An assessment of the current state of risk-sharing arrangements and its stakeholder's perspectives in the Dutch healthcare sector

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Abstract

The increasing pressure on the healthcare sector is urging for an innovative solution to keep quality and cost effectiveness in optimum shape. There are a variety of different related concepts that emerged over the last few decades that could possibly add value to solvability of this problem. One of these concepts is called 'performance-based risk-sharing arrangements', also abbreviated as PBRSAs. PBRSAs are agreements between a payer and manufacturer (of either pharmaceutical products or medical devices) where the actual price is based on future performance or results. This research will contain a systematic literature review that looks at the current state of affairs and trends concerning such arrangements, and will also contain a qualitative part in which 14 individuals have been interviewed representing four different stakeholders. There has been experimented with PBRSAs since the beginning of this millennium and there still is a great doubt that this is or can become an effective business model. This research has shown that there is willingness among various stakeholders in the Dutch healthcare sector to innovate and to expropriate with PBRSAs, but there are still many obstacles that need to be tackled, in particular, breaking through current financial policy patterns.

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Contents

Definitions

In this report many (relatively) unknown concepts and definitions are discussed. For this reason, an overview has been added to prevent obscurities and ambiguity.

Table with definitions/concept

P4P, Pay-for-performance, value-based purchasing	Comprises models that attach financial incentives/disincentives to provider performance. (Rosenthal, Frank, Li, & Epstein, 2005)
Risk-sharing (arrangement), RSA	A broadly interpretable concept, business model, or scheme, in healthcare where the risk of excessive financial costs is divided among stakeholders based on pre-set terms and conditions in order to increase accessibility (Piatkiewicz, Traulsen, & Holm-Larsen, 2017)
Performance-based risk-sharing (arrangement), PBRSA	As stated above, but with the inclusion of performance-based elements. Especially applicable in situations where the supplier of any type of medical solution wants to incorporate a financing scheme that is based on performance/results. (Carlson, Chen, & Garrison, Performance-Based Risk-Sharing Arrangements: An updated international review, 2017)
Value-based pricing, VBP	Is a pricing strategy which sets itself primarily based on perceived/estimated value instead of the 'actual' cost. (Terms such as value-based pricing are also often used in a general way, but they do not necessarily constitute risk sharing unless there is an explicit agreement in place that links payment to outcomes.) (Neumann, Chambers, Simon, & Meckley, 2011) (Garrison & Towse, Value-Based Pricing and Reimbursement in Personalised Healthcare: Introduction to the Basic Health Economics, 2017)
Value-based healthcare	Is a broad model in which providers and hospitals are paid based on health outcomes. It's different from a regular fee-for-service model; instead its value is determined based on health outcomes versus costs of delivering. (Pessaux & Cherkaoui, 2017)
Bundle payments, Bundled Payments	Packaged pricing where health care providers are paid for the effectively achieved result. (Miller, 2013)
Stakeholder(s)	Any group or individual who can affect or is affected by the achievements of the organization's objective. (Schiller, Winters, Hanson, & Ashe, 2013)
Health care sector	The entirety of industries and services that are related to the process of providing health care to (all types of) patients.

Table 1: Definitions and concepts elaborated

Introduction

Inreda Diabetic is an organization that is fully occupied with the development of an artificial pancreas that is currently almost ready to be rolled out on the market. This artificial pancreas is primarily intended for people with diabetes, but is also potentially applicable to people who no longer have a natural pancreas at all. The aim of Inreda Diabetic is to put this innovative medical solution on the market in an accessible manner. At the same time, Inreda Diabetic strives for a sustainable business model which is expected to continuously check its own results to maintain or improve the quality of the product (and its service). An idea was suggested by an individual to delve into a so-called (performance-based) risk sharing model. Such model, also often referred to as an arrangement or scheme, can be designed in different ways with unique thresholds. These models based on outcomes are a relatively new phenomenon and have already been experimented with in different foreign markets and situations. (Garrison, et al., 2015)

There are a variety of different related concepts that emerged over the last decades, for example; pay-for-performance, risk-sharing, performance-based and outcome-based. (LaPointe, 2018) The terms value-based pricing is also often used in a general way, but does not necessarily constitute risk sharing unless there is an explicit agreement in place that links payment to outcomes. (Neumann, Chambers, Simon, & Meckley, 2011) The scheme to be analysed for this specific research is most often described as 'performance-based risk sharing' (PBRSA), in some cases solely as 'risk-sharing' (RSA). (Garrison, et al., 2015) According to research there has been a significant increase in the usage of these types of schemes especially in the years 2006 till 2011 (Carlson, Yeung, Sean, Gries, & Garrison Jr., 2014). The benefits coming from these are for example to mitigate the negative impact of uncertainty. (LaPointe, 2018) Under these agreements the payment for 'medical solutions' is linked to the value that is achieved with this, rather than the volume. Pre-set conditions between the providing and financing party are to be measured within the real world to see if the performance meets the required standards that were set. (Keckley, 2012)

These types of models can make an innovative contribution to a complex financial problem as health expenditure is rising. (NCSL Privacy Policy, 2019) In most cases it's making medical solutions more accessible, but there are also disadvantages occurring regularly. One argument against this is that medical solutions may be pushed onto the market too quickly. (Zaric & Xie, 2009) A possible argument against this could be the complexity and the added administrative burdens that come with such arrangements. (Carlson, Yeung, Sean, Gries, & Garrison Jr., 2014) More recent articles regarding this topic also mention the importance of characterizing the stakeholders in this area such as manufacturers, payers and policy makers. This is necessary to better understand the benefits and challenges according to Carlson et al. (2017). Furthermore, it is suggested to be necessary to research the attitudes and perceptions of various stakeholders. Also, evaluating the results and experiences with schemes implemented thus far. (Carlson, Sullivan, Garrison, Neumann, & Veenstra, 2010) This is in line with the current need of Inreda Diabetic to gain knowledge of the most important stakeholders and his or her opinion on (performance-based) risk-sharing arrangements. Due the fact that many health systems around the world are different per country, it is decided to analyse stakeholders from Dutch soil exclusively for this specific research. Also, in terms of feasibility it's more logical from the researcher's perspective to exclusively speak with Dutch stakeholders. (Schütte, N Marin Acevedo, & Antoine, 2018)

In summarization, the aim of the research is to analyse the perspectives of stakeholders when it comes to performance-based risk-sharing arrangements in the Dutch healthcare sector. When the perspectives of the various stakeholders have been mapped, there is a better overall picture of the sector. For this reason, the research question is formulated as follows: *"What are the perspectives of Dutch stakeholders regarding (performance-based) risk-sharing arrangements in the healthcare sector?"* This will also include a systematic literature review concerning international experiences, trends and opinions regarding performance-based risk-sharing (and to a certain degree similar models). Medical devices and drugs are both referred to as medical solutions and will both be included for this research in order to increase the scope of research. First of all, the theoretical framework will provide clarity about performance-based risk-sharing, including a systematic literature review. Afterwards interviews will be conducted with the various stakeholders in the Dutch healthcare sector. The combination of international experiences and specific questioning of the Dutch stakeholders on this topic will hopefully provide clarity about the status and the future of performance-based risk-sharing. Possible ambiguities can be highlighted and appointed for further research.

Theoretical Framework

The theoretical framework consists of two parts. The first part contains the systematic literature review and the second part is about the stakeholders and their selection process. A systematic literature review will be executed first to get a broader and clearer understanding of the current status and trends of (performance-based) risk sharing schemes.

Systematic literature review

The aim of a systematic literature review is to gradually generate a selection of scientific articles that are relevant to the basis of this research in a systematically responsible manner. A number of keywords will be used to search for the right amount of articles on this subject. Findings from these articles will be used to write a synthesis as a fundamental basis for the research from which an X number of questions can be formulated. The systematic literature review is set to be analysed on a global scale, but only including data from western civilizations. The goal of the SLR is to identify, critically evaluate and integrate the findings of all relevant studies. Furthermore, it is required for the systematic review to be objective, systematic, transparent and replicable. (Piper, 2013) The detailed methods for the systematic literature review are explained in the appendix (B).

Synthesis

Types of risk-sharing business models

According to Zaric & Xie (2009) there are several types of risk-sharing models in existence some of which are based on sales volume, achievement of specific clinical thresholds and also models that have cost-effectiveness thresholds. The authors describe more in depth about several risk-sharing models in this study. The first, which can be categorized as a model based on "achievement of specific clinical thresholds", and can be explained as a system where a new drug (one can possibly also say a medical solution in general) is entered into the healthcare system on a trial basis (see table 2). When the eventual pre-determined target outcomes are achieved, the medical solution will be funded on an on-going basis. In another article this is called an outcome-based scheme (see table 2). (Garrison, et al., 2015) This can also be executed on individual basis, i.e., per patient, when taking into account predefined clinical criteria. Furthermore, the same study suggests that price-volume (which could also be classified as financial-based schemes) agreements are widely used (see table 2). (Carapinha, 2008) (Garrison, et al., 2015)

In Australia for risk-sharing agreements refer to "the ability of the government to recoup from the manufacturer of high-cost medicine a percentage that exceeds the annual budgeted amount for the managed consumption of a new medicine." (Caraphina, 2008, p. 62-63) In other words, if the government's annual budget for a specific medicine is exceeded then the manufacturer has to pay a percentage over the exceeded amount. Such arrangements are often referred to as price-volume arrangements. Especially reports from the UK National Health Service have been writing about risk-sharing plans for multiple sclerosis treatment which involves the monitoring of patients for ten years. In this model it is also required to incorporate threshold parameters to determine cost-effectiveness. If the cost-effectiveness threshold is not achieved, then a payment of rebate has to take place. (Zaric & Xie 2009, p. 838) The authors later add that beside the previously stated models there are several other risk-sharing frameworks possible, but there appears to be very little available publicly.

Three fundamental types of PBRSAs	
Price volume	Annual budgeted amount for a specific *medicine* is set by a government. If this is surpassed then the manufacturer has to pay a percentage over the exceeded amount. (Carapinha, 2008)
Achievement of specific clinical thresholds	The patients are given a new drug for a trial period. If patients respond accordingly to the clinical criteria they are allowed to proceed. If not; the patient has their *drug* costs up to that point reimbursed by the manufacturer (Zaric & Xie, 2009)
Cost-effectiveness thresholds	A *new drug* is entered into the health-care system on a trial basis. If the drug achieves its target financial outcomes, then it will be funded on an on-going basis. (Zaric & Xie, 2009)

Table 2: Three types of risk-sharing models by Zaric & Xie (2009)

In another study (Garrison L. P., et al., 2013) authors distinguish between two different arrangements of which fit the definition of a risk-sharing arrangement. Drawing these distinctions was based on previous taxonomies that have been published in the literature. It is mentioned that risk-sharing schemes do not always include a research component and it mainly focuses on the health outcomes achieved on an individual patient level, rather than at a population level. As mentioned before, the authors separate two types of PBRSA schemes in this article. 1) CED (coverage with evidence development) are schemes where the goal is to provide coverage while evidence for the specific medical solution is still being developed (see table 3) and 2) PLR, a performance-linked reimbursement scheme which its goal to is to achieve control over its cost effectiveness of new innovative technology in the real world (see table 3).

In a more recent study an even further categorization of PBRSAs took place. Carlson et al. (2017) defined PBRSAs broadly and used four different categorical cases. The first one is CED (which is stated in the paragraph above). The second called CTC, which stands for “conditional treatment continuation which can be explained as continuation of coverage for individual patients where short-term treatment goals are met (see table 3).” Thirdly, the authors speak of PLR (also stated in the previous paragraph) which explains itself as “performance linked reimbursement that is supposed to be arrangements where the reimbursement level for covered products is tied to the measure of clinical outcomes.” And lastly, there is FU, financial or utilization, defined as “an arrangement where reimbursement is tied to the measure of financial or utilization outcomes (see table 3).”

Categorization of performance based risk-sharing arrangements	
Coverage of evidence development (CED)	Arrangements with the goal to provide coverage while evidence is still being developed.
Performance-linked reimbursement (PLR)	Arrangements with the goal to achieve control over its cost effectiveness of new innovative technology.
Conditional treatment continuation (CTC)	Arrangements with the continuation of coverage for individual patients achieving short-term treatment goals.
Financial or utilization (FU)	Arrangements where reimbursement is tied to the measure of financial or utilization outcome.

Table 3: Categorization of PBRSAs by Carlson et al. (2017)

Certain models and/or arrangements are sometimes called risk-sharing, but are actually price discounts, because there is no explicit evidence generation involved that is tied to the payment. Also, value-based pricing is often generally used to talk about risk-sharing, but this can only rightfully be done when an explicit agreement is in place that links outcomes to payment. (Neumann, Chambers, Simon, & Meckley, 2011)

Europe is the leader of PBRSAs, but just as in other studies the administrative burdens can be difficult to enforce. One could say that PBRSAs can be divided into multiple categories that can be subdivided into a number of types (referencing to CED, CTC, PLR and FU). In addition separately, one could also make another distinction between financial-based schemes and outcome-based schemes according to Garrison et al. (2015), but here they also speak about RSAs instead of PBRSAs. The latter is more aligned with the research goal for this specific research.

Success ratio of risk-sharing scheme's & pro's and con's

According to Carlson et al. (2014) risk-sharing agreements have proven to be successful. In the pharmaceutical industry, payments by result agreements are used in which the manufacturer finances his or her medical solution until the results meet predefined requirements. In this way expensive treatments can be made more accessible. For example; Sunitinib and sorafenib are drugs belonging to a treatment of renal cell carcinoma (kidney cancer) where the initial costs were covered by the manufacturer. (Kiernan, 2016)

According to Navarria et al. (2015), PBRSAs are used more frequently in the case of medical products when there is a high risk-benefit ratio. This could indicate that there is an advantage in scenarios of a risky solution. Furthermore, the authors write that at PBRSAs it works a little better when there is reliable data on the efficacy and safety of the product. (Navarria, et al., 2015) The success of PBRSAs in the future is strongly depended on the parties who try to incorporate these arrangements. Both parties have to create mutual benefits and need to entail minimal administrative burden when developing and implementing such schemes. (Carlson, Yeung, Sean, Gries, & Garrison Jr., 2014)

To conclude this sub-question, it can be stated that it is difficult to give a well-founded and conclusive conclusion about the success ratio of PRBSAs because there is simply a certain amount of uncertainty about it. However, the advantages and disadvantages are often discussed. The advantages are of course the easier entry of the market by the payer in the first instance takes a lower risk and has lower costs. At the same time, it is also an advantage for the manufacturer because it can therefore sell its medical solution faster. However, this is at the same time a risk for the manufacturer. This risk may perhaps be interpreted as an extra motivation for the manufacturer to enter the market with a qualitative, and especially, an effective product. This means that all parties benefit from such a model (including the user of the medical solution).

Pros and cons of (performance-based) risk sharing arrangements	
Pros	***Cons***
• Proven to be successful in some cases (Carlson, Yeung, Sean, Gries, & Garrison Jr., 2014) • Increased accessibility to (expensive) treatments (Kiernan, 2016) • Earlier market access and pricing efficiency (Carlson, Yeung, Sean, Gries, & Garrison Jr., 2014)	• Works better when there is reliable data on the efficacy and safety of the medical solution (Navarria, et al., 2015) • Success is strongly depended on the parties who try to incorporate these arrangements (Carlson, Yeung, Sean, Gries, & Garrison Jr., 2014) • Often involved with high administrative burdens (Carlson, Yeung, Sean, Gries, & Garrison Jr., 2014)

Table 4: Pros and cons of PBRSAs

Trends of recent years

According to relatively recent research concerning the trends of performance-based risk sharing arrangements (PBRSAs) by authors Carlson, Chen & Garrison (2017) it is suggested that the overall enthusiasm is still increasing. They back this up by doing a search yielded of 437 arrangements between the years 1993 and 2017 and gathering data from the Washington PBRSA Database. A slowing pace was observed around 2012, but in 2014 it went back up again. The number of cases reported in 2016 might be higher than shown here (Figure 2) due to the research ended prior to 2017.

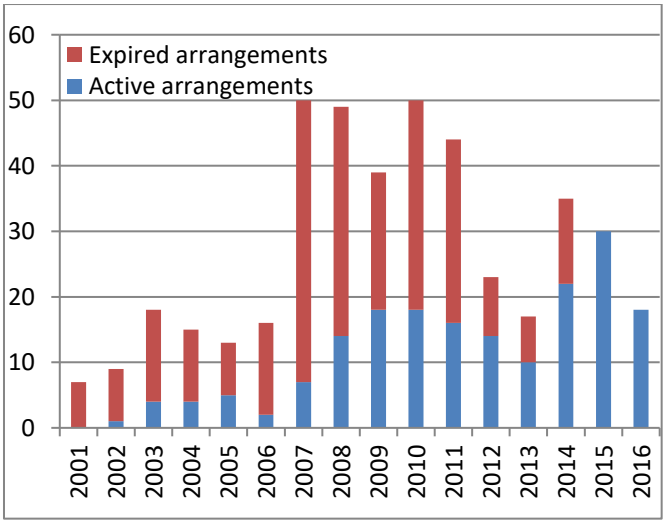


Figure 1: Trend of PBRSAs in recent years (Carlson, Chen, & Garrison, Performance-Based Risk-Sharing Arrangements: An updated international review, 2017)

Another study that has looked at the trends of PBRSAs in recent years was done by Yu, Chin, Oh & Farias (2017). This systematic review research specifically looked at PBRSAs in the pharmaceutical market in the United States. In this article authors also show to have found an increasing trend within the US-specific PBRSAs market for drugs. These findings are based on a systematic literature review. A total of N=1128 articles detected have led to an inclusion of N=22. The findings conclude here that a total of 26 PBRSAs were identified whereas 16 (62%) of them were announced or initiated during the years 2015 till 2017, so you may say that there has been a severe increase in the number of PBRSAs in recent years. A limitation for this study is the small amount of total identified PBRSAs. Also in another study it shows that there has been an increasing trend between 2007 and 2011 of PBRSAs identified. The review here shows 148 PBRSAs in these years to be initiated, although the pace of arrangements developed seems to be slowing down. (Carlson, Yeung, Sean, Gries, & Garrison Jr., 2014)

A study done in 2014 made a more in depth analysis if the different types of PBRSAs. The authors made the distinction between the CED, PLR, CTC and FU types of performance based risk-sharing agreements (as also mentioned earlier in this systematic literature review). As shown in the next figure (Figure 3) you can see the trend of the four different types of schemes starting from 1997 till 2013. There are also hybrid arrangements that contain two or more components from the different types of PBRSAs. The review identified 148 arrangements, but also here the pace of initiation seems to be slowing down.

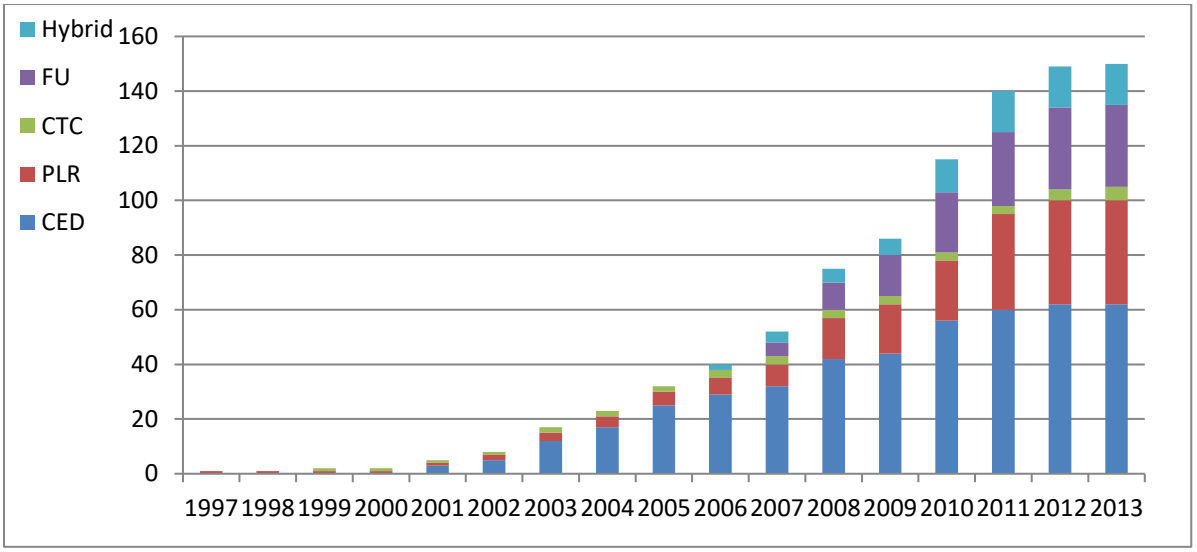


Figure 2: Number of performance based arrangements by year (Carlson, Yeung, Sean, Gries, & Garrison Jr., 2014)

Besides the quantitative research, also qualitative research is done to better understand current trends in the use of performance-based risk-sharing agreements. Garrison et al. (2015) conducted in-depth interviews with stakeholders from pharmaceutical companies, payer organizations, and industry experts in the United States and European Union. In addition to the interviews they also administered an online survey to identify stakeholder's perceptions towards risk-sharing business models. The study shows that PBRSAs are only used by a relatively small group in the USA, although interest in such models still seems to be increasing (according to the in-depth interviews). Later on in the study it is also mentioned that a limitation of the study is the possibility that the database used may not include the entirety of the PBRSAs due to "the confidential nature of agreements".

Suggestions & recommendations when designing the model

A systematic literature review from 2010 looked at various forms of risk-sharing business models and revealed a number of characteristics that do or do not contribute to a successfully organized scheme. (Adamski, et al., 2010) The authors suggest that risk sharing schemes should be rejected when current standards with a relatively low cost which is already in effect with a proven long term outcome. In addition, schemes shouldn't be (partly) financed by government agencies. It is also important that the patient in question is compliant in the process. And finally it is also suggested that the administrative burden is not too high compared to health and financial benefits. In addition it is also proposed that schemes are based on robust evidence when considered. It is more or less required to have easily measurable evidence to determine effectiveness.

Neumann et al. (2011) think there is a possible future for risk-sharing when drug manufacturers acquire more experience with risk-sharing schemes and further learn about information systems that do the measurements. The same authors established a list with key success factors for risk-sharing agreements. Consisting of; manufacturers, payers (health insurer), physicians (hospitals) and patients. These stakeholders are more or less the same as the stakeholders selected for the qualitative part of this study. There are too many key success factors mentioned in the article to name them all. The entire list will be displayed in the appendix (appendix C). The general tone of the key success factors in this article say something about the necessity of clear indicators (biomarkers) for measurement. This fact, which has been mentioned before in other articles, also falls under the administrative section, which is often complex and time-consuming. The authors also state a number of conditions such as the need for objective outcome measures, clear outcome reporting flows and clear clinical advantages of the offered product compared to the competition. However, this list has been described in a limited way (see the appendix C for the entire list).

When to use a PBRSA model
A PBRSA model does contribute..
when standards are not yet set and long term prospects are unsure. (Adamski, et al., 2010)
when financing doesn't come from government agencies. (Adamski, et al., 2010)
when patients are compliant in the process. (Adamski, et al., 2010)
when administrative burdens are not too high. i.e.; relatively easily measurable biomarkers compared to financial benefits. (Adamski, et al., 2010)
when objective outcome measures can be provided. (Neumann, Chambers, Simon, & Meckley, 2011)
when clear clinical advantages are provided. (Neumann, Chambers, Simon, & Meckley, 2011)

Table 5: When to use performance-based risk-sharing arrangements

A universally accepted model for risk sharing agreements will be unlikely because every medical solution has to deal with unique situations and variables. That is why a risk-sharing model must always be tailor-made. (Carapinha, 2008) In addition, risk-sharing arrangements should be considered when the objective and scope of the scheme are explicit and transparent and also the new medical solution is for a high priority disease area with expected net health gain. (Adamski, et al., 2010)

Garrison et al. (2013) evaluated experiences with PBRSAs, but found it hard to find profound evidence. Through a systematic literature research the authors found no studies to evaluate the overall economic impact. All of the studies only included qualitative discussions; with to a certain extent costs estimates were reported. To summarize the findings the authors have looked at the developments pertaining to PBRSAs per country. Overall they conclude that PBRSAs are a logical response to the increasing pressure for detecting greater evidence of real-world effectiveness versus long-term cost-effectiveness.

Stakeholders and it's perspectives

Garrison et al. (2015) have done a study that consists of a survey and interviews with key stakeholders to find out what the experiences are with RSAs. Data from a total of 14 key stakeholders was collected through interviews consisting of respondents from pharmaceutical companies, payer organizations and industry experts in the United States (9) and European Union (5). Twelve of the fourteen interviewees reacted mildly optimistically about the future potential of RSAs in the United States. The authors also distinguish between outcome-based schemes and financial-based schemes. The financial-based version is predicted being noticeably more positive by each stakeholder than the outcome-based variant. This is because outcome-based models are difficult to utilize because measuring clinical health outcomes accurately is a difficult task. Outcome-based agreements are discussed further as difficult to implement due to the high transaction costs. Most of interviewees reacted sceptically; more specifically they mention the challenge of the correct implementation and execution. This argument is also provided in another study (Carlson, Sullivan, Garrison, Neumann, & Veenstra, 2010) where it is said that key stakeholders such as manufacturers and payers appear to be willing to discuss or agree to these types of schemes. However the challenges may take its toll. They mention "high transaction costs, administrative burden, insufficient information systems, and provider push-back, that limit the long term impact and viability of health outcome based schemes."

A study done in Israel by Hammerman et al. (2012) has explored the views and concerns through in-depth interviews of the main stakeholders concerning risk-sharing mechanisms and its potential for accurate budget-impact forecasting. The authors further elaborate on the advantages and disadvantages that come in par with the adoption of risk-sharing arrangements. Although, the risk sharing arrangement that is proposed here, does not operate in the context of clinical performance but rather with the total budget utilized. Such financial arrangements are described as: "In a typical case, when the total budget impact or the amount paid for treating a single patient exceeds the target that the technology sponsor and the payer agreed upon, then the technology sponsor is required to reimburse the payer." (Hammerman et al. 2012, p. 737) Its success according to the authors is dependent on its perception as a win-win situation for all the stakeholders involved.

The study conducted by Garrison et al. (2015) therefore looked at experiences with risk-sharing arrangements in general (within the EU and USA). What this study did not do is look within the framework of the Dutch healthcare sector and also didn't involve all relevant stakeholders. By conducting the interviews specifically with the Dutch stakeholders it is possible to better estimate what the stakeholders know about PBRSAs, and, it is also better to estimate to what extent it is already being used in practise. Furthermore, it is stated in Garrison et al. (2010) that there are a number of challenges for PBRSAs to be effective. Questions about this can be asked to the Dutch stakeholders to explore what Dutch stakeholders think about this and what their experiences are with this. Hammerman et al. (2012) did in-depth interviews, but not in a clinical environment and only in financial arrangements. In the context of the qualitative part in this study, it concerns all types of PBRSAs.

Methods

This chapter will explain the methodological detail of the research. First, it will be explained how the stakeholders are determined. The positioning of the stakeholders in the context of power vs. interest will also be presented. Subsequently, it will be discussed how the interviews of the stakeholders have been set up and implemented.

Analytical framework

For this research it is necessary to select the right stakeholders that may be relevant for this research. There are a number of theories and techniques that can be used for the selection procedure. The classic definition of a stakeholder is articulated as: “any group or individual who can affect or is affected by the achievements of the organization’s objective”. This specific definition reflects the business management context. (Schiller, Winters, Hanson, & Ashe, 2013) Stakeholders can be identified by one or multiple of the following attributes: (1) stakeholders power to influence the firm, (2) the legitimacy of the stakeholder’s relationship with the firm, and (3) the urgency of the stakeholder’s claim on the firm. This theory provides a clear comparative framework in which stakeholders can be compared from an objective point of view. (Mitchell, Agle, & Wood, 1997) In addition, Mathur et al. (2007) suggests there is a set of questions with guidelines in ensuring that all important stakeholders are considered (Appendix A).

A framework for stakeholder identification, specifically in health research, is designed by authors Schiller et al. (2013). According to the authors, stakeholders are a very important source of information in health research, where new perspectives and insights can be obtained to tackle complex problems in this environment. The authors have created a stakeholder framework comprised of seven categories with detailed sub-groups. Consisting of; (1) research community, (2) practitioners and professionals, (3) health and social service providers, (4) civil society organizations, (5) public, (6) private business and (7) policy makers and governments.

Figure 3: Framework for stakeholder identification in health research (Schiller, Winters, Hanson, & Ashe, 2013)

Besides the identification process, there are also multiple articles that are providing techniques for the mapping of stakeholders. It suggests that the most common method of mapping out the stakeholders is by doing so on a matrix which has two key attributes of stakeholders on its axes. Such attributes can be impact/priority or power/interest for example. The idea is that you get an overview in which the relevant stakeholders are mapped in a matrix based on the determined x and y axis.

The assessment of the positioning per stakeholder is not systematic, but is done on the basis of available information and assessment power of the researcher. (Bryson, 2004) The power of each stakeholder is important to understand, because 'it brings the focus on empowering or controlling the impact of the different stakeholders during the engagement.' Power possessed can be determined as direct or indirect; it can be in the ability to affect short term actions or have its effect in the longer term on a project. Same goes for interest; interest may be obvious, but can also be hidden. If a conflict occurs between different stakeholders it is important to identify these interests in order to avoid conflicts from emerging. You may approach stakeholders separately if needed. (Mathur, Price, Austin, & Moobela, 2007)

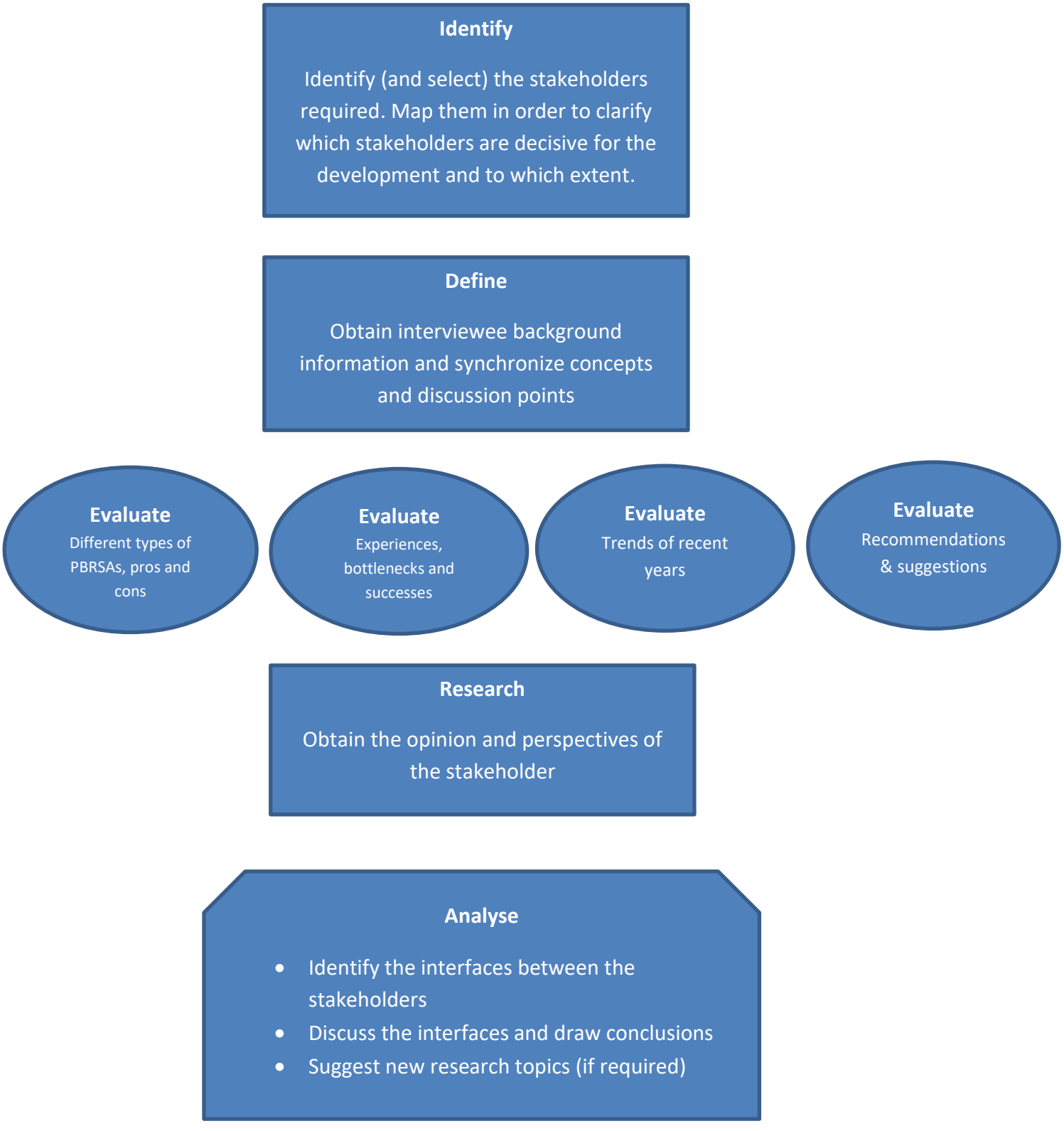
The analysis model consists of five steps. 1) Identify, 2) define, 3) evaluate, 4) research and 5) analyse. The aim of the research is to answer the research question: *'What are the perspectives of Dutch stakeholders regarding performance-based risk-sharing arrangements in the healthcare sector?'* In order to arrive at this answer, it is first required to find the relevant stakeholders concerning this specific topic (i.e.: Dutch stakeholders in the healthcare sector that are affiliated or involved with the process of establishing agreements between health care involved parties). Furthermore, it is required to get insights into the perspectives from them (i.e.: 'perspectives regarding PBRSAs from relevant stakeholders').

The first step has its goal to identify, map and select the stakeholders that are relevant to be interviewed. When the interviewee's are found, it is important to ensure that the interviewer and the interviewee have the same inter- perception of the relevant subjects. At this moment it is also important to include more specific information from the stakeholder in order to get a good picture of his or her position. Thereafter, the information presented by the systematic literature review must be discussed and evaluated with the interviewee. After the evaluation, the opinions and perspectives of the various stakeholders must be identified. And finally, the results that have been delivered must be used to come to conclusions and generate possible new research topics.

Step	**Goal**
Identify	Identify and map the stakeholders
Define	Define theory with interviewee and obtain background information
Evaluate	Evaluate researched material in the systematic literature review with stakeholders
Research	Obtain the perspectives of the stakeholders
Analyse	Analyse the new material and develop conclusions and possible new questions

Table 6: Basic structure of the analytical framework

Analysis model



Determining the stakeholders

Determining the relevant stakeholders was done after a brainstorm session with the internal and external supervisors. Based on the expertise of all supervisors, it was decided to focus the qualitative research on manufacturers, hospitals, patients and health insurers. The government and DiabetesFonds (largest foundation that stands for the interests of the diabetes patient) are also considered for the interviews, but for now, and in the context of limited research time, are left out for research.

Mapping the stakeholders

As discussed in the theoretical framework, stakeholder mapping will be used to determine the positions of the stakeholders in relation to each other. (Bryson, 2004) Underneath this paragraph you can find the matrix in which the most important stakeholders are positioned between the axis of 'interest' (horizontal) and 'power' (vertical). The quadrants of the matrix are:

1) **Manage closely:** The most important set of stakeholders with relatively high power and power and should be prioritized for satisfaction.
2) **Keep Satisfied:** This group has a decent amount of power that needs to be managed, but interest is on a lower level.
3) **Keep Informed**: The stakeholders in this group are high in interest, but low in power which means their satisfaction doesn't have to be prioritized.
4) **Monitor:** This group has to be monitored accordingly, but in lower effort due their relatively low interest and low power.

A total of 4 stakeholders were included in the matrix. These stakeholders can in some cases be divided into multiple sub-stakeholders. Keep in mind that the stakeholder matrix (figure 3) is based on the Dutch healthcare system. The assessment of the positioning is done on the basis of available information and assessment power of the researcher which is further elaborated for each stakeholder in the next section of this chapter.

Positioning of the stakeholders

Health insurers are a very powerful stakeholder when it comes about arrangements. The health insurer, as long as it keeps to the laws and regulations, can ultimately determine how the financing of medication and other medical solutions are arranged.

The **manufacturers** on the matrix are much lower in terms of power than health insurers, but the interest of this stakeholder could be estimated somewhat stronger. This is because the manufacturer is relatively more dependent on the established business model. They are placed lower on the vertical axis (power) because a health insurer will be decisive, and in many cases the manufacturer does not have a monopoly on the offered product. Although, If there is a monopoly on the offered product then one could argue that the power of the manufacturer is just as high, or even higher than that of the health insurer (this is also dependent on the impact of the product in question).

The **hospitals** are also a stakeholder that can in principle be divided into different sub stakeholders. This is because, in addition to regular hospitals, you also have academic hospitals. Furthermore, in these hospitals you could also look at the different departments within the entire organization. All in all, the hospitals have been scaled as relatively low in power, but relatively high in interest. This is partly done because it is estimated that hospitals will have to put some time and energy into the preconditions of risk-sharing business models as administration plays a major role in many of the PBRSAs schemes.

The **patients** are a stakeholder that ultimately depends on the medical solution. One patient is not the other, so you might be able to say that some patients have a higher interest than others. But in the end you could assume that the patient is simply looking for an accessible medical solution for his or her problem, and as long as this is done in an ethical manner, the interest in the business model would not be very high. In terms of power, a patient also has relatively little to bring in, although there can be achieved a lot by means of a patient's resurgence through a large and broad support.

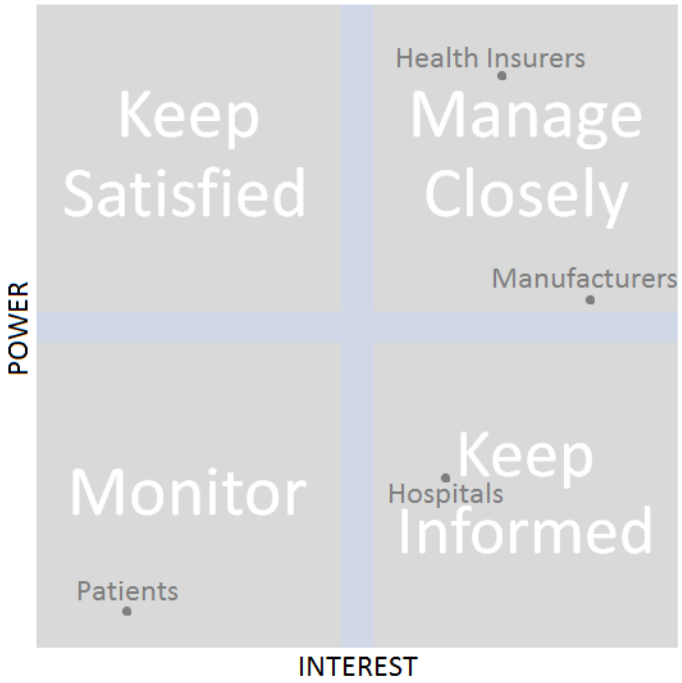


Figure 4: Stakeholder Matrix – Power/Interest in risk-sharing business models

Interviews

This research will contain semi-structured interviews. Semi-structured interviews, instead of a structured interview where all questions are rigorously set, will allow new ideas and questions to be brought up during the interview. (Bernard, 2011) These more or less spontaneous questions may help in some cases to answer the main and sub questions. All interviews were conducted in the months of November 2018 till January 2019. A total of 14 interviews took place. The selection of participants is partly based on an internal network with the aim of a balanced mix between the relevant stakeholders. The final distribution has therefore also resulted in 4 patients, 4 experts from the drugs and medical device industry (which are all referred to as 'manufacturers' for convenience), 3 experts from different branches of hospital organizations and 3 experts from health insurers.

Background of the interviewees

As discussed in the previous paragraphs, it was decided to only interview hospitals, manufacturers, patients and health insurers for this specific research. To assess the answers of these stakeholders in the results carefully, the backgrounds of these will be explained here in an anonymous way.

#	Interviewees	(Function) Task description
1	*Health insurer **A***	(Investment manager) Actively engaged in the realization and speeding up of innovation in healthcare.
2	*Health insurer **B***	(Policy advisor) Engaged in purchasing methodologies and strategic purchasing policy. Also active as a researcher into the functioning of financial incentives in healthcare.
3	*Health insurer **C***	(Purchasing manager) Responsible for the purchase of healthcare, also at a number of hospitals.
4	*Manufacturer **A***	(Business Development Manager) Responsible for the phase after R&D, bringing product to the market.
5	*Manufacturer **B***	(Managing Director) Contractor of medical solutions.
6	*Manufacturer **C***	(Director) Founder of an innovative medical device.
7	*Manufacturer **D***	(Manager Health Insurer Relations) Responsible for contact with the health insurers on behalf of a large pharmaceutical company.
8	*Hospital **A***	(Internist) Doctor in hospital, frequently in contact with the patient and the peripheral affairs.
9	*Hospital **B***	(Project leader) Responsible for several project groups within a hospital
10	*Hospital **C***	(Internist-Endocrinologist) Doctor in hospital, frequently in contact with patient and peripheral affairs.
11	*Patient **A***	(Patient) Diabetes mellitus.
12	*Patient **B***	(Patient) Diabetes mellitus.
13	*Patient **C***	(Patient) Suffers from auto-immune disease and depression.
14	*Patient **D***	(Patient) Diabetes mellitus.

Table 7: Interviewee's information

Setting up for the interviews

For the interviews in this research certain themes will be prepared in the form of a guide which will help executing the interview properly within the boundaries of required topics to be discussed. These themes are adjusted to the different types of stakeholders that will be interviewed; also adjustments might take place after gathering new insights from earlier respondents. In all interviews, the interviewer asks about the function of the interviewee and the related responsibilities. On the basis of that question, the representation of the interview in relation to the entire stakeholder group can hopefully be better assessed. In addition, a number of general questions are asked about the current state of affairs in health care (with and expected answer belonging to the environment of the interviewee) and a number of questions will be asked about the personal experiences in this system. Next, the knowledge is tested on risk-sharing business models, outcome-based, performance-based, etc. This can be clarified on the basis of example cases if necessary and/or possible. The advantages and disadvantages of this model are then discussed, and attempts are also made to filter these out from practical experience (more in depth questions make come forward during this stage). In some cases when applicable, there could also be asked for specific preconditions in which risk-sharing business models must be implemented so that it can be of interest to the relevant stakeholder. Finally, questions will be asked about the expected future perspectives.

The final selection of the individual interviewees did not go completely random. This was done partly on the basis of a network from Inreda Diabetic, partly from the researchers' network and some through third parties. Not every requested individual had time or interest for an interview. Ultimately, on the basis of the relevant themes that had to be dealt with, the right people within the framework of the stakeholder were selected. This consideration was in some cases made by the investigating party, but sometimes also by the requested party. Manufacturer 'A' and 'C' are from one and the same organisation, but manufacturer 'B' and 'D' are from two others organisations. The interviewee's hospital 'A', 'B' and 'C' are all from the same hospital, but different departments within the organisational structure. All of the four health insurers (A, B, C, D) are representatives from different organisations.

Analysis of the results

The fifteen interviews taken are recorded in audio and then transcribed into a text document. This is done separately for each interview over the course of the research. When everything is transcribed the coding takes place where an overview of all themes (as discussed earlier) is horizontally lined up. Subsequently, all interviewees are randomly put together in a vertical line. In this structure there are many interviewees with opinions and arguments from all the stakeholders interviewed. An example of the overview is shown below (table 3). Not all themes could be answered or treated with each stakeholder thoroughly. This was also the case with specific themes that weren't able to be answered by an individual interviewee. For example, a theme of the interviews was to discuss the personal experiences with PBRSAs. But as expected in advance, only a small minority had experience with such arrangements.

	T1: Current healthcare system	***T2: Different types or PBRSAs***	***T3: Advantages and disadvantages of PBRSAs***
Interviewee A	x	y	*no answer*
Interviewee B	*no answer*	xy	y
Interviewee C	x	y	x

Table 8: Example overview of thematic coding

The overview offers the possibility to compare statements between the interviewees in an orderly manner. As stated above, indicated with 'y' and 'x', statements are not always the same and in this way a discussion arises. The disagreement should lead to debate and hopefully this debate brings new innovative solutions to the table.

Results

After briefly discussing the function and working environment of the stakeholder concerned, the current knowledge of performance-based risk-sharing arrangements is immediately discussed. This part of the conversation was often crucial. Performance based risk-sharing is an understanding that encompasses a broad meaning and can be interpreted in several ways. It was important to sketch a clear example case as interviewer to clearly indicate what is meant with performance-based risk-sharing.

Current healthcare system (pros and cons)

The Dutch healthcare system is doing relatively well according to Van den Berg et al. (2010) (additionally added literature) when compared to other countries. The total expenditure on care in the Netherlands has doubled since 1990 and 2010 with 20%. The costs seem to be increasing, partly due to the aging of the population. However, there is one thing definitely worth to mention in this study. It is concluded that health insurers are mainly purchasing on the basis of price, rather than quality. This could imply that quality may be decreasing over the course of time when proceeding its ways in this sector.

To start with the health insurers, it was quite clear that every interviewee in this group indicated that healthcare is currently being paid for each action. A risk-sharing business model could 'remedy' this according to ‘health insurer C’. At the moment, everyone in the chain is optimized in a way to obtain their own margin and turnover. This system, in the case of implemented risk-sharing like schemes, has to be redesigned and can cost a lot of time, energy and ultimately, money. But, risk-sharing is not proven to be the only solution for this. Also, according to ‘health insurer C’, the risk of purchasing healthcare arises from the fact that 1) not every patient is the same and reacts in the same way to a particular treatment (actuarial risk), but you also have 2) the risk where there are extra costs with insufficient quality of a specific treatment or when making a decision about whether or not a patient should be treated in the first place.

‘Health Insurer A’ especially mentioned the negative sides of the current system. As previously stated: “Do we want a system that is based on volume, in opposition of a system on value”? He calls this a big challenge to change here. Finding the right criteria for measuring the 'value' is probably also very difficult. He further states that this is a major point of discussion in (Dutch) healthcare right now; “is the incentive (financial reward) in the right place?” At the moment we are being asked to treat patients as much as possible.

‘Manufacturer C’ has appointed that currently a 4-year remuneration takes place in the Netherlands in terms of medical solutions being classified as ‘OK’ for patients. In some cases, the medical solutions do not work well. That integrated system that medical solutions are reimbursed for 4 years until there is a new evaluation moment is also not logical in the eyes of manufacturer C. A more frequent check should take place for higher control of quality.

Current healthcare system (pros and cons)	
Pros	***Cons***
• Doing relatively well compared to other countries (van den Berg, Heijink, Zwakhals, Verkleij, & Westert, 2010) • Other designed systems are not proven to be better	• Costs seem to be increasing due to aging population (van den Berg, Heijink, Zwakhals, Verkleij, & Westert, 2010) • Health insurer's when purchasing prioritise price over quality, which could lead to lower healthcare quality overall • Reimbursing individual (medical related) actions is prioritized due to incentives than the overall effective quality of treatments

Table 9 – Current healthcare system (pros and cons)

Different types or PBRSAs

From the medical devices perspective, according to 'manufacturer A' it is suggested that risk-sharing concepts aim to reduce the risks between the stakeholders, taking into account that all stakeholders benefit from it. It is later added by the interviewee that this can ultimately be translated into cost savings. In the context of a manufacturer of a medical device that should serve as a solution for a chronic illness, this could be elaborated as a model in which the health care insurer does not have to pay the full amount in the first instance, but on the basis of the results achieved in a later term of the treatment the 'full' payment will be done, respectively. In this way there is a great responsibility for the manufacturer, but this brings all kinds of possible advantages and disadvantages that will be discussed later in this chapter.

'Manufacturer B' mentions you can measure your results on multiple levels: "What do you charge to the product (manufacturer) and what do you charge to the practitioners? And how do you measure this and you set up this system?" Risk-sharing mechanisms can also be implemented in regular agreements such as a bonus-malus system that has to do with outcome parameters. For example, an outcome parameter can be based on the number of emergency admission.

An example of risk-sharing in the pharmaceutical industry, according to 'manufacturer D' is a scenario where it could be that you want to market a medicine that only works in 80% of the cases. This must of course come forward from testing beforehand. With a risk-sharing model you could say that you will pay for this in 100% of cases, but in the cases where it does not work, these costs must be included by the provider. You should therefore budget these expected costs. In this way you create a mechanism that should contribute to the more adequate sorting out of your patients that you are going to treat with this specific medicine. Because when the drug does not work it costs the manufacturer money. Another mechanism that also falls under the heading of risk sharing could include when you want to try out a treatment and invest in the model. When there are savings in that new model, you receive a fitting compensation for this.

Health insurer C' says an interpretation of (performance-based) risk-sharing could also be bundle payments, according to one of the health insurer interviewees. Bundle payments are some sort of packaged pricing where health care providers are paid for the effectively achieved result, instead of paying for each individual action that leads up to the eventual end of the treatment.

Advantages and disadvantages of PBRSAs

'Health insurer B' pointed out that pay for performance proved to be ineffective (which implies something different than PBRSAs). He explains this by saying "that when a certain target has to be achieved that often all energy is focused on this, which could be at the expense of the whole." An important principle of risk-sharing is that you get what you pay for, while the current healthcare system pays for each action by every link in the process. He goes further into this subject by appointing the integral financial responsibility. An example of this is mentioned as 'paying per customer instead of paying per product component'. According to the interviewee, there are positive international examples of this, because here the provider is rewarded for delivering quality products and maintaining a good cost policy.

'Manufacturer C' sees a performance-based risk-sharing agreement as a business model in which the manufacturer has a more dominant role in the existence of his or her product. At the moment you only need to get an approval to enter the market, but with a performance-based risk-sharing mechanism, the manufacturer is forced to do everything that is necessary to get a good delivered product onto a very competitive market. In result of this the manufacturer is forced to maintain a high quality standard in this way.

A different approach, from 'manufacturer C's' perspective, is that by means of risk-sharing you ensure that the responsibility remains with the manufacturer to guarantee a higher quality. But not only measure the intrinsic quality but also the aftercare. The current system is mainly aimed at obtaining 'approval', after which the aftercare largely disappears. If you can make that approval a continuous process then the sense of responsibility at the manufacturer's part will become higher.

Advantages(*)	Disadvantages(*)
• Integral financial responsibility • Positive international examples are proven to be effective when it comes to good cost policy and delivering quality products • Manufacturer has a more dominant role in the existence of his or her product	• Pay-for-performance mechanisms are ineffective because too much energy is focused on achieving specific targets • Manufacturer gains more responsibilities and financial risk

Table 10 – Advantages and disadvantages of PBRSAs

(*) There are more advantages and disadvantages, but these listed here are solely from the interviews.

Future perspectives and trends

'Manufacturer C' advocates a step-by-step market entry. As evidence is created by effectively coming up with solutions, the manufacturer would have to be rewarded with an increasingly larger sales volume. Up scaling fundamentally based on results/outcomes from these medical solutions. This is also advantageous for the manufacturer by being able to scale up production numbers in a controlled manner.

An example in practice, stated by 'health insurer A' of a risk-sharing mechanism is an Amsterdam start-up where an artificial intelligence system has been developed that includes the technology to assess a suspicious skin area through a photograph. Of course, this concept has many advantages because having a check up with a doctor takes time and money. By means of a digital system used through a simple mobile phone camera, it can thus be assessed whether a doctor's visit is necessary or not. If the application detects something that is worrying, the health insurer will pay an appropriate amount for this. If nothing is detected through the application, then there is no cost for the health insurer. In this situation, there are only a few administrative issues and the contractual agreement between the parties has been agreed in a very straightforward and direct manner. In this setting it can therefore be optimally implemented.

In addition to these possible approaches there is another perspective that is highlighted by 'health insurer C'; "Do you want a relationship with your supplier in a risk-sharing model? In fact, you just want a high-quality product from your supplier." This question cannot be answered with this research but is certainly interesting for further research.

According to 'Manufacturer B', insurers are more and more willing to think about outcome-based financing. However, this has been said for many years already in this sector. At the moment, many services and treatments are being purchased through different packages, which make the process for change fairly difficult. With these packages is meant that purchases are made on the basis of prescribed conditions that fall within a certain purchasing framework, so that everything can be purchased in a certain structure and that everything can therefore be categorized for accountability. An example of this is that in 2011 a large organization involved in solutions for diabetes started to market products in 2011 through a risk-sharing method. The duration was almost 7 years to fully roll out the system. Likely it can be done much faster with the experience obtained, but that it takes a lot of time and energy is clear. "Operational deployment remains difficult and you run into all sorts of limitations and obstacles, but on strategic level it's definitely a good step." Subsequently, it was asked whether the ultimate urge to change in terms of care system is mainly hindered by the health insurer. To this the expert answers that the health insurers are indeed an important link in this, because they ultimately pay the bill, and if you cannot arrange these new systems financially, also with due observance of the current regulations, then you are in a difficult situation. With risk-sharing you have to look at the integral results; thus the savings in other cost categories (for example fewer hospital visits or emergency admissions). All these costs are covered by other pots, so there has to be a willingness to negotiate with each other to see how the overall comprehensive system can be looked at in order to set it up again, and do this better. This is expected to take a relatively long time.

Enablers and barriers

A barrier according to ‘manufacturer D’ that in the Netherlands it is favourable working in a traditionally oriented economy when it comes to the pharmaceutical companies. People tend to stick to the well-known forms of purchasing. This conservative attitude could be an obstacle in new innovative policies. At the same time, the interviewee stated that risk-sharing was one of the concepts that was looked at and definitely considered by the represented company in question.

‘Manufacturer B' called out a disadvantage that it is difficult to set up PBRSAs financially, because there will be many changes in the calculation of potential costs. If looked at all integral outcomes, the savings in all other cost types should be considered, for example with diabetic patients: fewer hospital visits, fewer emergency admissions, less insulin use, etcetera. All of these costs fall under separate pots, so there must already be willingness to go to the table together to see how we can look at the total costs. Besides you need a lot of data to properly arrange such financial systems.

Another problem with the implementation of these concepts, according to ‘manufacturer A’ is the initial demonstration of the effectiveness of performance-based risk-sharing models. In a controlled environment it is a lot easier to get favourable results. In practice the results are often a lot less successful. The main reason is probably that the human factor has a more prominent role outside a controlled environment, and this often disturbs the results in practice. In addition to that complexity of practical feasibility, there are a number of advantages. Firstly, part of the risk has been removed from the health insurer, because the purchase costs are lower, and the other costs are financed on the basis of successful outcomes. In addition, it is often the case that these models are filled in combination with, as mentioned earlier, customer-oriented financing instead of financing per component.

‘Health insurer B’ states that the financing system will be arranged differently with a risk-sharing model. This will cost a lot of energy to organize this. It must be considered beforehand whether these changes are worth it. Furthermore, it has been discussed, in the Netherlands, that there is the ambition to achieve a purchase percentage of 50% based on outcomes within the next 5 years (as of December 2018). PBRSAs could be applied under these given ambitions. An advantage may be that with such arrangements you clearly identify what needs to be funded, so you are more focused on the costs per customer instead of costs per action. These methods have already produced positive examples internationally. In this way you reward the provider on delivering quality and managing the costs. And to pay for this form of financial integrality at customer level, some health insurers are therefore positive about it. But as mentioned, it is a very labour-intensive method, which is far from being used on a large scale, as of now.

‘Hospital A’ explicitly mentions that an extra workload regarding administration is not desirable for hospital staff; this is confirmed by ‘Hospital B’ and ‘C ‘In addition, ‘B’ also mentions that there is a lot of disorganized care. In a possible performance-based risk-sharing model, the hospitals should also be included in its possible benefits. Also 'B' mentions that measuring on outcomes is already a familiarity and that measuring on outcomes is probably the direction that is headed when speaking in terms of Dutch healthcare. So in that respect, a risk-sharing mechanism that has outcomes (I.e. Performance) as measurement might be appropriate.

‘Manufacturer A’ appointed from his own product/organization that it may be advantageous for them to apply PBRSAs. A piece of risk falls away from the health insurer, such as the costs of the initial investment. The aim is also to reduce the risks of each stakeholder, as in the form of the products becoming cheaper overall. Whether such an arrangement for the organization of ‘manufacturer A’ will be implemented is not yet certain, but for the time being few barriers are being seen.

‘Health Insurer A’ was also asked about the administrative complications that come with such schemes. Recognition from the interviewee was indeed there. An example of this was given with medicines worth of 100,000 euros per patient per year. The dose of the medicine must then decrease by a certain percentage over a certain period. Sometimes the savings are for the hospital, but other times the health insurer benefits from this. But what has happened is that both parties make agreements with each other so that the savings can be divided fairly. These are also called shared-savings. Obviously this example is more aimed at the savings side, but the adjustment of such a mechanism is quite complex to do.

Enablers	Barriers
• Risk-sharing arrangements are one of the concepts definitely considered • Some of the risk can be removed from the health insurer, because the purchase costs are lower, and the other costs are financed on the basis of successful outcomes • Incorporated as customer-oriented financing instead of financing per component • In the Netherlands it said there is the ambition to achieve a purchase percentage of 50% based on outcomes within the next 5 years (as of 2019)	• In the Netherlands it is favourable working in a traditionally oriented economy when it comes to the pharmaceutical companies • PBRSAs are financially difficult to set up structure wise due to data and separate pots • In practice often difficult to operate successful thus far • Extra workload regarding administration is not desirable for most of the stakeholders

Table 11 – Enables and Barriers for PBRSAs

Conclusion

That performance-based risk-sharing arrangements include a broad concept is clear to understand from the various forms of PBRSAs that are publicly available. In addition to PBRSAs in themselves, there are also other innovative arrangements proposed to be conceived between the various stakeholders in the healthcare sector. Within this framework there is a necessity for research that would explore the perspectives of the various stakeholders that will be faced with this. The research question therefore is formulated as: "What are the perspectives of Dutch stakeholders regarding (performance-based) risk-sharing arrangements in the healthcare sector?" To answer this research question, a systematic literature review was started to create a foundation of knowledge that could be used in the qualitative part of the research. In total 14 interviews from four different stakeholders were carried out.

Providing what emerged from the 14 interviews conducted for this study is that all stakeholders see, with emphasis on manufacturers, health insurers and hospitals that innovation should come about when designing the financial part in the Dutch healthcare sector. A volume based system that is now maintained should be distorted to a system in which quality of medical solution has a more prominent role. According to the results of the interviews this is also described as a system which, until now, is mainly focused on taking actions that can generate revenue instead of effectively solving the actual problem in a cost efficient manner.

A number of things have emerged from the synthesis of the systematic literature review. There appear to be several distinctions when talking about the number of PBRSAs types. A distinction can be made on the basis of four categories: Coverage of evidence development (CED), Performance-linked reimbursement (PLR), Conditional treatment continuation (CTC) and Financial or utilization (FU). (Garrison, et al., 2015) The stakeholders that were interviewed were not yet ready with these different concepts to be able to indicate what they preferred, because their scientific knowledge on these topics were not developed enough in order to formulate an informed opinion. This could be due to a gap between science and practice or perhaps other unknown reasons that may have to be looked into in further research. Furthermore, the success ratios of PBRSAs have been evaluated. In miscarriage, examples such as Sunitinib and Sorafenib are used to show success with PBRSAs. (Kiernan, 2016) There is one example from the own results of this research that can be given to a certain extent, that a success story has taken place. However, this is still relatively new and fairly simply furnished. Real complete well-organized PBRSAs did not present themselves from the various stakeholders at the time of the interviews.

It is further suggested that PBRSAs can ensure that accessibility to treatment is increased. Market entry could also be faster and the price efficiency better. However, drawbacks are mentioned: reliable data such as the safety of the product is considered to be important. (Navarria, et al., 2015) Success depends on all parties involved with the introduction of these arrangements, and in addition there are also multiply authors that conclude that administrative burdens can be very high when applying such arrangements. When looking at the increase in the trends of such arrangements, there is a clear upward trend to be observed which in recent years seems to be slowing down slightly, but an increase is still present on average. (Carlson, Yeung, Sean, Gries, & Garrison Jr., 2014) An advantage of PBRSAs according to most of the interviewee's may be that there is a more dominant role for stakeholder 'manufacturer', because the manufacturer has a higher interest in the quality standard after delivery of the medical solution. I as a researcher would presume this could therefore ensure that the quality of medical solutions will increase on average and to a certain degree may resolve the problem of too many costs because of the volume oriented systems as we have now.

The literature makes a number of recommendations that can contribute, or not, when it comes to PBRSAs: 1) When long-term prospects are still unsure, 2) when funding does not come from government agencies and 3) when patients work well within the construct of the arrangement. In contrast to these recommendations, there are also counteracting situations, such as: 1) when the administrative costs do not outweigh the financial benefits, 2) when outcomes of medical solutions cannot be properly represented when it comes to a results analysis and 3) when there are no clinical benefit achieved with the medical solution in question. (Adamski, et al., 2010) (Neumann, Chambers, Simon, & Meckley, 2011)

The most optimistic stakeholder were from the manufacturer's side, although negative argumentation also took place here. For example, it has been said that the Dutch system is fairly traditionally conservative orientated and is not inclined to change policy unless the benefits are very significant. In addition, another interviewee also mentioned that a PBRSAs system might be very difficult to organize because many costs that are made in treatments are paid from different budget pools. This makes it a very complicated process to change this. Based on these two arguments, you could say that health insurers are opposed to changing. But as the health insurers themselves indicate, it is important to change and switch to new, cost-saving systems. As stated above, the goal is to purchase 50% of the healthcare in the next 5 years that is based on outcomes, according to one of the interviewees belonging to the health insurer stakeholder.

As described earlier in this research (see methods), not every stakeholder has the same power or interest when it comes to PBRSAs, obviously. This implies that some stakeholders have a higher interest, but less power and vice versa. May it be clear that the manufacturers have the most interest, but certainly not the most power compared to the health insurers. In order to implement change, the health insurer will therefore be the most important link in achieving this. Naturally, support must be created among all the other stakeholders as well, but it has also become clear from the interviews that health insurers are decisive when it comes to reformed policy methods. It was suggested that government impulses may help to push back the restrained attitude of health insurers.

Just like the qualitative part of this report, the systematic literature review has also looked at the perspectives of the various stakeholders concerning the implementation, usage and future of PBRSAs. In the case of the SLR, however, as described in the theoretical framework, it has been looked beyond the boundaries of the Dutch domain. Over the entire spectrum, and thus all stakeholders, the risk-sharing mechanisms are viewed relatively optimistically. A distinction is made between 'financial based' and 'outcome based'. Outcome-based (can be considered as performance-based) are harder to implement and executed according to the stakeholders. Arguments such as high transaction costs, administrative burden, insufficient information systems and provider push backs that limit the long-term impact and viability of such schemes are all mentioned here. (Garrison, et al., 2015) (Carlson, Sullivan, Garrison, Neumann, & Veenstra, 2010) Overall it is suggested that it is required for all stakeholders to be involved in the process and thriving for a win-win situation. (Hammerman, Feder-Bubis, & Greenberg, 2012)

As the synthesis written from the SLR, the qualitative part of this research also has to conclude that PBRSAs are difficult to implement in the systems currently in place, but it certainly does not seem impossible. In order to do this well, the parties that wish to do so will have to go deeper into the requirements and preconditions of such arrangements. As mentioned in one of the interviews, it may be an idea to implement government-driven change, because it seems that established entities like to stick to proven working systems. Perhaps it is also necessary that pressure on the health care sector has to increase, so that a forced innovative measure remains the only solution. In that case PBRSAs could possibly just be the perfect solution.

Practical implications

Arguments such as high transaction costs, administrative burden, insufficient information systems, provider push backs and also argumentation that at the moment primarily Dutch health care is geared to focus its relieve on actions in opposition to quality. This clearly indicates that there is a necessity, and probably therefore a willingness, to set up new forms of financing flows, which will give quality (which should imply effectiveness) a more prominent role in this domain. Added to this, it was also mentioned in this study that the Dutch health care system is fairly traditionally oriented and therefore is expected to not quickly make any major progressive changes to its financial system. This is also due to a fairly large interconnected financial system, which means that PBRSAs can be too big of a change to implement, at least in the short term. Another practical solution towards this problem can imply resolving the current disadvantages of PBRSAs and simply suppress them with innovative solutions. Inreda Diabetic may have a product that can tackle these disadvantages. Administrative burdens, for example, are much lower because the artificial pancreas makes all data and measurements are visible via the internet through a live feed. Parameters could be set to automatically check the values and systems. In addition, the artificial pancreas has many financial advantages that may be worth to consider the investing in all the additional costs arising from structural reform.

Theoretical implications

The theoretical implications in this study relate to the results of the interview held with the relevant stakeholders, partly prepared in aid of the systematic literature review. There was a noticeable gap between the majority of interviewee's knowledge and the current record of PBRSAs in scientific research. Nevertheless, there were indeed relevant points, produced from the literature study, that were known to those who were interviewed. It was suggested that the stakeholders (the health insurers in particular) need a boost to further experiment with this. One of the proposals is to see whether the government can play a role in this. This research has also been of added value because of the fact that, in addition to the PBRSAs overall assessment, there has been made a clear division between the involvements of multiple stakeholders that take part in PBRSAs.

Future research

There are a number of directions that can be named for further research. First of all these suggestions could be explored in national research and international research. It is of national importance to look at the shortcomings of PBRSAs in the Dutch healthcare system. This is because in the international domain you have to deal with large, differently arranged healthcare systems with all kinds of financial flows. Another point for further research could be to look at the possible effect of the government when it provides subsidies or regulations that can be beneficial for the majority of stakeholders to bet on PBRSAs. Another direction for further research could be to analyse to what extent the disadvantages of PBRSAs can be overcome with innovative solutions. For example, what would happen to these arrangements if a large part of the administrative burdens were to be eliminated? Perhaps in these scenarios the stakeholders, and in particular the health care insurers, do see it as a opportunity to take a progressive stand towards PRBSAs.

Limitations

Some limitations to this research are that not all stakeholders have been questioned for the qualitative part of this research. In addition, the current selection of interviewees mainly set its standard to arrange an interview in the first place, instead of consciously selecting experts in this area. There has been a pre-selection to some extent, but that was not the case for the entire spectrum of interviewees. In addition, there is a limitation to this research that there are quite a lot of variants (technically infinite variants) when it comes to PBRSAs or just the risk-sharing mechanism overall. Furthermore, patients 'A',' B', 'C' and 'D' are all not familiar with performance-based risk sharing arrangements. In addition, for the same reason very limited detailed information has been extracted from the 'hospital' stakeholders.

What has become clear after the execution of the SLR and the qualitative part of the research is that there is a much deeper and more concrete description in the literature about the different types of PBRSAs compared to the understanding of these concepts from the 'normal' world. This contrast, which appears to me (subjectively) fairly large, also made it difficult to ask detailed feedback from the concluded SLR results during the qualitative part. Because of this, interviews were often based on example cases. Because of this reason finding possible pitfalls or bottlenecks in the implementation of such arrangements is much more difficult, because you are almost always brainstorming about hypothetical situations. And even when it comes to concrete examples in the qualitative part of this study, it is about very limited and simple risk-sharing mechanisms.

Appendix A: Set of questions to identify stakeholders

Vivek N. Mathur et al. (2007) suggests there is a set of questions with guidelines in ensuring that all important stakeholders are considered. The following questions are directly taken from the article:

- *Who are responsible for the project (and its different components/aspects)?*
- *To whom are statutory responsibilities owed?*
- *Who are the intended users/beneficiaries of the project?*
- *Who are the voiceless, but affected by the project?*
- *Who can negatively affect the success of the project through their opposition/non-cooperation?*
- *Who run (or belong to) organisations with relevant interests?*
- *Who have the ability to represent the interests of those unable to participate (e.g. future generations, non-human entities)?*
- *Who have the authority to make judgements on behalf of those they are representing?*
- *Who have unique knowledge related to any aspect of the project?*
- *Who have historical or cultural links to the area or to any issues that the project raises?*
- *Who depend on the resources (natural or other) which may be affected by the project?*
- *Are a few identified stakeholders representing interests of diverse groups (are they sufficiently representative)?*

Appendix B: Systematic Literature Review

The aim of a systematic literature review is to gradually generate a selection of scientific articles that are relevant to the basis of this research in a systematically responsible manner. A number of keywords will be used to search for the right amount of articles on this subject. Findings from these articles will be used to write a synthesis as a fundamental basis for the research from which an X number of questions can be formulated. The systematic literature review is set to be analysed on a global scale, but only including data from western civilizations. The goal of the SLR is to identify, critically evaluate and integrate the findings of all relevant studies. Furthermore, it is required for the systematic review to be objective, systematic, transparent and replicable. (Piper, 2013) The systematic literature review synthesis tries to answer its main question and five sub-questions which are further explained in the appendix (B).

SLR Research question and sub-questions

To give the systematic literature review a guideline when it comes to obtaining concrete results that can lead to a streamlined discussion, a central research question will be formulated along with a number of sub-questions. The central research question for the SLR (=systematic literature review) will not be the same as the central research question for the overall research. Therefore the central research question for the SLR can be formulated as:

SLR RQ: *"What does the recent literature (of the last 15 years) have to say about (performance-based) risk-sharing arrangements in the healthcare sector?"*

To support the main question, 5 sub-questions are formulated

SLR SQ1: *Which kind of risk-sharing business models are most often used?*
SLR SQ2: *What is the success ratio of these models and what made it go right or wrong?*
SLR SQ3: *What are the trends of recent years and what conclusions can be drawn from them?*
SLR SQ4: *What is suggested or recommended when it comes to the design of these models?*
SLR SQ5: *Which stakeholders are mentioned in the literature and what is said about them?*

Identification criteria

The systematic literature review will be conducted on the basis of two selection criteria. First, it will be determined which database will be used. A requirement here is that the database is available through the University of Twente. For this reason Scopus has been selected because it is a very broad database which should contain a very high percentage of the relevant articles for this study. The second selection criterion is the search string that will be suitable for obtaining the right set of articles for this topic. The search string will be based on a set of appropriate search terms which are applicable on the related research question.

In addition to selecting the databases, a search string must be set up. The search string consists of synonyms for framed subjects that are relevant to the systematic literature research. In this systematic research it is the intention to provide a well-founded basis which can serve as a foundation for the qualitative part. More specifically, the aim is to obtain specific information about value/outcome/performance-based business models that have been or are being used in the healthcare sector. In the table shown below the related terms and key concepts are listed:

Table of terms and keywords used	
Relevant business models	• Value-based pricing* • Outcome-based* • Performance-based* • Risk-sharing* • Reimbursement based* • Pay(-)for(-)performance*
Additional filters	• Scheme(s) • Business model(s) • Arrangement(s)
Environment	• Health care (sector) • Medical environment

Table 12: Table of terms and keywords used

The terms and keywords above are the basis for setting up the search string that will be used in Scopus. The search string will use the terms above in different ways to make sure all relevant articles are involved no essential information will be missed in this systematic research. Below is the search string that has been applied to Scopus. The date of search is on October 23, 2018. The search string is limited to articles published in 2004 or later due to maintaining relevancy.

Scopus	
Search String	((ABS ("P4P" OR "Pay-for-performance" OR "Pay for performance" OR "Value-based*" OR "Performance-based*" OR "Outcome-based*" OR "Value based*" OR "Performance based*" OR "Outcome Based*" OR "Reimbursement-based*" OR "Reimbursement based*" OR "risk-sharing*" OR "risk sharing*")) AND (ABS ("Arrangement*" OR "Business model*" OR "Scheme*")) AND (ABS ("health*" OR "medical*"))) AND (LIMIT-TO (PUBYEAR , 2018) OR LIMIT-TO (PUBYEAR , 2017) OR LIMIT-TO (PUBYEAR , 2016) OR LIMIT-TO (PUBYEAR , 2015) OR LIMIT-TO (PUBYEAR , 2014) OR LIMIT-TO (PUBYEAR , 2013) OR LIMIT-TO (PUBYEAR , 2012) OR LIMIT-TO (PUBYEAR , 2011) OR LIMIT-TO (PUBYEAR , 2010) OR LIMIT-TO (PUBYEAR , 2009) OR LIMIT-TO (PUBYEAR , 2008) OR LIMIT-TO (PUBYEAR , 2007) OR LIMIT-TO (PUBYEAR , 2006) OR LIMIT-TO (PUBYEAR , 2005) OR LIMIT-TO (PUBYEAR , 2004))
Total results	515 documents (as of 23-10-2018)

Table 13: Scopus search string

Article selection criteria

Articles were included in the review if they focused on anything that is explained as models such as risk-sharing, performance-based, outcome-based, etc. It is also important that it is applied in western healthcare systems for a more appropriate comparison. Furthermore, the articles must use information and data from practice, some theoretic models are not included. In total of the 515 found articles, a total of exactly 24 remain after the selection. The 24 selected articles will be used to answer the central research question and sub-questions of this systematic literature review.

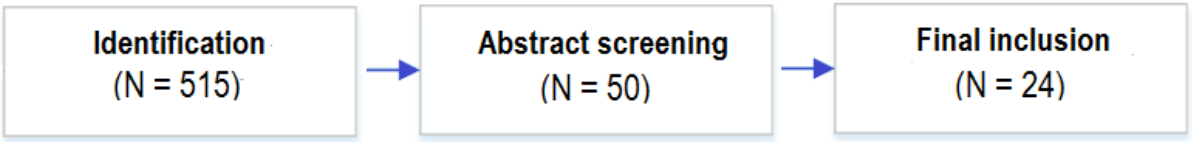


Figure 6: Process of article inclusion

The selection was done in two rounds. First only the title and abstract were read in order to filter the first batch of incompetent articles. If the title or abstract gave the assumption that it could fit to the selection criteria, it was placed on a separate 'stack' waiting for round two of the selection procedure. In the second round more in depth reading took place throughout the whole article to see if the pre-determined selection criteria matched with the content of the article.

Method of synthesis

The total gathered articles are then used to synthesise an answer for the systematic literature research questions. The first step in order to do so is by identifying or developing a thematic framework which can be used to properly write the synthesis. In order to arrive at an appropriate framework for answering the SLR research questions, a research paper was examined that analyses various frameworks and discusses the advantages and disadvantages of this. Barnett-Page and Thomas (2009) claim that a textual narrative synthesis is an approach that is a proven powerful tool when dealing with different types of research (qualitative, quantitative, economic etc.). Also, according to Lucas et al. (2007) a textual narrative synthesis is relatively good to develop a more transparent heterogeneity between studies.

Tools and techniques are obtained from Snitsvelt et al. (2012) to carry out the 'narrative' synthesis. In total the authors describe there are four elements of a synthesis to consider: 1) Developing a theory, 2) developing a preliminary synthesis of finding of included studies, 3) exploring relationships in the data and 4) assessing the robustness of the synthesis. For the second, third and fourth element there are tools and techniques proposed. For developing a preliminary synthesis of findings of included studies it is suggested to create textual description of studies, forming of groupings and clusters, transforming the data into a common rubric, using vote counting as a descriptive tool and applying thematic and content analysis for translating data. For the third element, exploring relationships in the data, it is proposed to use graphs, frequency distributions, funnel plots, idea webbing and conceptual mapping, qualitative case descriptions and more. For the final element, assessing the robustness of the synthesis, it is suggested to weigh the evidence through validity assessment. For a more detailed overview take a look at appendix B.

Appendix C: Stakeholder mapping

Broad category	*Sub-category*	*Types of indivduals/groups*
Those who affect the project	Those involved in delivery of the project	Developer
		Client
		Owner
		Investor(s)
		Project manager/management team
		Banks
		Insurer(s)
		Contractor(s), sub-contractor(s) and suppliers
		Professional consultants (e.g architectural, engineering and financial)
	Those who determine the context	Local authority - planning department etc.
		Regional government departments
Those who are affected by the project		Non-departmental public bodies such as environment agency, housing corporation etc.
	Directly affected	users of the buildings, spaces, facilities etc.
	May be directly or indirectly affected depending upon the context	Local/surrounding community members
		General Public
		Local community groups such as resident associations, or other community-based groups
		Specific demographic groups such as those based on race, ethnicity, gender, age etc.
		Environmental/social campaigning organisations
Others who may be interested		Rsearchers/ Academics
		Media
		Potential users/clients for future projects

Table 14 – Stakeholder mapping - Mathur, V.N. et al. (2007)

Appendix D: Tools and techniques for narrative synthesis

Tools and techniques for narrative synthesis	
Element of synthesis	*Suggested tools and techniques*
Developing a theory of how the intervention works, why and for whom?	No specific tools or techniques identified. However, it is noted that tools and techniques suggested for other elements of the synthesis can contribute to developing the theory of change
Developing a preliminary synthesis of findings of included studies	Textual description of studies, groupings and clusters, tabulation, transforming data into a common rubric, vote counting as descriptive tool, thematic, and content analysis for translating data.
Exploring relationships in the data	Graphs, frequency distributions, funnel plots, forest plots and L'Abbe plots; moderator variables and sub-group analysis; idea webbing and conceptual mapping; reciprocal and reputational translation; qualitative case descriptions; investigator/moderator triangulation; conceptual triangulation.
Assessing the robustness of the synthesis	Weight of evidence (for example, Harden and Gough 2012); best evidence synthesis; validity assessment (for example, the CDC approach); reflecting critically on the synthesis process; checking the synthesis with authors of primary studies.

Table 15 – Tools and techniques for narrative synthesis - Popay et al. (2006)

Appendix E: Key-success factors for risk-sharing agreements

Key success factors for risk-sharing agreements	
Stakeholder	
Manufacturers	Ability to measure outcomes in short time frame, with clear indicator (biomarker). Undeveloped evidence base, opportunity to gather real-world evidence. Product with clinical advantage over lower-cost competitors. Few comorbid conditions, limited size of target patient population. Availability of multiyear clinical data (mid-life cycle rather than newly launched products). IT infrastructure to track and audit data and manage patient registries.
Payers	IT Infrastructure to track outcomes and switched patients, simple audit systems. Clear payment or reimbursement mechanism (free initial therapy preferable to later debates if outcomes are not reached). Unequivocal outcome measure (for example, valid biomarker). Clear outcome-reporting flow from physicians.
Physicians	Objective outcomes measures (for example, MRI or biomarkers). Opportunity to standardize dosing requirements and minimize overuse through physician training. Small patient population, few comorbid conditions, system to monitor adherence
Patients	Rapid enrolment process, simple data-release authorization. Clear clinical advantage of product, lack of alternatives. Participation in outcome reporting. Opportunity to improve adherence.

Table 16 – Key success factors for risk-sharing agreements - (Neumann, Chambers, Simon, & Meckley, 2011)

Bibliography

Adamski, J., Godman, B., Ofierska-Sujkowska, G., Osinska, B., Herholz, H., Wendykowska, K., & Gustafsson, L. L. (2010). Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers. *BMC Health Services Research*, 1-16.

Barnett-Page, E., & Thomas, J. (2009). Methods for the synthesis of qualitative research: a critical review. *BMC Medical Research Methodology*, 1-11.

Bernard, H. R. (2011). *Research Methods in Anthropology.* Plymouth: AltaMira Press.

Bryson, J. M. (2004). What to do when stakeholders matter: stakeholder identification and analysis techniques. *Public Management Review*, 21-53.

Carapinha, J. (2008). Setting the stage for risk-sharing agreements: International experiences and outcomes-based reimbursement. *South African Family Practice*, 62-65.

Carlson, J. J., Chen, S., & Garrison, L. P. (2017). Performance-Based Risk-Sharing Arrangements: An updated international review. *PharmacoEconomics*, 1063-1072.

Carlson, J. J., Sullivan, S. D., Garrison, L. P., Neumann, P. J., & Veenstra, D. L. (2010). Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. *Heath Policy 96*, 179-190.

Carlson, J. J., Yeung, K., Sean, D. S., Gries, S. K., & Garrison Jr., P. L. (2014). Current status and trends in performance-based risk-sharing arrangements between healthcare payers and medical product manufacturers. *Applied Health Economics and Health Policy*, 7.

Garrison, L. P., & Towse, A. (2017). Value-Based Pricing and Reimbursement in Personalised Healthcare: Introduction to the Basic Health Economics. *Journal of Personalized Medicine*.

Garrison, L. P., Carlson, J. J., Bajaj, P. S., Towse, A., Neumann, P. J., Sullivan, S. D., . . . Dubois, R. W. (2015). Private Sector Risk-Sharing Agreements in the United States: Trends, Barriers, and Prospects. *Managed Care & Healthcare Communications*, 632-640.

Garrison, L. P., Towse, A., Briggs, A., de Pouvourville, G., Grueger, J., Mohr, P. E., & Sleeper, M. (2013). Performance-Based Risk-Sharing Arrangements-Good Practices for Design, Implementation, and Evaluation: Report of the ISPOR Good Practices for Performance-Based Risk-Sharing Arrangements Task Force. *Value in Health*, 703-719.

Hammerman, A., Feder-Bubis, P., & Greenberg, D. (2012). Financial Risk-Sharing In Updating The National List of Health Services in Israel: Stakeholders' Preceived Interests. *Value in health 15*, 737-742.

Keckley, P. H. (2012). *Value-based pricing for pharamaceuticals: implications of the shift from volume to value.* Deloitte Development LLC.

Kiernan, F. (2016). The future of pharmacoenomic policy - does value-based pricing really have a role? *Journal of Pharmaceutical Health Services Research*, 5-9.

LaPointe, J. (2018, Nov 9). *What is Value-based care, What It Means for Providers?* Retrieved Nov Friday, 2018, from Recycle Intelligence: https://revcycleintelligence.com/features/what-is-value-based-care-what-it-means-for-providers

Lucas, P. J., Arai, L., Baird, J., Arai, L., Law, C., & Roberts, H. M. (2007). Worked examples of alternative methods for the synthesis of qualitative and quantitative research in systematic reviews. *BMC Medical Research Methodology*, 1-7.

Mathur, V. N., Price, A. D., Austin, S., & Moobela, C. (2007). Defining, identifying and mapping stakeholders in the assessment of urban sustainability. *International Conference on Whole Life Urban Sustainability and its Assessment*, 1-18.

Miller, H. D. (2013). From Volume To Value: Better Ways To Pay For Health Care. *Minnesota Medicine*.

Mitchell, R. K., Agle, B. R., & Wood, D. J. (1997). Toward a theory of stakeholder identifciation and salience: defining the principle of who and what really counts. *Academy of Management*, 853-886.

Navarria, A., Drago, V., Gozzo, L., Longo, L., Mansueto, S., Pignataro, G., & Drago, F. (2015). Do the Current Performance-Based Schemes in Italy Really Work? "Success Fee" A Novel Measure for Cost-containment of Drug Expenditure. *Value in Health 18*, 131-136.

NCSL Privacy Policy. (2019). Retrieved March 11, 2019, from NCSL: http://www.ncsl.org/aboutus/ncsl-privacy-policy.aspx

Neumann, P. J., Chambers, J. D., Simon, F., & Meckley, L. M. (2011). Risk-Sharing Arrangements That Link Payment For Drugs To health Outcomes Are Proving Hard To Implement. *Health Affairs*, 2329-2337.

Pessaux, P., & Cherkaoui, Z. (2017). Value-based healthcare: a novel approach to the evaluation of patient care. *HBSN*, 125-126.

Piatkiewicz, T. J., Traulsen, J. M., & Holm-Larsen, T. (2017). Risk-Sharing Agreements in the EU: A Systematic Review. *PharmacoEconomics Open*, 109-123.

Piper, R. J. (2013). *http://sites.cardiff.ac.uk.*

Rosenthal, M. B., Frank, R. G., Li, Z., & Epstein, A. M. (2005). Early experience with Pay-for-performance. *JAMA*, 1788-1793.

Schiller, C., Winters, M., Hanson, H. M., & Ashe, M. C. (2013). A framework for stakeholder identification in concept mapping and health research: a novel process and its application to older adult mobility and the built environment. *BMC Public Health*.

Schütte, S., N Marin Acevedo, P., & Antoine, F. (2018). Health systems around the world – a comparison of existing health system rankings. *Journal of Global Health*.

Siddaway, A. (n.d.). *What is a systematic ltierature review and how do I do one?* Retrieved January 2019, from semanticscholar.org.

Snilstveit, B., Oliver, S., & Vojtkova, M. (2012). Narrative approaches to systematic review and synthesis of evidence for international development policy and practice. *Journal of Development Effectiveness*, 409-429.

van den Berg, M., Heijink, R., Zwakhals, L., Verkleij, H., & Westert, G. (2010). Health care performance in the Netherlands: Easy access, varying quality, rising costs. *Eurohealth Vol 16 No 4*, 27-29.

Yu, S. J., Chin, L., Oh, J., & Farias, J. (2017). Performance-Based Risk-Sharing Arrangements for Pharamaceutical Products in the United States: A Systematic Rewiew. *Journal of Managed Care & Specialty Pharmacy*, 1028-1040.

Zaric, G. S., & Xie, B. (2009). The Impact of Two Pharmaceutical Risk-Sharing Agreements on Pricing, Promotion, and Net Health Benefits. *Value in Health*, 838-845.