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

Sanne Allers\textsuperscript{a,}\textsuperscript{*}, Frank Eijkenaar\textsuperscript{a}, Erik M. van Raaij\textsuperscript{a,b}, Frederik T. Schut\textsuperscript{a}

\textsuperscript{a} Erasmus School of Health Policy & Management, Erasmus University Rotterdam, Netherlands
\textsuperscript{b} Rotterdam School of Management, Erasmus University Rotterdam, Netherlands

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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: 1) shift the focus from commercial value towards societal value; 2) support dissemination of innovations beyond the local level; 3) help innovators to convey their valuable ideas.

1. Introduction

Healthcare innovation has a major impact on the quality, affordability and availability of care [1–3]. 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 [4,5]. 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 [6] and implemented in practice [7–10].

The influence of payment mechanisms on innovation is of distinct concern in the context of healthcare [11]. 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 [12–14]. 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. [15] 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 Léhoux 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 [16]. 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. [15], 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.

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 might play an important role in the early stages of innovation [17], once innovations become embedded in the practice of (largely) publicly financed healthcare systems, payment for the resulting healthcare products comes mainly from collective sources [18]. This has spurred the recent scientific attention for responsible innovation in health [19], 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 [20]. The literature on responsible innovation in health has focused mostly on different features that innovation should possess to qualify as being responsible [12], and on the role innovators and healthcare managers have in fostering such innovations [13]. 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 [21]. 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) [22]. 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 [23], venture capital funds provide the money to translate prototypes into certified products [6], transforming these innovations into more profitable commodities [24,25]. Subsequently, research on later-stage implementation of innovations shows that payment mechanisms either facilitate or obstruct innovation, depending on the payment method [26–28] and the disruptiveness of the product relative to existing practices [29–31]. 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. Methodology

We conducted a comparative case study in order to identify the role of funding and reimbursement throughout the healthcare product innovation process [33]. Case studies are an appropriate strategy for studying phenomena within complex and dynamic environments, especially where there may be strong interactions between influential factors [34,35]. It is an appropriate method for an in-depth analysis of processes rather than exploring the influence of isolated (quantitative) variables [36]. 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 [37]. Hence, our study focuses on innovations with the potential to significantly change the provision of care and replace existing processes, i.e., radical innovations [38]. 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 [11]. 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 [39,40]. 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 [41]. 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 [42]. 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 healthcare 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 [43]. 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 [43]. HIT tools include information infrastructure products for the healthcare system, as well as administrative tools or products that enable providers and patients to use IT infrastructure in clinical care [43]. 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 [44]. 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 (Appendix 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 (see Table 1), with an average length of 69 min. 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.

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 version 9, following the qualitative coding guidelines from Corbin and Strauss [45]. 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 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 Fig. 1.

<table>
<thead>
<tr>
<th>Case</th>
<th>Occupational background during innovation project</th>
<th>Number of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Researcher</td>
<td>4</td>
</tr>
<tr>
<td>B</td>
<td>Medical professional</td>
<td>1</td>
</tr>
<tr>
<td>C</td>
<td>Engineer</td>
<td>1</td>
</tr>
<tr>
<td>D</td>
<td>Medical professional</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>CEO of start-up</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Researcher</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Medical professional</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Business development coordinator</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Sales department of hospital</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Healthcare insurer</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 1
Respondents per case, by occupational background.
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.

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 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.

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 Fig. 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.

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.

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. Earmarked 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 unplan-
able, 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).

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 produced 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 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 startups 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).

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
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).

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 (Fig. 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 (Fig. 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.

Fig. 3. The direct and indirect effect of 5 C-factors on successful progression through the healthcare innovation process.
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.

4.3.1. Compatibility with dominant practices

4.3.1.1. 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 an 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).

4.3.1.2. 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 [46], that was a difficult hurdle for innovations on the road to market access and implementation [47]. 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.

4.3.1.3. 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 they 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 healthcare 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 10–15 years ahead and predict whether their innovation will ever become sufficiently accepted to receive reimbursement.

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 at 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.

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 for 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 healthcare 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.

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 almost a perfect storm that has to arise.

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?”; healthcare insurers also look at the support among medical professionals when considering whether to reimburse an innovation.

“The healthcare 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).

5. Discussion

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 [4,48–50]. 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 [29–31,51], 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 [52,53]. In contrast, several studies suggest that competition may not always stimulate innovation [54–56], while most studies have produced inconclusive results and point out the need for further research [57,58]. 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 [59], efficiency [60], and accessibility [7,61].

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 [37]. These resources ought to be allocated with the societal objective to improve population health rather than making a profit. Fig. 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 fulfill (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. [15]. 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 [62], commitment [63], competences [64] and social capital [65] 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.

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 potential significantly 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.

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 15 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 competency competences, and the social capital of the innovator team is strong.

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.

Ethical approval

Ethical approval for this study was granted by the internal review board of Erasmus School of Health Policy & Management, Erasmus University Rotterdam, with reference IRB 20-19 Allers.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The data that has been used is confidential.

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Appendix A. Supplementary data

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