a comprehensive perspective, focusing either on a single phase of an innovation in the whole process or on the influence of one specific payment mechanism. Consequently, these studies were unable to shed light on the interrelated influences of payment before and after the specific phase studied, the transformation of innovations throughout the process, or the synergistic influences of non-financial factors that determine the eventual impact of payment. In order to better grasp the financial influences throughout the innovation process, we decided to focus our next two research questions on studying these processes.

Q2: What financial influences do innovators encounter when developing, translating, and implementing innovative products in the Dutch healthcare system?

In order to address this question in chapter 3, we conducted qualitative case studies of four healthcare product innovations, two of which were a medical device and two of which a health information technology (HIT) tool. Each of these innovations emerged in the academic setting of a technical university or an academic hospital and showed evidence of great benefits for patients. We performed interviews with the actors involved in these innovations, to reconstruct the process these innovators had gone through and the relevant influences they had encountered.

We identified for each of these innovations lengthy innovation processes ranging from five to twenty years, while adoption in practice remained (very) limited. For the development of product innovations, the payment consists of 'soft' public money to keep academia afloat, generally being sufficient to work on innovative ideas. Afterwards, however, translating an innovative prototype into a marketable commodity requires large amounts of private capital for validation, certification, and production of the innovation. This already creates significant financial barriers for devices, but less for HIT tools as they generally require less investment in hardware. Eventually, attempting implementation of product innovations in the Dutch healthcare sector poses significant financial challenges. These include uncertainties regarding the appropriate payer, a low number of potential users, and the not-invented-here syndrome. All in all, although we identified a difference in the phases when financial barriers significantly start to impede medical devices and HIT tools, eventually, each of these product innovations is impeded due to financial barriers.

In line with the systematic review, we concluded that payment plays an especially impeding role for innovations without obvious commercial value, innovations particularly disrupting existing practices, and innovations attempting implementation beyond the local setting. The potential for commercial value of an innovation constitutes the main factor determining the chances of securing payment and successfully proceeding through the innovation process (Figure 1). In contrast to the findings from the systematic review, this primary focus on commercial value was not only imposed by private capital but also present in requirements for public subsidies and reimbursement mechanisms. In addition to the importance of commercial value, four contextual factors were found to significantly influence the innovation process directly and indirectly via payment: compatibility of the innovation with existing practices, and the commitment, competences, and social capital of the innovators. As we highlight in the figure, there are many instances in which personal characteristics of innovators are a decisive factor in obtaining payment rather than features and benefits of the innovation itself.

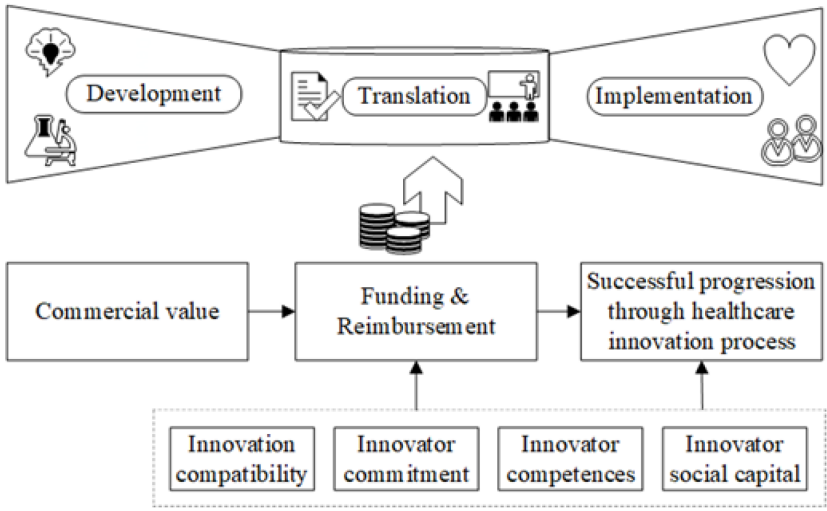


Figure 7.1. Adapted framework from chapter 3 on the influence of payment on healthcare product innovations.

Q3: What financial influences do innovators encounter when developing, translating, and implementing innovative processes in the Dutch healthcare system?

As a next study, in chapter 4, we conducted qualitative case studies of four process innovations that attempt to integrate care between organisations. This is a widely recognized manner of improving the quality of care through *"structured efforts to provide coordinated, pro-active, person-centered, multidisciplinary care by two or more well-communicating and collaborating care providers either within or across sectors"* (241). Even though the benefits of integrated care are widely recognized,

implementation of these processes remains difficult in practice, with research and policy often pointing at financial barriers as a potentially crucial impeding influence. To analyse the influence of financial factors on the process of developing and implementing integrated care projects, elaborate descriptive analyses of these projects were made. To this end, we conducted interviews with the actors involved in the projects, analysed documentation related to the projects, and constructed a framework visualising the impact of all relevant factors on the outcomes of these projects.

Generally, we found that for projects requiring only small changes in practice (i.e., non-disruptive), respondents argued there was sufficient financial wiggle room in current payment mechanisms to develop and implement integrated care in local practices. Moreover, even for the project that required larger changes (i.e., more disruptive), there seemed to be ways of resolving financial conflicts of interest through agreements between the providers and payers involved. Thus, we found a more nuanced role of payment for process innovations in this study compared with the role of payment in product innovation projects in the previous study. Nevertheless, financial leeway (i.e., sufficient financial freedom due to slack resources or flexible budgets to reallocate investments) was emphasized to be essential for developing and implementing the necessary changes in practice.

We concluded that while payment plays an important role in the progress of process innovations, its influence is neither deterministic nor isolated. This is because the likelihood of realizing a positive outcome is affected by the alignment between the complexity of a project and the fulfilment of several key conditions, specifically the willingness to change, the alignment of interests and uniformity of goals, the availability of sufficient resources to change, and effective management of external stakeholders. Financial resources can be directed to fulfilling these conditions, as they for example can be used to increase willingness to change or manage stakeholders.

After our studies aiming to understand the role of payment throughout innovation processes, we aspired to address some of the most severe financial barriers by searching for promising solutions to a) scale-up innovative HIT tools beyond their locally implemented settings and b) bring innovative medical devices through the valley of death towards sustainable implementation in practice. Our final two research questions focus on these challenges.

Q4: Which complexities do innovators encounter in the scale-up of innovative health information technologies in the Dutch healthcare system, and what are promising strategies to address these complexities?

To answer this research question in chapter 5, we complemented our own scientific perspective with other fields of science, bringing aspects into the light that had not previously been identified. Specifically, our a) structural perspective of identifying facilitators and barriers that systematically influence the scale-up of innovations was complemented with b) an ecological perspective, focusing

on the aspects of the local context that need to be adapted before an innovation can be scaled to a new setting, and c) a critical perspective, taking into account that during scale-up both the local context and the innovation itself change in a process of mutual adaptation. Building on these cross-disciplinary perspectives, we focused on understanding the complexities that HIT innovations encounter during attempts of replicating and scaling best practices after successful local implementation. A case study was performed of a remote patient monitoring innovation that was successfully implemented in a Dutch academic hospital, but proved to be difficult to scale-up, by interviewing the actors involved in the project.

Through an abductive analytical process of theory and empirical data, we found that two aspects tend to be overlooked in the practice and research of innovation scale-up. The first aspect is the level at which scale-up is attempted, distinguishing local scale-up from broader scale-up. The complexities associated with innovation scale-up and the strategies applied to make scale-up happen differ depending on the level at which scale-up is considered. Whereas at the local level scale-up was realized through informally working around structural barriers, at the broader level a tension arises between the structural and the critical perspective. The structural perspective presupposes a certain level of stability from the innovation to describe and embed it in formal structures, while the critical perspective highlights the necessity of ongoing malleability of the innovation. This results in an impasse for the actors involved to decide on how to proceed. The second aspect overlooked involves the path dependencies stemming from pre-existing local circumstances, which are not easily adaptable and complicate the scale-up of innovations in that particular setting.

Based on these findings, we conclude that it is essential for scale-up of innovations to provide leeway for ingenuity in local contexts, even in the most formalized structures such as regulations and reimbursement mechanisms. In addition, it is important to realize that the implementation and scaling of innovation is always complex, something that should not be ignored or downplayed. Acknowledging the complexity associated with innovation scale-up is the first step to developing appropriate strategies.

Q5: Which financial barriers for innovative medical devices in the translation phase are perceived as most urgent by various stakeholders in the Dutch healthcare system, and which solutions do they deem most promising?

For our final research question, in chapter 6 we adopted the Delphi study methodology including the perspectives of multiple relevant stakeholders that were not or insufficiently represented throughout the other studies of this dissertation. A total of 72 Dutch experts on the process and payment of healthcare innovations were included as respondents from five stakeholder groups of innovators, care providers, health insurers, (social) venture capitalists, and (semi-) government. Furthermore, we shaped the methodology in such a way that allowed for an explicit link between

the urgency with which financial barriers ought to be addressed and promising solutions that are suitable for addressing these barriers. Specifically, we were interested in the priority assigned to the identified barriers and the perceived suitability of the suggested solutions to address those barriers. In addition, we were interested in the degree to which consensus could be reached on these barriers and solutions and differences therein between and within various stakeholder groups.

The many financial barriers that were identified, 33 in total, showed the complexity of the financial challenge, but also that stakeholders are well-aware of the issues that need solving. Many of these financial barriers were in line with the findings from our earlier studies on product innovation processes in chapters 2 and 3. Eight barriers stood out as being prioritized with high consensus to be solved with the highest urgency, and for which 22 suitable solutions were proposed. The proposed solutions show the necessity of all stakeholders to jointly address the challenge, advocating strategies of transparent and timely communication between innovators and regulatory and financial bodies; introducing alternative payment methods; and calling attention to discontinuation of low-value forms of care. Overall, the consensus on the urgency of barriers and suitability of solutions appeared to be high between the stakeholder groups but lower within the groups. This suggests that opinions diverge not necessarily based on the position that respondents hold, but that attention should be paid to the possibility of key actors not agreeing with a certain approach. Nevertheless, one barrier was prioritized by all stakeholders, namely the lack of payment for required changes in the workflow to effectively implement and use an innovative medical device in practice. Furthermore, we found particular dissensus among the respondents about the desirability of moving away from the current decentralized multi-payer system towards a more centrally governed system of healthcare innovation payment.

Based on these findings, we concluded that solutions involve both improved payment mechanisms as well as improved innovation governance. Most importantly, respondents perceive the urgency of viewing product innovations as part of a broader care pathway. This requires change management of the product itself as well as the surrounding process whenever technological innovation is pursued. For this purpose, the respondents propose moving the innovation towards practice at an earlier stage involving the users in developing and validating the innovation in a process of co-creation. It is vital that this process of co-creation and change management in the envisioned context of implementation is financially supported, rather than only paying for the innovative device.

7.3 General conclusions

Based on our findings, we can draw six general conclusions. In the next section, we formulate relevant implications for policy, practice and future research, and discuss these in light of relevant literature.

7.3.1 General conclusions

1. Payment mechanisms can impact healthcare innovation in many different ways, depending on features of the innovation itself, characteristics of the people involved in the innovation project and other contextual factors.

The first conclusion is that specific payment mechanisms can impact healthcare innovation in many different ways, depending on features of the innovation itself, characteristics of the people involved in the innovation project, and other relevant contextual factors. In chapter 2, for example, the review of scientific evidence showed that reimbursement mechanisms influence disruptive innovations differently from non-disruptive innovations. Chapter 3 highlighted the differences in financial barriers encountered for medical devices and health information technologies throughout the phases of the innovation processes. And chapter 4 emphasized the synergistic influences of financial and non-financial factors such as trust, leadership, and stakeholder management. It is therefore difficult to draw general conclusions about the facilitating or impeding influences of specific payment mechanisms for innovation. This also implies that there is no one-size-fits-all financial solution to facilitate valuable innovation in healthcare.

2. Dominant payment mechanisms typically incentivize healthcare innovations that offer high commercial value rather than value for health or society.

In addition to acknowledging that the influence of payment depends on many contextual factors, the (potential) value of an innovation is central to understanding the role payment has in healthcare innovation processes. Several chapters of this dissertation found that dominant payment mechanisms typically incentivize healthcare innovations that offer high commercial value (i.e., favourable prospects for high financial returns on investment), rather than value for health or society at large. Chapter 2, for example, showed the influence of private capital focusing solely on the potential profits of an innovation thus *"generating health gains by accident not by design"* (59). Chapter 3 identified the persistent request for a business case that shows the commercial potential of an innovation, from the earliest research subsidies onwards. And chapter 4 highlighted the challenge of reducing revenue for vested interests when innovating care processes, irrespective of the potential benefits for the patient. However, given the large amounts of public resources distributed in healthcare systems to support innovation and the urgency of the societal challenges healthcare systems are facing, the primary aim of paying for innovation should be to facilitate value for health or society.

3. Many of the identified financial barriers are caused by gaps between or misalignment of different payment mechanisms, rather than within a single payment mechanism or in a single process phase.

Often, financial barriers stem from disparities or misalignments among various payment mechanisms and innovation phases. For example, in chapter 3 we found competing health insurers to be unwilling to reimburse the same innovations. Or in chapter 4, in which we found that fragmentations between different reimbursement mechanisms caused severe disincentives to integrate care. And in chapters 2 and 3 we identified that gaps in funding between the development and translation phase, when public research subsidies end before private investors are willing to step in, causes many healthcare innovations to disappear. It is noteworthy that we were only able to identify these financial barriers because of the broad perspective adopted in our research, taking into account the entire innovation process and all payments that play a role in parallel or consecutively.

4. Financial leeway in the healthcare sector is essential for fostering innovation; it is vital to support the work required in every phase of the innovation process and facilitate efforts to change.

As stated in the very beginning of this dissertation, to innovate means to introduce change. Innovation requires human action to adapt the innovation and the context in every phase of the innovation process. Consequently, innovations – of both products and processes – are rarely fixed entities that exist separately from the people that interact with it. We emphasized the necessity of iterative adaptation to shape innovation projects based on contextual conditions in chapter 4, local ingenuity in chapter 5, and the acknowledgement of innovation as part of broader care pathways in chapter 6. The importance of stimulating innovation development and implementation in practice, to ensure a good innovation-context fit, is becoming increasingly obvious. However, initiatives of experimentation and co-creation with users and efforts for change management require financial support. Thus, we argue that financial leeway in the form of slack resources and flexible budgets in the healthcare sector is crucial for innovation.

5. Valuable innovations are very unlikely to proceed beyond the local setting, due to the absence of a transparent and explicitly value-driven national system of reimbursement as well as a limited understanding of scaling-up healthcare innovations.

Our findings in chapters 2, 3 and 5 show that valuable innovations are often being forced to take the path of locally fragmented implementation supported by temporary funds rather than being sustainably reimbursed and implemented more broadly. Consequently, we found that innovations, especially when aiming to bring about disruptive changes, are very unlikely to proceed beyond the local setting. We identified at least two potential reasons for this. As a first reason, several studies indicated an absence of a transparent and explicitly value-driven national system of reimbursement, which results in the near absence of innovations receiving national coverage. The limited chances of valuable innovations to be supported beyond the local setting results in two challenges. First, many of these innovations never succeed in acquiring reimbursement on a scale large enough to

sustainably support them. Second, the lack of broader implementation results in fragmentation in which receipt of innovative care by the patient is based solely on his or her specific local provider and insurer. The second reason why innovations are often not spread beyond the local setting is an insufficient understanding of scaling-up healthcare innovations among both researchers and policy makers. For innovations to be implemented broadly, for example through a nationwide reimbursement agreement, it is often argued they need to present a fixed entity. However, this notion is at tension with the necessary local adaptation of context and innovation, through which an innovation continuously changes. In short, when considering broader scale-up of innovations, stakeholders get stuck in the impasse between a simultaneous need for stability and malleability. As long as these issues are not addressed, valuable innovations will not have a chance to spread beyond their local settings.

6. The absence of strategies to effectively replace existing care practices with valuable innovations and to address the losses involved with these changes, form an increasingly complex challenge impeding valuable healthcare innovation.

Finally, this dissertation provides evidence for barriers when the innovation involves replacing existing care activities or shifting care between providers. Often, these barriers are related to a (fear of) potential losses in revenue, especially in case of short-term investments with long-term benefits or in case of innovations inducing a wrong-pocket-problem (i.e., when costs are incurred by one entity while benefits accrue to another). However, the resistance of vested interests towards innovations often also has non-financial reasons. Respondents of the studies in chapters 3, 4 and 5 mentioned the potential loss of interesting tasks in care provision (e.g., specific types of patients they had always cared for were now shifted to other providers) and uncertainties associated with changing the way things have always been. Consequently, we found that the chances of implementing an innovation in healthcare are significantly better when the innovation is presented on-top-off existing activities rather than as replacing them. In this case, there is no need to disrupt financial or other interests, as everyone can continue doing business as usual. However, this strategy is not a sustainable form of paying for innovation in view of expanding healthcare expenditures. Moreover, chapter 6 found that disincentivizing low-value forms of care is one of the most promising solutions to provide room for valuable innovations. Nevertheless, currently there is an absence of strategies in policy and practice of healthcare innovation to address the losses often associated with implementing valuable innovations. This forms an increasingly complex challenge impeding valuable healthcare innovation.

7.4 Implications for policy, practice and research

Our general conclusions contain important implications for policy, practice, and research.

7.4.1 Implications for policy and practice

1. Payment for healthcare innovation should be based on the features of the innovation itself as well as on the context in which it is embedded.

The first general conclusion implies that potential solutions to solve financial barriers should be assessed and contemplated per type of innovation, also considering contextual factors. The synergy between financial and non-financial influences formed a recurring theme throughout this dissertation and highlighted several aspects to be considered when deciding on payment.

The first aspect are the contextual conditions in which the innovation will be embedded. This includes for example the willingness to change of users, the resources required for an innovation to work, or the engagement of external stakeholders. Such contextual factors determine which payment incentives are needed to realize a successful innovation, for instance payments for buying a novel product, for convincing professionals to provide care collaboratively or for educating patients in self-care. This requires innovators to correctly assess what types of payment their innovation might need and bring this up with insurers, investors and possibly regulatory authorities.

The second aspect is the disruptiveness of the innovation for existing care processes. When disruptiveness is high, the need for payment adaptations is larger. When innovations are compatible with existing care practices, they have an easier time getting implemented and paid for within the existing payment structures. The implication is that it is desirable to implement a (more) flexible payment system in healthcare, with the opportunity to deviate from existing payment mechanisms when necessary. Especially when fundamental challenges require major innovative solutions, there should be room to support more disruptive innovations. Examples of such flexibility in the payment system can be found in the investment in collaboration initiatives between primary care and social services through public transformation payments (333); temporary reimbursement fees for eHealth consultations and telemonitoring of patients when the covid-crisis enforced distance (334); and bundled payments for integrated care of chronically ill patients (264). However, such payment adaptations remain quite rare and short-term, even when the need for disruptive changes is high. To better support this need requires that the government, regulatory authorities, patient and professional interest groups, insurers, and investors collaboratively agree on the areas where adaptations in payment are most urgently needed, create the necessary adaptations, and execute them.

2. Payment for healthcare innovation should be shaped with a primary focus on incentivizing value for health and society.

Ideally, payment mechanisms facilitate innovations with high potential benefits for health and society. The predominant focus of current payment mechanisms – rewarding innovations with the largest potential to sell, make a profit for the payer, or result in the largest savings – is not directed at the values that healthcare innovations should be stimulated to pursue. In line with the increasing scientific attention for responsible innovation in health (216), a reorientation in the focus of payment for innovation is needed to support innovations that respond to urgent health challenges, address collective needs and inequalities, and make healthcare more sustainable. While we do not advocate complete ignorance with regards to commercial potential, innovations should only be paid for when they have significant potential for health and societal value.

To facilitate this reappraisal of values, it is vital to explicitly prioritize health and societal value in payment mechanisms. This priority-setting could, for example, be implemented through public funding supporting mission-driven innovative research on urgent challenges without requiring evidence of a commercial business case (335); through multi-year value-based procurement by care providers or insurers, investing in specific relevant challenges (336,337); and/or through a broader understanding of value in the basic benefit package, moving beyond the cost-effectiveness of a technology towards coverage of services and technologies that deliver value with respect to a-priori determined challenges (338,339). Our findings repeatedly showed that private capital supports innovation that will likely be reimbursed through insurance coverage or through other structural forms of payment. In this way, not only can public payment mechanisms be used to incentivize valuable innovations, but also the willingness of private investors to financially support these innovations hence inducing spillover effects for value (340).

Eventually, it will be a matter of (democratic) political decision-making, informed by professional interest groups, to determine the most urgent and relevant values which our health and society need. Naturally, the specific priority-setting can diverge between different sectors of healthcare, depending on the needs of the setting, and likely requires different payment mechanisms to facilitate them. Moreover, a criterion of proportionality can be included in the evidence requirements reflecting the prioritized values for health and society. Where possible, requirements should be kept to a minimum to give innovations sufficient opportunities to live up to their promise.

3. Payment for healthcare innovation should consider the entire innovation process.

In order to incentivize valuable healthcare innovation to progress through the entire innovation process, it is crucial to develop and target payment mechanisms while taking the entire process into consideration. Rather than focusing on financial solutions only for certain segments of the

innovation process, collaboration between different payers is necessary to accommodate paying for value from the beginning to the end. Herein lies a challenge for payers to proactively communicate and align their strategies to jointly support innovation pathways rather than innovation phases, for example through partnerships between public and private payers. Moreover, alternative payment models oriented towards sector- and domain-crossing reimbursement could help bridge the gaps between payment mechanisms that valuable healthcare innovations seem unable to cross (341). However, this also implies that researchers and policymakers maintain a comprehensive view on the innovation process, so their conclusions focus on supporting a valuable innovation to make it through the entire process.

4. Sufficient financial leeway should be created to facilitate the work and resources going into healthcare innovation processes.

The need for unearmarked funds to develop innovative ideas, for capital investments from organisations to purchase innovations, and for slack resources to support implementation and change efforts, all point to the necessity of having sufficient financial leeway to facilitate valuable innovative ideas to come to fruition in practice. Hence, in a financially constrained healthcare sector, it is important to create sufficient financial wiggle room in the resources available to protect the opportunity for innovation, rather than earmarking every euro to the most efficient use of care provision. An example of a resource that could provide such financial leeway is a so-called free spending space for health insurers (342). This initiative would allow insurers to spend a percentage of their budget on innovations that are not (yet) admitted to the basic benefits package, or on any resources necessary for the changes required in practice. In addition, it is important to facilitate multi-year financial agreements between healthcare providers and payers for providing sufficient time and financial certainty to implement changes (252). Finally, for financial leeway to have the appropriate effect, it is important that these resources are mainly reserved for the time and commitment of people involved in the innovation projects, in order to support their (often unpaid) efforts for change.

5. Opportunities for broader-scale implementation and reimbursement should be increased for valuable innovations through stronger innovation governance.

We have seen in our research that local ingenuity is essential for the successful implementation of an innovation. However, we also found that many innovations stagnate in local settings, failing to reach implementation on a scale necessary for sustainability while remaining dependent on temporary funds. Therefore, we argue that when an innovation has the potential to add value on a larger scale, there should be more opportunities for scaling these innovations up beyond the local setting. This would require stronger innovation governance on a national level, for example through a revision of the evidence requirements for insurance coverage to become more transparent and explicitly value

driven. However, research has shown that the lack of scale-up persists in both more and less decentralized healthcare systems (343,344). Rather than solely concentrating on centralizing its governance, it is therefore imperative to introduce measures specifically facilitating the broader adoption of innovation. Such measures ought to stimulate room for local ingenuity in formalized structures such as national reimbursement systems.

6. Strategies to deal with the (financial) losses associated with valuable innovation replacing existing care practices should be developed.

The absence of strategies to effectively replace existing care practices with valuable innovations and to address the (financial) losses involved with these changes, form an increasingly complex challenge impeding valuable healthcare innovation. Therefore, both in policy and in practice there is an increasing need to develop such strategies. For these strategies to work, they should either involve a reallocation of tasks in which every party stands to gain something, or a mandate for a decision-making party to decide who loses and who wins.

7.4.2 Implications for future research

Based on the findings of this dissertation, we see three important directions for future research. The first direction focuses on the evidence that is required and used in the decision-making process around paying for healthcare innovations. The question we want to pose is as follows: *What kinds of evidence are appropriate, proportional and attainable in the decision-making process around paying for healthcare innovation and how should such evidence be used in the light of aiming to stimulate valuable innovations for health and society?* We found that evidence on value for health and society is rarely used to decide which innovations get paid for and which do not. Typically, only evidence of commercial value or at most cost-effectiveness is required. For many valuable innovations, this is unhelpful since the benefits are often very narrowly defined or difficult to measure, such as whether an innovation stimulates coordination between care providers or whether an innovation facilitates the reduction of health(care) inequalities in a society. Several research projects are currently ongoing that deal with this question. In the health technology assessment (HTA) field, there are initiatives to develop methods that are more appropriate for medical devices and care services as well as being better able to include societal values (118,345,346). Moreover, the Dutch healthcare institute is performing research on using evidence obtained in practice rather than in experimental settings and on cyclically removing care that is insufficiently evidence-based from coverage (347). Even though these research projects show the growing awareness of focusing on other types and other uses of evidence when deciding on payment for healthcare innovation, many questions associated with this challenge remain to be answered.

A second direction for research could encompass an international comparison of the ways in which (different types of) healthcare innovations are being paid for and the impact of that on the degree

and speed of implementation and scale-up of valuable healthcare innovations. Specifically, an interesting question in this regard is: *What are the advantages and disadvantages of having a competition-based healthcare system for the barriers that innovations face and what is the impact on the values that are incentivized?* Data from our studies are not conclusive about the influence of competition in healthcare on innovation. There is evidence for facilitating effects, showing the willingness of providers and insurers to invest in innovative care to distinguish themselves from their competitors. However, there is also evidence about impeding effects, with the not-invented-here syndrome as an important barrier to valuable innovation and the limited resources that are made available for innovations because of the focus on cost and price reductions. Future research is needed to improve our understanding of the impact of competition in healthcare on the amount and type of innovation that is facilitated.

The third direction for research would be to identify appropriate strategies to deal with the (financial) losses often associated with valuable healthcare innovations, both in the short and the longer term. This research question could be formulated as follows: *How to design strategies to address (financial) losses associated with the implementation of valuable healthcare innovations and how can these be effectively embedded in the governance of healthcare innovation?* In the discussion of our findings, we pointed out that the absence of strategies to deal with losses (in terms of both revenue and tasks) that often incur during healthcare innovation processes pose a challenge that needs to be dealt with urgently. Lessons from literature on transition sciences, a relatively novel field of science studying the gains and pains of sociotechnological transitions, show the need for parties to acknowledge that there will be losses associated with innovation and emphasizes that innovation governance currently neglects to deal with the repercussions of sociotechnological innovations (348,349). However, research has not yet provided us with answers on how exactly to address these losses in healthcare systems to make room for innovations that add value to health and society.

7.5 Closing words

This dissertation was written in turbulent times for healthcare systems worldwide, not least the Dutch one. For half of the research period, the world was gripped by the COVID-19 crisis, showing not only the vulnerability of our healthcare system but also its resilience. Innovations were developed and implemented at high pace wherever necessary, and the aim to provide valuable care overtook any disincentive present in the system (financial, personnel-related, regulatory, or otherwise). If only for the time being, this sentiment provided the push that many innovations needed to come to fruition. After the pandemic, our healthcare system did not fully return to a state of business as usual. Society had seen and felt the limits of what our system could provide, and the Dutch government went from a narrative of 'having the best healthcare system in the world' to arguing 'if we want to prevent falling further behind on the top-countries in terms of quality of healthcare we need to take

action now' (350). So, our system has started to change. Payment systems are adapted (albeit slowly), regulations are revised, responsibilities have shifted, and the laws governing and structuring the healthcare system are increasingly under discussion. We cannot predict what the results will be for healthcare innovation in the Netherlands, but we do urge decisionmakers, care providers and innovators to use these turbulent times to push for a change in the right direction, switching the focus towards value for health and society.

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Supplements chapter 6

Supplement chapter 6.A. Consensus and rating of all solutions

Supplement table 6.A. Overview of all solutions provided by respondents in the 2nd and 3rd questionnaire for all 33 barriers with median, 25th and 75th percentile and classification as low, moderate, or high consensus on degree of suitability.

Solutions[1]		*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
Barrier 1: There is uncertainty about the burden of proof required for obtaining (different types of) payment.					
1.	**Involve the parties responsible for structural reimbursement at an early stage.**	6	5-7	High	n/a
2.	Allow exceptions to the burden of proof if users are open to it, but clearly communicate about the risks and responsibilities involved.	4	3-6	Low	n/a
3.	Focus on the progress of evidence-based innovations by accepting them for reimbursement without competition.	6	3-6	Moderate	Low
4.	**Ensure that payers reach consensus on the goals and prerequisites of innovation payment among themselves.**	6	5-6	n/a	High
5.	**Create an accessible, clear, and, especially, unambiguous overview of the required burden of proof, for example, per type of innovation.**	6	5-7	n/a	High
6.	**As an innovator, inform yourself better and at an earlier stage about the burden of proof for financing.**	6	5-7	n/a	High
Barrier 2: It is challenging to demonstrate, in the translation phase, that an innovation meets current standards of science and practice.					
7.	**Allow the innovation to be conditionally reimbursed by the insurer until evidence of it meeting current standards of science and practice has been demonstrated.**	5	5-6	Moderate	High
8.	In the context of basic benefit package management, assess whether the test for meeting current standards of science and practice is proportional and refrain from using it in case of disproportionality.	5	4-6	Moderate	Moderate

Supplement table 6.A. (continued)

Solutions[1]		*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
9.	Allow exceptions to the burden of proof if users are open to it, but clearly communicate about the risks and responsibilities involved.	4	3-5	Low	n/a
10.	Let go of the clinical burden of proof and shift the burden of proof to practical functionality and participation in the healthcare field during a trial period.	5	3-6	Low	n/a
11.	**Involve the parties responsible for structural reimbursement at an early stage.**	6	5-7	High	n/a
12.	**Allocate small subsidies to healthcare organizations for testing innovations, with the obligation to share the data with the supplier of the device.**	6	5-6	High	n/a
13.	Educate healthcare providers better in testing innovations to reduce the loss of time and money.	5	4-6	Moderate	Moderate
14.	Finance innovations as much as possible by healthcare providers and not through scientific subsidies.	5	4-6	n/a	Moderate
15.	Award Social Return on Investment (SROI) a prominent role in the assessment of innovations.	5	4-6	n/a	Moderate
Barrier 3: It is challenging to sufficiently demonstrate the cost-effectiveness/efficiency of an innovation in the translation phase.					
16.	Allow the innovation to be conditionally reimbursed by the insurer until cost-effectiveness has been demonstrated.	6	4-6	Moderate	Moderate
17.	In the context of basic benefit package management, assess whether the test on cost-effectiveness is proportional, and refrain from using it in case of disproportionality.	5	4-6	Moderate	Moderate
18.	Allow exceptions for the application of an innovation at the request of users before cost-effectiveness is proven, but clearly communicate about the risks and responsibilities involved.	5	3-5	Low	n/a

Supplement table 6.A. (continued)

Solutions[1]		*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
19.	**Involve the parties responsible for structural reimbursement at an early stage.**	6	5-7	High	n/a
20.	Allocate more funds for scientific research on cost-effectiveness.	5	3-6	Moderate	Low
21.	Focus on large RCT trials and allocate funding for them.	4	3-5	Low	n/a
22.	**Allow alternative forms of burden of proof; instead of an RCT, a trial period in which evidence can be collected in practice.**	6	5-7	High	n/a
23.	**Allocate small subsidies to healthcare organizations for testing innovations, with the obligation to share the data with the supplier of the device.**	6	5-6	High	n/a
24.	**Educate healthcare providers better in testing innovations to reduce the loss of time and money.**	5	5-6	High	n/a
25.	Pay for multi-centre implementation trajectories, thereby reducing the costs of reimbursement per centre.	6	4-6	n/a	Moderate
Barrier 4: It is challenging to sufficiently demonstrate the possibilities for scaling up an innovation in the translation phase.					
26.	**Map out scaling possibilities as early as possible.**	6	5-6	High	n/a
27.	Allow alternative forms of evidence; instead of a Randomized Controlled Trial (RCT), consider a trial period during which evidence can be gathered in practice.	5	4-6	Moderate	n/a
28.	Allow health insurers to jointly invest in an innovation.	5	4-6	Moderate	n/a
29.	**Collaborate with multiple healthcare providers during the prototyping phase to increase the evidence base.**	6	5-6	High	n/a
30.	**Communicate widely about innovative solutions that work, involving healthcare providers, health insurers, and the Dutch healthcare authority.**	6	5-7	High	n/a
31.	Experiment with a payment title per postal code area (to expedite the implementation of innovation in neighbourhoods with greater health challenges).	4	3-6	Low	n/a

Supplement table 6.A. (continued)

Solutions[1]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
Barrier 5: Unlike, for example, for new pharmaceuticals, the added value of a medical device must be demonstrated repeatedly at various healthcare providers.				
32. Share more best practices within the Netherlands.	6	6-7	High	n/a
33. Collaborate with multiple healthcare providers during the prototyping phase to increase support.	6	5-7	High	n/a
34. Integrate regional general practitioner organizations into regional support structures.	4	4-5	Moderate	n/a
Barrier 6: Unlike, for example, for new pharmaceuticals, the added value of a medical device must be demonstrated repeatedly to governments and payers in different European countries.				
35. Share more best practices within Europe.	6	6-7	High	n/a
36. Establish European guidelines for the payment of medical devices and the criteria they must meet.	5	4-6	Moderate	Moderate
37. Introduce a European authority to assess innovative medical devices, analogous to the work of the European Medicines Agency (EMA).	5	4-6	n/a	Moderate
Barrier 7: There is uncertainty about the benefits of financing innovative medical devices (return-on-investment). It is difficult to formulate a positive business case.				
38. Establish a helpdesk for innovators struggling with the development of a business case.	5	4-6	Moderate	Moderate
39. Establish guidelines for the development of a business case.	5	3-6	Moderate	Low
40. As an innovator, describe the impact of an innovation based on existing theories regarding impact pathways, and provide guidance by payers.	5	4-6	Moderate	Moderate
41. Accept that the goal is not commercial growth (return on investment) but rather increased productivity (delivering more care for the same resources).	6	5-7	High	n/a
42. Conduct standard market surveys regarding interest in and the need for an innovation.	5	4-6	Moderate	Moderate

Supplement table 6.A. (continued)

Solutions[1]		*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
43.	**Identify enthusiastic healthcare professionals who can serve as ambassadors.**	6	5-7	Moderate	High
44.	**Disseminate the innovation across multiple (healthcare) organizations and sectors.**	6	5-6	High	n/a
45.	Raise funds for the innovation through crowdfunding.	4	3-5	Low	n/a
46.	**Explore the possibility of integrating the product with existing products in the same category. This can simplify the investment process, leveraging an existing network for the targeted user market.**	5	5-6	High	n/a
47.	Reduce dependency on the willingness of health insurers to pay by increasing the mandate of the Dutch Healthcare Authority to determine rates and performance descriptions.	4	4-5	Moderate	n/a
48.	Mandate health insurers to reimburse all innovations that meet a nationally accepted framework for appropriate care.	6	3-6	Moderate	Low
49.	Require innovators to demonstrate in writing, before receiving funding, that multiple healthcare providers and patients have indicated that the innovation is valuable.	4	3-6	n/a	Low
50.	Encourage health insurers and venture capitalists to jointly invest in an innovation, with the insurer ultimately reimbursing the innovation in full.	5	4-6	n/a	Moderate
Barrier 8: Preventative medical devices have no business case within the cure sector.					
51.	**Expand the basic benefit package of the Health Insurance Act (Zvw) with preventative innovations.**	6	5-6	High	n/a
52.	Completely put the responsibility of payment for preventative innovation under the Social Support Act (WMO).	4	4-6	n/a	Moderate
53.	Improve the validation of preventative innovations.	5	4-6	n/a	Moderate

Supplement table 6.A. (continued)

Solutions[1]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
Barrier 9: Uncertainty regarding possibilities for financing innovation in the Dutch healthcare market.				
54. Organize open days where innovation can be assessed by experts, including insurers, healthcare organizations, and the government, who can guide innovators to the appropriate channels.	5	4-6	Moderate	n/a
55. Establish one or a few service points, on behalf of the government, health insurers, and healthcare providers, where innovators can obtain information.	6	5-6	High	n/a
56. Make legislation and regulations more accessible by using formats such as infographics, vlogs, and stories.	6	5-6	High	n/a
57. Organize long-term, high-quality coaching and support for innovators provided by experienced peer healthcare innovators.	5	4-6	Moderate	n/a
58. Guide innovators from a collaboration between regulatory agencies and health insurers (for example, Health Innovation-NL), ensuring a clear distribution of responsibilities.	5	4-6	Moderate	n/a
59. Gain insight into the experienced bottlenecks in Dutch healthcare innovation payment.	5	5-6	High	n/a
60. Incorporate an introduction to the organization and payment of healthcare (innovations) in relevant higher education and university programs.	6	5-6	High	n/a
61. Increase attention within healthcare institutions for translation of innovation when training healthcare workers.	6	5-6	High	n/a

Supplement table 6.A. (continued)

Solutions[1]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
Barrier 10: Fragmented payment from investors and grant providers. The large number of funds and grants as well as the fragmentation between different project phases.				
62. Enhance collaboration among payers involved in financing healthcare innovation, including ministries, subsidiaries, and investment companies.	6	5-6	High	n/a
63. Focus on simplifying and harmonizing the payment landscape at regional, national, and EU levels.	6	4-6	Moderate	Moderate
64. Mandate investors and grant providers to assess, for each new funding opportunity, whether similar funding opportunities already exist.	4	3-5	Low	n/a
65. Encourage investors to commit to innovation projects for the entire innovation process and make them co-responsible for its success.	4	4-6	Moderate	n/a
66. Enhance information provision about the (non-)responsibilities of different parties (health insurers, National Healthcare Institute, Dutch Healthcare Authority) in relevant higher education and university programs.	5	4-6	n/a	Moderate
Barrier 11: Lack of uniformity in reimbursement by different health insurers.				
67. Implement a systemic change towards one national health insurance or one regional health insurer.	4	1-5	Low	n/a
68. Establish agreements at the level of the Dutch Association of Health Insurers (ZN) regarding (the conditions for) reimbursement.	5	5-6	High	n/a
69. Incentivize health insurers to make agreements and follow each other's contracts by incorporating appropriate incentives.	6	5-7	High	n/a
70. Establish agreements within policy frameworks with health insurers to implement a congruent healthcare procurement policy for innovative devices.	6	5-6	Moderate	High

Supplement table 6.A. (continued)

Solutions[1]		*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
71.	**Expedite clarification by the National Healthcare Institute (ZIN) regarding the inclusion of an innovation in the basic benefit package.**	6	5-7	High	n/a
72.	Mandate health insurers to reimburse all innovations that meet a nationally accepted framework for appropriate care.	5	3-6	Low	n/a
73.	Establish a widely accepted framework for payment, which is uniformly applied by all relevant parties, including health insurers, the National Healthcare Institute (ZIN), and the Dutch Healthcare Authority (NZA).	6	4-6	Moderate	Moderate
74.	**Focus on simplifying and harmonizing the payment landscape at regional, national, and EU levels.**	5	5-6	Moderate	High
Barrier 12: Dependency on temporary grants and investments due to the limited willingness of health insurers to pay for the translation phase.					
75.	Provide earlier and increased financial support from health insurers.	5	3-6	Low	n/a
76.	Mandate health insurers to embrace 1 to 2 innovations per year.	3	2-5	Low	n/a
77.	Invest more in innovative medical devices for specific conditions with a smaller market but with significant added value.	5	4-6	Moderate	n/a
78.	Increase investments in innovations from innovation funds within healthcare institutions.	5	4-6	Moderate	n/a
79.	Acquire 'future' innovations for healthcare institutions by prepaying for them and being allowed to use the innovation on a trial basis as soon as it becomes available.	5	4-6	Moderate	n/a

Supplement table 6.A. (continued)

Solutions[1]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
80. Allow the Dutch Healthcare Authority (NZa) to set a reimbursement rate that can be claimed without a contract with health insurers.	4	2-6	Low	n/a
81. Implement a choice selection from a list of innovations, where the smallest health insurers are given the first opportunity to choose and receive the benefits of their investments first.	4	2-4	Low	n/a
Barrier 13: The objectives of temporary funding (subsidies) versus structural reimbursement (insurance contracts and basic benefit package) are not aligned.				
82. Align the objectives of temporary funding more closely with the objectives of structural reimbursement.	6	5-6	High	n/a
83. Provide temporary funding only when there is already some level of certainty of structural reimbursement.	5	2-6	n/a	Low
Barrier 14: Too much of the temporary financing is earmarked money.				
84. Allocate a standard, non-designated innovation budget.	5	4-6	Moderate	n/a
Barrier 15: Interest among various parties (healthcare providers, health insurers, and suppliers) to maintain the status quo.				
85. Prohibit discounts for the use of existing medical devices to healthcare providers.	4	2-5	Low	n/a
86. Intervene in power positions hindering innovation by strengthening the role of the Authority for Consumers and Markets (ACM).	5	4-6	Moderate	n/a
87. Limit profits for existing medical devices to create a more leveled competitive playing field.	4	3-5	Low	n/a
88. Adjust medical guidelines in such a way that they allow for innovative alternatives.	6	5-6	High	n/a
89. Reduce the level of detail in national laws and regulations to make change less cumbersome.	5	5-6	High	n/a

Supplement table 6.A. (continued)

Solutions[1]		*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
90.	**Conduct independent research on innovation, involving individuals without vested interests in the existing practices.**	6	5-7	High	n/a
91.	**Involve end-users at an early stage.**	7	6-7	High	n/a
92.	**Make adopting innovation more financially rewarding for healthcare providers to create an incentive for change.**	6	5-7	High	n/a
93.	**Agree with health insurers about which medical devices will no longer be reimbursed once the cost-effectiveness of the innovative alternative has been demonstrated.**	6	5-7	High	n/a
94.	**Promote a culture that values the faith and courage necessary to conceive and adopt innovative solutions, both among healthcare providers, health insurers, and the government.**	6	5-7	High	n/a
95.	Establish, where necessary, stronger decision-making authority to implement innovation.	5	4-6	Moderate	n/a
Barrier 16: The process surrounding a medical device must change along and the necessary money, time, and efforts for this are often not paid for.					
96.	**Innovate and validate in the context for which the innovation is intended.**	6	6-7	High	n/a
97.	**Involve specifically those users who are not the innovative pioneers.**	5	5-6	High	n/a
98.	Coach innovators early on in achieving change and impact, based on existing theories.	6	4-6	Moderate	Moderate
99.	**Consider not only the TRL (technology readiness levels) but also the SRL (society readiness levels) when assessing an innovation for payment.**	6	5-6	High	n/a
100.	**Finance the communication and meetings between innovator and user which are necessary for the co-creation of an innovation.**	6	5-7	High	n/a

Supplement table 6.A. (continued)

Solutions[1]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
101. Start with the necessary changes in care processes, and only then consider which (innovative) medical devices can be used in those changed processes.	5	4-6	n/a	Moderate
Barrier 17: Lack of healthcare personnel (time) to work on innovation.				
102. Establish a support centre for healthcare personnel to assist in securing financing for innovation.	4	3-6	Moderate	Low
103. Make the healthcare profession more attractive by reducing administrative burdens and improving working conditions.	6	5-7	High	n/a
104. Create opportunities for healthcare personnel to dedicate time to innovation alongside their basic duties.	6	6-7	High	n/a
105. Make existing funding applicable for the deployment of healthcare personnel.	6	5-7	High	n/a
Barrier 18: The not-invented-here syndrome among healthcare providers: unwillingness to invest in an innovation developed elsewhere.				
106. Map out scaling possibilities as early as possible.	6	5-7	High	n/a
107. Establish learning networks around innovative devices where knowledge can be exchanged among stakeholders.	6	5-6	High	n/a
108. Collaborate for similar innovations with other end-users and innovators.	6	5-6	High	n/a
109. Increase the mandate to standardize innovation by health insurers or policymakers.	5	4-6	Moderate	n/a
110. Reduce competition among healthcare institutions by working together collaboratively, for instance through professional associations.	6	4-6	Moderate	n/a
111. Expand certification possibilities regarding the use of products for patient groups beyond the one for which the device is initially certified.	5	4-6	Moderate	n/a

Supplement table 6.A. (continued)

Solutions[I]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
112. Communicate broadly about innovative solutions that work, involving healthcare providers, health insurers, and the Dutch Healthcare Authority (NZa).	6	5-7	High	n/a
Barrier 19: Fragmentation of costs and benefits, resulting in one party paying for the innovation while another party benefits: the wrong-pocket problem.				
113. Implement sector and domain-crossing reimbursement codes.	6	5-6	Moderate	High
114. Implement shared savings structures.	6	5-7	High	n/a
115. Establish pathway innovation teams with the mandate to shift reimbursement within the care pathway.	6	5-6	Moderate	High
Barrier 20: Fragmentation of costs and benefits over time, causing the costs that need to be incurred to precede the benefits by far.				
116. Develop a comprehensive business case that identifies alternative financial benefits, such as the potential for labour savings.	6	5-6	High	n/a
117. Encourage a long-term vision among health insurers to foster willingness to finance the implementation of innovations before the benefits become apparent.	6	5-6	High	n/a
118. Agree on objectives between healthcare institutions and health insurers, providing multi-year support to institutions to allow innovations to become profitable.	6	5-7	High	n/a
119. Promote multicentre implementation projects to lower the costs of implementation per centre.	5	4-6	n/a	Moderate
Barrier 21: Payment for and provision of healthcare are compartmentalized (siloed); it is difficult to obtain payment for innovations falling under multiple compartments.				
120. Implement sector and domain-crossing reimbursement codes.	6	5-6	Moderate	High

Supplement table 6.A. (continued)

Solutions[1]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
121. Implement integrated care pathway reimbursement.	6	5-7	High	n/a
122. Implement regional reimbursement.	5	3-6	Moderate	Low
Barrier 22: Innovation is financially costly for healthcare providers, while the available resources from healthcare providers to pay for innovation are limited.				
123. Allocate a separate budget for healthcare providers for innovation investments, including relatively small acquisition costs.	6	5-6	High	n/a
124. Invest in innovations through an independent fund, alleviating the need for healthcare institutions to use their own resources.	5	4-6	Moderate	n/a
125. Formulate a clear innovation vision within healthcare institutions and invest in the innovations that support this strategy.	6	5-7	High	n/a
126. Demonstrate through best practices that investments in innovations yield value for healthcare institutions.	6	5-7	High	n/a
127. Improve the argumentation for and financial justification of an innovation by innovators.	5	4-6	Moderate	n/a
128. Establish a price ceiling for innovations.	4	2-4	Low	n/a
129.Provide training for healthcare purchasers about the pricing policies of the innovation industry and align procurement policies accordingly.	4	4-6	Low	n/a
Barrier 23: The large-scale production of innovative medical devices is costly for the innovator.				
130. Allocate additional funds from the government or health insurers for the production of medical devices.	4	3-5	Low	n/a
131. Collaborate with industrial partners producing similar products.	5	4-6	Moderate	n/a
132. Divide the production process into smaller components to create multiple end products in a shorter timeframe.	4	4-5	Moderate	n/a
133. Internally train individuals at startups and accumulate internal knowledge to scale up the production of innovative products.	5	4-6	Moderate	n/a

Supplement table 6.A. (continued)

Solutions[1]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
Barrier 24: Insufficiently clear vision and/or proactive policy in the field of healthcare innovation from the government.				
134. Develop a clear vision on the payment for innovation at the Dutch Healthcare Authority (NZa).	6	5-6	High	n/a
135. Develop (a clear vision on) the frameworks for innovation at the National Healthcare Institute (ZIN).	6	5-6	High	n/a
136. Encourage a paradigm shift within the government to no longer view healthcare solely as a cost but primarily as a source of benefit for which a focus on innovation policy is necessary.	5	4-7	Moderate	n/a
137. Annually establish at national level the amount of money that ought to be invested in medical devices and conduct systematic evaluations to determine whether this amount is realized.	4	2-6	Low	n/a
138. Introduce horizon scanning of innovative medical devices to anticipate and prepare for their introduction and financing.	5	4-6	Moderate	n/a
139. Introduce a subsidy scheme to study the package-worthiness of innovative medical devices.	5	4-5	Moderate	n/a
140. Mandate companies to hire an innovation coach from a government agency to increase the likelihood of success for innovations.	2	2-4	Low	n/a
Barrier 25: EU legislation in relation to competition policy makes it difficult for governments to pay for and steer innovation.				
141. As a government, take the lead in aggregating and directing private financial resources.	4	3-5	Low	n/a
142. Apply EU legislation with less stringency.	4	3-5	Low	n/a
Barrier 26: The high level of detail and prescriptive nature of laws and regulations about healthcare at the national level limits opportunities for financing innovation.				
143. Reduce the level of detail in national regulations regarding quality frameworks.	5	4-6	Moderate	n/a

Supplement table 6.A. (continued)

Solutions[1]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
144. Reduce the level of detail in national regulations regarding privacy legislation.	5	4-6	Moderate	n/a
145. Reduce the level of detail in national regulations regarding reimbursement conditions.	5	4-6	Moderate	n/a
146. Expand certification possibilities regarding the use of products for patient groups beyond the one for which the device is initially certified.	5	4-6	Moderate	n/a
Barrier 27: Limited transparency about the actual cost price of an innovation, and therefore what the pricing should be based on.				
147. Implement guidelines and policies from public authorities such as ZIN and NZa regarding the basis for pricing innovations.	5	4-6	Moderate	n/a
148. Implement guidelines and policies from public authorities such as ZIN and NZa regarding the level of transparency about the development costs and cost structure of innovations.	5	4-6	Moderate	n/a
Barrier 28: The high costs and lengthy processes involved in meeting all the prerequisites regarding regulations and certification before health insurers proceed with payment.				
149. Allocate subsidies for the certification process.	5	5-6	High	n/a
150. Reimburse the costs of certification through health insurers.	4	2-5	Low	n/a
151. Ensure that approval for the innovation is arranged with the appropriate authorities (ZIN, CE certification) at an earlier stage before seeking financing.	5	2-6	Moderate	Low
152. Incorporate innovations conditionally into the reimbursement system before the prerequisites are finalized.	5	3-6	Low	n/a
153 Provide assistance and guidance from health insurers as partners in the process.	6	5-6	High	n/a
154. Eliminate commercial 'notified bodies' and transition to a system where the government makes certification decisions (similar to the U.S. FDA).	5	4-6	Moderate	Moderate

Supplement table 6.A. (continued)

Solutions[1]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
155. Expedite the process of providing clarity regarding certification.	5	5-6	Moderate	High
156. Accelerate decisions from public authorities regarding the inclusion of innovations in the basic benefit package.	5	4-6	Moderate	Moderate
157. Adopt valuable innovations more quickly among healthcare providers, rather than each developing their own version.	6	6-7	High	n/a
158. Reduce the administrative burden by adopting a more pragmatic approach to risks, focusing solely on real risks instead of maintaining complete quality systems.	6	5-6	Moderate	High
159. Gain insight into the experienced bottlenecks of laws and regulations.	5	5-6	High	n/a
160. Guide innovators with a collaboration of regulatory agencies and health insurers (such as Health Innovation-NL), ensuring a clear allocation of responsibilities.	6	4-6	n/a	Moderate
161. Allow certification of an innovation to apply to all target groups, rather than requiring separate certifications for each group.	5	4-6	n/a	Moderate
Barrier 29: The large number of innovations being developed makes it difficult for payers to choose what and how much to finance.				
162. Ensure that the prerequisites are met before applying for reimbursement from health insurers.	6	5-6	High	n/a
163. Include enthusiastic healthcare professionals in a payment application to demonstrate the broad support to potential payers.	6	5-7	High	n/a
164. Increase information provision for payers about what works for whom and under which conditions through data-driven learning.	6	5-6	High	n/a

Supplement table 6.A. (continued)

Solutions[1]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
Barrier 30: Innovation often makes healthcare more expensive, also due to the lack of discontinuation of payment for existing, low-value care.				
165. Actively phase out low-value forms of care (including the use of certain medical devices) and make them financially less attractive.	6	6-7	High	n/a
166. Implement outcome-based financing, based on comprehensive data on what works and for whom.	6	5-7	High	n/a
167. During the development of innovative medical devices, proactively consider and create guidelines for removing low-value alternatives.	6	5-7	High	n/a
168. Increase the focus on the care pathway surrounding an innovative medical device, and not only for the pilot organization's care pathway.	6	5-7	High	n/a
169. Systematically conduct evaluation research on medical devices within the basic benefit package to determine whether they still provide added value and should continue to be reimbursed.	6	5-7	High	n/a
Barrier 31: Innovations rarely add value in terms of ecological sustainability, affordability, or personnel sustainability.				
170. Set as a basic requirement for payment that the ecological sustainability or affordability of healthcare is enhanced and/or the staff shortage is reduced.	6	4-7	Moderate	n/a
171. Implement outcome-based payment based on comprehensive data on what works and for whom.	6	5-7	High	n/a
172. Establish a central innovation team within which various parties jointly assess whether an innovation proposal meets the principles of appropriate, sustainable care before allowing the innovation into healthcare practice.	5	2-6	Low	n/a
173. Do not unconsciously differentiate between complex and 'simple' innovations; instead, focus solely on their impact when allocating payment.	6	5-6	High	n/a

Supplement table 6.A. (continued)

Solutions[1]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
174. Reduce the incentive for growth; use payment primarily for solutions that make healthcare more affordable, inclusive, and sustainable (for example, funding prevention or public health initiatives).	6	5-7	High	n/a
175. Conduct governmental research on innovation policies without relying on external private consultants, who prioritize technological growth and high private investments.	5	4-6	Moderate	n/a
Barrier 32: Lack of collaboration between the world of innovation and healthcare practice, resulting in innovation being driven by a (technology) push rather than a (problem) pull.				
176. Ensure that innovators actively engage with healthcare practitioners to develop innovation through co-creation with end-users.	7	5-7	High	n/a
177. Establish as a condition for subsidies and investments that innovations are tested and/or valorised in everyday practice.	6	6-7	High	n/a
178. Allocate funding specifically for conducting a co-creation process through active collaboration with all stakeholders.	6	5-7	High	n/a
179. Provide funding, such as vouchers, that companies and healthcare institutions can use for the validation of innovations.	5	2-6	Moderate	Low
180. Be aware of the complexity of healthcare practice during research and development of innovations and acknowledge the practical environment in which the innovation ultimately needs to be implemented.	6	5-7	High	n/a
181. Simplify the structure and conditions of innovation payment structures, making them accessible and understandable not only for technically oriented entrepreneurs.	5	4-6	n/a	Moderate

Supplement table 6.A. (continued)

Solutions[1]	*Median*	*25th - 75th percentiles*	*Degree of consensus on priority after round 2*	*Degree of consensus on priority after round 3*
Barrier 33: The world of healthcare innovation is dominated by a like-knows-like network.				
182. Encourage payers to visit healthcare institutions more frequently to understand the context where the issues occur that require innovations.	5	4-6	Moderate	n/a
183. Proactively allocate funding more frequently to innovators who are not well-known by payers.	4	4-5	Moderate	n/a

I Solutions in bold were assigned (somewhat/very) high suitability with overall consensus.

Supplement chapter 6.B. Consensus on solutions by stakeholder group

Supplement table 6.B. Level of consensus on degree of suitability for 183 solutions, by stakeholder group.

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
Barrier 1: There is uncertainty about the burden of proof required for obtaining (different types of) payment.					
1. Involve the parties responsible for structural reimbursement at an early stage.	High	High	Moderate	High	High
2. Allow exceptions to the burden of proof if users are open to it, but clearly communicate about the risks and responsibilities involved.	Moderate	Moderate	Moderate	Low	Low
3. Focus on the progress of evidence-based innovations by accepting them for reimbursement without competition.	Moderate	Low	Moderate	Moderate	Low
4. Ensure that payers reach consensus on the goals and prerequisites of innovation payment among themselves.	High	Moderate	Low	Moderate	High
5. Create an accessible, clear, and, especially, unambiguous overview of the required burden of proof, for example, per type of innovation.	Moderate	High	High	Moderate	Moderate
6. As an innovator, inform yourself better and at an earlier stage about the burden of proof for financing.	Low	High	Moderate	High	High
Barrier 2: It is challenging to demonstrate, in the translation phase, that an innovation meets current standards of science and practice.					
7. Allow the innovation to be conditionally reimbursed by the insurer until evidence of it meeting current standards of science and practice has been demonstrated.	Low	High	High	High	Moderate

Supplement table 6.B. (continued)

Solutions[1]		*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
8.	In the context of basic benefit package management, assess whether the test for meeting current standards of science and practice is proportional and refrain from using it in case of disproportionality.	Moderate	High	Moderate	Low	Moderate
9.	Allow exceptions to the burden of proof if users are open to it, but clearly communicate about the risks and responsibilities involved.	Moderate	Moderate	Moderate	Low	Low
10.	Let go of the clinical burden of proof and shift the burden of proof to practical functionality and participation in the healthcare field during a trial period.	High	Low	Low	Low	Low
11.	**Involve the parties responsible for structural reimbursement at an early stage.**	High	High	Moderate	High	High
12.	**Allocate small subsidies to healthcare organizations for testing innovations, with the obligation to share the data with the supplier of the device.**	Moderate	High	High	Moderate	Low
13.	Educate healthcare providers better in testing innovations to reduce the loss of time and money.	Moderate	High	High	Low	Moderate
14.	Finance innovations as much as possible by healthcare providers and not through scientific subsidies.	High	Moderate	Moderate	Low	Low
15.	Award Social Return on Investment (SROI) a prominent role in the assessment of innovations.	High	Moderate	Moderate	Low	High
Barrier 3: It is challenging to sufficiently demonstrate the cost-effectiveness/efficiency of an innovation in the translation phase.						
16.	Allow the innovation to be conditionally reimbursed by the insurer until cost-effectiveness has been demonstrated.	High	High	Moderate	Moderate	Moderate

Supplement table 6.B. (continued)

Solutions[1]		*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
17.	In the context of basic benefit package management, assess whether the test on cost-effectiveness is proportional, and refrain from using it in case of disproportionality.	High	High	High	Low	Moderate
18.	Allow exceptions for the application of an innovation at the request of users before cost-effectiveness is proven, but clearly communicate about the risks and responsibilities involved.	High	Moderate	Low	Low	Moderate (low rating)
19.	**Involve the parties responsible for structural reimbursement at an early stage.**	High	High	Moderate	High	High
20.	Allocate more funds for scientific research on cost-effectiveness.	Low	Low	High	Low	Moderate
21.	Focus on large RCT trials and allocate funding for them.	Low	Moderate	Moderate	Moderate	Low
22.	**Allow alternative forms of burden of proof; instead of an RCT, a trial period in which evidence can be collected in practice.**	High	High	High	High	High
23.	**Allocate small subsidies to healthcare organizations for testing innovations, with the obligation to share the data with the supplier of the device.**	Moderate	High	High	High	Low
24.	Educate healthcare providers better in testing innovations to reduce the loss of time and money.	Low	High	High	Moderate	High
25.	Pay for multi-centre implementation trajectories, thereby reducing the costs of reimbursement per centre.	High	High	Low	Moderate	Moderate
Barrier 4: It is challenging to sufficiently demonstrate the possibilities for scaling up an innovation in the translation phase.						
26.	**Map out scaling possibilities as early as possible.**	Low	High	High	High	High

Supplement table 6.B. (continued)

Solutions[1]		*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
27.	Allow alternative forms of evidence; instead of a Randomized Controlled Trial (RCT), consider a trial period during which evidence can be gathered in practice.	High	Moderate	Moderate	High	Moderate
28.	Allow health insurers to jointly invest in an innovation.	High	Low	Moderate	High	Moderate
29.	**Collaborate with multiple healthcare providers during the prototyping phase to increase the evidence base.**	High	Moderate	High	High	High
30.	**Communicate widely about innovative solutions that work, involving healthcare providers, health insurers, and the Dutch healthcare authority.**	High	High	High	High	High
31.	Experiment with a payment title per postal code area (to expedite the implementation of innovation in neighbourhoods with greater health challenges).	Low	Moderate	Moderate	Low	Low
Barrier 5: Unlike, for example, for new pharmaceuticals, the added value of a medical device must be demonstrated repeatedly at various healthcare providers.						
32.	**Share more best practices within the Netherlands.**	High	High	High	High	High
33.	**Collaborate with multiple healthcare providers during the prototyping phase to increase support.**	High	High	High	High	High
34.	Integrate regional general practitioner organizations into regional support structures.	Low	Moderate	Moderate	Moderate	Low
Barrier 6: Unlike, for example, for new pharmaceuticals, the added value of a medical device must be demonstrated repeatedly to governments and payers in different European countries.						
35.	**Share more best practices within Europe.**	Low	High	High	High	High
36.	Establish European guidelines for the payment of medical devices and the criteria they must meet.	Low	Moderate	Low	Moderate	High

Supplement table 6.B. (continued)

Solutions[1]		*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
37.	Introduce a European authority to assess innovative medical devices, analogous to the work of the European Medicines Agency (EMA).	Low	Moderate	High	High	Moderate
Barrier 7: There is uncertainty about the benefits of financing innovative medical devices (return-on-investment). It is difficult to formulate a positive business case.						
38.	Establish a helpdesk for innovators struggling with the development of a business case.	High	Low	Low	High	Low
39.	Establish guidelines for the development of a business case.	High	Low	Moderate	Low	Low
40.	As an innovator, describe the impact of an innovation based on existing theories regarding impact pathways, and provide guidance by payers.	High	High	High	Moderate	Low
41.	**Accept that the goal is not commercial growth (return on investment) but rather increased productivity (delivering more care for the same resources).**	High	Low	High	High	High
42.	Conduct standard market surveys regarding interest in and the need for an innovation.	Low	Moderate	High	Moderate	Moderate
43.	**Identify enthusiastic healthcare professionals who can serve as ambassadors.**	High	High	High	High	Low
44.	**Disseminate the innovation across multiple (healthcare) organizations and sectors.**	Moderate	Moderate	High	High	Moderate
45.	Raise funds for the innovation through crowdfunding.	Low	Low	Low	Moderate	Moderate (low rating)
46.	**Explore the possibility of integrating the product with existing products in the same category. This can simplify the investment process, leveraging an existing network for the targeted user market.**	Moderate	Moderate	High	High	Moderate

Supplement table 6.B. (continued)

Solutions[1]		*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
47.	Reduce dependency on the willingness of health insurers to pay by increasing the mandate of the Dutch Healthcare Authority to determine rates and performance descriptions.	Moderate	Moderate	Moderate	Moderate	Moderate (low rating)
48.	Mandate health insurers to reimburse all innovations that meet a nationally accepted framework for appropriate care.	Low	High	Low	Low	Low
49.	Require innovators to demonstrate in writing, before receiving funding, that multiple healthcare providers and patients have indicated that the innovation is valuable.	Low	Low	Low	Low	Low
50.	Encourage health insurers and venture capitalists to jointly invest in an innovation, with the insurer ultimately reimbursing the innovation in full.	Moderate	High	High	Low	Moderate
Barrier 8: Preventative medical devices have no business case within the cure sector.						
51.	**Expand the basic benefit package of the Health Insurance Act (Zvw) with preventative innovations.**	High	Moderate	High	High	High
52.	Completely put the responsibility of payment for preventative innovation under the Social Support Act (WMO).	Low	Low	Moderate	High	Low
53.	Improve the validation of preventative innovations.	Moderate	Moderate	High	Moderate	High
Barrier 9: Uncertainty regarding possibilities for financing innovation in the Dutch healthcare market.						
54.	Organize open days where innovation can be assessed by experts, including insurers, healthcare organizations, and the government, who can guide innovators to the appropriate channels.	High	Moderate	High	Moderate	Low
55.	**Establish one or a few service points, on behalf of the government, health insurers, and healthcare providers, where innovators can obtain information.**	Low	Low	High	High	High

Supplement table 6.B. (continued)

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
56. Make legislation and regulations more accessible by using formats such as infographics, vlogs, and stories.	Moderate	Low	Moderate	High	High
57. Organize long-term, high-quality coaching and support for innovators provided by experienced peer healthcare innovators.	Low	Low	Moderate	Moderate	Moderate
58. Guide innovators from a collaboration between regulatory agencies and health insurers (for example, Health Innovation-NL), ensuring a clear distribution of responsibilities.	Low	Moderate	Moderate	Moderate	Moderate
59. Gain insight into the experienced bottlenecks in Dutch healthcare innovation payment.	Moderate	High	High	High	Moderate
60. Incorporate an introduction to the organization and payment of healthcare (innovations) in relevant higher education and university programs.	Moderate	Moderate	High	High	Moderate
61. Increase attention within healthcare institutions for translation of innovation when training healthcare workers.	Moderate	High	High	High	Moderate
Barrier 10: Fragmented payment from investors and grant providers. The large number of funds and grants as well as the fragmentation between different project phases.					
62. Enhance collaboration among payers involved in financing healthcare innovation, including ministries, subsidiaries, and investment companies.	High	High	High	Moderate	High
63. Focus on simplifying and harmonizing the payment landscape at regional, national, and EU levels.	Low	Low	High	High	High
64. Mandate investors and grant providers to assess, for each new funding opportunity, whether similar funding opportunities already exist.	Low	High (low rating)	Moderate	Moderate	Moderate (low rating)

Supplement table 6.B. (continued)

Solutions[1]		*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
65.	Encourage investors to commit to innovation projects for the entire innovation process and make them co-responsible for its success.	Moderate	Low	Moderate	Moderate	Low
66.	Enhance information provision about the (non-)responsibilities of different parties (health insurers, National Healthcare Institute, Dutch Healthcare Authority) in relevant higher education and university programs.	High	Moderate	Low	High	Moderate
Barrier 11: Lack of uniformity in reimbursement by different health insurers.						
67.	Implement a systemic change towards one national health insurance or one regional health insurer.	Moderate	Moderate (low rating)	Moderate	High (low rating)	Low
68.	**Establish agreements at the level of the Dutch Association of Health Insurers (ZN) regarding (the conditions for) reimbursement.**	High	Moderate	Moderate	High	Moderate
69.	**Incentivize health insurers to make agreements and follow each other's contracts by incorporating appropriate incentives.**	Moderate	High	Moderate	Moderate	High
70.	**Establish agreements within policy frameworks with health insurers to implement a congruent healthcare procurement policy for innovative devices.**	Low	High	High	Low	High
71.	**Expedite clarification by the National Healthcare Institute (ZIN) regarding the inclusion of an innovation in the basic benefit package.**	High	Moderate	Moderate	High	Moderate
72.	Mandate health insurers to reimburse all innovations that meet a nationally accepted framework for appropriate care.	Moderate	Moderate	Moderate	Moderate	Low

Supplement table 6.B. (continued)

Solutions[1]		*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
73.	Establish a widely accepted framework for payment, which is uniformly applied by all relevant parties, including health insurers, the National Healthcare Institute (ZIN), and the Dutch Healthcare Authority (NZA).	High	High	Low	Moderate	Moderate
74.	**Focus on simplifying and harmonizing the payment landscape at regional, national, and EU levels.**	Low	Low	High	High	High
Barrier 12: Dependency on temporary grants and investments due to the limited willingness of health insurers to pay for the translation phase.						
75.	Provide earlier and increased financial support from health insurers.	Moderate	Low	Moderate	Moderate (low rating)	Moderate
76.	Mandate health insurers to embrace 1 to 2 innovations per year.	Low	Low	Moderate	High (low rating)	High (low rating)
77.	Invest more in innovative medical devices for specific conditions with a smaller market but with significant added value.	Low	Low	Moderate	Moderate	Low
78.	Increase investments in innovations from innovation funds within healthcare institutions.	Low	Moderate	Moderate	Low	Low
79.	Acquire 'future' innovations for healthcare institutions by prepaying for them and being allowed to use the innovation on a trial basis as soon as it becomes available.	High	Moderate	High	Moderate	Low
80.	Allow the Dutch Healthcare Authority (NZa) to set a reimbursement rate that can be claimed without a contract with health insurers.	Moderate	Moderate	Moderate	Low	Moderate (low rating)

Supplement table 6.B. (continued)

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
81. Implement a choice selection from a list of innovations, where the smallest health insurers are given the first opportunity to choose and receive the benefits of their investments first.	Low	Moderate (low rating)	Low	Moderate (low rating)	Moderate (low rating)
Barrier 13: The objectives of temporary funding (subsidies) versus structural reimbursement (insurance contracts and basic benefit package) are not aligned.					
82.Align the objectives of temporary funding more closely with the objectives of structural reimbursement.	Moderate	High	Moderate	Moderate	High
83. Provide temporary funding only when there is already some level of certainty of structural reimbursement.	Moderate	Low	Low	Low	Low
Barrier 14: Too much of the temporary financing is earmarked money.					
84. Allocate a standard, non-designated innovation budget.	Moderate	Moderate	High	Moderate	Moderate
Barrier 15: Interest among various parties (healthcare providers, health insurers, and suppliers) to maintain the status quo.					
85. Prohibit discounts for the use of existing medical devices to healthcare providers.	Moderate	Moderate (low rating)	Moderate	Moderate (low rating)	Moderate (low rating)
86. Intervene in power positions hindering innovation by strengthening the role of the Authority for Consumers and Markets (ACM).	Moderate	Moderate	Moderate	Low	High
87. Limit profits for existing medical devices to create a more leveled competitive playing field.	Low	Low	Moderate	Moderate	Low
88. Adjust medical guidelines in such a way that they allow for innovative alternatives.	Moderate	High	High	Moderate	High
89. Reduce the level of detail in national laws and regulations to make change less cumbersome.	High	High	High	High	Moderate
90. Conduct independent research on innovation, involving individuals without vested interests in the existing practices.	High	Moderate	Moderate	High	High

Supplement table 6.B. (continued)

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
91. Involve end-users at an early stage.	Moderate	High	High	High	High
92. Make adopting innovation more financially rewarding for healthcare providers to create an incentive for change.	High	High	High	High	High
93. Agree with health insurers about which medical devices will no longer be reimbursed once the cost-effectiveness of the innovative alternative has been demonstrated.	High	High	High	High	High
94. Promote a culture that values the faith and courage necessary to conceive and adopt innovative solutions, both among healthcare providers, health insurers, and the government.	High	High	High	High	Moderate
95. Establish, where necessary, stronger decision-making authority to implement innovation.	High	Moderate	Moderate	Moderate	Moderate
Barrier 16: The process surrounding a medical device must change along and the necessary money, time, and efforts for this are often not paid for.					
96. Innovate and validate in the context for which the innovation is intended.	High	High	High	High	High
97. Involve specifically those users who are not the innovative pioneers.	Low	High	High	High	High
98. Coach innovators early on in achieving change and impact, based on existing theories.	Moderate	Moderate	High	Moderate	High
99. Consider not only the TRL (technology readiness levels) but also the SRL (society readiness levels) when assessing an innovation for payment.	High	High	High	Moderate	High
100. Finance the communication and meetings between innovator and user which are necessary for the co-creation of an innovation.	High	Moderate	High	Moderate	High

Supplement table 6.B. (continued)

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
101. Start with the necessary changes in care processes, and only then consider which (innovative) medical devices can be used in those changed processes.	Low	Moderate	Moderate	Moderate	Moderate
Barrier 17: Lack of healthcare personnel (time) to work on innovation.					
102. Establish a support centre for healthcare personnel to assist in securing financing for innovation.	Low	Low	Moderate	Low	Moderate
103. Make the healthcare profession more attractive by reducing administrative burdens and improving working conditions.	Low	Moderate	High	Moderate	High
104. Create opportunities for healthcare personnel to dedicate time to innovation alongside their basic duties.	High	High	High	High	High
105. Make existing funding applicable for the deployment of healthcare personnel.	Moderate	Moderate	High	High	Moderate
Barrier 18: The not-invented-here syndrome among healthcare providers: unwillingness to invest in an innovation developed elsewhere.					
106. **Map out scaling possibilities as early as possible.**	Low	High	Moderate	High	High
107. Establish learning networks around innovative devices where knowledge can be exchanged among stakeholders.	High	High	High	High	High
108. Collaborate for similar innovations with other end-users and innovators.	High	High	High	Moderate	High
109. Increase the mandate to standardize innovation by health insurers or policymakers.	Low	Moderate	High	High	Moderate
110. Reduce competition among healthcare institutions by working together collaboratively, for instance through professional associations.	Low	Moderate	High	Moderate	Moderate

Supplement table 6.B. (continued)

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
111. Expand certification possibilities regarding the use of products for patient groups beyond the one for which the device is initially certified.	Low	Moderate	Moderate	Moderate	Moderate
112. Communicate broadly about innovative solutions that work, involving healthcare providers, health insurers, and the Dutch Healthcare Authority (NZa).	High	High	High	High	High
Barrier 19: Fragmentation of costs and benefits, resulting in one party paying for the innovation while another party benefits: the wrong-pocket problem.					
113. Implement sector and domain-crossing reimbursement codes.	High	Low	Moderate	High	High
114. Implement shared savings structures.	Low	High	High	High	High
115. Establish pathway innovation teams with the mandate to shift reimbursement within the care pathway.	Moderate	High	High	High	High
Barrier 20: Fragmentation of costs and benefits over time, causing the costs that need to be incurred to precede the benefits by far.					
116. Develop a comprehensive business case that identifies alternative financial benefits, such as the potential for labour savings.	Low	High	High	High	Moderate
117. Encourage a long-term vision among health insurers to foster willingness to finance the implementation of innovations before the benefits become apparent.	Low	High	High	High	High
118. Agree on objectives between healthcare institutions and health insurers, providing multi-year support to institutions to allow innovations to become profitable.	Low	High	High	High	High

Supplement table 6.B. (continued)

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
119. Promote multicentre implementation projects to lower the costs of implementation per centre.	Low	High	Moderate	Moderate	Moderate
Barrier 21: Payment for and provision of healthcare are compartmentalized (siloed); it is difficult to obtain payment for innovations falling under multiple compartments.					
120. Implement sector and domain-crossing reimbursement codes.	High	High	Moderate	High	High
121. Implement integrated care pathway reimbursement.	Moderate	High	High	High	Moderate
122. Implement regional reimbursement.	Low	High	Low	Low	Moderate
Barrier 22: Innovation is financially costly for healthcare providers, while the available resources from healthcare providers to pay for innovation are limited.					
123. Allocate a separate budget for healthcare providers for innovation investments, including relatively small acquisition costs.	Moderate	High	High	High	Moderate
124. Invest in innovations through an independent fund, alleviating the need for healthcare institutions to use their own resources.	Low	Moderate	Moderate	Low	Low
125. Formulate a clear innovation vision within healthcare institutions and invest in the innovations that support this strategy.	Low	High	Moderate	Moderate	High
126. Demonstrate through best practices that investments in innovations yield value for healthcare institutions.	High	High	High	High	High
127. Improve the argumentation for and financial justification of an innovation by innovators.	Low	High	Moderate	Moderate	Moderate
128. Establish a price ceiling for innovations.	Moderate (low rating)	Moderate (low rating)	Low	Low	Moderate (low rating)
129. Provide training for healthcare purchasers about the pricing policies of the innovation industry and align procurement policies accordingly.	Low	Moderate	Moderate	Moderate	Moderate

Supplement table 6.B. (continued)

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
Barrier 23: The large-scale production of innovative medical devices is costly for the innovator.					
130. Allocate additional funds from the government or health insurers for the production of medical devices.	Low	Moderate	Moderate	Low	Low
131. Collaborate with industrial partners producing similar products.	Moderate	Moderate	High	Moderate	High
132. Divide the production process into smaller components to create multiple end products in a shorter timeframe.	Low	Moderate	Low	Moderate	Moderate
133. Internally train individuals at startups and accumulate internal knowledge to scale up the production of innovative products.	Low	Low	Moderate	Moderate	Moderate
Barrier 24: Insufficiently clear vision and/or proactive policy in the field of healthcare innovation from the government.					
134. Develop a clear vision on the payment for innovation at the Dutch Healthcare Authority (NZa).	High	Moderate	High	High	Moderate
135. Develop (a clear vision on) the frameworks for innovation at the National Healthcare Institute (ZIN).	High	Moderate	High	High	Moderate
136. Encourage a paradigm shift within the government to no longer view healthcare solely as a cost but primarily as a source of benefit for which a focus on innovation policy is necessary.	High	Moderate	High	Moderate	Low
137. Annually establish at national level the amount of money that ought to be invested in medical devices and conduct systematic evaluations to determine whether this amount is realized.	Low	Low	Moderate	Low	Low
138. Introduce horizon scanning of innovative medical devices to anticipate and prepare for their introduction and financing.	Moderate	Moderate	Moderate	Moderate	Moderate

Supplement table 6.B. (continued)

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
139. Introduce a subsidy scheme to study the package-worthiness of innovative medical devices.	Moderate	Moderate	Moderate	High	Low
140. Mandate companies to hire an innovation coach from a government agency to increase the likelihood of success for innovations.	Moderate	Low	Low	Low	Low
Barrier 25: EU legislation in relation to competition policy makes it difficult for governments to pay for and steer innovation.					
141. As a government, take the lead in aggregating and directing private financial resources.	Low	Moderate	Moderate	Low	Low
142. Apply EU legislation with less stringency.	Moderate	Moderate	Moderate	Moderate (low rating)	Low
Barrier 26: The high level of detail and prescriptive nature of laws and regulations about healthcare at the national level limits opportunities for financing innovation.					
143. Reduce the level of detail in national regulations regarding quality frameworks.	Moderate	Moderate	Moderate	Moderate	Moderate
144. Reduce the level of detail in national regulations regarding privacy legislation.	Moderate	Moderate	Moderate	Moderate	Low
145. Reduce the level of detail in national regulations regarding reimbursement conditions.	High	Moderate	High	Moderate	Low
146. Expand certification possibilities regarding the use of products for patient groups beyond the one for which the device is initially certified.	High	Moderate	High	Moderate	Low
Barrier 27: Limited transparency about the actual cost price of an innovation, and therefore what the pricing should be based on.					
147. Implement guidelines and policies from public authorities such as ZIN and NZa regarding the basis for pricing innovations.	Low	Moderate (low rating)	Moderate	Moderate	High

Supplement table 6.B. (continued)

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
148. Implement guidelines and policies from public authorities such as ZIN and NZa regarding the level of transparency about the development costs and cost structure of innovations.	Moderate	Low	High	Moderate	High
Barrier 28: The high costs and lengthy processes involved in meeting all the prerequisites regarding regulations and certification before health insurers proceed with payment.					
149*.Allocate subsidies for the certification process.	High	High	High	High	Low
150. Reimburse the costs of certification through health insurers.	Moderate	Low	Moderate	Moderate (low rating)	Low
151. Ensure that approval for the innovation is arranged with the appropriate authorities (ZIN, CE certification) at an earlier stage before seeking financing.	Low	Low	Moderate	Moderate	Low
152. Incorporate innovations conditionally into the reimbursement system before the prerequisites are finalized.	Moderate	Moderate	High	Low	Low
153. Provide assistance and guidance from health insurers as partners in the process.	Moderate	Moderate	High	High	High
154. Eliminate commercial 'notified bodies' and transition to a system where the government makes certification decisions (similar to the U.S. FDA).	Low	Low	Moderate	Moderate	High
155. Expedite the process of providing clarity regarding certification.	High	High	High	Moderate	High
156. Accelerate decisions from public authorities regarding the inclusion of innovations in the basic benefit package.	High	High	Moderate	Moderate	Moderate
157. Adopt valuable innovations more quickly among healthcare providers, rather than each developing their own version.	High	High	High	High	High

Supplement table 6.B. (continued)

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
158. Reduce the administrative burden by adopting a more pragmatic approach to risks, focusing solely on real risks instead of maintaining complete quality systems.	Low	High	High	High	Moderate
159. Gain insight into the experienced bottlenecks of laws and regulations.	High	High	Moderate	High	Moderate
160. Guide innovators with a collaboration of regulatory agencies and health insurers (such as Health Innovation-NL), ensuring a clear allocation of responsibilities.	Low	Moderate	High	High	Low
161. Allow certification of an innovation to apply to all target groups, rather than requiring separate certifications for each group.	High	Moderate	Moderate	High	Moderate
Barrier 29: The large number of innovations being developed makes it difficult for payers to choose what and how much to finance.					
162. Ensure that the prerequisites are met before applying for reimbursement from health insurers.	Low	Moderate	Moderate	High	High
163. Include enthusiastic healthcare professionals in a payment application to demonstrate the broad support to potential payers.	Low	High	Moderate	High	Moderate
164. Increase information provision for payers about what works for whom and under which conditions through data-driven learning.	Low	Moderate	High	High	High
Barrier 30: Innovation often makes healthcare more expensive, also due to the lack of discontinuation of payment for existing, low-value care.					
165. Actively phase out low-value forms of care (including the use of certain medical devices) and make them financially less attractive.	High	High	High	High	High

Supplement table 6.B. (continued)

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
166. Implement outcome-based financing, based on comprehensive data on what works and for whom.	High	High	Moderate	High	High
167. During the development of innovative medical devices, proactively consider and create guidelines for removing low-value alternatives.	High	High	High	High	High
168. Increase the focus on the care pathway surrounding an innovative medical device, and not only for the pilot organization's care pathway.	Low	High	High	High	Moderate
169. Systematically conduct evaluation research on medical devices within the basic benefit package to determine whether they still provide added value and should continue to be reimbursed.	Moderate	High	High	High	High
Barrier 31: Innovations rarely add value in terms of ecological sustainability, affordability, or personnel sustainability.					
170. Set as a basic requirement for payment that the ecological sustainability or affordability of healthcare is enhanced and/or the staff shortage is reduced.	Moderate	Moderate	Moderate	High	High
171. Implement outcome-based payment based on comprehensive data on what works and for whom.	Low	High	Moderate	High	High
172. Establish a central innovation team within which various parties jointly assess whether an innovation proposal meets the principles of appropriate, sustainable care before allowing the innovation into healthcare practice.	Low	Low	Moderate	Moderate	Low
173. Do not unconsciously differentiate between complex and 'simple' innovations; instead, focus solely on their impact when allocating payment.	Low	Moderate	High	High	Moderate

Supplement table 6.B. (continued)

Solutions[1]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
174. Reduce the incentive for growth; use payment primarily for solutions that make healthcare more affordable, inclusive, and sustainable (for example, funding prevention or public health initiatives).	High	Moderate	High	High	High
175. Conduct governmental research on innovation policies without relying on external private consultants, who prioritize technological growth and high private investments.	High	Low	Moderate	Moderate	Moderate
Barrier 32: Lack of collaboration between the world of innovation and healthcare practice, resulting in innovation being driven by a (technology) push rather than a (problem) pull.					
176. Ensure that innovators actively engage with healthcare practitioners to develop innovation through co-creation with end-users.	Moderate	High	High	High	High
177. Establish as a condition for subsidies and investments that innovations are tested and/or valorised in everyday practice.	High	High	High	High	High
178. Allocate funding specifically for conducting a co-creation process through active collaboration with all stakeholders.	High	High	Moderate	High	Low
179. Provide funding, such as vouchers, that companies and healthcare institutions can use for the validation of innovations.	Moderate	Moderate	Low	Low	Low
180. Be aware of the complexity of healthcare practice during research and development of innovations and acknowledge the practical environment in which the innovation ultimately needs to be implemented.	Low	High	High	High	High

Supplement table 6.B. (continued)

Solutions[I]	*Innovators*	*(Social) venture capital investors*	*Healthcare providers*	*Health insurers*	*(Semi) government*
181. Simplify the structure and conditions of innovation payment structures, making them accessible and understandable not only for technically oriented entrepreneurs.	High	Low	High	Moderate	Low
Barrier 33: The world of healthcare innovation is dominated by a like-knows-like network.					
182. Encourage payers to visit healthcare institutions more frequently to understand the context where the issues occur that require innovations.	Moderate	Moderate	High	High	Moderate
183. Proactively allocate funding more frequently to innovators who are not well-known by payers.	Low	Moderate	Moderate	Moderate	Low

I Solutions in bold were assigned (somewhat/very) high suitability with overall consensus.

Supplement chapter 6.C. Sensitivity analyses

Supplement table 6.C. Sensitivity analysis: classification of 33 barriers as low, moderate or high consensus on degree of priority based on the IQR and the percentage of respondents rating the barrier as somewhat or (very) high priority (5, 6 or 7) and the percentage respondents rating the barrier as (very) high priority (6 or 7).

	Barriers[I]	***Degree of consensus on priority based on the median and 25th-75th percentiles***	***IQR***[II]	***Percentage respondents rating barrier as somewhat or (very) high priority (5, 6 or 7)***[III]	***Percentage respondents rating barrier as (very) high priority (6 or 7)***[IV]
1.	**There is uncertainty about the burden of proof required for obtaining (different types of) payment, including aspects such as effectiveness, cost-effectiveness, and certification.**	**High**	**1**	79%	61 %
2.	It is challenging to demonstrate, in the translation phase, that an innovation meets current standards of science and practice. Burden of proof as a prerequisite for payment.	Moderate	2	58%	39%
3.	**It is challenging to sufficiently demonstrate the cost-effectiveness/efficiency of an innovation in the translation phase. Burden of proof as a prerequisite for payment.**	**High**	**1**	**82%**	48%
4.	It is challenging to sufficiently demonstrate the possibilities for scaling up an innovation in the translation phase. Burden of proof as a prerequisite for payment.	Low	2	46%	23 %
5.	Unlike, for example, for new pharmaceuticals, the added value of a medical device must be demonstrated repeatedly at various healthcare providers.	Low	2.75	46%	36%

Supplement table 6.C. (continued)

	Barriers[I]	*Degree of consensus on priority based on the median and 25th-75th percentiles*	*IQR[II]*	*Percentage respondents rating barrier as somewhat or (very) high priority (5, 6 or 7)[III]*	*Percentage respondents rating barrier as (very) high priority (6 or 7)[IV]*
6.	Unlike, for example, for new pharmaceuticals, the added value of a medical device must be demonstrated repeatedly to governments and payers in different European countries.	Moderate	2	58%	49%
7.	There is uncertainty about the benefits of financing innovative medical devices (return-on-investment). It is difficult to formulate a positive business case.	Moderate	2	73%	46%
8.	**Preventative medical devices have no business case within the cure sector.**	**High**	2	**89%**	73%
9.	Uncertainty regarding possibilities for financing innovation in the Dutch healthcare market.	Low	3	57%	36%
10.	Fragmented payment from investors and grant providers. The large number of funds and grants as well as the fragmentation between different project phases.	Moderate	2	70%	39%
11.	Lack of uniformity in reimbursement by different health insurers. No uniformity in reimbursement conditions nor any coordination of reimbursement practices amongst insurers.	Moderate	2	73%	42%
12.	Dependency on temporary grants and investments due to the limited willingness of health insurers to pay for the translational phase.	Low	2.75	46%	25%
13.	**The objectives of temporary funding (subsidies) versus structural reimbursement (insurance contracts and basic benefit package) are not aligned.**	**High**	**1.5**	76%	49%

Supplement table 6.C. (continued)

Barriers[I]		*Degree of consensus on priority based on the median and 25th-75th percentiles*	*IQR[II]*	*Percentage respondents rating barrier as somewhat or (very) high priority (5, 6 or 7)[III]*	*Percentage respondents rating barrier as (very) high priority (6 or 7)[IV]*
14.	Too much of the temporary financing is earmarked money.	**High (relatively low priority)**	**0**	23%	9%
15.	Interest among various parties (healthcare providers, health insurers, and suppliers) to maintain the status quo. In terms of time, costs, loss of revenue, and efforts that are associated with change.	Low	3	59%	43%
16.	**The process surrounding a medical device, such as the workflow or care pathway, must change along and the necessary money, time, and efforts for this are often not paid for.**	**High**	2	**88%**	66%
17.	Lack of healthcare personnel (time) to work on innovation. Workforce scarcity.	Moderate	2	70%	36%
18.	The not-invented-here syndrome among healthcare providers: unwillingness to invest in an innovation developed elsewhere.	Low	2.75	52%	34%
19.	**Fragmentation of costs and benefits, resulting in one party paying for the innovation while another party benefits: the wrong-pocket problem.**	**High**	**1.75**	**84%**	68%
20.	Fragmentation of costs and benefits over time, causing the costs that need to be incurred to precede the benefits by far.	Low	3	52%	27%
21.	**Payment for and provision of healthcare are compartmentalized (siloed); it is difficult to obtain payment for innovations falling under multiple compartments.**	**High**	**1**	79%	55%

Supplement table 6.C. (continued)

Barriers[I]		*Degree of consensus on priority based on the median and 25th-75th percentiles*	*IQR[II]*	*Percentage respondents rating barrier as somewhat or (very) high priority (5, 6 or 7)[III]*	*Percentage respondents rating barrier as (very) high priority (6 or 7)[IV]*
22.	Innovation is financially costly for healthcare providers, while the available resources from healthcare providers to pay for innovation are limited.	Low	3	59%	27%
23.	The large-scale production of innovative medical devices is costly for the innovator.	Low	2.75	25%	14%
24.	Insufficiently clear vision and/or proactive policy in the field of healthcare innovation from the government.	Low	2.75	52%	34%
25.	EU legislation in relation to competition policy makes it difficult for governments to pay for and steer innovation.	Low	2	34%	18%
26.	The high level of detail and prescriptive nature of laws and regulations about healthcare at the national level limits opportunities for financing innovation.	Low	**1.75**	55%	23%
27.	Limited transparency about the actual cost price of an innovation, and therefore what the pricing should be based on.	Low	2	46%	21%
28.	The high costs and lengthy processes involved in meeting all the prerequisites regarding regulations and certification before health insurers are willing or able to proceed with payment.	Moderate	2	33%	33%
29.	The large number of innovations being developed makes it difficult for payers to choose what and how much to finance.	Low	3	39%	18%
30.	**Innovation often makes healthcare more expensive, also due to the lack of discontinuation of payment for existing, less appropriate care.**	**High**	**1**	52%	52%

Supplement table 6.C. (continued)

Barriers[I]	***Degree of consensus on priority based on the median and 25th-75th percentiles***	***IQR***[II]	***Percentage respondents rating barrier as somewhat or (very) high priority (5, 6 or 7)***[III]	***Percentage respondents rating barrier as (very) high priority (6 or 7)***[IV]
31. Innovations rarely add value in terms of ecological sustainability, affordability, or personnel sustainability.	Low	3.5	36%	25%
32. Lack of collaboration between the world of innovation and healthcare practice, resulting in innovation being driven by a (technology) push rather than a (problem) pull.	Moderate	3	46%	46%
33. The world of healthcare innovation is dominated by a like-knows-like network. For instance, in the drafting of calls for grant applications, allocation of grants, and decisions regarding policy.	**High (relatively low priority)**	**1**	23%	7%

I. Barriers in bold were assigned somewhat or (very) high priority with high consensus after round 2 and 3.
II. Common classification of consensus establishment in Delphi studies (with a 7-point scale) when the Inter Quartile Range (IQR) is <2.
III. Common classification of consensus establishment in Delphi studies with the percentage respondents in at least somewhat agreement >80%.
IV. Common classification of consensus establishment in Delphi studies with the percentage respondents in (very) high agreement >75%.
Common classifications based on: Jünger, S., Payne, S. A., Brine, J., Radbruch, L., & Brearley, S. G. (2017). Guidance on Conducting and REporting DElphi Studies (CREDES) in palliative care: Recommendations based on a methodological systematic review. *Palliative Medicine*, *31*(8), 684–706. https://doi.org/10.1177/0269216317690685

Summary

Summary

Innovation, defined as *the design, invention, development and/or implementation of new or altered products, services, processes, systems, organizational structures, or business models for the purpose of significantly benefiting the individual, the group, or wider society,* seems to hold infinite promise to create value in healthcare and address increasingly pressing challenges. Yet, for this promise to come to fruition, valuable innovations must be enabled to proceed from a promising idea to being used in healthcare practice. One of the factors potentially influencing innovations' progress is payment. For every step in the process and every form of innovation, both the amount and type of payment available could influence the direction innovation will take. The central aim of this dissertation is to improve the understanding of the role of payment in healthcare innovation processes and explore promising solutions to advance the impact of payment on innovation with high potential value for health or society.

Chapter 1 provides an introduction into the general concepts underlying this dissertation and poses the research questions to be answered. Innovation can be seen as an expansive process of change, including all the steps necessary to induce change (from development, through translation, toward implementation) in many different forms (constituting a novel product or process). Regardless of its form, the definition of innovation prescribes the presence of benefits for either the patient, provider, or society at large. Given the large amount of public resources distributed in healthcare systems supporting innovation, the importance of adding value with positive impact for health or society is particularly high. The research in this dissertation aims to understand the influence of payment on the process healthcare innovations go through, in light of the potential value that innovation brings. For this reason, we adopt a broad perspective of the Dutch healthcare innovation field, and we apply a variation of research methods to different datasets collected from literature and healthcare innovation practice.

Chapter 2 presents a systematic review of the literature published between 2000 and 2022, narratively synthesizing articles discussing the influence of payment on healthcare innovation in OECD countries. Four key findings stand out: (i) Insufficient use of evidence on benefits and costs of innovation in financial decision-making may harm the development and implementation of potentially valuable innovations. Particularly payments from a private origin have a predominant focus on evidence of commercial value; (ii) Disruptive innovations do not fit well in existing, dominant payment mechanisms and care provision practices; (iii) Shortcomings in nationwide implementation and structural reimbursement opportunities for innovation cause many innovations to remain stuck in locally fragmentation based on temporary payments; (iv) Non-financial factors, including innovator characteristics and institutional support, are essential in overcoming financial barriers. Thus, the type and amount of payment are not isolated determinants of the progress of healthcare innovations.

In **chapter 3** we perform a qualitative case study of innovation processes in practice, from the perspective of the innovators themselves. By analysing four innovations, both medical devices and health information technology (HIT) tools with high potential to add value for patients, we infer the facilitating and impeding influences of payment on the progression of product innovations through the innovation process. We conclude that payment plays an especially impeding role for innovations without obvious commercial value, innovations particularly disrupting existing practices, and innovations attempting implementation beyond the local setting. In addition to these factors, the commitment, competences, and social capital of innovators were found to influence the innovations' progress via payment, both directly and indirectly.

Chapter 4 presents a second set of case studies, focusing on four projects aiming to integrate care processes between different healthcare organisations. We found a more nuanced role of payment for process innovations in this study compared with the role of payment in product innovation projects in the previous chapter. While payment plays an important role in the progress of process innovations, its influence is neither deterministic nor isolated. This is because the likelihood of realizing a positive outcome is affected by the fulfilment of several key conditions, specifically the willingness to change, the alignment of interests and uniformity of goals, the availability of sufficient resources to change, and effective management of external stakeholders. Nevertheless, financial leeway was emphasized to be essential for developing and implementing the necessary changes in practice.

After our studies aiming to understand the role of payment throughout innovation processes, we aspired to address some of the most severe financial barriers by searching for promising solutions.

In **chapter 5** we focus on understanding the complexities encountered in attempts to scale-up innovative HIT tools beyond their local settings and the strategies applied by actors to overcome these challenges. For a comprehensive theoretical perspective, we involve sociological and organisational perspectives to complement our economics and management perspectives on innovation. Based on the findings from an exemplary HIT innovation project, we conclude that scale-up attempts fail due to the demands of keeping the innovation both malleable and stable at the same time. Hence, we argue it is essential for scale-up of innovations to provide leeway for ingenuity in local contexts, even in the most formalized structures such as regulations and reimbursement mechanisms. In addition, it is important to acknowledge the inherent complexity of implementation and scaling up of innovation, something that should not be ignored or downplayed in policy.

In **chapter 6** we study financial barriers for innovative medical devices in the translation phase, aiming to bridge the 'valley of death' (referring to the many technological innovations that end at this point in the process) towards sustainable implementation. We perform a Delphi study asking a large panel of experts involved in the process and payment of innovative medical devices to suggest

and rate which financial barriers they perceive as most urgent and which solutions they deem most promising. After identifying 33 distinct financial barriers, the experts show that solutions involve both improved payment mechanisms as well as improved innovation governance. Most importantly, respondents emphasize the urgency of viewing product innovations as part of a broader care pathway. It is vital that a process of co-creation and change management is financially supported, whenever technological innovation is pursued.

Finally, in **chapter 7**, the main findings of the preceding chapters are summarized, and conclusions are drawn. In addition, we formulate implications for policy and practice as well as interesting topics for further research. Lessons from this dissertation emphasize the importance of (i) implementing a (more) flexible payment system in healthcare; (ii) more explicit prioritization of health and societal values in payment for healthcare innovation; (iii) collaboration between different payers and maintaining a comprehensive view on the innovation process; (iv) creating financial leeway to protect the opportunity for innovation; (v) increasing opportunities for scaling up valuable innovations beyond their local setting; and (vi) creating strategies to address (financial) losses involved with innovation. In conclusion, we urge for a reappraisal of values in the focus of payment mechanisms, switching the focus from commercial value towards value for health and society.

Samenvatting

Samenvatting

De belofte van innovatie, gedefinieerd als het uitvinden, ontwerpen, ontwikkelen of implementeren van nieuwe of gewijzigde producten, diensten, processen, systemen, organisatorische structuren of bedrijfsmodellen met als doel het bieden van significante baten voor het individu, de groep of de bredere samenleving, om steeds urgentere uitdagingen aan te pakken en om waarde te creëren in de gezondheidszorg is oneindig. Om deze belofte waar te maken, moeten waardevolle innovaties echter de kans krijgen om te groeien van een veelbelovend idee naar daadwerkelijk gebruik in de praktijk van de gezondheidszorg. Financiering wordt gezien als één van de factoren die de voortgang van innovaties mogelijk beïnvloeden. Voor elke stap in het proces en voor elke vorm van innovatie, kunnen zowel de hoeveelheid als het type beschikbare financiering van invloed zijn. Centraal in dit proefschrift staat het verbeteren van kennis over de rol van financiering in innovatieprocessen in de gezondheidszorg en het verkennen van veelbelovende oplossingen om de invloed van financiering op innovatie met hoge potentiële waarde voor gezondheid of maatschappij te bevorderen.

Hoofdstuk 1 biedt een inleiding over de algemene concepten die ten grondslag liggen aan dit proefschrift en zet vervolgens de onderzoeksvragen uiteen. Innovatie kan worden gezien als een uitgebreid proces van verandering, met inbegrip van alle stappen die nodig zijn om dergelijke verandering teweeg te brengen (van ontwikkeling, via translatie, naar implementatie) in verschillende vormen (een nieuw product of proces). Ongeacht de stap of de vorm, de definitie van innovatie schrijft voor dat er sprake is van significante baten, hetzij voor de patiënt, de zorgverlener, of de samenleving als geheel. Het belang van het toevoegen van waarde met een positieve impact op gezondheid of de maatschappij is bijzonder hoog, niettemin vanwege de grote hoeveelheid publieke middelen die in zorgsystemen worden geïnvesteerd ter ondersteuning van innovatie. Het onderzoek in dit proefschrift is erop gericht om de invloed van financiering op het proces dat zorginnovaties doorlopen te begrijpen, in het licht van de potentiële waarde die een innovatie meebrengt. We adopteren een breed perspectief van het Nederlandse zorginnovatieveld en passen verscheidene onderzoeksmethoden toe op data verzameld vanuit de literatuur en praktijk van zorginnovatie.

Hoofdstuk 2 presenteert een systematische review van wetenschappelijke literatuur gepubliceerd tussen 2000 en 2022, waarbij inzichten over de invloed van financiering op zorginnovatie in OESO-landen narratief worden samengevoegd. Vier bevindingen springen eruit: (i) Er wordt onvoldoende gebruik gemaakt van bewijs over de baten en kosten van innovaties in financiële besluitvormingsprocessen. Dit kan de voortgang van potentieel waardevolle innovaties schaden; (ii) Disruptieve innovaties passen niet goed in bestaande, dominante financieringsmechanismen en zorgverleningspraktijken; (iii) Een gebrek aan mogelijkheden voor landelijke implementatie en structurele bekostiging van innovatie zorgen ervoor dat veel innovaties blijven steken in lokale fragmentatie op basis van tijdelijke financiering; (iv) Niet-financiële factoren, zoals bijvoorbeeld karakteristieken van de innovator of de aanwezigheid van institutionele ondersteuning, zijn

essentieel om financiële barrières te overkomen. Dus, het type en de hoeveelheid financiering beïnvloeden de voortgang van zorginnovaties in samenhang met andere factoren.

In **hoofdstuk 3** voeren we een kwalitatieve casestudie uit van innovatieprocessen in de praktijk, bezien vanuit het perspectief van de innovators zelf. Door vier innovatieprojecten te analyseren, van medisch-technologische apparaten en eHealth hulpmiddelen met grote potentiële waarde voor patiënten, bestuderen we de faciliterende en belemmerende invloed van financiering op de voortgang van productinnovaties door het innovatieproces. We concluderen dat financiering vooral een belemmerende rol speelt bij innovaties zonder duidelijke commerciële waarde, bij innovaties die bestaande praktijken in grote mate verstoren, en bij innovaties waarvoor geprobeerd wordt om ze buiten de lokale omgeving te implementeren. Naast deze factoren blijken de toewijding, competenties en het sociale kapitaal van innovators de voortgang van innovaties zowel direct als indirect via financiering te beïnvloeden.

Hoofdstuk 4 presenteert een tweede reeks casestudies, gericht op vier projecten die tot doel hebben om zorgprocessen tussen verschillende zorgorganisaties te integreren ('integrated care'). We vonden een meer genuanceerde rol van financiering bij de procesinnovaties in deze studie vergeleken met de rol van financiering bij productinnovaties in het vorige hoofdstuk. Hoewel financiering ook een belangrijke rol speelt in de voortgang van procesinnovaties, is deze invloed noch deterministisch noch geïsoleerd. Dit komt doordat het realiseren van een positief resultaat wordt beïnvloed door verschillende belangrijke voorwaarden, waarop financiering slechts deels van invloed is; met name de bereidheid om te veranderen, het afstemmen van belangen en doelen om de richting van verandering te bepalen, de beschikbaarheid van voldoende middelen om te kunnen veranderen, en het effectief sturen van externe belanghebbenden. Desondanks wordt financiële ruimte benadrukt als een essentiële voorwaarde voor het ontwikkelen en implementeren van de noodzakelijke veranderingen in de praktijk.

Nadat de eerste studies zich voornamelijk hebben gericht op het begrijpen van de rol van financiering in innovatieprocessen, streven we naar veelbelovende oplossingen voor het aanpakken van enkele grote financiële barrières.

In **hoofdstuk 5** richten we ons daarom op het begrijpen van de uitdagingen die worden ervaren bij pogingen om innovatieve eHealth hulpmiddelen op te schalen buiten hun lokale omgeving, en de strategieën die men toepast om met deze uitdagingen om te gaan. Voor een sterkere theoretische benadering van deze studie betrekken we onderzoekers met een sociologisch en organisatorisch perspectief om ons economisch en management perspectief op innovatie aan te vullen. Op basis van bevindingen binnen een illustratief eHealth innovatieproject, zien we dat brede opschalingspogingen falen doordat de innovatie gelijktijdig veranderbaar en stabiel moet zijn. Om de spanning tussen deze vereisten te verlichten, en opschaling van innovaties mogelijk te maken,

stellen we dat het essentieel is om ruimte te bieden aan verandering van de innovatie binnen een lokale context. Deze ruimte is bovenal nodig in de meest geformaliseerde structuren zoals regelgeving en bekostigingsmechanismen. Bovendien is het belangrijk om de inherente complexiteit van opschaling van innovaties te erkennen, iets dat niet genegeerd of gebagatelliseerd mag worden in beleid.

In **hoofdstuk 6** focussen we op medisch-technologische apparaten die pogen de 'vallei des doods' te overbruggen (een term verwijzend naar de vele technologische innovaties die op dit punt in het proces verloren gaan) richting duurzame implementatie. We voeren een Delphi-studie uit waarin een groot panel van experts, betrokken bij het proces en de financiering van innovatieve medische technologie, wordt gevraagd om te benoemen welke financiële barrières zij als meest urgent beschouwen en te beoordelen welke oplossingen zij het meest veelbelovend achten. Na het identificeren van 33 verschillende financiële barrières in deze fase van het innovatieproces, geven de experts aan dat oplossingen zowel verbeterde financieringsmechanismen als verbeterd innovatiemanagement omvatten. De respondenten benadrukken de urgentie van het beschouwen van productinnovaties als onderdeel van een breder zorgproces. Het is daarom van groot belang dat processen van co-creatie en verandermanagement in de praktijk financieel worden ondersteund wanneer technologische innovatie wordt nagestreefd.

Tot slot worden in **hoofdstuk 7** de belangrijkste bevindingen van de voorgaande hoofdstukken samengevat en worden overkoepelende conclusies getrokken. Daarnaast formuleren we implicaties voor beleid en praktijk, evenals interessante richtingen voor verder onderzoek. De bevindingen uit dit proefschrift benadrukken het belang van (i) het introduceren van (meer) flexibele financieringssystemen in de gezondheidszorg; (ii) het explicieter prioriteren van gezondheids- en maatschappelijke waarden in financiering van innovatie; (iii) samenwerken tussen verschillende soorten financiers en daarbij het behouden van een volledig beeld van het innovatieproces; (iv) het creëren van financiële ruimte om mogelijkheden voor innovatie te beschermen; (v) het vergroten van kansen voor het opschalen van waardevolle innovaties buiten hun lokale omgeving; en (vi) het creëren van strategieën om (financiële) verliezen die gepaard gaan met innovatie aan te pakken. Tot slot pleiten we voor een herwaardering van waarden in de focus van financieringsmechanismen, het verleggen van de focus van commerciële waarde naar waarde voor gezondheid en maatschappij.

Dankwoord

Hier is het dan, het einde van een traject van jaren dat heeft mogen resulteren in mijn proefschrift. Ik ben dankbaar voor alle mensen die deze weg met mij hebben bewandeld, en op hun manier aan de vorming van dit boekje hebben bijgedragen.

Er is geen andere plek om dit woord van dank te beginnen dan bij mijn promotieteam. De Heren, zoals ik ze bijtijds gekscherend, maar vaker nog serieus, als collectief beschreef. Het waren de individuele, aanvullende kwaliteiten van deze heren welke hen tot zo'n prettig, effectief, en soms uitdagend promotieteam maakten. Ik ben trots dat ik deze academische beproeving onder, maar vooral ook met jullie heb mogen doorstaan.

Erik Schut, zonder jouw begeleidende wijsheid en kalmte was dit werk niet tot stand gekomen. Jij denkt voordat je spreekt, iets waar ik nog steeds van kan leren. Die rust maakt dat jij de gaten zag die wij over het hoofd zagen. Jouw deur stond de afgelopen jaren open voor mijn grootste en kleinste zorgen. Als ik over de drempel stapte, klonk altijd de stem van rede. Ook in tijden van plezier, op de kerstborrels en tijdens uitjes van de vakgroep, sprak ik graag met je. Dan vermaakte je ons met verhalen over je gezin, of over die keer dat je in een jurk een talentenshow won (iets over vroeg feminisme). Tegen het einde van de rit spraken we vaker over het afsluiten van onze beider academische wegen. Mijn proefschrift was bijna af, en jij kijkt voorzichtig richting een pensioen. Ik kan dus opgelucht ademhalen dat ik aan dit promotietraject ben begonnen, toen ik dat deed. Dank voor de wijze lessen die je deelde en het voorbeeld wat jij zet als waardig professor.

Erik van Raaij, zonder jouw begeleidende creativiteit en optimisme was dit werk niet tot stand gekomen. Jij vond de oplossingen voor (analytische) problemen waar wij niet uitkwamen, omdat er altijd een andere manier is van kijken. Wanneer jouw ogen begonnen te twinkelen tijdens teammeetings konden wij wel raden dat jij weer een plan had bedacht voor een nieuwe vraag, een visuele weergave of een befaamde woordspeling. Die laatste sneuvelden helaas te vaak onder de vele noten op de zang van onze coauteurs, maar deze ode zal nog lang resoneren. Jouw luchtige en plezierige begeleiding waren bij tijden één van de weinige lichtpuntjes in een stroom aan tegenvallers. Ik dank jou voor alle ideeën die je in dit proefschrift hebt gestopt. Alsook voor de bescheidenheid waarmee je je zo vaak hebt opgesteld om mij te laten doen wat ik goed achtte, in de wetenschap dat jij het goed zou keuren.

Frank, zonder jouw begeleidende tijd, energie en aanpassingsvermogen was dit werk niet tot stand gekomen. Niemand kan tegen jou op als het gaat over oog voor detail, en ik prijs mezelf gelukkig met alle moeite die jij in een onderwerp stak wat wellicht iets buiten jouw comfort zone lag. Jij kan doorzetten op tijden dat ik het al tien keer genoeg vond, en elke pagina in dit boekje is er beter van. Soms vraag ik me af of het enthousiasme waarmee jij mij als PhD kandidaat binnenhaalde, ooit

wankelde. Bijvoorbeeld toen ik stelde dat ik een kwalitatieve aanpak van het onderzoek wilde, of toen ik op eigen houtje aan een samenwerking begon met onze vakgroep governance. Met welk plan ik ook aan kwam zetten, jij keek me eens bedenkelijk aan en ging vervolgens toch weer zitten voor het allerbeste resultaat. Je deed altijd mee. Ik ben je dankbaar voor alle keren dat je naar me hebt geluisterd, met open oren maar ook met open hart. En ik dank je voor elke rode streep die je hebt gezet, want het liet me zien hoeveel ik nog te leren heb. Opdat we samen konden leren tijdens dit traject.

Cruciaal voor de inhoud van dit boekje zijn ook alle innovatoren, inspiratoren en dromers die ik de afgelopen jaren heb ontmoet. Helaas zijn jullie in veel te grote getalen om allen bij naam te noemen. Gelukkig zijn jullie in veel te grote getalen om allen bij naam te noemen! Buiten alle kennis en ervaringen die jullie met mij gedeeld hebben, zonder welke ik geen resultaten had gehad van mijn onderzoek, deelden jullie iets van veel grotere waarde: het besef dat een idee, een visie, een passie niet voldoende is, het is de overtuiging om dat idee tot je levenswerk te maken wat uiteindelijk het verschil maakt. Dit boekje is voor jullie.

Bijzonder dank aan iedereen bij Medical Delta en BeterKeten voor het ondersteunen en samenbrengen van al deze inspirerende mensen, en de ruimte die jullie gaven voor mijn onderzoek.

Ik dank de leden van mijn beoordelingscommissie, prof. Delnoij, prof. Rovers en prof. Koolman, voor hun kritische blikken op dit werk. Jullie goedkeuring vormde de finale, doch essentiële, stapsteen naar een bevestiging dat ik deze jaren iets van academische waarde heb gemaakt.

Veel dank gaat ook uit naar alle collega's bij de ESHPM, van de mede-PhD kandidaten aan de lunchtafels, tot de mededocenten voor de klassen, tot de medebetrokkenen in de (beleids)overleggen. Jullie maakten de organisatie waar ik al die jaren met plezier en trots heb gewerkt. Dank dat ik hier mezelf mocht zijn.

Speciaal waren de collega's van de vakgroep HSI, die mij al die jaren inspiratie hebben geboden en hun wijsheid met mij wilden delen, met onder meer Raf, Timo, Nèwel, Michel, Tadjo, Andreea, Lisa, Pim, Lieke, Mieke, Stephanie, Richard, Rudy, Peter, Tim, Marco en Wynand. Ik ben blij dat ik mijn proefschrift heb mogen schrijven in jullie gezelschap. Het maakt nederig om te zien met hoeveel toewijding er hier gestreefd wordt naar kennis. Het kleine aantal mensen en de kalmte van deze groep maakten dat ik me gehoord voelde en het bood mij een academische omgeving om te groeien.

Wanneer je zoveel van je tijd gezamenlijk doorbrengt, ontstaat er onvermijdelijk een speciale band tussen mensen. In het bijzonder wil ik binnen de vakgroep de volgende mensen danken voor een mooie vriendschap.

Anja, jij ving mij op toen ik binnenkwam bij de HSI en je nam me meteen onder je vleugels. Ik kon altijd bij jou terecht voor een luisterend oor en goed advies. Lange tijd deelden wij met zijn tweeën een kantoor, wat het makkelijk maakte om eindeloos te kletsen, het liefst onder het genot van een stukje chocolade dat in de middag uit jouw laatje verscheen. Ik koester onze vriendschap en geniet er als bonustante van om jouw familie te zien groeien.

Daniëlle, jij was vanaf de eerste dag een warme wind op werk. Door jouw natuurlijke enthousiasme en vriendelijkheid voelde ik me snel op mijn gemak, en met je idealisme spoorde je me aan om te geloven dat ik door kon zetten. Ik hoop dat je altijd blijft strijden voor je idealen.

Wouter, al neuriënd begaf jij je door je PhD. Hoe zwaar het ook werd, bij jou leek het altijd een feestje. Dank voor alle vrolijkheid die je uitstraalde en voor je aanstekelijke energie.

Nanne, wat was ik blij dat jij me een beetje voor de gek had gehouden met je vragen over het PhD-leven toen bleek dat je bij ons kwam werken. Ik heb genoten van onze tijd als collega's en van alle keren dat we samen hebben gelachen.

Met een bijzonder warme lach denk ik aan Celine en Frédérique. Zoals Anja mij opving in J8-01 , zo mocht ik jullie opvangen in dat mooie kantoor. En in de laatste jaren van mijn promotietraject, groeiden het aantal planten, slingers en inside jokes op het whiteboard gestaag. Celine, ik dank jou voor je openheid. Ik weet dat je dit zelf niet altijd zo ziet, maar hier schuilt jouw kracht en vertrouwen. Blijf je gevoel volgen, het krijgt je op de juiste plek. Frédérique, ook op jou kunnen mensen bouwen. Met een gerust hart droeg ik al mijn organisatorische taken aan je over, zelfs het regulier uitruimen van de vaatwasser. Met je doorzettingsvermogen weet jij bergen te verzetten. Lieve meiden, dank voor de lange dagen die we samen doorbrachten. Ik heb genoten van de theatershows, de etentjes en onze roadtrip door Amerika. Boven alles ben ik dankbaar voor jullie onvoorwaardelijke interesse in mijn werk. Zo wist ik zeker dat er in ieder geval twee mensen met evenveel verdriet naar mijn tegenslagen en met evenveel trots naar mijn successen keken. En zo hoort het, give the people...

In het bijzonder wil ik de volgende mensen op de faculteit bedanken voor een mooie vriendschap. Renaud, Judy, Carlos, Luis, Stijn, Leonie and Hamraz. From the Dutch sandwich lunches at the seventh floor till the beers in de Smitse, from the covid picknicks along the Maas till the fancy dinners under my Christmas tree, you added colour to my days within and outside the Bayle building. Thank you for all the international trivia you shared with me, for all the times you showed our individual

setbacks were only symptoms of a collective burden, and for all the times you lightened that burden with a joke or a cheers.

Thomas, wij wisten de afstand tussen de 6e en 8e verdieping met enige regelmaat te overbruggen, een prestatie die enkel ESHPM'ers werkelijk zullen begrijpen. Dank voor de lange gesprekken over onze gezamenlijk interesse in de financiering van waardevolle zorg, voor je leerzame inzichten, en voor de manier waarop je voor iedereen klaarstaat.

Chiara, Hamraz and Renée, the four of us formed the FP2P group. Throughout the years, we showed how interdisciplinarity and listening to other perspectives truly hold value in academia. I would never have understood the world of innovation as well without you. Thank you for unveiling this intriguing, and at times impermeable, world with me by shining your lights on it.

Ik ben niets zonder mijn sociale leven. Aan vrienden dichtbij en ver weg dank ik mijn energie en veerkracht. Iedereen die mij heeft laten lachen, vliegen en dansen en me heeft aangemoedigd om door te zetten, jullie hebben aan dit boekje bijgedragen.

Jessie, jouw onbevangenheid en eerlijkheid maken dat ik me veilig voel bij jou. Dank voor alle keren dat we hebben gehuild van het lachen, of dat we nog konden lachen door de tranen heen, voor de vragen die je mij stelt, waardoor ik weer een beetje eerlijker naar mezelf moet zijn, en voor het gevoel dat je mij begrijpt. Je tovert altijd een glimlach op mijn gezicht.

Samen met Sophie, Roos, Matthijs en Egid vormen we een hechte groep waar ik met lief en leed terecht kan. Sinds het begin van mijn tijd in Maastricht voelde ik in jullie een gelijkgestemdheid, een gevoel dat meegroeit terwijl wij zelf groeien. We mogen dan niet meer op maandagavond in themaverkleedkleren in de kelder een beerpong toernooi staan te houden, of op een donderdagse BOB marshmallows verbranden op de bar, mijn hart maakt nog steeds een sprongetje als ik jullie zie. Jullie zullen stuk voor stuk bijzondere dingen doen in jullie levens, en ik kan niet wachten om daarbij te mogen zijn. OVD.

Daphne, er zijn van die mensen met een eindeloos groot hart, volgens mij bestaat dat in jou. Toch ben ik dankbaar voor een plekje in dat hart. Als Twentse Tukker heb jij nu je plekje gevonden in Limburg, waar de deur altijd voor me open staat. Of liever gezegd de achterdeur. Waar jij bent, daar voel ik me welkom.

Samen met Jane, Stephanie, Maarten, Twan en Kevin vormt ons oud-bestuur een mooie vriendschap. We zijn ooit samengebracht om elkaar te complementeren. Zo voelt het nog steeds compleet als we samen zijn. We zeiden het toen al, samen sterk.

Lisa, toen we elkaar leerden kennen, de studieuze nerd en de relaxte partygirl, was de liefde tussen ons nog weinig aanwezig. Maar de sterkste vriendschappen vind je soms waar je ze het minste

verwacht. Over de jaren zijn we naar elkaar toe gegroeid, met onze avonturen in Canada, India en thuishaven Maastricht als dierbare herinneringen. Blijf winnen in het leven meis, je verdient het.

Marsha en Koen, zonder jullie had ik mijn weg naar de Achterhoek nooit gevonden, met zijn motoren, houtbijlen en achterdeuren die altijd voor iedereen openstaan. Als ik die hottub ooit realiseer, dan hoop ik dat jullie er met mij rondjes in komen draaien.

Mieke, wat een rijkdom om een vriendin te hebben die je al bijna je hele leven kent. Ik waardeer hoe jij je eigen creatieve pad kiest en al het moois dat daaruit voortkomt. Ik weet dat ik altijd bij jou terug mag komen.

Kay, als wij samen zijn, kijken mensen ons geregeld een beetje vreemd aan. Wij hebben onze eigen humor, en dat schept een speciale band. Dank voor alle giechelbuien.

Aan mijn lieve paranimfen, Sterre en Stephanie. Sterre, vanaf mijn start in Rotterdam was jij erbij en ik haalde opgelucht adem toen jij een maand na mij aan je eerste werkdag bij de ESHPM begon. Niemand heeft mij door de pandemie gesleept zoals jij. Meerdere hoofdstukken van dit boekje zijn geschreven terwijl ik bij jou aan de keukentafel zat, of jij bij mij. Met bewondering beschouw ik jouw kijk op het leven, onbezorgd, het komt toch altijd wel goed. Dat is iets waar ik als realist af en toe aan herinnerd moet worden. Jij hebt me laten inzien dat je niet altijd vooraf een richting hoeft te hebben om te komen waar je moet zijn. En je hebt me laten inzien dat geen enkele vorm van training voldoende is om een winnaarsmentaliteit op het sportveld te verslaan. Ik waardeer dat jij bij de laatste beproeving van dit traject naast me wil staan.

Stephanie, ook zonder jou had ik het einde van deze jaren niet gered. Niet op de laatste plaats vanwege alle keren dat jij mij na een lange werkdag van een warme maaltijd hebt voorzien vlak voordat ik omviel. Het is fijn om te weten dat je iemand hebt waar je onvoorwaardelijk op terug kan vallen, en bij jou weet ik dat. Door alle keren dat je mijn sleutel langsbrengt als ik mezelf weer buitensluit, dat je je agenda omgooit ten behoeve van mijn planning, dat je met gekke spulletjes van de markt aan komt zetten omdat je weet dat ik iets lekker vind. Ik waardeer je eigenwijsheid en je nieuwsgierigheid, die hebben mij plekken laten zien die ik nooit zelf had durven ontdekken. Ik zal proberen me dat te herinneren, de volgende keer dat ik weer achter je aan moet rennen om in een buitenlandse bus te springen. Dank voor het feit dat je altijd naast me staat, ook tijdens deze beproeving.

Mijn Limburgse roots bieden mij vastigheid, niet omdat ík er vandaan kom (dat is namelijk niet zo), maar omdat mijn familie er vandaan komt. Zij borgen mij. Mijn wonderlijke familie: oma Toos, Fenna en Mike, Luca en Cas, Mel, Karin en Paul, Susanne en André, Mara en Dirk, Stan en Fleur,

Monique en Richard, Mary-Anne, Har, Anneke, Fred en Petra. Dank voor jullie uitbundigheid, jullie gekkigheid, jullie levenslust. Het is een feestje om samen te kunnen zijn, jullie zijn de beste.

Fenna, van jongs af aan vonden wij in elkaar onze gelijke. Samen dansen op K3, dezelfde outfits op de camping en dan uren kletsen. Later wilden we beiden de wereld over reizen, emigreren, en uiteindelijk gewoon een veilig thuis vinden bij familie. Nog steeds kan ik bij jou terecht als ik een probleem heb, want de kans is groot dat jij hetzelfde hebt meegemaakt. Dank voor alle keren dat je riep "ik ook!" Ik hoop dat we nog lang dezelfde dromen blijven dromen.

Lieve Maaike, als grote zus wijs jij ons de weg. Ook op dit pad naar de PhD ben ik jou gevolgd, en wat een goede richting is dat geweest. Al jong wilde ik meegaan in jouw liefde voor boeken, jouw enthousiasme om te studeren, en jouw kracht om je stem te laten horen. Dit alles is mij tijdens dit traject goed van pas gekomen. Ik waardeer hoe jij het leven vormt naar een warm thuis, en hoe je de band met ons gezin nog altijd centraal zet in de drukte van alledag. Een belangrijk deel daarvan zijn je prachtige mannen Sebastiaan, Floris en Lorens, die ons leven zoveel mooier, en een tikkie chaotischer, maken. Jullie brengen ons geluk.

Lieve Cas, grote kleine broer, jij completeert ons drieën. Met je humor en je zachtheid weet jij mensen meteen voor je te winnen. Jij leerde mij de waarde van geduld, het belang van geloven in jezelf en doorzetten op je eigen weg. Ook deze lessen heb ik tijdens mijn traject meegenomen. Ik waardeer hoe jij verhalen kan vertellen en hoe je stil kan zijn als de wereld om je heen zich overschreeuwt. En natuurlijk geniet ik nog het meest als we samen het kerstdiner staan te koken.

Tot slot, er zijn twee mensen die mij echt op dit punt hebben gekregen.

Lieve pap, jij hebt mij meegegeven dat ik álles kan bereiken, zolang ik me er maar voor inzet. Jij leeft je leven met je hart, en mijn hart klopt soms net zo wild als het jouwe. Je gaf mij jouw liefde voor mensen, voor feest, en voor samenzijn. Je gaf mij ook je liefde voor wetenschap, nieuwe dingen ontdekken, en "gewoon uitzoeken hoe het zit". Voeg daar jouw enthousiasme over de zorg, en met name zorginnovaties aan toe, en voilà. De appel valt niet ver van de boom. Deze academische weg had ik niet zonder jouw inspiratie mogen durven bewandelen. Want, zowel figuurlijk als letterlijk, jij hebt me leren vliegen.

Lieve mam, jij bent de rots in de branding. Je leerde mij de waarde van zorgen voor elkaar, onvoorwaardelijk voor mensen klaarstaan, en vasthouden aan je pad. Als ik weer eens van alle drukte, emoties en indrukken omval, sta jij er om me op te vangen. Zelfs wanneer je mijn keuzes niet begrijpt, ben je bereid om me een duwtje in de rug te geven. Zonder jouw steun had ik deze academische weg niet volbracht. Want ik had nooit durven vliegen, zonder een veilige plek om te landen.

Sanne
Rotterdam, augustus 2024

PhD Portfolio

PhD Portfolio

Name	S. (Sanne) Allers
Department	Erasmus School of Health Policy and Management (ESHPM)
PhD period	September 2019 – May 2024
Promotors	Prof. dr. F.T. Schut
	Prof. dr. ir. E.M. van Raaij
Copromotor	dr. F. Eijkenaar

Education

- Bachelor of Science (cum laude) in 'Healthcare Sciences', Maastricht University, the Netherlands.
- Master of Science in 'Global Health', Maastricht University, the Netherlands.
- Master of Science (cum laude) in 'Health Economics, Policy and Law', Erasmus University Rotterdam, the Netherlands.
- University Teaching Qualification, Risbo, the Netherlands.

International peer-reviewed publications (published or under review)

- Allers, S., Eijkenaar, F., van Raaij, E. M., & Schut, F. T. (2023). The long and winding road towards payment for healthcare innovation with high societal value but limited commercial value: A comparative case study of devices and health information technologies. *Technology in Society*, *75*. https://doi.org/10.1016/j.techsoc.2023.102405
- Allers, S., Eijkenaar, F., Schut, F. T., van Raaij, E. M. (2024). Aligning ambition and reality: a multiple case study into the synergistic influences of financial and other factors on the outcomes of integrated care projects. *International Journal of Integrated Care, 24(3)*. Doi: 10.5334/ijic.7736
- Allers, S., Carboni, C., Eijkenaar, F., & Wehrens, R. (2024). Understanding the complexities of eHealth innovation scale-up: a cross-disciplinary analysis and a qualitative case study. *Journal of Medical Internet Research, forthcoming.*
- Allers, S., Eijkenaar, F., Schut, F. T., van Raaij, E. M. (2024). Translating innovative medical devices from prototype to practice: a Delphi study of urgent financial barriers and promising solutions. *Health Policy and Technology. Under review.*
- Allers, S., Eijkenaar, F., van Raaij, E. M., & Schut, F. T. (2022). Paying for healthcare innovation: a systematic review of the influence of funding and reimbursement on innovation processes in healthcare. *Journal of Open Innovation: Technology, Market and Complexity. Under review.*

Conferences and seminars

- Medical Delta symposium, Rotterdam (2019)
- How to survive the medtech implementation adventure symposium, Enschede (2019)
- LSH010 Impact of eHealth on our (mental) health seminar, Rotterdam (2020)
- Innovation for Health symposium, Rotterdam (2020)
- LSH010 Innovation starts in Rotterdam seminar, digital meeting (2020)
- European Innovation Fest, digital meeting (2020)
- EuHEA PhD and Early Career Researcher conference, digital meeting (2020)
- Interdisciplinary collaboration Young Medical Delta symposium, digital meeting (2020)
- LSH010 How to finance your healthcare innovation, digital meeting (2020)
- Sustainability in healthcare Medical Delta seminar, digital meeting (2021)
- Fitting care in practice seminars Dutch Healthcare Authority, digital meeting (2021)
- EuHEA PhD and Early Career Researcher conference, digital meeting (2021)
- Medical Delta symposium, digital meeting (2021)
- RSM Innovation Management seminar, digital meeting (2021)
- LSH010 From value proposition to business model, digital meeting (2021)
- Innovation for Health symposium, Amsterdam (2022)
- Medical Delta Brilliant failures seminar, Delft (2022)
- IPSERA conference, Jönköping (2022)
- European Health Management Association conference, Brussels (2022)
- Annual conference of the Dutch Association for Health Economics, Maastricht (2022)
- Medical Delta symposium, Leiden (2022)
- Annual conference of the Dutch Association for Health Economics, Rotterdam (2023)
- Academy of Health research meeting, Seattle (2023)
- International Health Policy Conference, Milan (2023)
- Innovating in health service delivery panel discussion, Delft (2023)
- Medical Delta symposium, Rotterdam (2023)
- ESHPM/EUR research seminars, Rotterdam (2020-2023)

PhD training

- Searching, finding and managing your literature, Erasmus University Rotterdam (2019)
- Didactics & group dynamics, Erasmus University Rotterdam (2019)
- Innovation Management, Erasmus University Rotterdam (2020)
- Coaching and intervision, Erasmus University Rotterdam (2020)
- Case study research, Politecnico di Milano (2020)
- How to finish your PhD, Erasmus University Rotterdam (2020)
- Academic writing, Erasmus University Rotterdam (2021)
- Professionalism & Integrity, Erasmus University Rotterdam (2021)
- Media awareness, Erasmus University Rotterdam (2023)

Supervising and teaching experience

- Tutor in the bachelor course 'the Dutch healthcare system' (2019-2021)
- Tutor and supervisor in the bachelor course 'value-based healthcare' (2019-2023)
- Bachelor thesis coaching (2019-2021)
- Bachelor thesis supervisor (2021-2023)

Projects and committees

- Co-organizer EuHEA PhD and Early Career Researcher conference (2020)
- Co-organizer EuHEA PhD and Early Career Researcher conference (2021)
- Board member youngESHPM (2020-2021)
- Member of the EGSH graduate school PhD council (2020-2023)
- Member of the steering group 'social safety' (2020-2022)
- Member of the strategic workgroup 'vision for education' (2023)

About the author

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Sanne Allers (1996) focused the research for her dissertation on the various ways in which we pay for healthcare innovation, in terms of products and processes, and the value that is created through these innovations. She adopted a mixed methods study approach to represent innovation in its distinctive forms and aimed to include the perspectives of many different stakeholders in her studies. The results of her research are published in high-quality peer-reviewed journals. In addition, she presented her work to a wide range of audiences, including fellow researchers and innovators in practice. Alongside her research, Sanne enjoyed teaching. She taught in several bachelor courses in the fields of healthcare management and healthcare economics, supervised and coached thesis students of the health sciences program, and served as a guest lecturer. Finally, she obtained her University Teaching Qualification (BKO) in 2023. While working on her dissertation, Sanne was a member of several representative boards and working groups at the Erasmus School of Health Policy and Management (ESHPM), including the Graduate School PhD Council, ESHPM PhD representation, the social safety steering group, and the working group on renewing the vision for education.

Before starting her PhD, Sanne completed a BSc. degree in Health Sciences (with distinction) and a MSc. degree in Global Health at Maastricht University. She then continued to complete a MSc. degree in Health Economics, Policy and Law (with distinction) at the Erasmus University Rotterdam. Sanne is currently working as a strategic policy advisor for the Council of Public Health & Society (Raad voor Volksgezondheid & Samenleving) in The Hague, the Netherlands.

In her spare time, Sanne enjoys cooking dinner with friends, spending time with her family, playing a friendly game of tennis, caring for disabled equestrians at her volunteer job, paragliding in the French mountains, dancing at music festivals, or escaping into books of fiction.