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Patterns in the influence of funding and reimbursement on the development and implementation of healthcare innovation: A systematic review

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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: 1) shortcomings in national reimbursement systems result in local fragmentation in the implementation of innovations; 2) lack of evidence on costs and benefits in financial decision-making may harm the development and implementation of potentially value-enhancing innovations; 3) more disruptive innovations encounter larger financial barriers; and 4) 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.

1. Introduction

Every day, new ideas, technologies, methods, and procedures are developed to improve the functioning of healthcare systems (Torbica and Cappellaro, 2010). Some authors even regard innovation as "the engine that drives the healthcare system" (Robinson, 2015). 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 (Omachonu and Einspruch, 2010). Unsurprisingly, innovation is often viewed as having a direct influence on the quality, affordability, accessibility, and hence, the future sustainability of healthcare systems (Garber et al., 2014; Varkey et al., 2008). 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 (Omachonu and Einspruch, 2010). Consequently, there is common concern about medical innovation raising healthcare expenditures to unsustainable levels, in part because of the widespread overuse of innovations (Roh and Kim, 2017). 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. The potential to deliver such societal value is not always a given, as there can be detrimental downsides in terms of producing social inequalities (Weiss et al., 2018), negative effects for healthcare professionals (Carboni et al., 2023), or unwarranted environmental impact (Moultrie et al., 2016). As summarized by Miller and Lehoux (2020), 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 (Vohora et al., 2004). Factors that are known to inhibit healthcare

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innovation processes include the inadequate measurement of health outcomes, regulatory burdens, communication failures, siloed delivery of care, and misaligned financial incentives (Steele et al., 2015). 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 (Carroll and Frakt, 2017; Girvan and Roy, 2020; Mot et al., 2017; Stossel, 2017). 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. 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* (Omachonu and Einspruch, 2010; West and Farr, 1990). 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 1) (Omachonu and Einspruch, 2010; Varkey et al., 2008). 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 1).[1] These phases are derived from stage-gate models, distinguishing successive phases (the stages) from idea to launch (Cooper, 2010). 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[2] stage-gate model developed by du Preez and Louw (2008) 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, to support innovations moving through these phases of the innovation process, a continuous process of financial inputs is needed. We distinguish two main categories of innovation payments supporting the innovation process: temporary payments (i.e., *funding*) and structural payments (i.e., *reimbursement*).

[1] Notice that these phases are very similar to the successive phases of the classical process model, with input (development), value-adding transformation (translation), and output (implementation).

[2] Fugle is the fusion of a funnel and bugle, illustrating the convergent and divergent parts of the innovation process model (du Preez and Louw, 2008).

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. (2017), (2018), 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 (Barnett-Page and Thomas, 2009; Lucas et al., 2007).

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. We focused on all products and processes with the aim to innovate healthcare, no matter the public or private origin of the innovative idea. 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 (Sorenson et al., 2011). 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.

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 A). Based on research by Bramer et al. (2017) 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.

3.3. Data extraction and analysis

We used a standardized data extraction form (see Appendix B) based on the specific aims of this study and forms used in similar reviews (Clarke, 2016; Lucas et al., 2007). 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 (Lucas et al., 2007). 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. Fig. 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 (Barnett-Page and Thomas, 2009). 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.

4. Results

In total, 16,518 articles were identified in our systematic search, with 8851 unique articles remaining after duplicates were removed. The screening of the titles and abstracts led to the removal of 8345 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 Fig. 2. Reference screening identified an additional 20 eligible articles, leading to a total of 157 articles for inclusion. These articles are listed in Appendix C, in order of the groups they were categorized in.

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).

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 Fig. 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.

4.1.1. Development phase of product innovations

The development of innovative products is funded through both

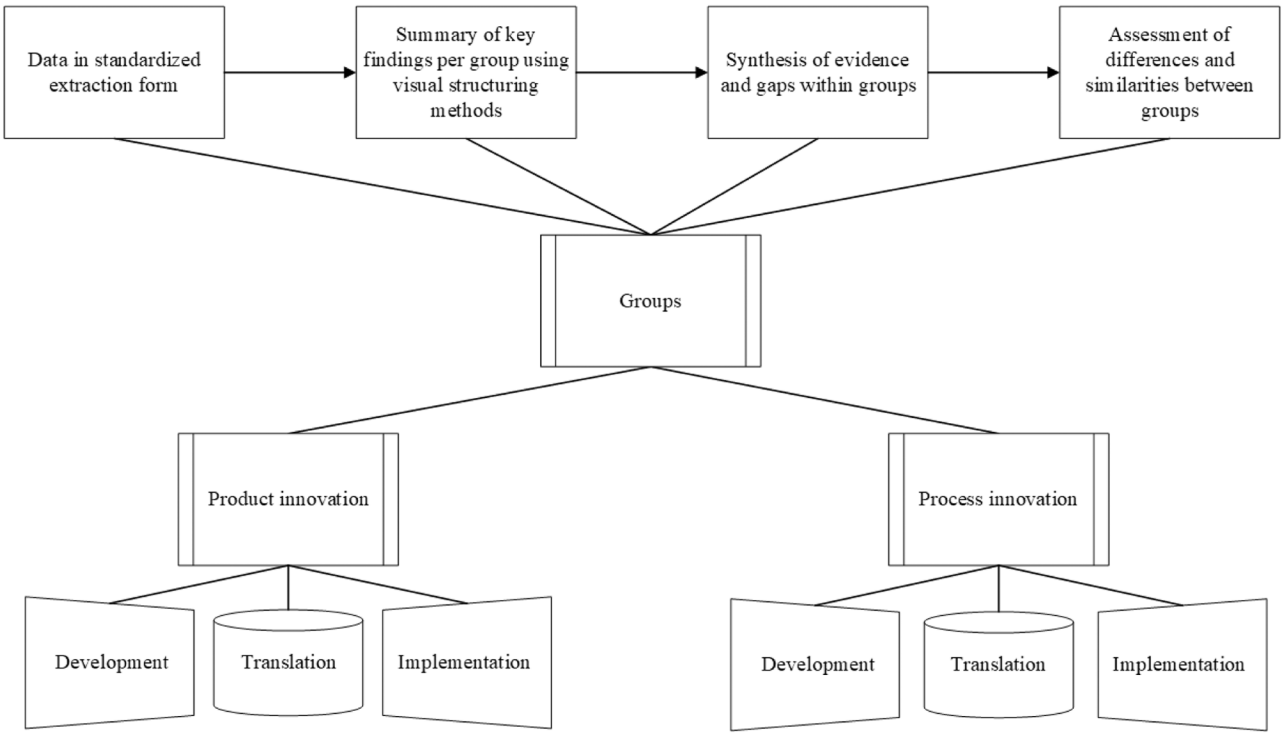

Fig. 1. Process of data extraction and synthesis and categorization of homogenous groups.

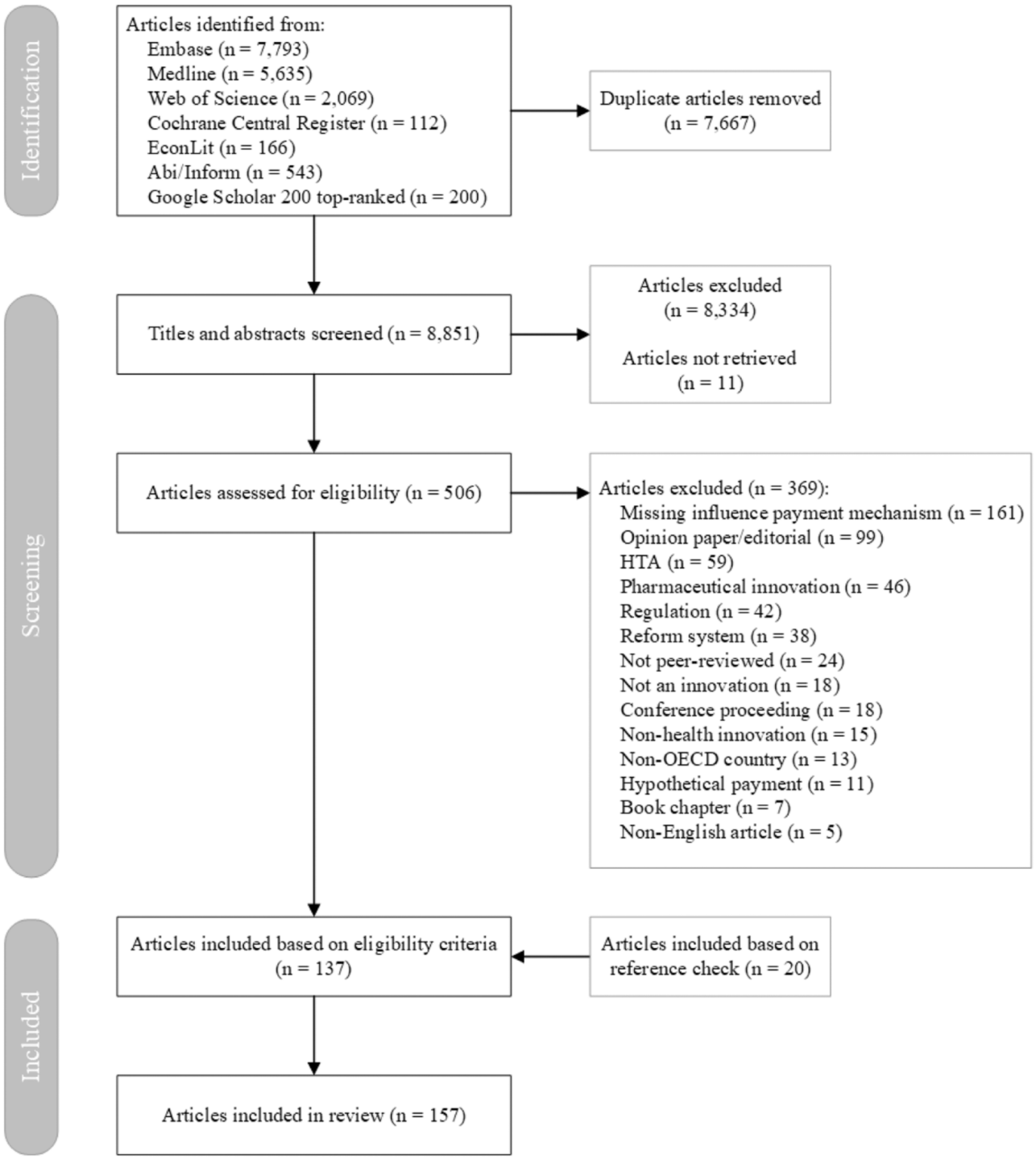

Fig. 2. Flow diagram showing selection process for articles for systematic review.

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.

4.1.1.1. 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. (2013) 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. (2012) found that public R&D grants are

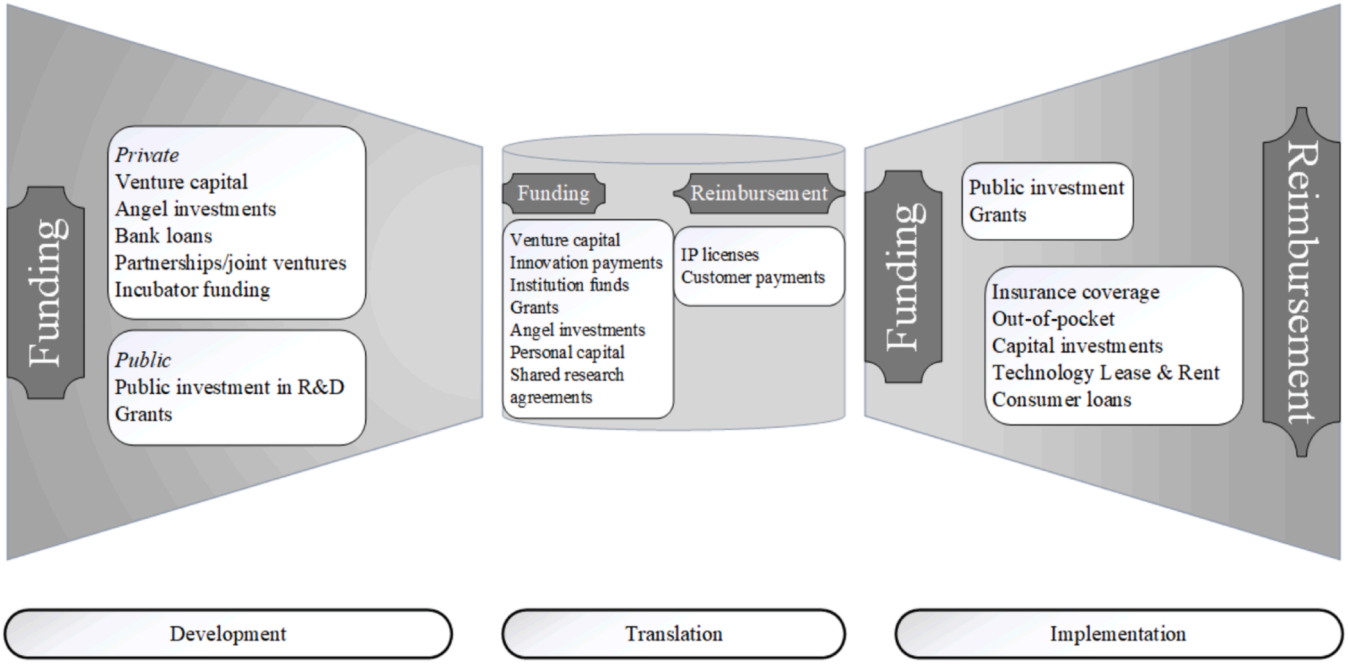

Fig. 3. Financial Fugle Model for product innovation based on the process model of du Preez and Louw (2008).

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 (Onken et al., 2019). 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. (2021) 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.

4.1.1.2. 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 (Lite et al., 2020; Shau et al., 2017). For example, Lehoux et al. (2016) 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 (Lehoux et al., 2016; Shau et al., 2017).

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 (Lehoux et al., 2016; Lehoux et al., 2017; Shau et al., 2017). 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 (Lehoux et al., 2016). As Lehoux et al. (2017) 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 (Lehoux et al., 2016; Shau et al., 2017). The focus on commercial value could, moreover, be a source of unrealistic return-on-investment requirements and time-to-market horizons (Grazier and Metzler, 2006). 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. (2015) 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.

4.1.1.3. 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 (2006) and Lettl et al. (2008) 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 (Grazier and Metzler, 2006).

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" (Campbell and Allen, 2016). Rotenstein et al. (2019) 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.

4.1.1.4. 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 (Bertram et al., 2012; Costa-Font et al., 2012; Keppler et al., 2015; Rotenstein et al., 2019). For example, based on their study of US investments in eHealth innovations after the introduction of reimbursement for such products, Lite et al. (2020) found that funding levels of innovative eHealth products significantly increased due to better prospects of adoption in the implementation phase.

4.1.1.5. Summary. 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.

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).

4.1.2.1. 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. (2016), 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 (Lehoux et al., 2016, 2017). Sebastianski et al. (2015), 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 (Ackerly et al., 2008; Keppler et al., 2015; Lehoux et al., 2016, 2017). 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" (Ackerly et al., 2008, p.73). 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.

4.1.2.2. 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 (Hernandez et al., 2015). 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 (Clyde et al., 2008; Ex et al., 2020; Ex and Henschke, 2019; Henschke et al., 2010a, 2010b; Judson et al., 2019). 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 (Hernandez et al., 2015; Martelli and van den Brink, 2014; Martelli et al., 2016; Wilke and Rathmayer, 2016), as well as issues around the negotiations for obtaining sufficient amounts of payment (Henschke et al., 2010; Hernandez et al., 2015; Sorenson et al., 2013), unclear requirements (Martelli and van den Brink, 2014; Wilke and Rathmayer, 2016), differences in approvals between regions or hospitals (Ex et al., 2020; Felgner et al., 2018; Henschke et al., 2010; Martelli and van den Brink, 2014; Sorenson et al., 2013; Sorenson et al., 2015), retractions due to safety concerns and conflicts of interest (Judson et al., 2019), concerns about the excessive implementation of innovations with only marginal benefits (Scheller-Kreinsen et al., 2011; Stafinski et al., 2011), and uncertainty about long-term reimbursement (Dranove et al., 2022; Henschke et al., 2010; Hernandez et al., 2015; Martelli and van den Brink, 2014; Sorenson et al., 2015; Federici et al., 2021). As Sorenson et al. (2013) 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.

4.1.2.3. 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 (Day-Duro et al., 2020). As Beaulieu and Lehoux (2018a) 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 (Varkey et al., 2008), innovative ideas often come from professionals who rarely have the focus and skills required to develop a business case (Isasi et al., 2016; Vanderford et al., 2013). 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 (Van Norman and Eisenkot, 2017; Vanderford and Marcinkowski, 2015; Weis et al., 2018).

4.1.2.4. Summary. 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.

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.

4.1.3.1. 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 a fixed payment provided for a bundle of care activities per diagnosis, such as a Diagnosis-Related Group (DRG) payment, 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 (Beck et al., 2019; Cappellaro et al., 2009; Freedman, 2012; Hatz et al., 2017; Oh et al., 2005; Rauner et al., 2011). Cappellaro et al. (2011), 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. (2014) found that DRG payments involve fewer incentives for innovation than fee-for-service payments (FFS), i.e., reimbursing providers for each individual care activity rather than per bundle of care for a diagnosed condition. This supports the notion that the more variable a reimbursement method is, the more rapidly innovations are implemented. However, Bodenheimer (2005) 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 (Baker and Atlas, 2004; Mas and Seinfeld, 2008; Teeter and Moora, 2000; Varabyova et al., 2017).

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 (Freedman, 2012; Raab and Parr, 2006a), differences in levels of insurance coverage (Gupta et al., 2013), different features of innovations which make them more or less vulnerable for financial incentives (Shih and Berliner, 2008; Varabyova et al., 2017), and different characteristics of professionals and hospitals (Bayindir and Karaca Mandic, 2016). 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 (Boriani et al., 2011; Scheller-Kreinsen et al., 2011), the incorporation of incremental improvements in healthcare products (Saing et al., 2019), the consistency of reimbursement updates across innovations (Borras et al., 2022), and the willingness of payers to cover innovative products (Nativel et al., 2019; Raab and Parr, 2006b, 2006c). According to a large-scale survey conducted by Sorenson et al. (2015), such differences determine whether DRG systems promote or hinder the uptake of innovations.

4.1.3.2. Evidence on costs and benefits. Ideally, decisions regarding the reimbursement of innovations are based on evidence about costs and benefits. 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. (2015) 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. (2012) 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. (2011) 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 (Ciani et al., 2017; Tarricone et al., 2017). 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 (Ciani et al., 2017; Felgner et al., 2018; O'Malley, 2010; Saing et al., 2019; Sebastianski et al., 2015).

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. (2014) 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 (Schreyögg et al., 2009; Torbica and Cappellaro, 2010).

4.1.3.3. 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 (Beaulieu and Lehoux, 2018b; Coye and Kell, 2017). In order to strengthen the financial incentives to implement such capital-intensive innovations, Levaggi et al. (2014) 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 (Pedroso

et al., 2022). This approach has been successful in facilitating the implementation of some innovations (Edlin et al., 2014; Triki et al., 2019).

4.1.3.4. 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 (Dos Santos et al., 2021; Carlson and Ehrlich, 2006; Kenigsberg et al., 2019; Messer et al., 2020; Monden et al., 2019; Wallace et al., 2000). 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. (2017) found that in Belgium, where out-of-pocket 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.

4.1.3.5. 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. (2006a) 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 (Bønaa et al., 2016), 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 (Bayindir and Karaca Mandic, 2016; Cappellaro et al., 2009; Cappellaro et al., 2011; Epstein et al., 2012; Gaglia et al., 2010; Grilli et al., 2007; Gupta et al., 2013; Kao et al., 2008; Shih and Berliner, 2008).

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 (Hughes et al., 2021; Gaglia et al., 2010; Grilli et al., 2007; Kao et al., 2008; Oderanti et al., 2021). For example, Oderanti and Li (2018) 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 (Oderanti and Li, 2018) and the high cost (Goldzweig et al., 2009), it is the difference between "who pays" and "who benefits" that constitutes a barrier to reimbursement of eHealth innovations (Greenhalgh et al., 2017).

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) (Plun-Favreau et al., 2016; Trosman et al., 2017; Yeat et al., 2015).

Another feature of disruptiveness is a large time gap between the necessary investments and the benefits of innovations. Rao and Pietzsch (2009) 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 (Adang and Wensing, 2008). 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" (Oh et al., 2019). 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 (Lacy et al., 2020; Palm et al., 2020). 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.

4.1.3.6. 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 (Cappellaro et al., 2009; Garber et al., 2014; Neumann et al., 2007; Teeter and Moora, 2000; Torbica and Cappellaro, 2010). 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 (Seidel et al., 2019; Teeter and Moora, 2000). This could, in turn, lead to (increases in) disparities in access to the best quality healthcare (Cappellaro et al., 2009; Sach et al., 2004; Schaefer et al., 2015; Sorenson et al., 2013; Torbica and Cappellaro, 2010; Neumann et al., 2007).

The reliance on local reimbursement was also found to reduce attention for evidence of cost-effectiveness in reimbursement decisions (Beck et al., 2019; Schaefer et al., 2015; Seidel et al., 2019). 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 (Beck et al., 2019; Cappellaro et al., 2009; Sach et al., 2004; Schaefer et al., 2015).

4.1.3.7. Summary. 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 costs and benefits. 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.

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 Fig. 4.

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 (Orrell et al., 2015), continuity of funding, the prioritization of research infrastructure rather than funds tied to a discrete project (Stickney et al., 2018), and impact metrics based on care practice rather than profit or commercialization requirements (Rotenstein et al., 2019). However, most development investments are linked to a for-profit business model (Lehoux, 2010), 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 (Robinson et al., 2017).

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 (Sorenson et al., 2013; Wilke and Rathmayer, 2016). 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 (Day-Duro et al., 2020; Van Norman and Eisenkot, 2017; Vanderford and Marcinkowski, 2015; Vanderford et al., 2013; Weis et al., 2018). 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 (Collins et al., 2016; Day-Duro et al., 2020; Van Norman and Eisenkot, 2017). As mentioned by Day-Duro et al. (2020): "Developing a culture of respect, valuing each individual and investing in people within each organisation were widely reported as drivers of success" (p.478).

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.

4.2.3.1. Reimbursement methods. Twenty-four studies examined the influence of reimbursement methods on innovative services and

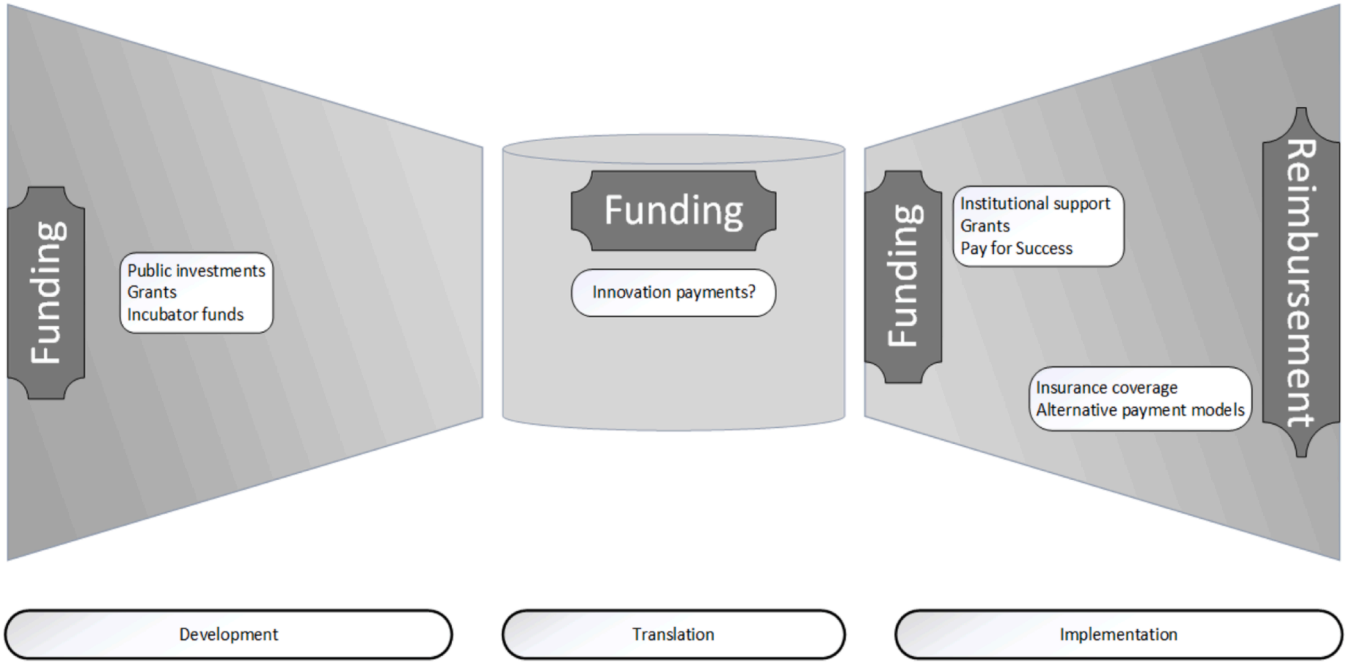

Fig. 4. Financial Fugle Model for process innovation based on the process model of du Preez and Louw (2008).

treatments. A key finding is that higher coverage rates and lower patient copayments lead to more implementation of innovative treatments (Crawford et al., 2016; Dietrich and Wevers, 2010; Freedman et al., 2015), although this relationship was not found in a study related to IVF treatments in Australia (Rawlings et al., 2017). 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 (Bech et al., 2009).

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 (Bodenheimer, 2005). Another US study found that FFS only facilitates complementary treatments, and not the substitution of existing care with more efficient treatments (Steele et al., 2015). 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 (Dranove et al., 2022; Berman, 2004; Lee et al., 2019; Scheller-Kreinsen et al., 2011; Sorenson et al., 2015). Furthermore, in a study of ultrasound elastography in the US, Moreno et al. (2017) found that DRG reimbursement codes are not automatically covered by insurers. This finding is confirmed by Dranove et al. (2022) who found that the adoption of innovative treatments increases ninefold if the code is promoted from provisional to permanent. Finally, Greenberg et al. (2001) 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 (Berman, 2004; Greenberg et al., 2001; Moreno et al., 2017).

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 (Baker and Phibbs, 2002; Bokhari, 2009; Freedman, 2012; Mas and Seinfeld, 2008). However, even cost-saving innovations have not always found their way into managed care hospitals (Walston et al., 2001). 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 (Adang and Wensing, 2008). 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 (Baker and Phibbs, 2002). A final finding is that prospective payment models may lose their inhibiting influence on the implementation of innovations over time (Maynou et al., 2021), when FFS and DRG reimbursement methods are also present in the system (Freedman, 2012), 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 (Bokhari, 2009).

4.2.3.2. 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 (Tong et al., 2021; Brookes et al., 2015; Kraft et al., 2015; Mairesse et al., 2015; Meit et al., 2009; Markus et al., 2013; Oh et al., 2019). As Thoumi et al. (2015) 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. (2016) 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 (Berman, 2004; Neumann et al., 2007; Thoumi et al., 2015; Markus et al., 2013). Meit et al. (2009) 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 (Thoumi et al., 2015).

4.2.3.3. 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 (Song et al., 2013). Saulsberry and Peek (2019) 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. (2021) showed the positive effect of pay-for-performance incentives on the implementation of an initiative improving antibiotic use. In addition, Lluch (2013) predicted that the introduction of bundled payments in several European countries will facilitate the implementation of tele-healthcare initiatives, while Christensen and Remler (2007) argued for global capitation payments to facilitate IT-based forms of care provision. Contrarily, Gunter et al. (2021) 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. (2018) 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.

4.2.3.4. 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 (Berman, 2004; Brookes et al., 2015; Kinderman et al., 2016; Kraft et al., 2015; Ross et al., 2011). Walston et al. (2001) managed to quantitatively distinguish between the impact of financial

factors and institutional factors on the implementation of medical process reengineering in over 2300 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. (2004) 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.

4.2.3.5. Summary. 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.

5. Discussion

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 costs and effects being taken into account (Dreger et al., 2021). Several studies suggest that this may be explained by a lack of harmonization between the results of health technology assessments (HTA) and reimbursement processes (Hoffmann and Graf von der Schulenburg, 2000; Krüger et al., 2014; Lingg et al., 2016; Tsoi et al., 2015). Even if harmonization does take place, this often only applies to national reimbursement pathways (Dakin et al., 2006), which tend not to be accessible to innovators. This is exacerbated by methodological issues around health technology assessments for medical devices and process innovations (Craig et al., 2015; Kirisits and Redekop, 2013; Normand, 2012; Tsiachristas et al., 2016). 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.

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 (Dranove et al., 2022; Lehoux et al., 2014). 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. (2001) established a dominant influence of non-financial factors whereas Fleuren et al. (2004) 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.

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. Moreover, the ratio of public versus private payments for innovation differs between healthcare systems, with private financing filling up gaps when public spending is falling short (Apostolopoulos et al., 2022). These differences limit the possibility to derive generalizable conclusions about the role of specific payment mechanisms 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.

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 and various payment-related problems that obstruct the development and implementation of value-enhancing innovation in healthcare. Several implications for policy and practice can be formulated to address these problems. First, to provide the opportunity for innovations in medical technology or care procedures to be implemented beyond the local level, payment mechanisms should facilitate such broader implementation. Therefore, governments should critically assess the decision-making processes to provide access to national reimbursement of value-enhancing innovations. Second, consistent and transparent guidelines should be created for assessing appropriate evidence on costs and benefits of medical technologies and care processes. Existing methods for the collection and use of evidence are largely tailored and applied to pharmaceutical innovations. Third, some of the most promising innovations in the near future are to be expected in fields categorized as being disruptive, such as personalized medicine and prevention. Reimbursement mechanisms should be developed that are more appropriate to facilitate these types of innovations, so they do not have to permanently rely on temporary funding mechanisms. Finally, the findings of this review emphasize the importance of innovator characteristics and institutional support for overcoming financial barriers. In addition to these lessons for policy and practice, we also add methodological insight with regards to the use of the Fugle process model of healthcare innovation. This article has shown the model is sufficiently comprehensive to include all activities related to the process of innovation, yet simple enough to comprehensibly structure the analysis and findings of innovation research. Furthermore, the contribution of this systematic review can be found in the suggestions for future research on payment mechanisms in healthcare innovation processes that could contribute to the sustainability of healthcare systems.

Ethics

Since the work performed is a systematic review of scientific articles, in which no subjects were involved, the authors have no ethical statement to make.

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CRediT authorship contribution statement

Allers Sanne: Writing – original draft, Visualization, Validation, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Eijkenaar Frank:** Writing – review & editing, Supervision, Formal analysis, Conceptualization. **van Raaij Erik M.:** Writing – review & editing, Supervision, Conceptualization. **Schut Frederik T.:** Writing – review & editing, Supervision, Conceptualization.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.joitmc.2025.100490.

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