CRANFIELD UNIVERSITY

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CURRENT STATE AND FUTURE DIRECTION OF ADOPTION OF PRODUCT SERVICE SYSTEMS IN HEALTH CARE

School of Aerospace, Transport and Manufacturing
PhD in Manufacturing

PhD
Academic Year: 2008 - 2017

Supervisor: Prof. Tetsuo Tomiyama
Associate Supervisor: Prof. Ashutosh Tiwari
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ABSTRACT

Health care systems are constantly challenged to deliver better quality of care at lower cost. Product Services Systems (PSS) aim to output a higher value to a customer, while reducing resource input required to achieve such value and sustainability. In the health care market this could help companies increase their focus on value for the patient, but also for the health care system as such. This focus on value can ultimately help drive down health care cost, which is one of the most pressing issues in health care systems today. The potential of PSS to address some of the major challenges in the health care market was recognised early in PSS research, however adoption in this field is still below expectation. Motivated by the potential of PSS in health care this work aims to explore the current status of adoption as well as drivers and barriers to future adoption in this market and evaluates if and how PSS can be designed and implemented by companies active in this market.

This work showed that PSS can be feasible and useful in this sector as they address relevant current challenges. Future changes in the health care market will likely make PSS even more relevant. Certain concepts of PSS are already applied in the market without leveraging the benefits of a fully developed PSS. Limitations in how the value for patients and other market actors is determined and made transparent is a major challenge in the adoption of PSS. An assessment method is proposed to enable companies to evaluate the value generation of their PSS offerings. In addition, a guideline for PSS design is proposed based on results of this work and field observations.

This thesis contributes to a better understanding of PSS adoption in health care by investigating mechanisms in the health care market to understand if PSS can be implemented in a useful manner and how PSS can be adopted in health care in the future. As PSS consists of a number of separate concepts that may be used by themselves and also outside a PSS concept, a detailed analysis was performed to evaluate how PSS concepts are already utilized by industry, as such partial implementations may be a good starting point for full PSS adoption.

Adoption of a PSS in any industry requires a measure to evaluate the success of a system implementation or the quality of PSS offerings. Given the complex market

network in health care, metrics for evaluations have been identified, linking different dimensions of clinical utility to PSS. Those metrics enable companies to assess PSS systems or scenarios, but also enable development teams to focus their PSS design efforts, as those assessment metrics provide a framework for PSS requirements engineering in this market.

Based on the results of the work outlined above, design guidelines were defined to support the development process of PSS in health care.

KEYWORDS

Product Service Systems, PSS, health care, patient value, clinical utility, health care market

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LIST OF ABBREVIATIONS

BBB	Blood Brain Barrier
CED	Convection Enhanced Delivery
GBM	Glioblastoma Multiforme (brain tumour)
MS	Multiple Sclerosis
FDA	Food and Drug Administration
PSS	Product Service Systems

LIST OF PUBLICATIONS

Mittermeyer, S., Njuguna, J. & Alcock, J., 2010. **Product–service systems in health care: case study of a drug–device combination.** The International Journal of Advanced Manufacturing Technology, pp.1–13.

1 INTRODUCTION

This chapter starts with a short description of the research background and the motivation for this thesis. Product Service Systems (PSS) have been identified as a promising approach to achieve better value for a customer while utilising less resources. The health care market is in need of a clearer focus on (patient) value and cost reduction. Despite this potential, adoption of PSS, in particular in health care is lower than expected. This thesis is motivated by this phenomenon and aims to contribute to a better understanding on factors relevant for the adoption of PSS in the health care market. This first chapter also gives an overview of the specific research contributions of this thesis. It concludes with an outline of the thesis structure to present the contributions in a concise manner.

1.1 BACKGROUND & MOTIVATION

By integrating products and services into product service systems (PSS), companies attempt to offer customers a solution that addresses the actual user need, rather than providing means to fulfil such need (Vasantha et al. 2012). While many industry sectors are seeing beginnings of adoption (Barquet et al. 2013), the health care market has been vastly neglected, despite the fact that early research in PSS identified this sector as great potential for sustainable product-service offerings (Köbler et al. 2009; Adeogun et al. 2010).

Product service systems aim to increase value for a customer (Mont 2001). To create value, the ratio of resources applied versus the result for the user has to be optimised and PSS offers an approach to this objective. PSS is therefore also referred to as innovation oriented towards sustainability (McAloone & Andreasen 2002). The stakeholders are not only the company and its customer, but also includes the interest of the society in sustainability. While typical product offerings provide a tool for a customer to ultimately achieve a certain value by using it, PSS attempts to consider the value, a customer expects. Often this leads to use oriented or even value oriented PSS, in which product ownership is not necessarily transferred to the user, but the product

and services are combined in a way that fulfils the need of the customer at the moment it is required under the circumstances the customer is in (Baines et al. 2007).

Most popular business models in the field of PSS have developed around “sharing economy”, where products are shared with a larger group of customers rather than producing products for each customer. Those models are especially of interest in use cases, where products are used only occasionally or where the total cost of ownership is relatively high.

PSS as a business model and approach to design new solutions has a very broad scope. It attempts to cover the entire life span of a products including the re-use or recycling process, but it also includes value considerations beyond the direct company to customer relationship. Social aspects are also part of the broad design approach proposed in PSS research (Kang & Wimmer 2008).

At the same time, the health care market is changing driven by the need to create more sustainable health care systems that provide added value to patients at significantly lower cost (Porter & Teisberg 2006). Many changes in the health care market do pose challenges that may be addresses by means of PSS and may even make it mandatory to create business models and offerings that embrace a deeper integration of products and services. Companies will have to provide offerings that maximise the clinical benefit and quality of life for patients, while minimising the cost and resource consumption along clinical workflows.

Product service systems do face challenges in adoption in many markets, as clear and unambiguous design guidelines are missing. Despite the great potential of PSS and several very successful implementations in the industrial sector, there has been resistance for a broader adoption of the concept (Baines et al. 2007; Cook et al. 2006). Putting PSS into practise requires a completely new mind-set for both the company providing the PSS and the customer using the offered PSS (Tukker & Tischner 2006). A company developing a PSS needs to be culturally ready to adopt the concept (Mont 2002b). PSS adoption may include changes in organization and a significant investment of money and time (Baines et al. 2007). Vasantha et al. reviewed the state of research in design methodologies for PSS concluding that the field is still not fully matured and requires more specific guidelines for design methodologies (Vasantha et al. 2012).

Despite the clear need to develop the field further, in recent years, research work on design methods even slowed down (Qu et al. 2016a).

After over two decades of research, there is still a gap between theoretical concepts and tools for PSS and practical guidelines and knowledge for companies willing to explore PSS as a new business model. Attempts to develop a generic solution to close this translational gap have not been successful so far in providing companies enough guidance to reshape their business model into a PSS based model.

The research described in this thesis is motivated by questions such as:

- Can PSS solutions help in practice to address the specific market needs in health care?
- Is a PSS design and implementation feasible in the context of health care given that the health care market is significantly different to industry sectors?
- How is the role of PSS impacted by changes and trends in the health care sector?
- Are there aspects of PSS that are already adopted by the market, even though not in the context of PSS?
- How could a PSS be assessed, given that the market is a unique network of stakeholders, with relationships and mechanisms different to other markets?
- What are design guidelines for PSS in health care that can facilitate the development of PSS offerings in this market?

This thesis contributes to knowledge related to the questions above to facilitate future adoption of PSS in healthcare.

1.2 RESEARCH AIM AND OBJECTIVES

Based on the motivation outlined above, a specific research question can be phrased:

> *"What is the status of product-service systems (PSS) adoption in health care and how can future PSS adoption be facilitated?"*

The main research contribution of this thesis is to close gaps in research and knowledge in regard to the current and adoption of PSS in health care and its future potential. A concept like PSS can only be developed and implemented in health care if (i) PSS solutions help to address market needs, (ii) companies are incentivised by the market to engage in PSS development, (iii) there are no barriers preventing PSS from being used and (iv) companies have the required methods and tools available for a successful implementation.

This work contributes to the points above by looking into mechanisms in the health care market to understand if PSS can be implemented in a useful manner. To also project PSS adoption in health care into the future, market trends were analysed that may either drive or hinder implementations of PSS in this market.

As PSS entails a large number of concepts that may be used by itself and outside a PSS concept, a detailed analysis was performed to evaluate in how far PSS concepts are already implemented by industry, lowering the barrier for a full implementation of PSS.

Adoption of a concept like PSS in industry requires a measure to evaluate the success of a system implementation or the quality of PSS offerings. Given the complex market network in health care, a metrics for evaluation have been identified, linking different dimensions of clinical utility to PSS. Those metrics allow for evaluation of PSS systems, but also for focused development of PSS offerings, as they provide a framework for PSS requirements engineering in this market.

Based on the results of the work outlined above, design guidelines were defined to support the development process of PSS in health care. Those guidelines have been retrospectively validated in a case study.

To address these gaps in knowledge and to answer the research questions defined above, the following aims and objectives have been defined.

1.2.1 Practical Feasibility and Utility of PSS in Health Care

The first aim is to evaluate the feasibility and utility of PSS in health care to address the question if PSS in health care can provide benefits in realistic market scenarios, as predicted in PSS research. To evaluate this aim, a case study was carried out analysing a business-to-customer and business-to-business scenario, with the objective to confirm or disprove the practical feasibility and utility of PSS in health care.

While benefits of PSS in health care are discussed in literature, there is limited experience reported on how a PSS would fit into real life market scenario, considering all market stakeholders relevant for PSS development, implementation and adoption in health care. This first aim also is set up to provide market relevant information on how a PSS would impact the network of market actors and to evaluate if PSS in health care is feasible and adding value.

1.2.2 Impact of Changes in Health Care on PSS

A second research aim of this work is to investigate how changes and trends in the health care market may impact the adoption of PSS. The health care market is rapidly changing and those changes may have an impact on future adoption, feasibly and utility of PSS in this market.

In PSS research benefits and challenges of PSS are discussed in detail, however this has not been aligned with trends and changes in the health care market to understand how those market changes will drive or inhibit adoption of PSS in this sector. The objective of this aim is to provide an understanding of future potentials and risks for PSS implementations in health care and define the drivers and inhibitors of PSS in health care.

1.2.3 Existing Adoption of PSS Aspects in Health Care

The third aim is to understand which aspects of PSS may already be adopted in healthcare, without being implemented in a broader concept of PSS.

The PSS concept consists of many different aspects, which by itself can be applied in business models. PSS adoption in health care has been found to be limited, however certain aspects of PSS are implemented in offerings and well-studied. Despite this existing practical and theoretical expertise, no analysis has been carried out from a PSS perspective. The objective is to provide a detailed overview of what the real adoption of PSS components is in health care. This will allow to explore avenues to extend existing offerings organically into full PSS business models.

1.2.4 Assessment of Clinical Utility of a PSS

The fourth aim is to select a method for assessing clinical utility that allows to consider all aspects of value generated for stakeholders and validate such method in the context of health care.

PSS inherently focusses on the creation of user value. The health care market is characterised by a complex network of market stakeholders for all of which a successful PSS needs to provide value. While technology assessment methods are proposed in research and also applied in practice for certain product offerings, no assessment method is available to evaluate the value generation and clinical utility of PSS. The objective of this research aim is to identify a method allowing companies to assess the performance of a PSS with regard to value generation considering all market stakeholders. Such a method could be applied in the design, validation, benchmarking of PSS, giving companies better guidance in the process of PSS design and implementation.

1.2.5 Design Guidelines for PSS in Health Care

The last research aim is to develop design guidelines that can be applied by companies interested in offering PSS solutions in health care.

In research, many different design methodologies are discussed for PSS with limitations on practical applicability due to the fact that those methods are often too generic, as they attempt to cover many different market scenarios. The objective of this aim is to provide a set of guidelines derived from results of prior objectives and field observations that allow companies to develop design processes for PSS offerings.

1.3 RESEARCH STRATEGY

Based on the research question and the motivation of this thesis set forth in the sections above the main purpose of this thesis is to address several key areas of research in order to facilitate the development of PSS business models in the health care sector. For this purpose, the following research approach has been identified:

- **Step I:** Review existing literature and research on the two areas of interest, namely PSS and the health care market, to establish an understanding of the current state of the art, potentials and challenges in both areas and to identify the research gap.
- **Step II:** Review literature and research relevant to the areas of knowledge contribution identified in the section above.
- **Step III:** Evaluate the practical utility and feasibility of PSS in health care
- **Step IV:** Identify future trends in health care and evaluate their impact utility and feasibility in health care.
- **Step V:** Evaluate the adoption of aspects incorporated in PSS in the health care market today.
- **Step VI:** Identify and validate a method for assessing clinical utility of a PSS in health care.
- **Step VII:** Develop design guidelines for PSS design in health care.

1.4 THESIS STRUCTURE

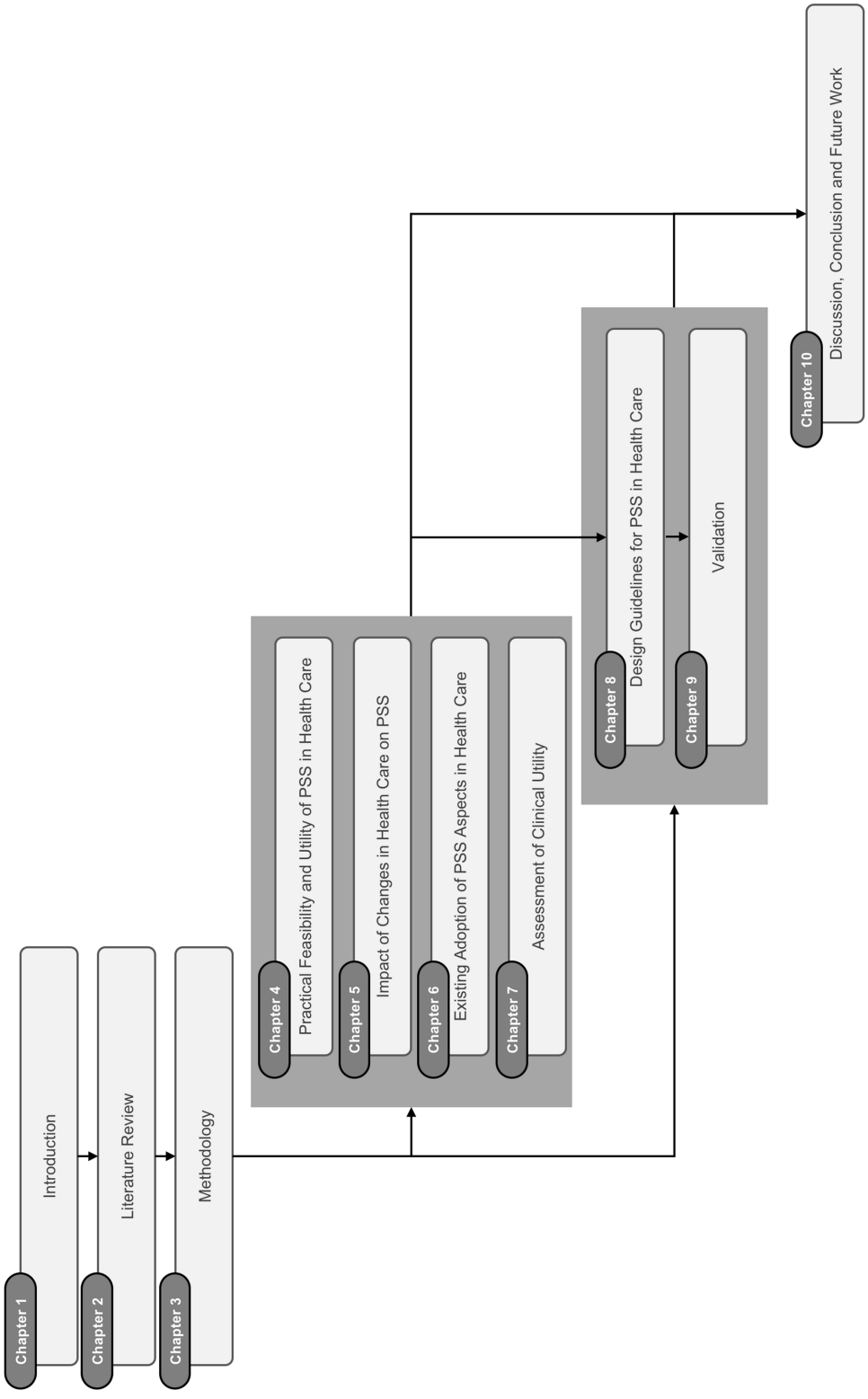
Figure 1-1 illustrates the thesis structure. The work is structured into 10 chapters detailed out below:

- *Chapter 1:* **Introduction**
  The first chapter introduces the areas of research, namely product service systems and the health care sector and defines the research question, objectives and contributions to knowledge. Lastly, the structure of the thesis is outlined.
- *Chapter 2:* **Literature Review**
  The second chapter summarises the comprehensive literature research on product service systems in general and PSS design methodologies in particular, as well as on the special characteristics of the health care market relevant to PSS development and implementation in this sector. This chapter concludes with the outline of the research gap addressed by this thesis.
- *Chapter 3:* **Methodology**
  The third chapter outlines the research approach and strategy to address the research question.
- *Chapter 4:* **Practical Feasibility and Utility of PSS in Health Care**
  Chapter 4 aims to clarify if PSS can contribute in health care and address some of the particular challenges in this market. Further, it was investigated how feasible PSS implementations are in this market.
- *Chapter 5:* **Impact of Changes in Health Care on PSS**
  After clarifying if and how PSS could be used today in chapter 4, this chapter focuses on changes in health care to develop an understanding of how PSS can be utilized in the future, as the market faces new challenges and different market mechanisms.
- *Chapter 6:* **Existing Adoption of PSS Aspects in Health Care**
  In chapter 6 PSS was dissected into separate concepts to evaluate if those concepts already are implemented by industry and constitute a parital adoption for PSS.
- *Chapter 7:* **Assessment of Clinical Utility in PSS**
  In this chapter, the focus was on how PSS and PSS offerings can be assessed in the context of health care. With several market actors involved in a health care

system, metrics other than commertial success are necessary to stear PSS projects into the right direction.

- *Chapter 8:* **Design Guidelines for PSS in Health Care**
  With the knowledge developed in the previous chaptors, design guidelines have been developed. Those guidelines may support the implementation of PSS in a highly regulated and complex market.
- *Chapter 9:* **Validation**
  Chapter 9 focused on validating the design guidelines proposed in chapter 8 in a retrospective case study.
- *Chapter 10:* **Discussion, Conclusions and Future Work**
  Chapter 10 summarises the overarching discussion and conclusions of this thesis, the limitation of the research and proposes further research in the field.

Figure 1-1: Thesis Structure



2 LITERATURE REVIEW

This chapter is divided into two main sections. The first section contains a review of literature in the two fields of interest, namely product service systems and health care. This review was conducted to establish the required knowledge base for this thesis and to facilitate the identification of the research gap.

The second section is summarising literature reviews specifically conducted for each research objective.

2.1 BACKGROUND RESEARCH IN PSS AND HEALTH CARE

In the first part of this section, PSS research is reviewed, while the second part of the background research focuses on the health care market to establish a knowledge base for the two areas of interest for this research.

Definitions of PSS are reviewed in a first step. This is of relevance in the context of this thesis, as PSS originated in environmental research, with a focus on ecological sustainably and those origins are reflected in some of the PSS definitions. While PSS in health care would not be focused on environmental sustainability, this sector has been mentioned as a field for application. Logically, many PSS definitions proposed in literature are generic enough to cover sectors outside the environmental sector. Benefits and challenges of PSS and PSS implementation have been analysed exhaustively in research. Literature on those topics forms a useful knowledge base to address the research objectives at hand. This is also true for classification of PSS, as classification of different PSS can provide orientation how PSS development and implementation compares with either competitors or with regard to the potential and scope of PSS. Existing PSS design methods have also been reviewed in the literature review phase and results are outlined and discussed. This is of particular importance, as existing methodologies provide valuable input for the PSS design guidelines tailored to the health care sector.

In the second part, literature on the health care domain is discussed. The health care market is defined and specific characteristics of this market are outlined, such as market actors, payment systems and the regulated nature of design processes.

2.1.1 Product Service Systems

Product Service Systems (PSS) are integrated, marketable combinations of products and services with the goal to fulfil customers' needs (Goedkoop et al. 1999). PSS focuses on selling value to the customer rather than selling products (Baines et al. 2007). Although its potential was previously discussed in research (Köbler et al. 2009), PSS has not been widely adopted among companies in the health care industry consisting of medical device companies and pharmaceutical companies.

Product Service Systems can provide an excellent model to develop the offerings required by this market in the future. The design of PSS however has to be tailored to the industry sector it is applied to. The Industry Classification Benchmark has been proposed as a way to consistently distinguish between sectors and sub-sectors in PSS research (Durugbo et al. 2010). The health care sector in this classification contains three subsectors, namely "Health Care Equipment" (medical device manufacturers), "Pharmaceuticals" and "Biotechnology". Companies in these sub-sectors do need tools, techniques and methods (Vasantha et al. 2012) that give guidance in how PSS could be applied in the health care sector.

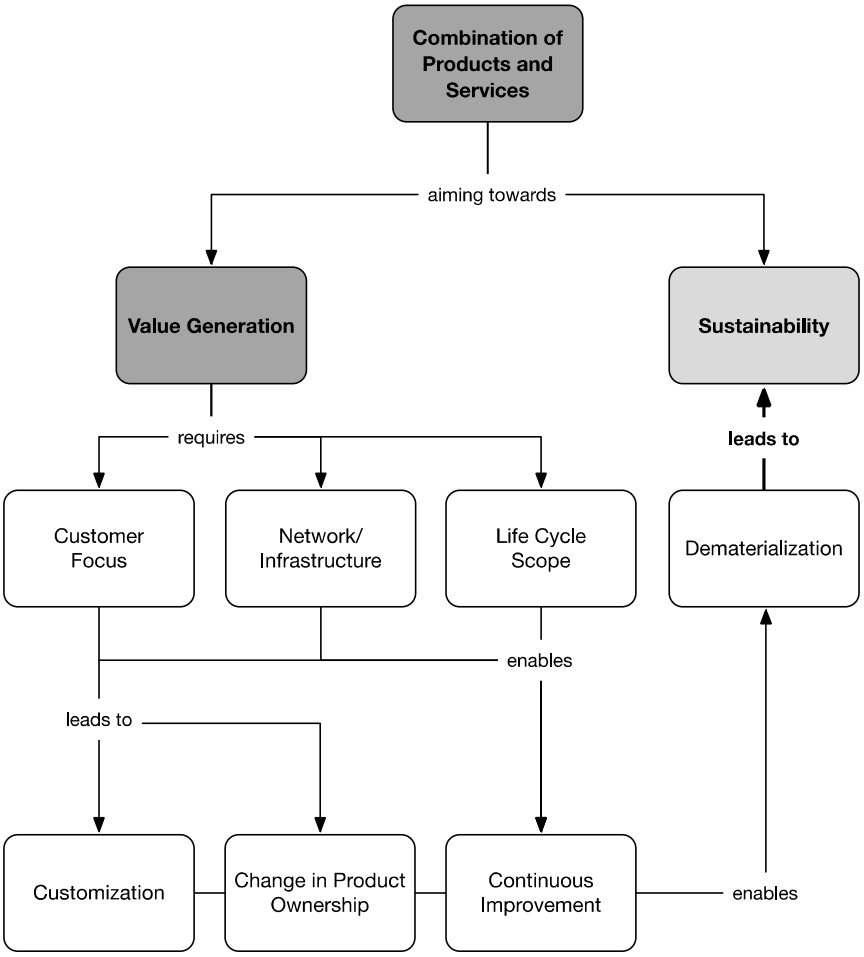
2.1.1.1 Definition of Product Service Systems

Product Service Systems (PSS) have been discussed in research for more than two decades. Table 2-1 summarizes definitions given by different authors. Baines et al. reviewed the definitions of PSS and concluded that a PSS can be best described as an integrated product and service offering that delivers value in use and offers the opportunity to decouple economic success from material consumption and hence reduce the environmental impact of economic activity (Baines et al. 2007). While the combination of services and products as well as the goal to generate value by addressing the need of a customer are integral components of every definition, the aspect of (environmental) sustainability is not included in all definitions for PSS put forward by authors in this field. This phenomenon was also discussed by Tukker in his review of PSS literature (Tukker 2015) as well as by Beuren et al. (Beuren et al. 2013). Environmental sustainably is only included in about half of the publications and there

is also no trend over time apparent to lean towards inclusion or exclusion of this aspect in definitions for PSS.

It is interesting to note that some authors do include aspects and features of PSS in their definitions. The importance of networks of actors and infrastructures in PSS are incorporated (Goedkoop et al. 1999; Mont 2002a; Wang et al. 2011). In addition, Goedkoop et al. already entertains the concept continuous improvement in PSS, which is a feature of PSS frequently discussed in the PSS research field. Zhang et al. also include the life cycle scope of PSS in their definition (Zhang et al. 2012). Other features and aspects of PSS such as dematerialisation, customer focus and customisation, ownership of products and continuous improvements are often discussed in the context of PSS, but not included in the definition. Those aspects and features of PSS may not apply to all PSS and usually can all be related back to the goal of PSS to generate value. Therefore, they are implicitly covered by all common definitions. Sustainability has an ambivalent role in this structure. It has been postulated as a goal for PSS early in the research of this field, but on the other hand it can also be seen as result of other features of PSS, that are triggered again by the goal of value generation (see **Error! Reference source not found.**).

Figure 2-1: Goals and features of Product Service Systems



Reference	PSS Definition	Combination of services and products	Value Generation	Environmental sustainability
(Goedkoop et al. 1999)	A product service-system is a system of products, services, networks of players and supporting infrastructure that continuously strives to be competitive, satisfy customer needs and have lower environmental impact than traditional business models.	✔	✔	✔
(Mont 2002a)	A system of products, services, supporting networks and infrastructure that is designed to be: competitive, satisfy customer needs and have a lower environmental impact than traditional business models.	✔	✔	✔
(Manzini & Vezzoli 2003)	An innovation strategy, shifting the business focus from designing (and selling) physical products only, to designing (and selling) a system of products and services which are jointly capable of fulfilling specific client demands.	✔	✔	
(Brandstotter & Haberl 2003)	A PSS consists of tangible products and intangible services, designed and combined so that they are jointly capable of fulfilling specific customer needs. Additionally, PSS tries to reach the goals of sustainable development.	✔	✔	✔
(Wong 2004)	Product Service-Systems (PSS) may be defined as a solution offered for sale that involves both a product and a service element, to deliver the required functionality.	✔	✔	
(Baines et al. 2007)	A PSS is an integrated product and service offering that delivers value in use. A PSS offers the opportunity to decouple economic success from material consumption and hence reduce the environmental impact of economic activity.	✔	✔	✔
(Wang et al. 2011)	"Elements of PSS [are]: product, service, and supporting net- works and infrastructure; Goals of PSS [are]: strives to be competitive; maximum customer value; lower environmental impact.	✔	✔	✔
(Berkovich et al. 2011)	By supplying an integrated bundle of hardware, software, and service elements, the customer problem is solved completely. These bundles are known as product service systems (PSS) or hybrid products.	✔	✔	
(Zhang et al. 2012)	An Integrated Product Service System (iPSS) "is a systematic package in which intangible services are attached to tangible products to finish various industrial activities in the whole product life cycle"	✔	✔	
(Boehm & Thomas 2013)	A Product-Service System (PSS) is an integrated bundle of products and services which aims at creating customer utility and generating value.	✔	✔	

Table 2-1: Definitions for PSS in research

2.1.1.2 Classification of Product Service Systems

The most commonly used classification of PSS systems puts PSS in three different categories, namely *product oriented* PSS, *use oriented* PSS and *result oriented* PSS, depending on what a company is actually offering to a customer and how deep the integration of products and services is (Tukker 2004).

In product-oriented PSS the focus is on selling products, much like in a traditional business model, however additional services are offered in combination with the product, such as service or maintenance agreements, insurance policies, training or consulting (Tukker 2015). Product-oriented PSS are on the product heavy side of the PSS spectrum (Tukker 2004) and relatively easy to implement by companies, as it does not require as much of a change in business models and company culture. The focus is still to increase sales of products. Product-oriented PSS allow companies to extend their offerings over the entire life cycle of a product (such as recycling of products or product components) and consider those aspects in the product design (Baines et al. 2007).

In use-oriented PSS typically the ownership of the product stays with the provider, who is offering the use of the product, a pool of products or different products fulfilling the same use, accompanied with service components necessary to provide the customer with the use of the product without transferring ownership (Beuren et al. 2013). Typical examples are renting, sharing and pooling models, such as car sharing. Companies applying use-oriented PSS aim for increased use of their products to reduce cost (Baines et al. 2007).

In result-oriented PSS, products are only potential means to achieve an agreed upon result between a PSS provider and a customer and are therefore not even pre-determined (Tukker 2015).

The classification outlined above is vastly accepted within research, however the classification of PSS is considered to still be work in progress and should be further investigated (Beuren et al. 2013). One attempt to evolve the traditional classification model for PSS was proposed by Gaiardelli et al. adding an additional dimension to include the network and relationship aspect (Gaiardelli et al. 2014). This approach extended the one-dimensional classification into a two-dimensional representation of PSS offerings. This more sophisticated classification allows not only mapping entire PSS, but also individual service components. Additionally, PSS designs can be

benchmarked against existing competitive PSS offerings. Most importantly, is allows companies to map out a pathway from traditional manufacturing business models into PSS with different levels of service integration (see **Error! Reference source not found.**).

Figure 2-2: Classification Model for PSS by Gaiardelli et al.

2.1.1.3 Benefits of Product Service Systems

Benefits of PSS can be classified into four categories, depending on who the beneficiary is (Tran & Park 2015; Beuren et al. 2013): Customers, PSS providers, environment and society.

Customers can profit from flexible and customised services, higher quality of the offerings and as a result continuous satisfaction (Aurich et al. 2010), as PSS provider are in closer contact with their customers throughout the lifecycle and data collected on product performance can be used for continuous improvement (Sundin 2009). Despite some resistance to this concept, customers in general profit from paying for the use or - even more advantageous - the result without taking ownership of product components. This takes away all cost of ownership from the customer in terms of operation, availability, maintenance, insurance and recycling (Mont 2002a).

In return to higher quality and value for the customer and a closer customer relationship, PSS provider can expect increased customer loyalty and dependency, allowing

providers to protect their market share by increasing switching cost to competitors (Aurich et al. 2010). The potential to differentiate own offerings from competitors also enables providers to increase market share beyond their existing customer base (Cavalieri & Pezzotta 2012). On the cost side, dematerialisation allows to reduce production cost. Products may also be reused in combination with several different services. This is especially true for software components of products, which can easily be repurposed and recombined with services to provide additional benefit for a customer group or to exploit new markets.

The benefits of PSS for the environment are often even included in the definition of PSS, as a reduction of consumption of resources is an integral part of PSS (Li et al. 2010). The shift of ownership responsibilities from customers to providers also is likely to positively impact resource consumption, as provides are incentivised to develop long lasting products also considering recycling and refurbishment already in the design. Besides the benefit to have environmental issues being addressed by PSS, society also can profit from an increased demand of jobs in the field of service provision (Baines et al. 2007).

PSS can also be a means to increase the acceptance of innovation in the marketplace as services can be designed to decrease or eliminate the barrier to adopt new technologies, which can help providers to bridge the performance gap between a mature technology phasing out of a market and novel technology being introduced to the customer (Schmidt et al. 2016).

2.1.1.4 Challenges in Implementation of Product Service Systems

Challenges in implementing PSS in industry have been extensively discussed in research, as those challenges led to a low adoption rate of PSS throughout all industries. Vezzoli et al. summarised barriers for PSS implementation discussed in literature (see Table 2-1), dividing barriers into three groups, namely customer related, company related and context-related barriers, which summarise the environmental and social barriers (Vezzoli et al. 2015).

Customers create barriers for PSS, as they often are reluctant to accept ownerless consumption and often still link possession of a product and taking the advantage of the use or the result generated by the use of a product. This may be because there is not

sufficient awareness of cost of ownership throughout the lifetime of a product (Mont 2002b).

Secondly, potential PSS providers themselves face internal challenges implementing PSS, as it requires a cultural change in the organisation. Certain functions of a company have an inherent conflict of interest when transferring from a traditional product offering to PSS. A sales organisation incentivised though numbers of sold units may struggle with a PSS that promotes the reuse and an extended life time for a product. PSS development profits from a close involvement of users and other stakeholders in the network, which again forms another cultural barrier for companies, as they traditionally are reluctant to share sensible information with other parties. Besides those cultural challenges, companies also face logistical issues, if they attempt to develop PSS offerings. PSS are inherently complex to design, test, implement and manage. The development process typically relies on contributions from actors beyond the traditional research and development team. The lack of common terminology internally (between company functions) as well as externally (between companies in a supply chain or between the company and customers) is a significant barrier to the development and implementation of PSS.

The third area of challenges for PSS is concerned about social and environmental concerns. Since typically the cost of impact on the environment or the society is not factored in, PSS cannot fairly compete against traditional (product based) business modes and markets are incentivised to gravitate towards those traditional offerings, if no governmental policies are in place to correct for this (Vezzoli et al. 2015). Another social barrier for PSS outlined by Vezzoli et al. can be cost for labour. If those costs are high enough for customers to prefer a traditional product offering, PSS offerings will not be able to compete in the market place (see Table 2-2).

Benefits of PSS		Challenges for PSS	
Consumer	• Higher quality • Higher satisfaction • Personalised offering • Continuous improvements	• Lack of acceptance for ownerless consumption • Lack of awareness of cost of ownership over the lifetime of a product	**Consumer**
Provider	• Higher customer loyalty • Continuous improvement and innovation by collecting use data over lifetime of product • Cost reduction due to dematerialisation of offering • Monetising development knowledge by selling consulting and training services	• Complexity of design, test and implementation of PSS • Complexity to manage PSS • Requirement to change the mind set and culture towards PSS • Lack of alignment and common terminology between functions and divisions • Reluctance to share sensible product information • Conflicting interests between development and sales	**Provider**
Environment	• Reduction of resource consumption due to dematerialisation of offering • Design for recyclability due to providers' responsibility for entire life cycle	• Consumption of environmental resources is not factored into prices for traditional product offerings	**Context-related barriers**
Society	• Creation of new jobs due to the increase need for service	• Increased cost of labour makes traditional product offerings more attractive	

Table 2-2: Benefits and Challenges of PSS implementation based on (Tran & Park 2015; Vezzoli et al. 2015)

2.1.1.5 Existing PSS Design Methodologies

By analysing case studies, Morelli (2006) proposed a generic design process in seven steps (see Table 2-3).

Design step	Description
Definition of value proposition	Definition of the final needs of the end user
Market analysis	Outline of the market players and the network between those players
Product/Service definition	Definition of the architecture and functionalities of the system
Use-case analysis	Analysis of several conditions of use to define functions, requirements and priorities
Tentative architecture	PSS prototype development
Test	PSS prototype testing
Final definition	Refinement of the tentative architecture based on test results

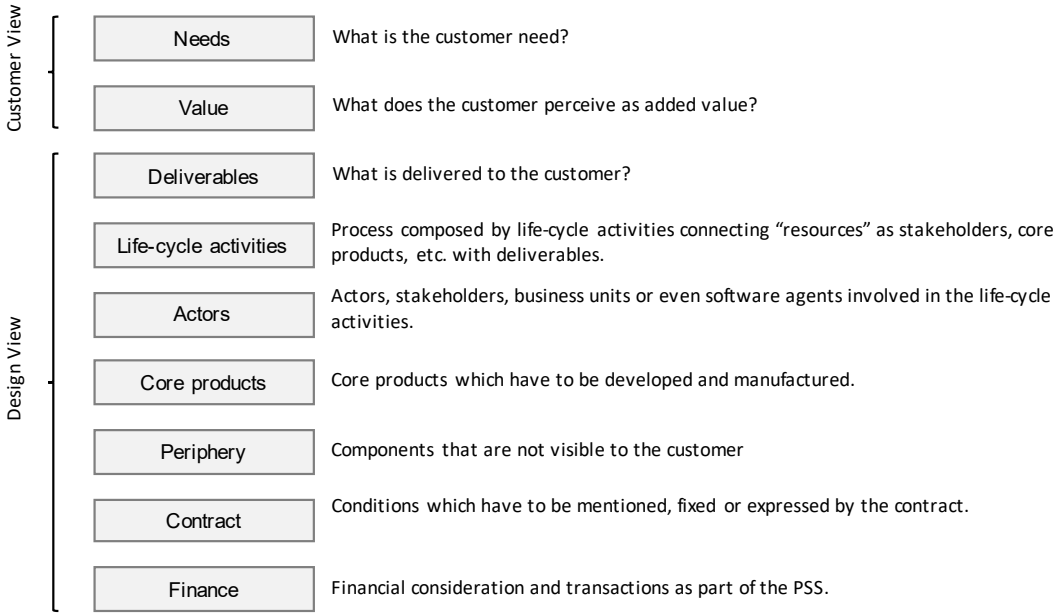
Table 2-3: PSS design steps defined by Morelli (Morelli 2006)

Along this generic design process, many modified methods for designing PSS have been proposed in the last decade.

Bertoni et al. proposed to utilise value driven design (VDD) methods in PSS design methodologies to provide PSS designers with a toolset to bridge the gap between high level customer values and requirements and specifications of products and services and to evaluate early design decisions in a meaningful manner (Bertoni et al. 2016).

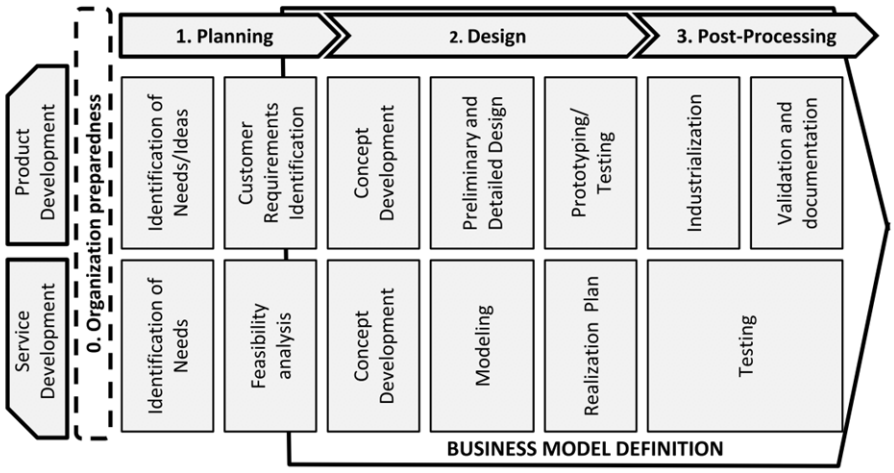
A PSS layer model was introduced by Müller et al. (2009) as utilised in a case study for micro energy systems (home solar systems) in rural areas of developing country (Müller et al. 2009). The methodology is focusing on the early stage of PSS development to evaluate PSS ideas and concept studies. Nine classes (layers) are defined to support the modelling of PSS and its elements. Those layers are mapped against a timeline allowing designers to consider all classes at any time over the life-cycle of a PSS (see **Error! Reference source not found.**).

Figure 2-3: PSS Layer Model proposed by Müller et al.(Müller et al. 2009)



Marques et al. (2013) developed a method that maps steps in product development and service development along three development phases, namely a planning phase, a design phase and a post processing phase (see **Error! Reference source not found.**). The model validated with a case study on mobile municipality services (Marques et al. 2013).

Figure 2-4: PSS development methodology proposed by Marques et al. (Marques et al. 2013)



Other methods have been reviewed and evaluated extensively in the last years (Vasantha et al. 2012; Qu et al. 2016b). Criteria have been developed to support PSS designers in the selection of the most applicable design methodology for a given project (Tran & Park 2015).

Tan et al. analysed the status of research with regard to development methodologies for PSS and identified a research gap for such methodologies. In the absence of dedicated design methodologies, most methods for designing PSS are derived from traditional product development (Tan et al. 2006). Instead of approaching the design of PSS with a "green-field mind-set" (Tukker & Tischner 2006) often industry tends to design systems using current practice in product design. This inherent limitation may be the reason for the restricted adoption of PSS in industry (Cook et al. 2006). PSS is adding complexity in terms of design. In fact, it is adding new dimensions to the development process (Morelli 2006), since it is not sufficient to solve a problem defined by only design input requirements. In addition to this technological aspect, one needs to take in account the social as well as the cultural component. An understanding of the mind-set of involved actors (such as users, and providers) is crucial to the design of a sophisticated PSS. Considering this complexity, PSS designers require methodologies and tools to visualise the network of actors and their needs (Ceschin et al. 2014). The same is true for the graphical representation of immaterial components versus tangible products. Such visualisation allows to better understand relations and to manage the different phases of design (Ericson et al. 2009). PSS are complex systems having implications in technology, human resources, marketing, customer relations and communication, so it appears reasonable to derive a design methodology for PSS from involved disciplines, such as social studies, marketing, management, engineering and information science (Morelli 2006). Despite the identified need to provide generic (Tukker 2015), but also sufficiently detailed methods for PSS design (Vasantha et al. 2012), still no solid guidance is provided to designers for the development of PSS offerings, limiting the adoption of PSS in many industry sectors.

In 2012, Vasantha et al. reviewed design methodologies for PSS and summarised the issues in PSS design methodologies identified in research. Existing methods are too general and lack integration of service and product development paths (Aurich et al. 2006), as often service development is following product development (Maussang et al. 2009). The authors also pointed out that the role of a PSS designer is not sufficiently

defined in research and the need to develop business models along with PSS has not been discussed enough in research. To evaluate PSS the authors proposed six categories, namely context specification, positioning and importance of stakeholders, design stages, development cycle, life cycle consideration and representation.

Tukker summarised the contributions of different design methodologies in his PSS review (Tukker 2015). The review identifies publications contributing to visualisation methods, information feedback systems enabling or informing PSS design, assessment of customer satisfaction or needs for PSS design, ex ante economic value evaluation, and other fields.

In 2016, Qu et al. reviewed PSS design, evaluation and operation methods concluding that research on PSS design methods has been in the focus of the research field, however the analysed methods still showed limitations in application of methods in industry, usable tools and in the emphasis on the interdependencies between product and services as well as dependencies of actors in the network (Qu et al. 2016b). The contribution of methods included in this review have been classified into six perspectives, namely the customer perspective, modelling techniques, visualisation methods, modularity methods, TRIZ and system dynamics.

The lack of consistency between reviews in how contributions to the field are classified can be interpreted as symptom of the underlying issue of a missing common understanding of PSS and PSS design methods. The development of a common ontology remains a research task for the field, necessary to increase adoption of PSS in industry sectors (Vasantha et al. 2012). Despite the focus on PSS methods in research, adoption in industry is still insufficient (Sakao & Mizuyama 2014). Matschewsky et al. summarised challenges associated with adoption of new methods by industry (Matschewsky et al. 2015). A lack of clear and replicable decision criteria within a method increases the resistance of companies to adopt a method, as well as the perception that applying those methods is a time-consuming process. Methods need to fit companies' specific needs and have to be adaptable. Ideally, methods do allow to utilise existing processes in a company.

2.1.2 Health Care Market

2.1.2.1 Health Care System Characteristics

The World Health Organization (WHO) describes a health care system as a system that:

> *"…delivers quality services to all people, when and where they need them. The exact configuration of services varies from country to country, but in all cases, requires a robust financing mechanism; a well-trained and adequately paid workforce; reliable information on which to base decisions and policies; well-maintained facilities and logistics to deliver quality medicines and technologies."*[1]

The criteria health care systems are compared and evaluated against are access, cost and quality (Shortell 2004). Health care systems in most developed countries are challenged today by both quality and cost issues, raising questions about long term sustainability (Chernew & Sabik 2010). Technological advances, patients' expectations and aging populations are constantly increasing the cost pressure (Pammolli et al. 2012). Many approaches have been evaluated and put in place to optimise the resources allocation in the health care systems to regain control over health care budgets, however with very limited success. Recent research emphasises the fact that focusing on the outcome value rather than regulating the input or output may be a more valid approach to design sustainable health care (Lega et al. 2013). Porter and Teisberg proposed to create competition in health care on value rather than available resources or approved budgets to achieve a sustainable system (Porter & Teisberg 2006).

2.1.2.2 Funding Models for Health Care Systems

With regard to funding of services provided, health care systems can be classified into four models. In developed countries, the Beveridge Model, the Bismarck Model and the Private Insurance Model are most common (Wallace 2013). In many developing countries, Out-Of-Pocket models are typically the only available system to access health care (Leive & Xu 2008).

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[1] http://www.who.int/topics/health_systems/en/

The Beveridge Model is based on public funding and predominantly public health care providers. Services are provided by the government and are funded by tax funds. The provision and funding of health services by the government is resulting in the fact that there are no medical bills. Cost is controlled by the government a sole payer in the system (Eikemo & Bambra 2007).

The Bismarck model is characterised by mandatory, private insurance plans funded by deductions in payroll. The cost is shared between employees and employers. The focus is on cost control, resulting in more strict regulations on classification of health services and associated cost (Sawicki & Bastian 2008).

In contrast, the Private Insurance Model is based on private funding. The provision of health services and the funding of those is managed by private entities (Kulesher & Elizabeth Forrestal 2014).

While the Beveridge Model provides care for everyone and cost are controlled by the government, it inherently is exposed to the dangers of poor quality. In contrast, the Bismarck Model is more likely to produce higher quality but cannot ensure access to health care for everyone at affordable cost (Cichon & Normand 1994).

To achieve more optimal solutions, many countries operate a mixture of models. The National Health Insurance (Tommy Douglas Model) is an example of a hydride of the Beveridge Model and the Bismarck model, in which the private providers offer health services, but payment is funded by government insurance programs and or taxes (Wallace 2013).

2.1.2.3 The Health Care Market and PSS

For the purpose of this work, the scope of health care or the health care market is defined as all activities directly or indirectly connected to the provision of care to a patient. This in particular includes any products, devices and services provided by industry to either patients, their care givers or their physicians. The health care industry mainly comprises of medical device companies and pharmaceutical companies (Durugbo et al. 2010).

Both types of companies traditionally focus on products. Also the regulatory framework is focused around the development and manufacturing of products.

PSS is covering multiple dimensions, which may make it a relevant approach in health care. McAloone and Anderson (2002) describe three characteristics of PSS (McAloone & Andreasen 2002). In time domain, PSS is covering a multiple, interdependent life cycle phases and actions along the product life time. In the artefact system domain, it includes multiple, interdependent systems. While there may be a predominant system focusing around the key use, other auxiliary systems may be also within the scope of PSS. In the value domain, PSS covers a multiple stakeholders' values, defining how the system is utilized and how is behaves in the context of the other domains.

The three domains described by McAloone and Anderson (2002) define the scope of PSS and show the relevance to health care. The health care market is a highly interrelated network of market actors, for which PSS is an approach to develop new offerings that optimize value for the entire network. In this market, certain systems and processes (like relegations) may be in place that need to be considered in their interaction with a PSS. System life cycles do play a particularly important role in health care, as care often is a process, rather than a transaction at one point in time.

The scope of PSS is broad enough to capture the complexity of health care, optimizing value for the entire system, rather than single market actors, which has been identified as a major shortcoming of health care systems in the past (Porter 2010).

2.2 Research Gap and Summary

The literature research on product service systems, existing PSS design methods and specific characteristics of the health care market unveiled that both areas have hardly any overlap in research publications, despite the potential of PSS in health care. This lack of literature putting PSS into the health care context forms a research gap that this thesis attempts to address.

The analysis of both areas of research showed that benefits of PSS do address challenges in the health sector and therefore industry adoption of PSS in health care should be higher than currently experienced in the industry and reported in research (Köbler et al. 2009).

Despite many generic PSS design methods are discussed in research, practical guidelines for companies to execute a PSS development project are not available (Aurich et al. 2010). This lack of practical guidelines and a tailored methodology for PSS development in the health care sector likely is contributing to the low adoption.

The literature review started with an overview on PSS definitions to confirm that PSS is defined broadly enough to also be applicable in health care. The classification of PSS was analysed, as classification of PSS is an efficient way to put a PSS in perspective to traditional design and business models.

Existing PSS design methods have been reviewed extensively for this research. It became apparent, that many proposed methods also have been reviewed and put into context by other authors, so the focus was on the results and conclusions of those systematic reviews, as those provided the most valuable information with regard to this research. Requirements for PSS design methodologies can be identified from literature.

Informed by the literature review in PSS, a review of academic publications on the health care market was carried out. The focus of the review was on special characteristics of this market, namely the different, often indirect funding models for health care, the market actors involved and the regulations guiding design processes in the health care industry.

The research gap can be further detailed by looking into the specific aspects of PSS adoption in health care:

- Is it reasonable to adopt PSS in health care, given the market characteristics?
- Is PSS adoption in health care also sustainable, meaning does is not only address current but also future needs of the market and its actors?
- What is the realistic status of PSS adoption in health care given that many aspect of PSS can and are used in daily business, however are often not recognized in the context of PSS, but rather as measures to address specific challenges?
- How could a company asses the success of a PSS implantation and how can a PSS development team develop useful requirements given the complexity of the market, where not only the customer (patient) need has to be addressed but also the need of many other actors such as payers, regulatory authorities and users (physicians)?

- How can the design process be guided based on the regulatory framework in the health care market and the special characteristics of the network of market actors?

Those questions map out the research gap of what the current status of PSS adoption s in health care, what drivers and inhibitors there are for future adoption and how adoption may be facilitated in the future?

Addressing this gap should give companies a better understanding if PSS is a feasible and useful business model in their particular situation, and if so, how to initiate an implementation and potentially how to leverage already existing partial implementations of PSS aspects.

3 METHODOLOGY

This section summarises the methods applied to achieve the objectives defined at the beginning of this research.

3.1 RESEARCH APPROACHES

3.1.1 Inductive versus Deductive Research

Inductive research is based on the observation. The data gathered during the observation is reviewed for patterns that allow to postulate a tentative hypothesis leading to a theory, which can be empirically validated using data that has not been used in the observation phase. In contrast, deductive research originates from a hypothesis, which is confirmed by observations (Leedy & Ormrod 2010).

This thesis followed an inductive research approach, in which observations from literature and case studies were used to develop a better understanding of the current role and the future potential of PSS in health care.

3.1.2 Qualitative versus Quantitative Data Collection

On a high level, research approaches can be divided into quantitative and qualitative research approaches, depending on the data utilised for the research (Patton 2005).

Quantitative research methodologies are applied, when research can be based on experiments that allow to produce quantifiable results analysed with statistical methods, with the aim to verify or falsify a theory and determine if such theory has predictive value. It requires the researcher to be independent from the experiment to not introduce bias. While qualitative research allows to conduct research in an objective and controlled way, it often does not provide the same depth in results and conclusions than quantitative research (Patton 2005).

Qualitative research methodologies aim produce an in depth understanding of a problem of phenomenon, by investigating it in a natural setting. Results are open for

interpretation as researchers aim to identify patterns and develop an understanding of the underlying theory.

As nature of the proposed research is exploratory, mainly qualitative research methodologies were selected for this thesis.

3.1.3 Qualitative Content Research

Qualitative content research is a method for classifying written or oral content into categories of similar meanings (Mayring 2000) used as a method for analysing documents (Moretti et al. 2011). It can be used either with qualitative or quantitative data (Elo & Kyngäs 2008). This research method is a subjective interpretation of content in text data by means of a systematic classification process of coding and identification of themes or patterns in the data (Hsieh & Shannon 2005).

Qualitative content analysis can be carried out in two different approaches: Inductive and deductive content analysis. The inductive approach is of benefit, if existing knowledge is either not available or too fragmented. The deductive approach is applicable in cases where categories are based on prior knowledge and the goal is the validation of a theory (Cavanagh 1997).

Both inductive and deductive qualitative content research was used in this thesis for several research objectives.

As the research involves two different research domains and abstract concepts in both domains had to be analysed and be brought to a common terminology, qualitative content research allowed to utilise existing data from literature to provide input to address the research question at hand.

3.2 RESEARCH STRATEGY

The research aims defined in chapter 1 require different approaches to produce meaningful results in order to get to the pre-defined research objectives resulting from the aims.

The first two aims are concerned about literature reviews to (i) establish the knowledge base in the two research domains and to identify the research gap and to (ii) acquire knowledge and an understanding of the state-of-the-art related to each research objective defined.

The third aim is focusing on the evaluation of the practical usability and feasibility of PSS in health care. To address the related objective, a case study was selected as the appropriate strategy, as real life data from a case study can best provide insight into the practicality.

A deductive as well as inductive qualitative content analysis approach chosen for the subsequent objectives.

The last aim took the input from previous objectives and field observations in order to develop design guidelines for PSS design in health care that can be adopted by companies working this this sector, in an inductive research setting.

4 PRACTICAL FEASIBILITY AND UTILITY OF PSS IN HEALTH CARE

4.1 LITERATURE REVIEW

The literature review unveiled that PSS methods have been developed and discussed by research, but PSS still lacks industry adoption, in particular in health care, despite the fact that PSS provides benefits and solutions to issues and challenges in this sector. This led to the conclusion that developing and implementing PSS in health care is feasible and can add value.

The goal of this objective is to provide insight into the practical feasibility of PSS in health care, so it was deemed appropriate to confirm this conclusion by applying an existing generic PSS design method to a case study that allowed to evaluate the usability and feasibility of PSS in a business-to-customer as well as a business-to-business scenario. Issue and shortcomings of a generic method identified by means of this case study can provide input for the development of a PSS design method tailored to the health care market.

For this case study, a novel, complex treatment approach involving hardware, software and service components was selected. By covering hardware, software and service components, the case study offered a broad spectrum of offerings that could be developed around the system components. It also allowed to construct both a business-to-business as well as a business-to-customer scenario to investigate potential differences between those two market settings. A third criteria for selecting this particular case study for this research was the access to data. The researcher had direct access to the project and stakeholders, allowing to utilise first-hand information. This access enabled the researcher to select a fairly complex setting as a case study, which can provide more practical insight than over-simplified scenarios. This innovative treatment method for brain tumours requires a highly interdisciplinary approach to transfer it from research to market (Ding et al. 2010). As the treatment includes drugs as well as several medical devices, results of this case study should widely be applicable for the more generic, emerging segment of drug-device combinations.

The combination of drugs and medical devices is a recent trend in the health care sector (Wu & Grainger 2006). This is particularly true for the field of local delivery, which necessitates that pharmaceutical companies and medical device manufacturers work jointly on the research and development issues (Hupcey & Ekins 2007). In contrast to systemic delivery of therapeutics, where drugs are given by pills or intravenous injection, local drug delivery allows the drug to be placed exactly at the location in the body where it is needed. This leads to a high therapeutic concentration at the target, while the systemic concentration in the body is relatively low, causing less side effects and toxicity.

4.1.1.1 Technological Background

Despite impressive advances in medicine, the treatment of diseases related to the brain such as certain types of aggressive brain tumours and many neurodegenerative diseases still presents one of the biggest areas of unmet medical need (Vogelbaum 2005). This is mainly due to the fact that the brain is protected by the "blood brain barrier" (BBB), which prevents it from being damaged or poisoned by substances in the human blood stream (Ding et al. 2010). While being vital for healthy people, this barrier becomes a major obstacle for the treatment of many diseases affecting the central nervous system (CNS). Promising drugs for the treatment of primary brain tumours such as Glioblastoma Multiforme (GBM) or neurodegenerative diseases such as Parkinson's, Alzheimer's, Multiple Sclerosis (MS), and epilepsy have failed in human trials over the last decades, although these drugs showed great potential in preclinical studies (Vogelbaum 2005). Those disappointing results are most likely derived from the fact that the drug molecules never reached their target within the brain (John H Sampson et al. 2010).

Convection-enhanced delivery (CED) is a promising approach to circumvent the BBB. The drug is delivered directly to the target site within the brain tissue, by placing a catheter into the clinical target and applying a positive pressure gradient to push the drug into the tissue. In practice, this approach, which is superficially simple, has been found to be highly complex, since the distribution of the drug is heavily depending on patient specific anatomical structures and pathology (J.H. Sampson et al. 2010). Planning therefore is a very crucial part of the procedure and the technique requires a

multidisciplinary approach to achieve significant improvement of the patient outcome (Rosenbluth et al. 2013).

From a technological perspective, a tailored system of a safe and effective drug, a patient specific treatment planning system and a dedicated set of devices (such as catheters and pumps) is necessary to ensure the delivery of the correct drug in the correct concentration to the correct target area in a defined period of infusion. The state of the art in this area is represented by catheter systems that promote convection-enhanced diffusion as the infusion mode. Additionally, users, in this case the relevant health-care professionals, need to be trained in the usage of the software and hardware tools provided in order to use them in the most optimum manner.

An overview of the system is as follows. Several magnetic resonance (MR) image series of the patient's brain are acquired for planning purposes. These scans are loaded into a planning software tool in order to plan the exact locations of the drug target and entry points of catheters placed into the target tissue. This planning must be based on the patient specific imaging data as it has to take in account the individual anatomy and pathology of the patient.

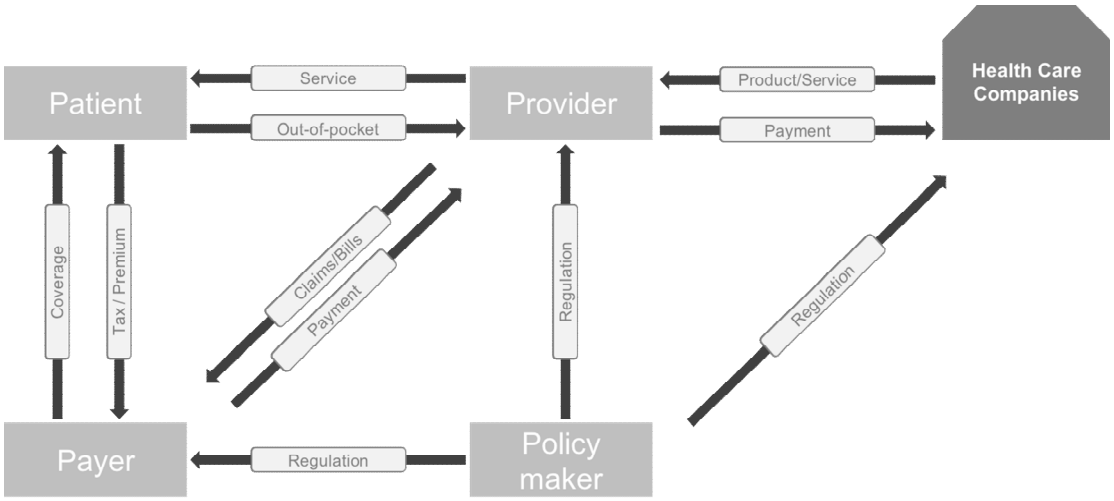
The main target of this pre-operational planning is to make sure that a convective flow is established within the solid tissue of the brain and that no drug leaks into the cerebrospinal fluid (CSF) compartment. Secondly, a maximum coverage of the previously defined clinical target volume is the goal of the planning exercise. Once the treatment plan is finalised, the required data needs to be transferred to the operating room (OR). The neurosurgeon will then place the catheters according to the plan using the planning data for navigational purposes. Once all catheters are in place and are connected to the infusion pumps containing the drug, the patient will be scanned again to verify the actual position of the catheters. For infusion, the patient will be hospitalised for several days to allow the whole drug volume to enter the patient at the required low, constant flow rate. During and after the infusion there may be several control scans to monitor the treatment.

Main groups of actors such as consumers, commercial companies and governmental policy makers have been identified to drive and shape PSS adoption motivated by potential benefits for each of those actors deriving from more sustainable, cost effective and customer focused market approaches (Mont 2002b; White et al. 1999) Also

financial institutions are seen as an important group of actors with regard to PSS (Mont & Lindhqvist 2003). Those actors and the network connecting them are crucial components for a PSS (Mont 2002a). In order to predict PSS adoption in a market future trends and developments have to be interpreted with regard to how this will affect the actors and their network. Morelli et al. propose methods for the analysis of actors in the market and the relationships between those market entities as the basis for successful PSS implementation (Morelli 2006).

Error! Reference source not found. is mapping out the five different groups of market actors and their relationships to each other, in particular streams of product and service provision as well as monetary flows.

Figure 4-1: Map of key actor and their relationships in a health care system



4.1.1.2 Patients

The patient as "end user" creates the actual need for a health service. Unlike in other markets, patients are not simply consumers of a health care service. Unless patients are paying for health services out-of-pocket, payments are typically decoupled from the provision of services and handled through either private of pubic payers, which often limits the awareness of cost. The goal of patients is to maximise their quality of life that may be negatively impacted by a medical condition (Porter 2010).

4.1.1.3 Payers

Payers can be public or private. Depending on the funding model of the health care system, a mixture of payers may be available for the society to choose from. Insurance programs and companies play another major role in defining the framework of the market. Governmental health care insurance programs such as MEDICARE in the U.S. steer the market by their reimbursement policies (Tompkins et al. 1999). Besides the proof of safety and efficacy, those institutions also require additional information of the costs and benefits resulting from the adoption of a new treatment approach, compared to "standard care".

The reimbursement of drugs and procedures has a direct impact on the R&D strategy of technology providers. Studies showed that pharmaceutical companies tend to directly reinvest revenue into new R&D programs (Smith and Summers). The drug pricing set by MEDICARE or other payers affects the expected revenue and therefore has an impact on amount of money invested in R&D and as a consequence on the timelines of development programs.

4.1.1.4 Providers

Providers can be individuals, institutions or networks providing services preventive, curative, promotional or rehabilitative health care services. Due to the specialisation in medical health care, an entire network of specialised providers is involved along a diagnostic and therapeutic workflow (e.g. radiologists for diagnosis, medical oncologists, radiotherapists and surgeons for treatment of cancer). The goal of providers is to efficiently provide health services to patients. In health care systems that entertain private providers, another goal is to create profit (Folland et al. 2013).

4.1.1.5 Policy Makers

A developed health care system is highly regulated by governmental policy makers (Folland et al. 2013). Regulation and government policies cover the three main criteria for health care systems, namely *access*, *cost* and *quality* (Shortell 2004). Policies on funding typically create a mixture of the traditional funding models (Wendt et al. 2009) and attempt to improve accessibility to health care for society. Regulations on quality typically affect providers as well as health care companies. This is necessary to mitigate

the high risks often associated with the provision and development of health care services, medical devices and pharmaceutical products.

Governmental regulatory authorities like the Food and Drug Administration (FDA) in the United States influence development costs for drugs, medical devices or services by setting the standards, requirements and restrictions for R&D. Governmental authorities can also shift the focus of R&D within companies by special regulations. An example of this is an accelerated approval process for technology to treat "orphan diseases" (e.g. rare diseases with small patient population) , if the unmet medical need is higher than the incentive of the market (EC 2000). Therefore, governmental policies clearly influence the market and its players in the health care sector.

Considering the potentially high risks, regulatory bodies require a proof of safety and efficacy to be documented by the approval-requesting company in order to approve the marketing of drugs, medical devices or services.

4.1.1.6 Health Care Companies

Health care companies such as medical device companies and pharmaceutical companies provide products, services and combinations thereof to different providers in the system. Pharmaceutical companies as well as medical device companies are driven by market incentives and primarily try to maximise their return on invest (Folland et al. 2013).

4.2 METHODOLOGY

The seven-step methodology suggested by Morelli (see Table 2-3) has been followed in this case study for the definition of value proposition, a market analysis, the product/service definition and a use-case analysis.

Especially for the business-to-business PSS, the testing phase, followed by the final definition, is replaced by individual discussions with contract partners (in this case pharmaceutical companies). Instead of having the market challenging the system, the PSS has to be individually tailored to a specific customer. In this case study, only the generic part of the development is reported.

Major parts of the business-to-business model outlined in the presented case study have been applied in a collaboration between pharmaceutical company A and medical device company B (see Table 4-1**Error! Reference source not found.**) to carry out a multinational clinical trial. This initial model was then modified based on a retrospective analysis of the collaboration. The enhanced model has been validated in several expert discussions, between medical device company B and pharmaceutical companies similar to pharmaceutical company A with regard to business relevant variables. Experts include senior management involved in the collaboration as well as clinical collaborators (Christoph Pedain, PhD; Krystof Bankiewicz, MD, PhD). Meetings took place between 2006 and 2008.

The business-to-customer model has been developed based on expert discussions between pharmaceutical company A (NeoPharm, Inc.) and medical device company B (Brainlab AG), validated in subsequent expert discussions between medical device company B and pharmaceutical companies substantially similar to pharmaceutical company A.

Company	Investor structure	No. of employees
Pharmaceutical company A	Public traded	10-500
Medical device company B	privately held	500-1000

Table 4-1: Company information

The case study refers to direct, convection-enhanced delivery of therapeutic agents into brain tissue to treat aggressive brain tumours or neurodegenerative diseases.

4.3 RESULTS

4.3.1 Market Analysis and Value Proposition

As outlined before, a system based on infusion via convection-enhanced diffusion (CED) shows promise as a delivery method for drugs to allow them to reach therapeutic concentrations in a significant volume of the brain. This approach however is

technically very challenging. Considerable research is required to develop tools for the delivery of drugs via catheters placed into the solid target tissue.

The current state of the art is represented by the successful development of a software tool to aid the critical step of pre-operative planning of the infusions. This has allowed a deeper understanding of the underlying principles to be accumulated by the development team.

Since such knowledge and tools are usually not available within pharmaceutical companies, a joint approach is then required to bring the delivery technology, in combination with a working drug, to the market.

This special technological situation combined with the restrictive regulatory framework leads to two consecutive use cases:

(i) A business-to-business PSS to provide a "one-stop-shop" for pharmaceutical companies to manage clinical development and to open up the market by getting approval for the drug-device combination

(ii) A business-to-customer PSS to grow market acceptance once the market is opened up by having regulatory approval.

These two cases are discussed in more detail below.

The first scenario is required to open up the market for a drug in combination with the drug infusion systems. In such a scenario, the PSS would mainly be focused on the "business to business" relationship between the medical device company delivering software and hardware tools and the pharmaceutical company providing the drug.

In this scenario, the medical device company has to convince pharmaceutical companies of the potential of the technology. Further, it has to justify, in comparison with current practice, any additional risks associated with aspects of the treatment such as the required surgery.

Identifying information gaps for all actors in the market serves as an indicator of the issues that need to be addressed by suitable PSS in order to enhance the acceptance of the infusion method and create the market. Table 4-2 shows a list of actors in the market including their generic goals and the main restrictions they face.

Actor	Goal	Restrictions
Patients	Optimal treatment	Training/knowledge of doctors
Doctors	Provision of optimal treatment	Knowledge Availability of drugs Availability of tools Training Access to innovative developments
Pharmaceutical & Medical device companies	Profitable provision of drugs and medical devices	Clinical input Verification Validation Reimbursement Clinical feedback
Insurance companies	Cost efficient, safe and effective treatment	Knowledge about technologies Availability of cost data (treatment costs and cost of care)
Regulatory Authorities	Safe and effective treatment	Knowledge about technologies

Table 4-2: Market actors and their restrictions (needs)

After the market is opened up by means of the business-to-business PSS, a second "business-to-customer" PSS scenario is required to ensure fast market acceptance and market penetration of the drug-device combination.

The generic value proposition for convection-enhanced delivery, valid for both PSS scenarios is to reliably deliver a therapeutic agent to a specific clinical target within a patient's brain.

In the first, business-to-business PSS, this value proposition offers the pharmaceutical company, as the "user" of the system, firstly, all the required tools (products) to operate the system successfully (e.g. planning software, reviewing software, data management infrastructure) and, secondly, the services (consulting, data management, quality assurance, trainings, review processes, on-site support) to successfully run a clinical trial, minimising the risk of trial failure.

In the business-to-customer PSS, the value proposition is targeted towards the neurosurgeon, as the "user" of such a system. The user can minimise the risks of

treatment by having available the right tools (e.g. planning software, catheters, infusion pumps, etc.) and services (e.g. training, on-site support, etc.).

Creating this market penetration is obviously of value for both providers of the drug device combination.

4.3.2 User Analysis

Based on Morelli's proposed methodology (Morelli 2006), the users of both PSS scenarios have been analysed. In the business-to-business model, a pharmaceutical company in the market of brain tumours would be the customer for the products and services. In the second business-to-customer model, the customer would be any neurosurgeon who wants to treat brain tumour patients with this specific drug-device combination.

Table 4-3**Error! Reference source not found.** shows the results of the actor analysis for the business-to-business PSS, where pharmaceutical companies are the user.

Pharmaceutical companies	
Goals	Have approved drugs on the market to effectively treat high-grade brain tumours.
Key Problems	The blood-brain-barrier (BBB) prevents large molecules from entering the brain through the blood cycle.
Problem solving strategies	Circumvent the BBB by directly delivering the therapeutic agent to the target tissue within the brain.
Requirements to be met by the problem-solving strategies	Availability of reliable, easy to use technology for direct drug delivery Availability of users capable of using the technology
Current theories	Drug distribution within the brain is dependent on patient specific anatomy and pathology.
Tacit knowledge	To be effective, the anti-cancer agent needs to reach therapeutic concentration level within the target volume
Design methods & criteria	Minimal invasive surgical procedures Surgical workflow based on well-known standard procedures Intuitive and fast planning of the surgery Patient specific planning
Users' practice	Pharmaceutical companies are used to perform and manage clinical trials without the technological complexity associated with local delivery of the drug
Perceived substitution function	Technological complexity of local drug delivery
Exemplary artefacts	-

Table 4-3: Market actor analysis - Pharmaceutical Companies

Table 4-4**Error! Reference source not found.** summarises the analysis of neurosurgeons as the target group for a PSS offered, once the market is created and the drug-device combination is available for routine clinical use.

Neurosurgeons	
Goals	Provide best possible treatment approach
	Be well educated and trained for treatment approach
	Minimise impact of treatment on daily life of patient
	Increase survival rates
	Improve quality of life
Key Problems	Probability of recurrence[1] is extremely high
	Prognosis is very poor, independent of the treatment
	Tumour resection[2] (surgery) is highly invasive
	Radiotherapy has major side effects
	Chemotherapy has minimal effect and major side effects
Problem solving strategies	Direct delivery of therapeutic agent to the tumour and surrounding tissue
Requirements to be met by the problem-solving strategies	Reliability of treatment method
	Ease of use of required tools
	Appropriate training
	Appropriate on-site support
Current theories	Drug distribution within the brain is dependent on patient specific anatomy and pathology.
Tacit knowledge	Minimal invasive treatment is required
Design methods & criteria	Minimal invasive surgical procedures
	Surgical workflow based on well-known standard procedures
	Intuitive and fast planning of the surgery
	Patient specific planning
Users' practice	Precise placement of biopsy needles in order to take tissue samples from a specified target volume within the brain.
Perceived substitution function	-
Exemplary artefacts	-

Table 4-4: Market actor analysis – Neurosurgeons

[1] return of disease after tumour removal

[2] Removal of tumour in a surgical procedure

4.3.3 Product and Service Definition

Derived from the user analysis, several service components have been identified as crucial for the success of both PSS scenarios (see Table 4-5). Those services may be combined with the product (software tool for treatment planning including a simulation of drug distribution within the brain tissue based on patient specific imaging data) to multiply the use of the software features. The software may, for example, not only be used by neurosurgeons to plan treatments. Reviewers auditing neurosurgeons in clinical trials to ensure high compliance to the outlined trial protocol may also use this tool. Outside the clinical field, the software may also be offered in a business-to-business context to help catheter developers in their development by simulating different design methods. Knowledge gathered during the development of the product can be directly translated into services to capitalise on this knowledge.

Services may also be tailored to both PSS scenarios. The training of neurosurgeons, for example, is required during a trial to minimise failure of the trial due to human error, but this is obviously also being of great importance once the treatment is available on the market.

The presentation of such services as training however may change depending on the target group. While for a small study, the PSS developers can do the training personally, the same training content may have to be provided by a service force if a worldwide trial is carried out. To translate this service into the business-to-customer scenario, with the possibility that any neurosurgeon has to be trained, supporting tools such as e-learning modules have to be applied to keep the quality of training high.

Services	Description
Planning software tool	The planning tool is the technological basis for the treatment. It can also be recombined with services.
Clinical trial preparation *Consulting on CED technologies* *Consulting on trial design* *Consulting on drug selection for CED* *Consulting on patient selection*	Results and expert knowledge gathered during R&D (incl. verification and validation) can be offered as a consulting service. This service covers the lack of technological expertise regarding CED methods in pharmaceutical companies.
Data management for clinical trials	Software may be used as platform to generate compatible data basis for review processes or retrospective analysis
Quality management for clinical trials	Software may be used as platform to review performance on a patient-by-patient basis. This reduces risk of trial failure, since corrective measures can be taken during the trial.
Training *Technological background of CED* *Obtaining useful medical imaging* *Use of software (catheter planning)* *Placement of catheters (surgical workflow)* *Infusion processes at bed site* *Re-training if required due to results of reviews*	Software tool and expert knowledge may be used to train all involved persons (neurosurgeons, radiologists, nurses)
On-site support	Use in-house experts trained on software to consult with neurosurgeons during the planning phase and the surgical procedure

Table 4-5: Product and Service Components

4.3.4 Use Case Analysis and PSS Architecture

Bearing in mind the previously defined product and service components, the two basic use-cases have been analysed to design and visualise PSS suitable to establish a new market and to maintain and grow such a market afterwards.

4.3.5 Business to Customer Scenario

Although chronologically second, the use case for the scenario after the market has been created has been analysed first, as the efforts to establishing the market may be to no purpose if the method of making the drug delivery route reliable, and clinically routine is not designed correctly.

Figure 4-2**Error! Reference source not found.** illustrates a (simplified) clinical workflow for a patient eligible for treatment. The figure shows the tools and the environment required as well as the clinical staff involved in the process of diagnosis and treatment. Once a patient enters the workflow, several diagnostic tests will be conducted. For brain tumour patients, this will include medical imaging. To acquire these medical images, a scanner, and scanner software to process the information, are required.

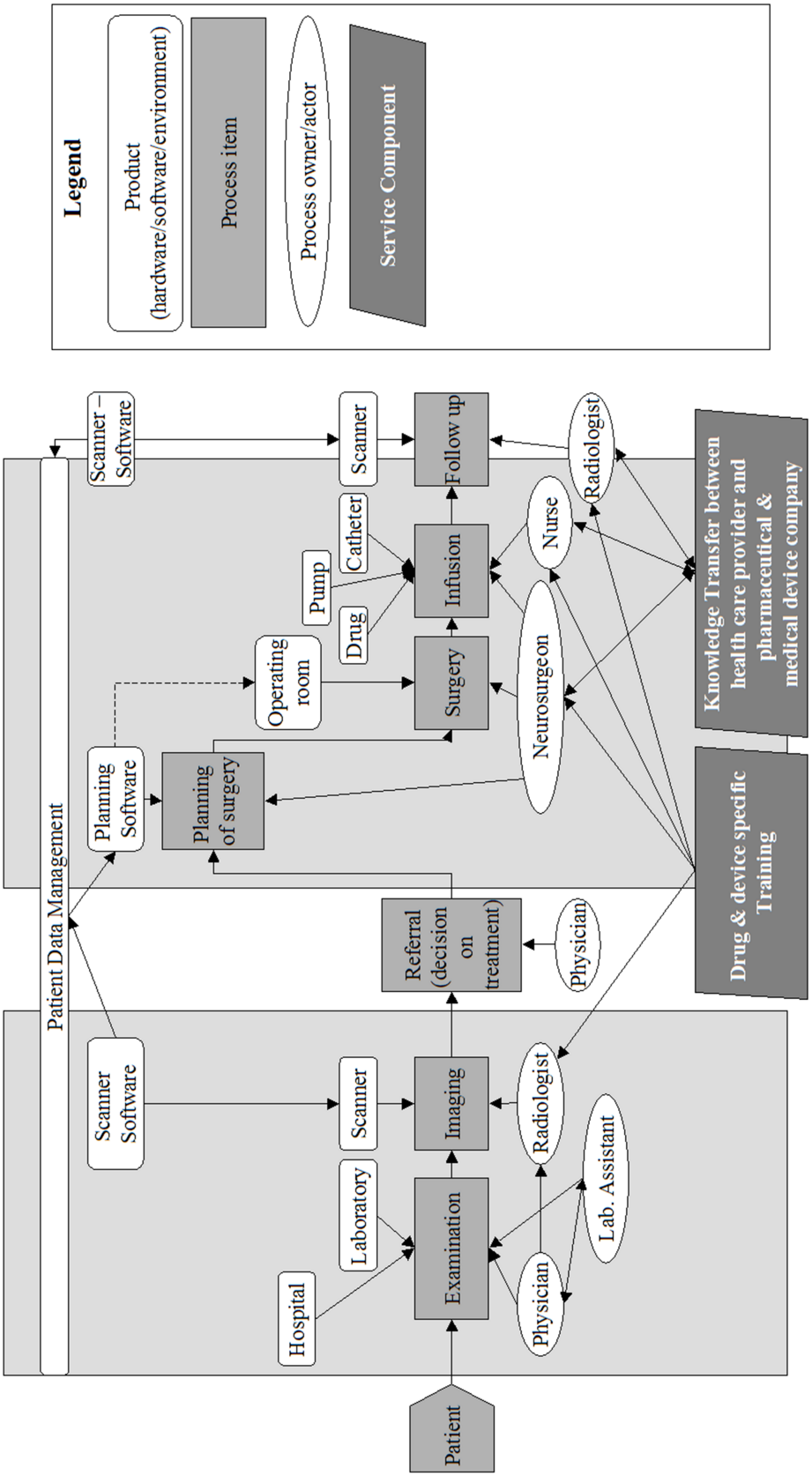
The flow of data and the processing has to be integrated into the system to further use this information for diagnosis, patient education, treatment planning and surgical treatment as well as for retrospective analysis and disease monitoring.

Once the patient is referred to treatment, the planning software may take available data from the diagnostic imaging (additional imaging may be acquired upon request) for the treatment planning. A neurosurgeon will then use the software tool to plan the treatment based on the patient-specific imaging data to ensure a high coverage of the clinical target. The finalised treatment plan can then be transferred to the OR, where the pre-planned catheters are surgically placed by the neurosurgeon.

Once the surgical procedure is completed, the infusion of the anti-cancer drug will be started at the intensive care station. To monitor the treatment outcome, follow-up scans are performed. The complexity of treatment planning for such drug infusion techniques requires additional services, such as training of neurosurgeons (to plan and actually place catheters correctly during surgery), radiologists (to acquire the right medical images for the treatment planning) and nurses (to correctly maintain the infusion).

As a single component, like a working drug is not sufficient to treat patients and therefore generate the safety and efficacy data required for market approval, an integrated PSS addressing all these requirements is mandatory to get a drug, delivered with a catheter-based infusion technique, onto the market.

Figure 4-2: Visualisation of use case for business-to-customer PSS



Looking at this proposed workflow, the required features of products and services can be recognised.

Table 4-6: Critical product features for a business-to-customer scenario lists the key features identified for the planning software in order to facilitate the catheter planning and placement process.

Key software features
Ease of use / no time-consuming planning
Automatic image analysis
Outline of clinical targets
Ability to communicate with hospital data management system (PACS[3])
Ability to fuse (overlay) scans from different time points
Compatibility with surgical navigation system
Integration with catheter technology (e.g. consideration of catheter diameter in the planning)
Integration with pump technology (e.g. consideration of pressure fluctuations caused by the pump)

Table 4-6: Critical product features for a business-to-customer scenario

[3] Picture Archiving and Communication System (PACS)

Additionally, the following service-oriented features have been identified for the business-to-customer scenario (see Table 4-7).

Key service features
Appropriate knowledge transfer from R&D into clinic
Training on planning software use
Consulting on surgical workflow
Training on catheter handling
Consulting on integration into hospital IT
Consulting on protocols for medical imaging required for planning
Easy access to information for retraining (e.g. web based e-learning tools)
Availability of on-site support, if required
Feedback processes to incorporate users feedback in enhanced developments

Table 4-7: Critical service features for a business-to-business scenario

4.3.6 Business to Business Scenario

Figure 4-3**Error! Reference source not found.** shows a visualisation of a use-case scenario as the basis for the business-to-business PSS required in order to obtain approval for clinical use for a drug-infusion method combination.

A pharmaceutical company developing drugs for brain tumours (or neurodegenerative diseases) would have to make decisions about how newly developed drugs in the R&D pipeline should be delivered to the clinical target.

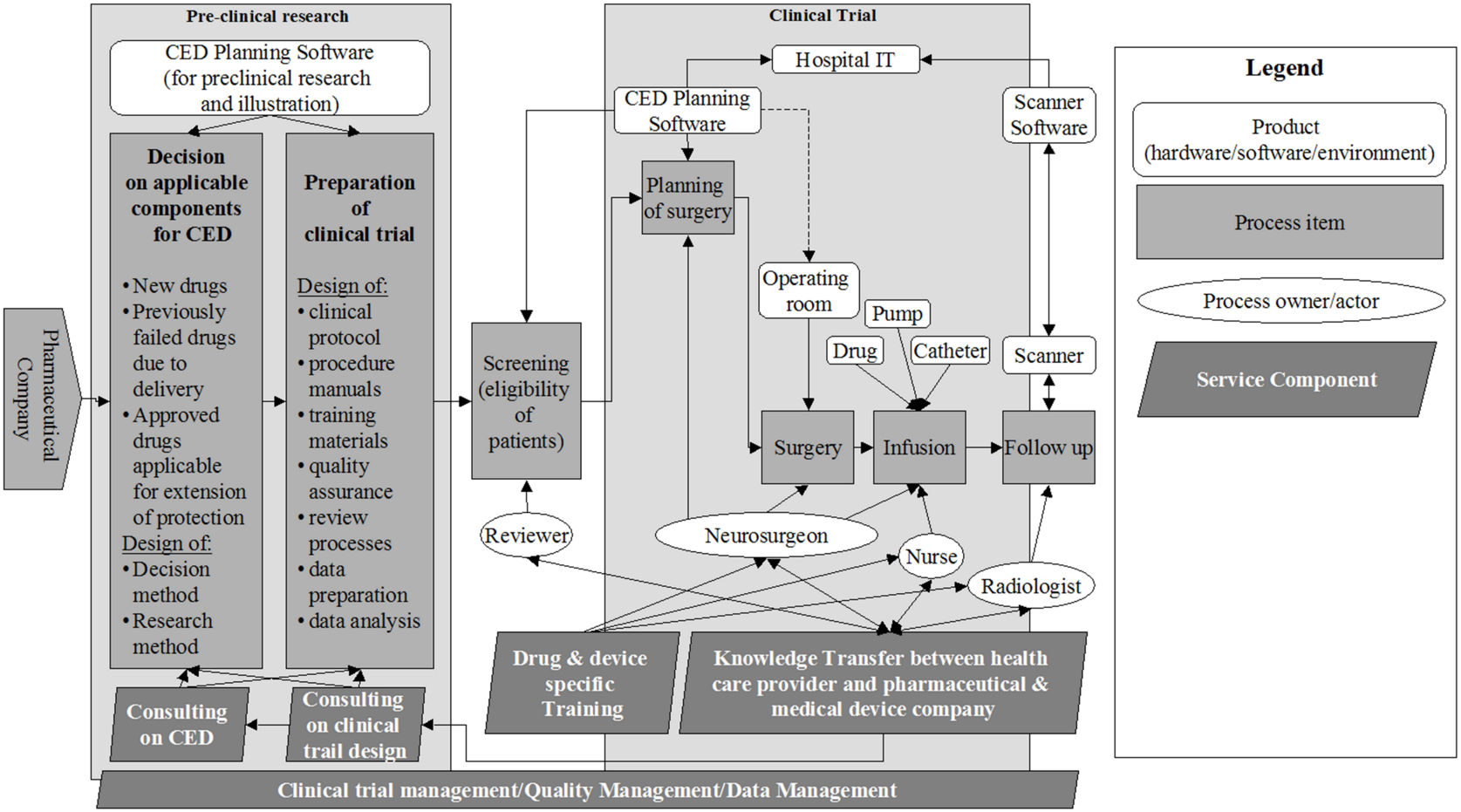
Such a company may also consider further screening of drugs which have been previously developed. Of interest would be those drugs where there is clear indication of effectiveness, but where the drug failed in previous trials for particular sets of reasons. Where those reasons for failure include the drug failing to reach the clinical target, or showing unacceptable side effects when given systemically (given orally or intravenously), such drugs may be reconsidered for use in combination with a new infusion system.

This screening process requires an in-depth understanding of underlying principles of the infusion mode, which can be offered to a pharmaceutical company as a consulting service, using knowledge derived from the knowledge base in R&D.

A significant barrier for pharmaceutical companies to actually use infusion as a delivery method for their molecules is that this technology adds to the complexity to the treatment and, therefore, also to the setup of a clinical trial. By offering services to close gaps of expertise and knowledge, those barriers can be eliminated.

By consulting drug companies on the design of the clinical trial in the planning phase and also the management of the trial, risks of trial failure can be mitigated.

Figure 4-3: Visualisation of use case for business to business PSS


Pre-clinical research
CED Planning Software (for preclinical research and illustration)
Decision on applicable components for CED
• New drugs
• Previously failed drugs due to delivery
• Approved drugs applicable for extension of protection
Design of:
• Decision method
• Research method
Preparation of clinical trial
Design of:
• clinical protocol
• procedure manuals
• training materials
• quality assurance
• review processes
• data preparation
• data analysis
Pharmaceutical Company
Consulting on CED
Consulting on clinical trail design
Clinical Trial
Hospital IT
CED Planning Software
Scanner Software
Planning of surgery
Operating room
Pump
Drug
Catheter
Scanner
Screening (eligibility of patients)
Surgery
Infusion
Follow up
Reviewer
Neurosurgeon
Nurse
Radiologist
Drug & device specific Training
Knowledge Transfer between health care provider and pharmaceutical & medical device company
Clinical trial management/Quality Management/Data Management
Legend
Product (hardware/software/environment)
Process item
Process owner/actor
Service Component

Key service features
Consulting on clinical protocols and procedures
Availability of training materials
Data management for clinical trials (especially processing of imaging data)
Quality management of clinical trials (review and audit processes by means of the planning software as a review tool)
Training on planning software use (for neurosurgeons)
Training on infusion procedures (for nurses)
Training on imaging protocols (for radiologists)
Consulting on surgical workflow (for neurosurgeons)
Training on catheter handling and placement (for neurosurgeons)
Easy access to information for retraining (e.g. web based e-learning tools)
Availability of on-site support, if required
Analysis of patient data during the trial to minimise risk of trial failure
Analysis of data in the light of predefined research questions
Feedback processes to incorporate users feedback in enhanced developments

Table 4-8: Critical service feature for a business-to-business scenario

Table 4-8 shows key service features identified for the business-to-business scenario in collaborative discussions between the project stakeholders.

4.4 DISCUSSION

Product Service Systems in health care have not been in the focus of PSS research in the past, although the concept holds great potential to address major challenges in this sector. The analysis of the presented case study suggests that further research on PSS applied in the field of health care is required to identify areas where benefits of PSS match unmet needs in the health care sector. Subsectors within the health care sector will have to be analysed with regard to potential added benefit by means of PSS. In addition, guidelines for designing and implementing PSS in a health care market environment have to be developed and validated in order to facilitate adoption in the industry.

Actors in the health care network are driven by expectations that will drive their needs in a particular PSS scenario. Understanding those expectations allows to characterise the network and the role of each actor to identify system design requirements for a PSS. An overview on those expectations is given in Figure 4-4. Details on each relationship are discussed below:

Patient-to-Provider Relationship

The central relationship in a health care market is the relationship between the patient and the health service provider. It is also the most personal one, as it required trust and involves the most human interaction (Glickman et al. 2010). Patients do expect to receive the best possible treatment for their condition, to maximise their quality of life. They trust providers to make informed, objective decisions about prevention, diagnosis and treatment based on the individual needs of a patient to maximise the individual quality of life. Patients also do expect to treat all information acquired in the process to be confidential. Bendapudi et al. conducted a study interviewing patients to identify patient expectations from a physician and concluded that a physician should be confident, empathetic, humane, personal, forthright, respectful, and thorough (Bendapudi et al. 2006).

In turn, providers do expect patient compliance to be able to achieve best possible outcomes for their patients.

Patient-to-Payer Relationship

Unlike in other markets, compensation for health services and products is usually organised indirectly. Depending on the health care system model, third party payers are compensating providers funded by insurance premiums, taxes or a mixture of both. Patients expect to have access to the best possible treatment through their health care plan and a broad coverage, affordable premiums or taxes and low deductibles (if applicable).

Payers do expect patients to pay premiums, taxes, deductibles and over-the-counter cost.

Patient-to-Policy Maker Relationship

Patient and the society is expecting policy makers to have oversight over access to health care, quality and cost. Patient do expect to have regulations in place to ensure that the safety and efficacy is guaranteed, as patient do not necessarily have the opportunity to do "market research" on providers like customers would do in other industries to find the best quality offering.

Provider-to-Payer Relationship

Providers want to focus on their main task to provide services to patients, but also expect to be adequately compensated for those services. Providers therefore do expect payers to reimburse them at reasonable rates following a transparent and simple to execute process.

On the other hand, payers do expect providers to treat patients at highest quality, to the best of their knowledge and with sufficient and correct documentation as basis for claims and payable bills.

Provider-to-Policy Maker Relationship

Provider expect to have freedom to treat patients to the best of their knowledge and therefore expect policy makers to minimise regulations that limits this freedom to treat.

Policy makers pose their expectations on providers through implementation of regulations. Providers are expected to be certified and properly trained and hold their clinical decisions against high ethical standards.

Payer-to-Policy Maker Relationship

Policy makes expect payers to provide an efficient mechanism to fund the health care system and compensate providers through an appropriate process.

Figure 4-4: Expectations of market actors in health care

Expectations by	Patient	Provider	Payer	Policy Maker
Patient		Best possible treatment available	Reasonable premiums and optimal coverage	Oversight to ensure access and control quality and cost for health care
Provider	Compliance		Simple process for reimbursement of services provided	No unreasonable limitation for treatment
Payer	Payment of premiums	Treatment of patient and correct documentation as basis for claims and bills		Reasonable regulations of market
Policy Maker	N/A	Highest quality of treatment	Efficient and sustainable funding mechanism	

4.5 CONCLUSIONS

To confirm the conclusions of the literature review and to collect relevant real-life data on PSS in health care, a case study was analysed.

The case study confirmed the utility and feasibility of PSS in health care in a business-to-customer and a business-to-customer.

The cost explosion and additional cost pressure resulting from globalisation is a serious threat to the industry also in the health care sector. PSS is a useful tool to reduce costs and resource consumption, while maximising the outcome. Companies can capitalise on the knowledge they generate during the research and development process of a product, by selling this knowledge in separate services. In addition, products may also be reused in combination with several different services. This is especially true for software products, which can easily be recombined with services to provide additional benefit for a customer group or to exploit new markets.

Due to the high degree of specialisation in medical health care and increased complexity of technology, integration of technologies, products and services becomes a whole field of new service components demanded by the customer.

Products (tools) and information have to be available at the right point and in required quality during more complex clinical workflows facing a significant increase of actors and interfaces caused by specialisation and digitalisation of patient data.

PSS offers the chance to establish an extremely close relationship to the user. This is of special benefit for developers in the health care sector, since the knowledge gap between developers (e.g. engineers or software developers) and physicians is generally quite wide. From a company's perspective PSS creates an access to customers as part of the R&D and quality management processes owing to this close relationship.

In a business-to-business scenario, closer relationships can be established between business partners. Those business relations are more likely to be of a cooperative nature, since PSS ultimately focus on the final benefit for the end user, which streamlines efforts of all partners towards the same goal. This stands in contrast to, for example, supply chain thinking, were each participant in the chain tries to maximise its revenue on the following company in the chain and in fact may not be aware of the final

customer. Processes can be optimised on a higher level by having this common final goal.

The interdisciplinary approaches required for the success of combinations of drug and drug-delivery techniques set a high requirement on communication between users and developers.

Since PSS causes the designer of those systems to focus on the final customer need, it is a very helpful tool for strategic considerations. The combination of products and services may have the critical mass to establish the market, while a product on its own may face too many barriers. Those barriers for a market entry can be specifically eliminated with additional services. In addition, knowledge created during the development process can be sold as consulting and training services leading to increased revenue but also creating additional benefit for the user.

Once on the market PSS can increase market acceptance compared to a product without supplementary services. Especially in the launch of a PSS, this can lead to a broader base of potential customers, for example if services are offered that educate customers in using a product that usually would just be used by a small group of experts. Additionally, the market penetration can be increased, if services and products are designed for an easier user adoption.

The case study showed that a generic PSS design method can be applied to offerings in both business-to-customer as well as business-to-business settings.

5 IMPACT OF CHANGES IN HEALTH CARE ON PSS

5.1 LITERATURE REVIEW

Main groups of actors such as consumers, commercial companies and governments have been identified to drive and shape PSS adoption driven by potential benefits for each of those actors deriving from more sustainable, cost effective and customer focused market approaches (Mont, 2002; White et al., 1999) but also financial institutions (Mont and Lindhqvist, 2003) are an important group of actors. Those actors and the network connecting them are crucial components for PSS (Mont, 2002). In order to predict PSS adoption in a market future trends and developments have to be interpreted with regard to how this will affect the actors and their network. Morelli et al. propose methods for the analysis of actors in the market and the relationships between those market entities as the basis for successful PSS implementation (Morelli, 2006). As the understanding of who the actors are and how those entities interact with each other is an important factor for any PSS implementation, this structure may also serve as a useful approach to investigate the potential for PSS adoption in a market and to identify drivers and inhibitors for such adoption.

5.2 METHODOLOGY

The objective is to identify changes and market trends in health care to ultimately evaluate the potential of PSS in the health care sector. The questions at hand are:

- Who are the actors deciding on PSS adoption in this specific market and how do they interact?
- What are the predominant trends in health care that will shape the future of this market?
- What is the impact of those trends on the actors in the market?
- How will these future developments influence the adoption of PSS in health care?

To address those questions and to fulfil this objective the following methodological steps have been identified:

1. Analyse current trends in health care
2. Analyse the impact of those trends on actors in health-care
3. Identify drivers and inhibitors for PSS implementation in health care

Major trends in health care have been identified by reviewing market reports and other text based content published by health care consulting companies. In an inductive content analysis, the text sources have been analysed for common codes and themes. Consulting companies in the health care field provide insight of how the market will develop in the future to their customers, therefore this data source was considered to be highly appropriate to identify codes and themes related to trends in health care. As data sources, content from homepages of the following companies have been reviewed and codes have been identified:

- HealthCatalyst
- PwC
- Acccenture
- NursesRx
- Revive Health

Those companies have been identified by an internet search (Google) for “trends in health care” (last search December 2016).

To confirm the relevance of the identified meta trends derived from the inductive content analysis, a key word search has been performed in SpringerLink to obtain the numbers of relevant publications per year from 2001 to 2010.

The trends identified in the first phase were reviewed and consolidated into “meta trends”. The known impact of those meta trends on actors in the market has been gathered from literature identified in the validation of trends.

In the subsequence phase the impact on relationships between actors was analysed using the identified impacts on actors. Those results were discussed in the light of PSS, identifying barriers and drivers for PSS in health care.

5.3 RESULTS

In a first step, trends in health care had to be identified as input for further research. As latest trends in a market may not be reflected immediately in research, published reports from consulting companies active in the field of health care were analysed for codes describing market trends.

The identified codes are listed inTable 5-1:

Code	Example Statements
Wearables / m-eHealth	"…70 million people in the U.S. are using **wearable tracking devices** to monitor their physical activity, sleep patterns, calorie consumption, and a whole lot more. This is an exciting new frontier with so much potential to improve patient care."
Patient centered care	"A significant change in the healthcare industry's approach to providing care is underway—**putting the patient at the center of care**. The goal is to improve patient satisfaction scores and engagement."
e-Health	"An **enterprise data warehouse** (EDW) is key to overcoming the current data challenges."
New technology	"…While the US health industry lags behind other industries, such as retail and telecommunications, in deploying emerging technologies such as artificial intelligence, drones and virtual reality, 2017 is the year to prepare for the **eventual arrival of these technologies** and their impacts on business models, operations, workforce needs and cybersecurity risk."
Demographic Change	"**Demographic shifts** and societal changes are intensifying pressures on health systems and demanding new directions in the delivery of healthcare. […] Ageing populations in both emerging and developed nations are driving up the demand for healthcare."
Educated patients	"**Educated patients** want helpful information from their health practitioners online, in person and in collateral. 72% of Internet users look online for health information, searching for information about their doctor, hospital and medical concerns before they book an appointment. There will be continued demand for educational healthcare content in the form of blogs, social media…"
Data Safety	"…research shows that patients are increasingly using digital health technologies, but they have **privacy concerns**. Healthcare consumers in the United States (70 percent) are at least "somewhat" concerned about the personal privacy of their electronic health records (EHRs) this year, up from 63 percent in 2014. Yet despite concerns about privacy, most US consumers say the benefits of being able to access medical information electronically outweigh the risks (65 percent, up from 53 percent in 2014).

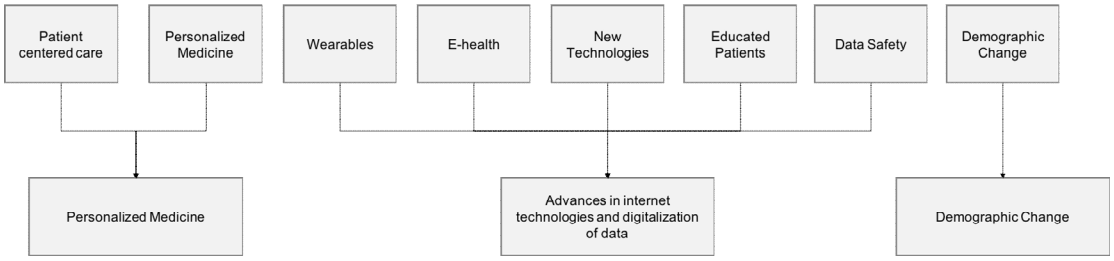
	"**Patient privacy issues** (including concerns about data breeches) will continue to be top-of-mind for providers, payers, and consumers,…"
Personalised Medicine	"**Precision medicine** is a dramatic shift from a "one-size-fits-all" approach to treatment based on the uniqueness of each person."

Table 5-1: Codes for Trends in Health Care

5.3.1 Meta Trends in Health Care

The codes identified in the inductive content analysis were further analysed for patterns, reflecting the underlying changes and trends in health care.

Figure 5-1: Meta Trends in Health Care



This analysis resulted in the identification of three meta trends in health care (see **Error! Reference source not found.Error! Reference source not found.**):

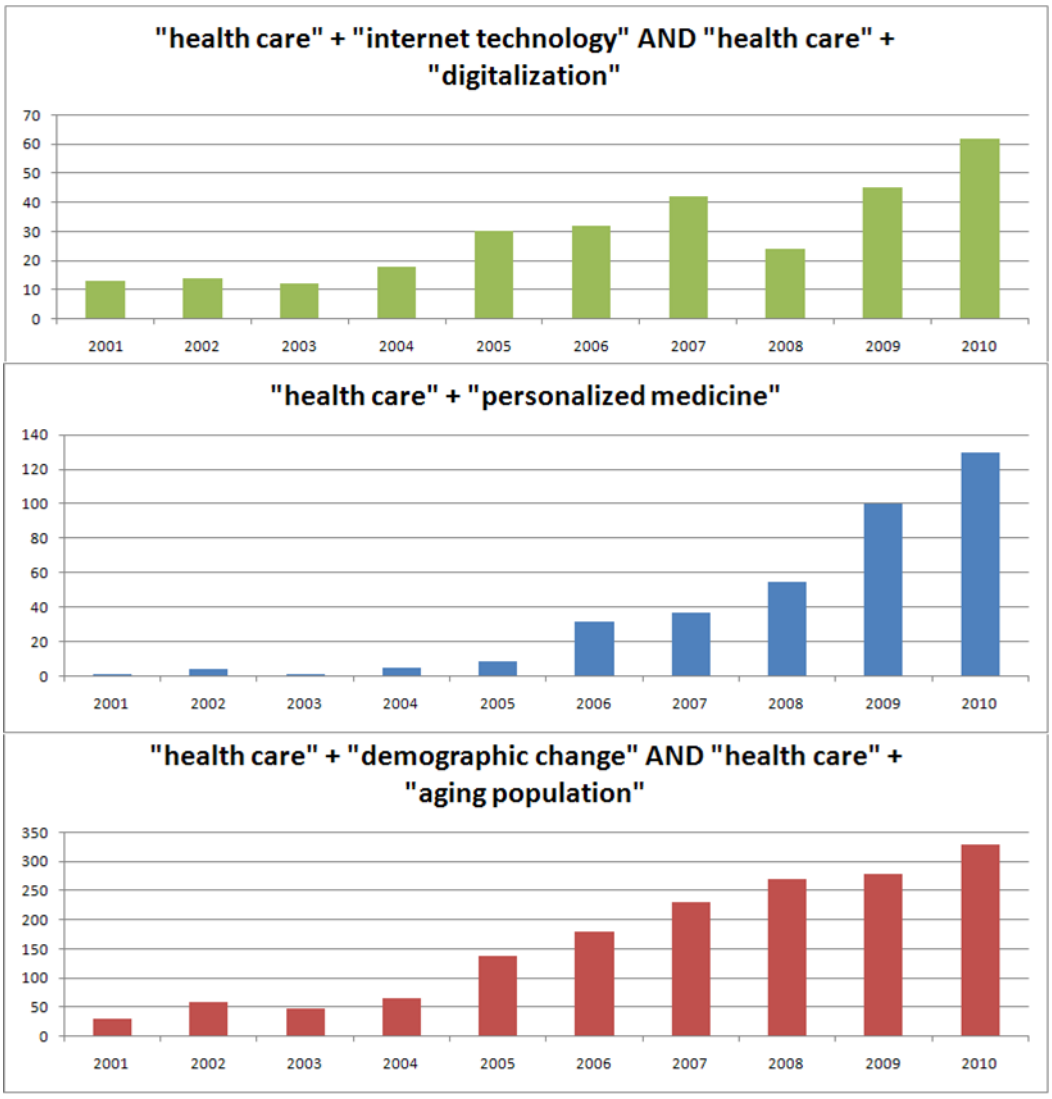
(I) *Advances in internet technologies and digitalisation of data* have been identified as one of the underlying trends in health care. Cloud computing, electronic heath records and mobile health are subtopics that require digitalisation and internet technology. The digitalisation enables patients to be more educated about their conditions.

(II) Technological advances within the health care sector, such as *personalised medicine*. The term *personalised medicine* summarises advances of genomic analysis, advances in medical imaging, and patient specific tailored drug delivery technologies, 3-D printing, etc.

(III) *Demographic changes and an aging population* will have a major impact on the market. The market will experience a shift from acute to chronic diseases with an increased need for services.

To validate the three identified meta trends, a key word literature search was conducted (see **Error! Reference source not found.**). Increasing numbers of publication over the years indicates the importance of the identified trends. While the search for the purpose of validation was limited to the years 2001-2010, a subsequent search in 2016 showed that the trends continue to be of increased importance. The two areas of "personalized health care" and "digitalisation" continue to be of increased importance. Applications of big data are increasingly important and build on digitalization of health data (Luo et al. 2016). Personalisation of health care was also in the focus of the market, as 3D printing methods became more sophisticated allowing to print tissue (Bradley 2018), prosthetics (Tack et al. 2016) and drug delivery systems (Hsiao et al. 2018).

Figure 5-2: Development of publication numbers



5.3.2 Impact on Market Actors

Error! Reference source not found. shows a matrix of the three meta trends identified in the step before versus the four main actor groups to structure effects of trends.

Actor	Digitalisation	Personalised medicine	Demographic Changes

Patients	• Easy access to information regarding
	  • Diseases
	  • Treatment options
	  • Best practice
	  • Quality for health care providers
		• Availability of information on individual risk profiles
		• Availability of tailored treatment options
		• Increased chance to proactively influence health status
			• Increased portion of chronic diseases
			• Increased need for services in health care
			• Increased collaboration required between patient and health care provider

Providers	• Easy access to patient information • Improvement in collaboration among experts • more competitive situation	• Increased complexity of diagnosis and treatment • Shift from treatment to prevention	• Shift in focus from acute to chronic conditions • Increased collaboration required between patient and health care provider

Payers	• Easy access to data measuring
	  • Safety
	  • Efficacy
	  • Cost efficacy
	  • Quality
	• Globalisation of health care market
		• Potential for increase in cost effectiveness
		• Potential for more complex insurance policies
			• Dramatic increase in health care cost

Policy Makers	• Blurring of health care legislations • Issues on ownership of medical data	• Increased complexity of approval processes • Issues on ownership of patient information • Adjustments in approval processes are required	• Shift to (chronic) diseases in elderly patients may require adjustments in approval processes to ensure patient access to newly developed treatments

Table 5-2: Impact of health care trends on actors

The digitalisation of data and the advances in internet technologies have a significant impact on every actor in the health care market. Information and medical data becomes independent from time and location which makes such data more accessible.

Patients have the opportunity to gather information about diseases and treatment options, even before they consult a physician. In addition, patients have the possibility to compare the quality of health care providers and to identify experts for their specific needs on their own, independently from their location (Matsumura et al. 2002).

Likewise, first line health service providers like general practitioners (GP) can more easily identify best practices for certain treatments, specialised experts for referral and latest research results on specific diseases they are confronted with (Masic et al. 2009). Internet technologies also allow to easily exchanging medical data like patient records or medical imaging among health care providers (Kane & Luz 2009).

The increased accessibility of information for patients and heath care providers changes the perception of the industry by both groups. Medical device companies as well as pharmaceutical companies find themselves increasingly exposed to the public. At the same time those technologies may allow the health care industry to more easily collect data during the development phases, but also in the market, to monitor safety, efficacy, patient outcome and cost efficacy of their products.

Along with an increased transparency with regard to the quality of health care providers, payers are enabled to monitor the efficacy of the insurance system and incentivise patients, providers and industry to act towards increased cost efficiency.

With worldwide accessibility of information, the health care market also experiences the effects of globalisation, which increases the market complexity also for payers and insurances, as patients have at least the theoretical possibility to get the required treatment in different countries all over the world (Kulesher & Elizabeth Forrestal 2014). This blurring of health care legislations also affects regulatory authorities that by nature traditionally focus on one country rather than a globalised market.

To reconfigure the health care sector into a patient-centered, outcome-based system, all actors have an urgent need to create, share, analyse and combine data in order to evaluate performance and improvements. With advances in technology, more data is generated during the diagnosis and treatment, which needs to be converted into meaningful, shareable information for providers to improve the clinical decision making process (Jain & Jain 2009). This often is referred to e-Health (Geissbuhler 2012). Recently, desktop based e-health evolved into m-health, utilising mobile devices (Istepanian et al. 2010). With wireless technologies becoming readily available in mobile devices including so called “wearables”, patients are generating more relevant data prior to and after a disease episode, as wearables and personal monitoring devices are moving from the consumer market in the health care sector. Changes in how health care services are delivered are mainly driven by changes in how information is shared

between health care providers and patients (Elwood et al. 2011). Health care information and resource services can be reached by anyone at any time, and independent from location, which removes traditional geographic, temporal or other barriers for services (Zhang et al. 2010). This opens up enormous potential to introduce new combinations of products and services in health care and an opportunity to make health care systems more efficient and sustainable and to serve the unserved by medical information services (Akter & Ray 2010).

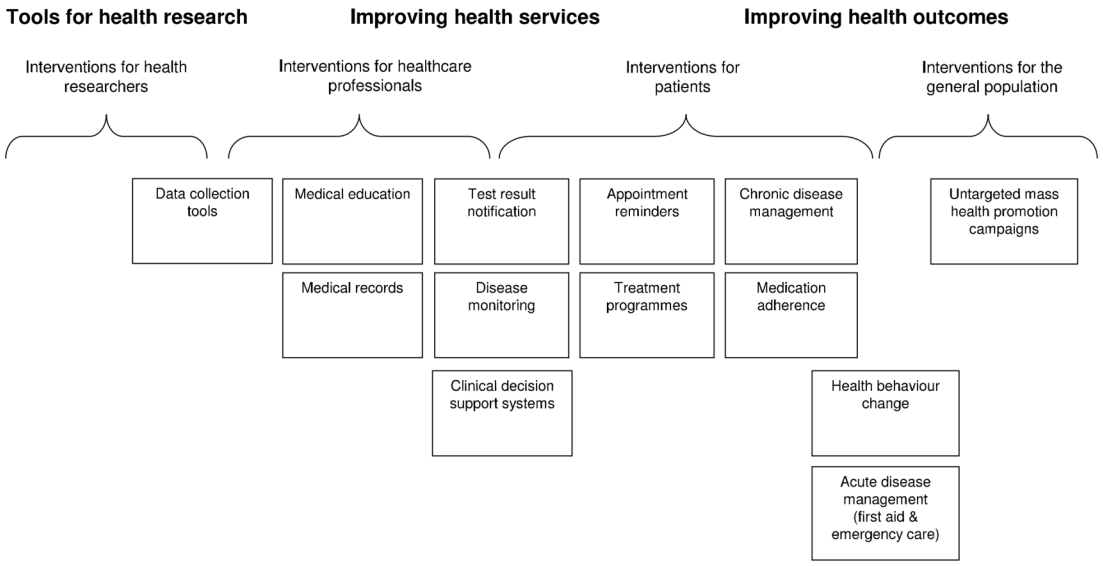
With recent developments towards patient-centered care, e-health and m-health, it is inevitable that the network among market actors will become more connected and more complex. Medical device manufacturers as well as pharmaceutical companies will have to adapt to the new paradigm and offer solutions that not only address feature requests from users like in traditional business models, but instead consider the health outcome and quality of life for the patient, the performance requirements for providers and the need to measure both outcome and performance for payer.

From the review of more than fifty definitions for the term e-health Oh et al. (2005) concluded that there is a tacit understanding of what e-health means and the fact that the term is used by individuals, academic institutions and other organisations in health care proves the importance of the concept (Oh et al. 2005). M-health is a relatively new field within e-Health. While clear and unambiguous definitions for m-health are not consolidated yet in research (Gagnon et al. 2016), it has been established that m-health can be described as medical practice that is supported by mobile devices (Mirza & Norris 2007) and m-health interventions are designed to improve delivery of health care services (World Health Organization 2011). M-health is inherently consumer driven and patient-centric. Key factors for successful implementation of m-health services have been identified by Akter et al. to be affordability, availability, awareness and acceptability (Akter & Ray 2010).

Mobile health tools can support health research, improve health services as well as health outcomes. To evaluate the effectiveness of m-health technologies Free et al. (2010) conducted a systematic review of controlled clinical studies that include either interventions delivered by means of a mobile device that was owned or directly used by the patient or a lay person, or clinical or practice aid delivered by a mobile device that was owned or directly used by a health care professional (Free et al. 2010). In addition, any clinical study with data related to health care or health research that was

collected or stored using mobile devices was included in the review. Based on the results, Free et al. proposed a classification for mobile electronic devices interventions (see **Error! Reference source not found.**).

Figure 5-3: Conceptual framework for mobile electronic device intervention classification (Free et al. 2010)



The overarching trend in health care technologies towards personalised medicine summarises many developments like using medical imaging for patient specific treatment planning, personalised drugs and even full genomic analysis. The amount of information generated by those technologies is enormous and only to be managed by applying latest information technology.

Patients will have information available about their individual risk profile for developing certain diseases and required access to tailored treatment (Dietel & Sers 2006). Based on this information, patients will be put in the position to proactively influence their health, rather than just reacting on certain conditions.

For health care providers, this will lead to a shift from treatment to prevention (Davis et al. 2005). For the health care industry, the shift from disease management to health management holds great potential for market growth as the customer base will grow beyond patient populations, as they are defined today. At the same time industry, will have to come up with ways to customise equipment and drugs. This will increase the complexity in research and development of treatments.

The health care insurance and governmental payers sector will also most likely be influenced by the fact that personalised data like risk profiles and genomic analysis is at least technically available, as this holds great potential to increase the cost efficiency for such insurances.

Regulatory authorities and governments will have to handle the issues related to ownership of such information as well as accessibility by third parties like insurance companies (Pfeiffer & Auer 2009).

Also, current approval processes for devices and drugs will be challenged by the plurality of variants for products to tailor treatments based on patient specific information. Patient-centered care is evolving to become dominant mind-set in health care, changing the role and interactions of patients and health care providers dramatically (Porter 2010). Very much like the role of customers in traditional PSS models, being an active part in the entire life cycle, the role of patients is changing to become an active and responsible partner in the process of diagnosis and treatment. Care is also no longer disease-centered, but focuses on the quality of life, very similar to how PSS is aiming for the customer end use.

Informed patients are expecting convenient access to healthcare and personalised care plans that are executed in a coordinated fashion across medical specialities (Brennan & Reisman 2007).

The changes in the dynamics of the health care market are influencing all actors in this market beyond patients and (health care) providers. Payers, such as health care insurances or governmental health care plans have to adopt processes. Reimbursement models will need to change to outcome based models rather than pay for service. Performance-based compensation will force providers to work on continuous improvement along the entire workflow from prevention, diagnosis, treatment and recovery (Porter & Teisberg 2006). Medical device manufacturers as well as pharmaceutical companies will be required to provide offerings that not only prove safety and effectiveness, but also lead to better outcomes and higher quality of life.

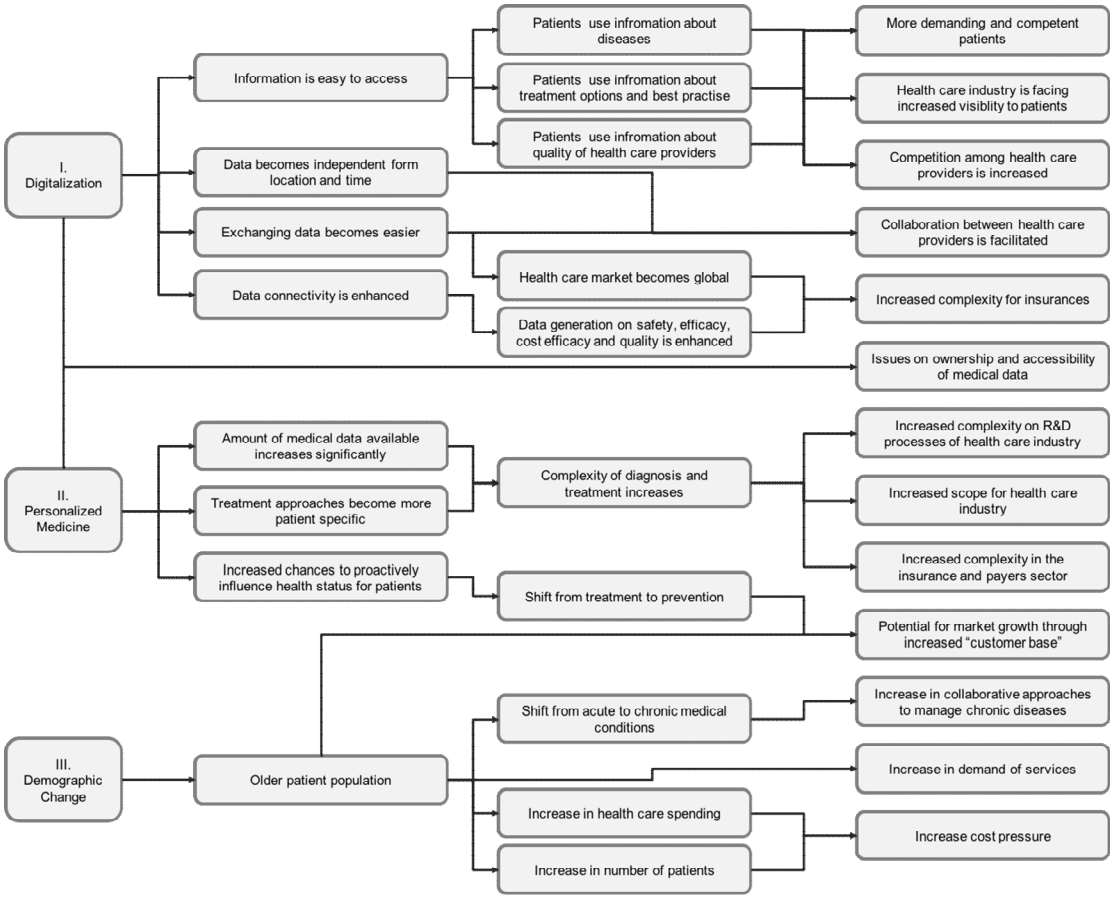
The demographic trend towards an aging population changes the characteristics of patients as one group of actors in the market. Along with an increase need for medical products and services, it shifts the relation of chronic diseases versus acute medical conditions towards chronic conditions (de Bruin et al. 2011). Older patients often also

require increased collaboration with the health care provider, especially in the management of chronic conditions (Gaikwad & Warren 2009). Service components may therefore likely gain importance for health care providers to stay competitive. The increased need for health care represents a significant potential for market growth for both medical device industry as well as pharmaceutical companies. At the same time this growth usually leads to an exponential increase in cost for health care, which needs to be managed by private and governmental insurance programs. The shift towards chronic conditions increases the pressure on regulatory authorities to improve approval processes to ensure patients' access to newly developed treatments.

5.3.3 Impact on Actor Relationships

Error! Reference source not found. shows how those interdependencies result in either drivers or barriers for PSS adoption.

Figure 5-4: Causality of trends in health care and effects on industry



Digitalisation leads to enhanced accessibility of information. Such information becomes independent from location and time and becomes easier to exchange or connect data. As a consequence, patients are more knowledgeable about their medical conditions, treatment options and available health care providers. With that knowledge, patients become more demanding (Neuberger 2000).

Health care providers find themselves in a more competitive situation, as the transparency of the market increases and also switching costs for patients to change the health care provider are significantly reduced. At the same time, the enhanced data exchange and data connectivity allows a new level of collaboration between providers. The pure business-to-business relationship between heath care providers and health care industry (medical device companies as well as pharmaceutical companies) also changes to a combination of B2B and B2C relationship as industry becomes more visible to patients. All those developments point towards drivers for PSS development and adoption as the patient's demand in sustainable, cost efficient offerings grows. More knowledgeable patients also will become an attractive resource to develop improved offerings with focus on the end use.

While there is strong indication that digitalisation will be a driver towards PSS, there are effects that may result in building barriers. With information and data being independent from location and time, the health care market becomes global and the amount of available data increases dramatically. This will lead to a more complex situation in a market that is highly regulated. Medical data often is very delicate information. While it is obvious that there is a clear benefit in combining information to enhance the overall system, such combination of information may be in conflict with the interest or even the human rights of a patient. Regulations on ownership of data will determine the ease of PSS implementation. Legal inertia in this regard may become a barrier to fast PSS adoption.

Market transparency will clearly enhance with the increase digitalisation. By having more information available, patient may act more proactively, but this may also lead to more passive patients if the available information cannot be presented in a clear way. Such a social inertia would be a significant barrier to PSS adoption.

Goal of personalised medicine is to tailor the treatment to the specific needs of the patient, taking in account genetic condition and other patient specific information.

Advances in personalised medicine will in general increase the complexity in the market. There will be more medical data generated and the information will be more delicate and in need of protection from unauthorised access. With the possibility to further differentiate diagnosis, treatments approaches also need to become more patient specific. While health care traditionally has been focusing on disease management, in other words react to a medical condition of a patient by diagnosis and according treatment, personalised medicine will shift this towards a more proactive heath management. Through genetic analysis, patients will know about their personal risk profiles to get certain diseases well ahead of the onset of an actual disease. Increased complexity per se is not necessarily a driver towards PSS, however the need to compensate such complexity could be to use the patient as a resource for development and especially the improvement of patient specific treatment approaches. The combination of services with products may allow establishing an information flow of feedback in order to have a system of personalised treatments optimise itself.

The shift from disease management to health management also changes the scope for the health care sector. While today nearly everyone at some point gets into the situation where he or she requires heath care, however this is limited in time and usually focuses on the specific medical condition, future health management will make everyone a customer of the health care system, even if such person is not a patient. Proactively managing health care means being a patient far earlier than any clinical onset of a disease.

This paradigm shift dramatically increases the market. Potentials for market growth through occupying those new market niches may increase the organisational inertia within health care provider organisations as well as in industry organisations with regard to PSS development and adoption.

Personalised medicine and genetic analysis will generate extremely delicate patient information. To regulate the ownership and access of such data governments and regulatory authorities will have to define a legal framework that takes into account the patients interest as well as the overall interest to increase efficiency in the health care system. Such regulatory inertia may slow down PSS development and can form a significant barrier to PSS adoption in this sector.

Along with technological changes within and around the health care sector, nearly all economies in the developed world face drastic demographic changes towards an aging population (Pammolli et al. 2012). Through advances in health care especially over the last hundred years the portion of elderly patients has been increasing dramatically. With the first “baby boomers” entering the age over 65, the strong age cohorts reach their time of retirement (Brown et al. 2003). This trend leads to a shift in the relation between acute and chronic medical conditions, as chronic diseases are more prominent in elderly patient populations. Chronic conditions usually require a collaborative approach between patient, potentially a care giver and the health care provider. The need for collaborations between the customer and the provider certainly can serve as a driver towards PSS, especially as this effect lines up with the trend towards more demanding and knowledgeable patients.

Elderly patients in many cases also require additional services to help manage their health and their medical conditions, which opens up great potential for the integration of services and products driven by customers’ need.

PSS is supposed to offer more efficient and sustainable ways to provide an end use to a customer. With increasing number of patients and the associated increase in health care spending, there will be significant demand on more cost-efficient solutions. This will clearly drive actors to develop and adopt PSS in the sector.

5.4 DISCUSSION

As future developments in the health care sector are crucial for business decisions both in the industry but also the legal authorities, consulting companies are gathering such information to offer it to health care companies. Those market reports may in some cases not fulfil scientific standards and may also be biased, as those reports often are used as means to make an argument for certain lobbying goals or to sell certain consulting services. Those sources have been used for inductive content analysis to develop an understanding of what the dominant developments in health care and underlying meta trends are.

To validate the relevance of the results, the number of scientific publications over one decade related to the identified trends was studied and showed that the identified trends

are also reflected in current research, also mostly studied individually and for specific fields of research.

Technological advances deriving from sectors outside health care, but influencing the market, are the use of internet technologies and digitalisation of data. These technologies will have a significant impact on health care. More than the other two trends - advances in personalised medicine and aging populations in the industrialised world - digitalisation has already changed the health care in the recent years. This topic has been consistently discussed in research, with a clear trend towards increasing numbers of publications.

In contrast, personalised medicine did not yet have such a dominant effect on the sector as research in this field has not yet translated into many clinical applications. This is also reflected in the over proportional increase in numbers of publications, starting from a very small basis.

The implications of an aging population in industrialised economies have been identified as a major impact factor in health care very early. There has been a very detailed discussion in research over the last decade and even before. Given the numbers of publications, this topic remains in the focus and is even getting more interest (see **Error! Reference source not found.**).

5.4.1 Drivers for PPS Adoption

These three meta trends are triggering a cascade of effects on actors in the market and their relationship. Technologies, broadly available in the future, will allow for new approaches to health care. Driven by customers demand and facilitated by auxiliary technologies, providers will have to consider PSS as potential business strategy.

Digitalisation facilitates the combination of products and services in this sector as in others as well. Being a driver on its own, it acts as a multiplier towards PSS as it forms the infrastructure to manage data and information derived from personalised medicine and genomic analysis, which again is a driver for PSS as it opens possibilities for new combinations of products and services.

Due to an aging population, the demand in services in health care will increase automatically.

5.4.2 Barriers for PPS Adoption

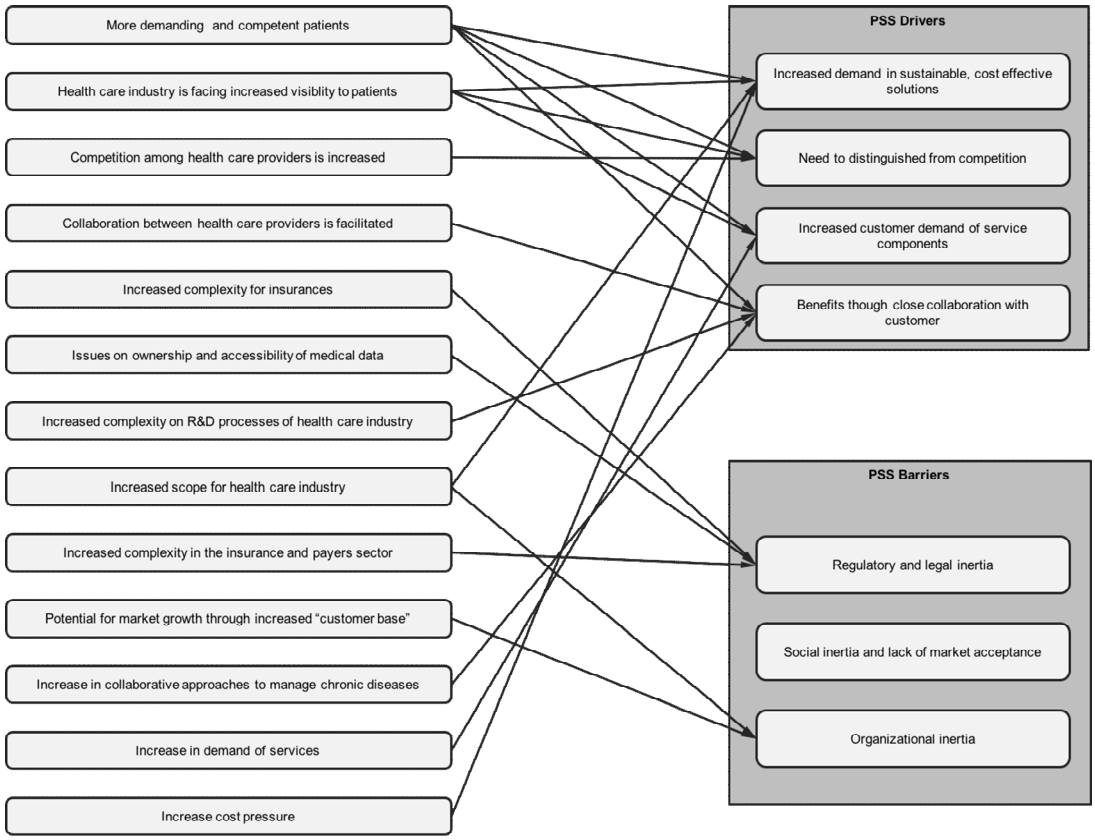
While all the mega trends in health care point towards PSS through many mechanisms, there are inherit barriers to PSS.

The major obstacle to adoption of PSS in health care however is the fact that this market is highly regulated and not based on a direct business relationship between customer (patient) and provider (e.g. physician), as payment is usually handled through a third entity like governmental or private insurance programs.

While technologically possible to exchange medical data more easily, allowing for collaborative approaches and new ways to combine services and products, the legal and regulatory framework for such models remains a significant issue.

Major legal and regulatory issues arise with technological advances. The setup of the legal and regulatory framework in an increasingly complex, globalised market is a challenging task for governments and regulatory authorities. Without such frameworks, players will tend to act conservatively. Such inertia can slow down the development and adoption of PSS.

Figure 5-5: Drivers and Barriers for PSS in Health Care



5.5 CONCLUSIONS

To evaluate the future usability and feasibility of PSS in the sector of interest, trends and changes in health care were identified and their impact on PSS was analysed.

Publically available market report data from consulting companies was used to conduct a content analysis in order to identify underlying trends causing changes in the market to adequately address the respective research objective. Impacts of trends and changes in health care on PSS design and implementation were analysed.

Product service systems in health care hold great potential to make the sector more cost efficient and provide sustainable solutions, however significant barriers to PSS adoption in this sector can be identified.

The future health care market generates more drivers towards PSS than many other sectors, however as it is one of the most complex ones, highly regulated and hard to globalise, the existence and design of a legal and regulatory framework clarifying the issues around PSS, will likely be a crucial factor to leverage PSS adoption in health care. For the purpose of educating authorities, a pragmatic approach would be to provide detailed examples of potential PSS implementations rather than discuss these issues on an abstract level. The potential of PSS needs to be outlined based on detailed case studies before analysing those case studies and draw general conclusions.

The analysis led to a detailed understanding of drivers and barriers of PSS adoption in health care and showed that PSS could even add more value to the market in the future. Health care is confronted with the challenge to reduce cost and increase value, while facing aging populations and increased cost for more sophisticated technology. Patients are demanding personalised medicine and are playing a more active and educated role in the process. Data becomes more readily available in the process which offers companies the opportunity to generate solutions beyond their current scope of diagnosis, therapy and recovery.

The understanding of drivers and barriers for PSS adoption in health care contributed to the development of the proposed design guideline.

6 EXISTING ADOPTION OF PSS ASPECTS IN HEALTH CARE

6.1 LITERATURE REVIEW

The health care market has been identified as a potential field of application for PSS early in PSS research (Mont 2002a) and continues to be a sector considered for PSS (Durugbo et al. 2010). Adeogun et al. discussed the potential of combining point-of-care products with services adding value for patient and operator (Adeogun et al. 2010). Services to be combined with such products are structured mainly around the information provided by the device. The authors highlighted the fact that many services ultimately will have to be provided by health care providers, so the relationship between those users and the product has to be studied in detail to utilise the full potential of on integrated PSS in this context.

Köbler et al. conducted an analysis of seven medical engineering companies in Germany (Köbler et al. 2009) and concluded that companies do not have the defined processes in place to develop a highly integrated PSS, however they also identified the increasing importance of information and communication technology is a driver towards adoption of PSS in health care.

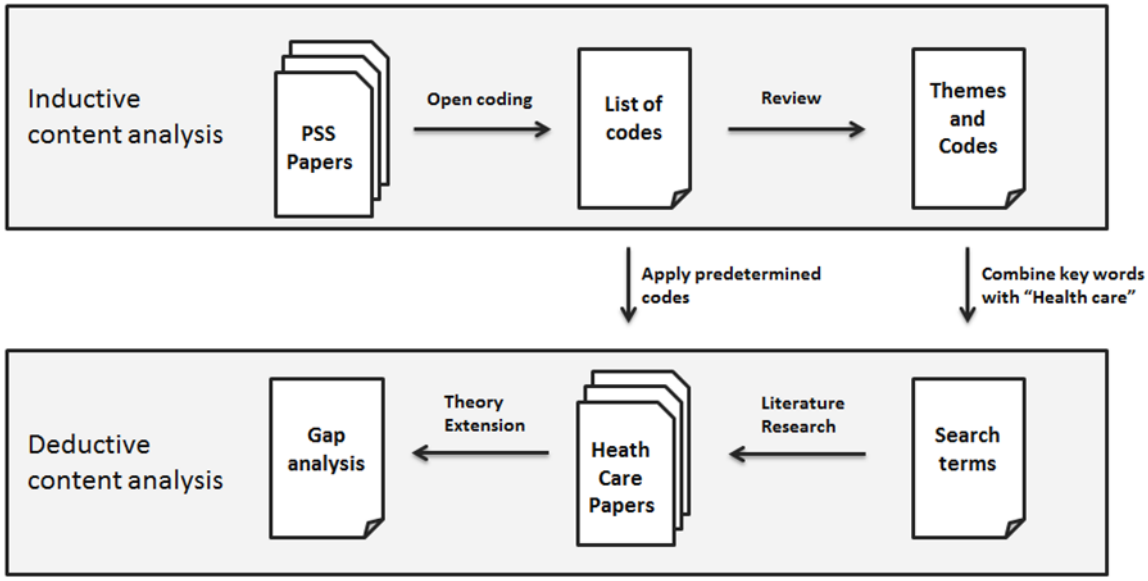
6.2 METHOD

Qualitative content analysis methods were used to bridge from PSS to different areas within health care and identify potential overlaps, gaps and partial adoption of PSS in health care, despite expected inconsistencies in terminology of those areas.

The hypothesis for this objective is that existing concepts, methods, business models and other tools used in the health care sector are aligned with PSS in regards to goals, features or requirements. Certain current or proposed implementations either reflect already partial implementations of PSS or can facilitate PSS adoption, but are missing the overarching concept view of PSS. In order to identify potential conceptual overlaps between aspects of PSS and other methods, concepts, models and tools in the field of health care, qualitative content analysis methods were applied to relevant literature

(Mayring 2000). Utilising methods for coding qualitative data was deemed necessary, as the foreseeable inconsistency of terminology between the different fields of interest for this particular research questions did not favour the use of more stringent search strategies. The analysis contained two major phases (see Figure 6-1**Error! Reference source not found.**).

Figure 6-1: Qualitative content analysis



The first part was an inductive content analysis (Elo & Kyngäs 2008) of scientific publications in the field of PSS. PSS publications included in the analysis had to meet the criteria of being cited over 100 times. This criterion reasonably ensured that major aspects and features of PSS were discussed and therefore would translate into a most complete list of codes generated from these publications.

Open coding was used to identify key statements in PSS publications describing goals, features as well as requirements and create an initial set of codes. Those non-hierarchical codes were revisited after completion of the initial analysis and a final set of codes was determined in the light of the research question for the following analysis.

Based on the approach for deductive content analysis (Mayring 2000), categories were mutually exclusively defined (Forman & Damschroder 2007). Key words from codes were used to generate an initial list of search terms, to be combined with "health care" for further research in the Web of Knowledge database. This list was extended by key

terms identified from initial review of abstracts, if the body of publications was considered to narrow. Reasonable limitations were applied to specific searches to identify most relevant publications. If possible, papers included in the analysis were limited to review articles and/or articles in the research area of “business economics”, by means of Web of Knowledge result refinement tools. Both initial limitations ensured that publications included in the abstract review did discuss the respective topics in a broader sense, i.e. not limited to specific solutions or discussing only technical issue and no economic impact of implementation. In cases, where the initial search returned less than 3 publications, the search was broadened by eliminating one or both restrictions mentioned above. In case this change in the search strategy did not lead to identification of more search hits, the limitation of searching “health care” and/or the respective search term in the title was extended to “topic” of the publication.

Abstracts of publications identified in the key term search were screened for relevance to the topic. To be included, the abstract of the publication had to indicate a generic discussion on the respective topic. Papers discussing tailored approaches and concepts in specific markets, indications or subspecialties were excluded to ensure focus on broadly available or discussed concepts. Publications meeting the criterion of a generic discussion were included and further analysed in the subsequent deductive content analysis to extend PSS concepts into heath care.

As result of the analysis, gaps and overlaps of PSS compared to concepts, methods, business models and other tools and technology used in the health care were identified and discussed.

6.3.1 Codes and Search Terms

To generate an initial list of codes, the two review papers on the topic of PSS with over 100 citations each were analysed. Eight codes were initially identified, which describe key features of PSS (Mont 2002b; Baines et al. 2007). A third review paper on PSS was included for verification purposes (Beuren et al. 2013). It did not fulfil the criterion of over 100 citations; however, this can be contributed to a more recent publication date:

Code	Example Statements in PSS
Dematerialisation:	
Any replacement, elimination or reduction of physical resources in a process.	A PSS system entails a product and a service component. The ratio of product versus service can vary. Service components can substitute products or product attributes, but can also add value along the value chain over the entire life cycle. A strategic approach to create a system solution, rather than only components with owns limitations is crucial for a successful implementation of PSS. PSS systems combine the trends of "servitisation" and "productisation". (Baines et al., 2007)
Value generation:	
Any definition or description of value and process to generate value	Product service systems focus on maximizing the value for the customer. Satisfying the customers actual needs is more important than the than selling a product. PSS manufacturers shift form a sales to a service orientation. Manufacturer networks have to cover the entire value chain
Sustainability:	
Any definition of sustainability, including resource, cost and environmental considerations.	Goal of PSS is to address the need to change current structures in production and consumption and reduce physical resources required to fulfill a customer's need.
Customer/Customisation:	
Any definition or description of the role of customers as well as description of design customer specific processes, products or services.	The focus of PSS is on the customer need, hence the exact mix of products and services can vary, but the result should be the same. This often is best achieved through customisation by adjusting flexible service components. The customer is involved actively in the design and improvement process of a PSS offering, over the entire life cycle.
Life cycle scope:	
Any definition or description defining the scope of an offering with regard to relevant time frames.	Manufacturers of PSS have to consider the entire life cycle of a product from design in collaboration with the end customer to the recycle and reuse concepts for products/components to be exchanged.
Product ownership:	
Any definition or description of models that separate use from ownership.	An important aspect of product service systems is that they promote ownerless use. For the customer, the desired result does not depend on ownership of the products required to achieve the result.

Continuous improvement:	
Any definition of description of models, processes and tools as well as requirements to implement continuous improvements.	PSS allows and requires continuous system improvements (design, quality, efficiency), as the relationship to the customer is very close. Customers should be involved in the design process and usage data and market feedback supports continuous improvement.
Network aspects:	
Any definition of description of internal and external networks and their requirements for any player in the market.	Beyond the product service combination, the systems include a supporting network and infrastructure. Close communication with customer and supplier. The entire network needs to work towards customer use, as one company may not achieve. Customer becomes designer and developer. Marketing become R&D. Cultural change within company and society

Table 6-1: Codes developed from PSS literature

6.3.2 Search strategy

The particular search strategy on all search terms is outlined in **Error! Reference source not found.**. Relevant search terms beyond the predefined codes were derived from key words in abstracts and additional internet research on the topics.

Error! Reference source not found. lists all papers included in the analysis, after abstract screening of all returned search hits as indicated in **Error! Reference source not found.**, including the title with highlighted key words.

Error! Reference source not found. gives an overview of the codes identified in the included papers.

"Dematerialisation" strongly correlated with e-health and electronic health records. In papers with other topics, dematerialisation was not identified as a code. As one would expect "Value Generation" was highly correlated with value-driven health care. The concepts of "Sustainability", "Customisation" and "Network" were prevalent across all publication topics. "Product Ownership Concept", as one of the key elements of PSS, was not discussed in any of the reviewed publications.

Table 6-2: Search Strategy

Search terms	"health care"	Search term	Restricted to reviews	Restricted to business economics	Search hits	Included publications
Dematerialization	Topic	Title	No	No	2	0*
Digitalization	Title	Topic	No	No	4	0*
Electronic Health Record OR Personal Health Record OR Electronic Patient Record	Title	Title	Yes	No	17	3
E-Health	Title	Title	Yes	No	4	3
Telemedicine	Title	Title	Yes	No	15	0
Value Generation						
Value based	Topic	Title	Yes	Yes	24	4
Pay for performance	Title	Title	Yes	Yes	8	
Sustainability	Title	Title	No	Yes	18	4
Customer/customization						
Consumer centric OR consumer centered	Title	Title	No	No	5	1
Patient centric	Topic	Title	No	No	26	2
Life cycle scope						
Disease management	Topic	Title	Yes	Yes	31	3
Product ownership concept						
Product ownership	Topic	Topic	No	No	3	0
Capital investment	Topic	Topic	No	No	72	0
Capital equipment	Topic	Topic	No	No	2	0
Leasing	Topic	Topic	No	No	72	0
Continuous improvement	Topic	Title	No	Yes	7	2
Network aspects						
Actors	Topic	Title	No	Yes	8	1

Included Publications	Title
(Pfeiffer & Auer 2009)	Challenges in the implementation of **electronic health care records** and patient cards in Austria
(Geissbuhler 2012)	**eHealth**: easing translation in health care.
(Black et al. 2011)	The Impact of **eHealth** on the Quality and Safety of Health Care: A Systematic Overview
(Uslu & Stausberg 2008)	Value of the **electronic patient record**: An analysis of the literature
(Colás et al. 2010)	Innovation in health care technology: is it part of the problem or part of the solution? **eHealth** gives the answer.
(Greenhalgh et al. 2009)	Tensions and Paradoxes in **Electronic Patient Record** Research: A Systematic Literature Review Using the Meta-Narrative Method
(Brown et al. 2003)	Health care economic analyses and **value-based medicine**
(Fink 2008)	**Value-driven health care**: Proceed with caution
(Hanley et al. 2003)	Estimating the monetary **value of health care**: lessons from environmental economics
(Porter 2008)	**Value-Based Health Care** Delivery
(Lega et al. 2013)	Is Management Essential to Improving the Performance and **Sustainability of Health Care** Systems and Organizations? A Systematic Review and a Roadmap for Future Studies
(Chernew & Sabik 2010)	Ensuring the **Fiscal Sustainability** of Health Care Reform
(Pammolli et al. 2012)	The **sustainability** of European health care systems: beyond income and aging
(Sibthorpe et al. 2005)	Emergent themes in the **sustainability** of primary health care innovation
(Bhandari & Snowdon 2012)	Design of a **patient-centric**, service-oriented health care navigation system for a local health integration network
(Abbasi et al. 2012)	Socioeconomic analysis of **patient-centric** networks: effects of patients and hospitals' characteristics and network structure on hospitalization costs
(Clugston 1997)	**Customer-centered** strategic diversification: specialty health care provider moves towards primary care.
(Coons 1996)	**Disease management**: Definitions and exploration of issues
(de Bruin et al. 2011)	**Pay-for-performance** in **disease management**: a systematic review of the literature
(Ziegler 1998)	**Disease management** - Mere fashion or potential solution?
(Swinehart & Green 1995)	**Continuous improvement** and TQM in health care: an emerging operational paradigm becomes a strategic imperative.
(Jackson 1999)	Achieving a culture of **continuous improvement** by adopting the principles of self-assessment and business excellence.
(Kaplan & Babad 2011)	Balancing influence between **actors in healthcare** decision making

Table 6-3: Included Publications

Table 6-4: Codes

Included Publications	Topic	Dematerialization	Value Generation	Sustainability	Customer/ Customization	Life cycle scope	Product ownership concept	Continuous improvement	Network
(Pfeiffer and Auer, 2009)	electronic health records	X		X	X			X	X
(Geissbuhler, 2012)	eHealth	X		X	X			X	X
(Black et al., 2011)	eHealth	X			X	X			
(Uslu and Stausberg, 2008)	Electronic patient record	X						X	
(Colas et al., 2010)	eHealth	X							
(Greenhalgh et al., 2009)	Electronic Patient Record	X			X			X	X
(Brown et al., 2003)	value-based medicine		X						
(Fink, 2008)	Value-driven health care		X	X					
(Hanley et al., 2003)	Value-driven health care		X						
(Porter, 2008)	Value-Based Health Care		X	X		X		X	X
(Lega et al., 2013)	Sustainability of Health Care		X	X		X			X
(Chernew et al., 2010)	Fiscal Sustainability of Health Care		X	X					
(Pammolli et al., 2012)	sustainability			X					
(Sibthorpe et al., 2005)	sustainability			X					X
(Bhandari and Snowdon, 2012)	patient-centric care	X							X
(Abbasi et al., 2012)	patient-centric networks			X	X				X
(Clugston, 1997)	Customer-centered diversification								
(Coons, 1996)	Disease management		X	X		X		X	X
(de Bruin et al., 2011)	Disease management, P4P			X		X		X	X
(Swinehart and Green, 1995)	Continuous improvement			X				X	X
(Jackson, 1999)	continuous improvement							X	X
(Kaplan and Babad, 2011)	actors in healthcare			X	X				X

6.3.3 Terminology of PSS Aspects

6.3.3.1 Dematerialisation

Only very few examples for replacement of products by means of services were identified. The most important field for dematerialisation is the digitalisation of patient data. Transforming paper based processes into digital information flows allows streamlining of processes, effective data analysis, and quality improvement (Uslu & Stausberg 2008).

Colas et al. describe an example for combinations of products, such as implantable devices and services, for example, remote follow up by means of telemedicine. Applying communication and information technology can reduce scheduled as well as unscheduled visits or follow-ups in clinic. This optimises utilisation of physical resources in health care (Colás et al. 2010)

6.3.3.2 Value Generation

A focus on value was developed not before the mid-1990s, while in the 1990s the focus was on regulating the output, like services provided. In the 1980s, the focus was on the resource side, controlling the input for health care, such as personnel, financial resources or technology. Both output and input regulations have proven to sub-optimally allocate resources in health care (Lega et al. 2013). Value in health care can be defined as outcome relative to cost spend, however this is not necessarily transparent to the actors in the market. Managers in health care have to face these inconsistent and conflicting expectations and goals (Lega et al. 2013). This lack of transparency is caused by the lack of measurement tools for outcome value, which can be very complex due the multifactorial, patient specific risk profiles. Brown et al. summarised several approaches to that problem (Brown et al. 2003). Similar issues in environmental economics led to research to translate methods to determine value of goods that are not monetarily priced, into the heath care sector (Hanley et al. 2003). According to Porter, “value” should represent the overarching goal to align very diverse stakeholders with otherwise conflicting goals in the market (Porter 2008).

6.3.3.3 Sustainability

In health care, sustainability is very much focused on cost, not resource or ecological aspects. However, the goal to develop sustainable health care systems is the main motivation for introducing new methods, approaches and tools. Pammolli et al. investigated main cost factors in health care to identify areas of policy interventions to ensure sustainability of the system (Pammolli et al. 2012). Generally, sustainability is considered in the context of entire health care systems. Lega et al. define sustainability as "maintaining quality and service coverage at affordable cost" (Lega et al. 2013). The sustainability of health care systems is threatened, as more sophisticated diagnostic and therapeutic technology and methods, demographic changes and more complex stakeholder networks are dominant cost drivers (Geissbuhler 2012). Sustainability is also an important consideration in strategic health care management. Pfeiffer and Auer point out that implementation of tools like electronic health records may not generate a positive return on investment within 3-5 years, However the opportunity to minimise mistakes and avoid medical complications addresses the cost issues, which ultimately is required to achieve sustainable health care systems (Pfeiffer & Auer 2009).

Sustainability is strongly linked to cultural and social aspects as well as networks. Sibthorpe et al. looked at 6 domains of sustainability (political, institutional, financial, economic, client and workforce) to show that sustainably strongly depends on relationships, social and political forces as well as the individual motivation and capacity of actors in the network (Sibthorpe et al. 2005).

6.3.3.4 Customer and customisation

The changing role of patients and the requirements to build patient-centric health care around patients are broadly discussed in the literature. Patients are more informed and can even interact remotely through interactive communication technologies. eHealth can provide continuous medical care, including patient self-management, increasing system efficacy and efficiency (Colás et al. 2010). This has an impact on relationships between provider and patients. It shifts responsibilities towards patients and their families (Geissbuhler 2012). A shift of focus towards the patient also allows to redesign processes in health care to become more patient owned and patient controlled, however consumer oriented health care requires further personalisation of services (Geissbuhler 2012). Such a patient centric approach is in particular required for the management of

chronic diseases (de Bruin et al. 2011). The fragmented structure of healthcare systems causes inefficiencies and quality issues, which can be addressed by means of information technology and patient centered digital documentation (Geissbuhler 2012). Social network analysis applied to map and measure relationships in health care, with a focus on patient and physician, showed the potential of patient-centered healthcare (Abbasi et al. 2012). For example, electronic health records do collect data focused on the patient, but independently from the different institutions where the patient may be treated, which puts the patient in a more actively involved position (Pfeiffer & Auer 2009). Longitudinal data collections across providers, care settings and time can lead to higher quality at lower cost. However currently not enough effort and time is dedicated to customise processes and systems (Black et al. 2011). If such longitudinal data collection includes tracking of cost, the actual patient value can be determined (Porter 2010). A major challenge for digital, patient-centric systems is the embedment in very dynamic and inherently unstable environments (Greenhalgh et al. 2009) and the risk that care may become less personal (Geissbuhler 2012), and the human side becomes more in the background (Greenhalgh et al. 2009).

6.3.3.5 Life cycle scope

Looking at the entire "life cycle" or in-health care "care cycle" or "course of disease" is a relatively new focus in literature. However, since the mid-1990s, disease management was already proposed as an integrated system approach with the aim to treat patients optimally over the entire course of their disease. This approach focused on diseases that allowed for straight-forward outcome measurements, several treatment options, high treatment cost, and potentially rapid return on invest (Coons 1996). Considering the entire course of diseases is increasingly relevant, as chronic diseases are becoming a major burden in health care systems due to aging populations. Chronic diseases are a particular challenge for health care systems as usually the system is fragmented, usually built to react on diseases, rather than proactively manage them. Pay-for-performance models have been implemented by several policy makers to stimulate disease management of chronic diseases. Those models, however, are still lacking evidence for gains in cost effectiveness and quality improvement (de Bruin et al. 2011). With increased implementation of digital systems and availability of data

mining tools, patient data can be efficiently organised for secondary use (Black et al. 2011).

6.3.3.6 Product Ownership

The concept of separating the use of a product from ownership is not discussed in research in a focused way. While several papers were found in the initial search for key words, no relevant paper was identified after screening of abstracts.

6.3.3.7 Continuous Improvements

Missing or wrong information becomes a problem with multidisciplinary teams and fragmented structures in health care. A proactive approach to collaborative care can help optimising quality and decrease cost (Pfeiffer & Auer 2009). The implementation of continuous improvement methods is strategically imperative for health care providers (Swinehart & Green 1995). However, to successfully adopt methods for continuous improvement, a change in an organisation's culture is required (Jackson 1999). Swinehart and Green investigated the potential of transferring total quality management approaches and methods into the health care sector, including principles of continuous improvements (Swinehart & Green 1995). Disease management systems do include feeding back information regarding the treatment outcome into the system to generate an improved database for future treatment guidelines and recommendations (Ziegler 1998). To continuously improve processes, assessment methods have to be consistent and feedback loops into development are crucial to "mature" an offering in complex clinical settings (Black et al. 2011). "Hidden work" generated through people using workarounds to operate a system needs to eliminated through such feedback (Greenhalgh et al. 2009). Continuous improvements, however, consider patient value, rather than only processes (Porter 2010).

6.3.3.8 Network aspects

Increasingly complex health care systems move network aspects into the focus of research. Information technologies enable collaborative care. However, the complexity leads to many interfaces in the care process that can generate quality and safety issues. Consistency and continuity are extremely important, as many stakeholders are

connected and increasingly interact (Geissbuhler 2012). Health care systems face the challenge to coordinate care for patients with chronic diseases, as several providers are involved over the course of disease. In such settings, the value for a patient is often determined by joint efforts by several different entities and providers (Porter 2010).

Another important aspect for functional networks is the sociocultural side. To increase patient acceptance it is crucial to inform patient about advantages through approaches and tools like EHRs (Pfeiffer & Auer 2009). Black et al. point out that sociotechnical factors are not considered enough in the implementation of patient information systems (Black et al. 2011). Outcomes must be public, to enable competition and improvement on outcome value (Porter 2010). Also on a single company or supplier network level, acceptance of new approaches is crucial. Improved management of health care is not sufficient, if cultural changes (e.g. with training) are not implemented (Lega et al. 2013). Swinehart and Green propose a "co-worker" view in health care supplier/customer relationships (Swinehart & Green 1995).

6.4 DISCUSSION

6.4.1 Dematerialisation

Based on the analysis presented above, dematerialisation is not a focus within health care. However, dematerialisation in many cases can be replaced by digitalisation. If it is a result of technological advances, such as digitalization, especially of patient health information, dematerialisation plays a role in health care. Dematerialisation towards service components may often be cost prohibitive and faces the challenge of unclear regulatory pathways in a very regulated market.

6.4.2 Value Generation

Value generation increasingly is discussed in research as in important concept towards sustainable health care and finds its way into practice, facing, however, practical challenges. The value of a diagnosis, treatment or invention is hard to measure objectively. This is most likely because value in health care is harder to measure and

may not be apparent immediately, while compensation for products and services is expected to occur shortly after provision in other industries. The value associated with an increase in quality of life may for example be generated with a significant delay after an intervention and may highly depend on expectations and circumstances of the patient.

6.4.3 Sustainability

The term sustainability is mostly used in the context of financial sustainability of a health care system or parts of it, but not necessarily related to sustainability from a patient's point of view, which would have a very different perspective.

The analysis of codes identified in publications, versus topics of such papers, showed a very high correlation between "sustainability" and "network" across most of the topics (see **Error! Reference source not found.**). Papers talking about sustainability also discussed network aspects in most cases. The reason for this may be that improving the network for stakeholders is often seen as congruent with increasing the efficacy, and hence the financial sustainability of a health care system. The code "sustainability" appeared to be discussed mostly disconnected from "dematerialisation" and "customisation", which indicated a very weak connection of basic concepts of PSS with one of its main goals sustainability.

6.4.4 Customer and Customisation

In health care, there is a clear move towards patient-centric health care. While a patient-centric concept for the most part can be equated with a customer-centric concept in other industries, the role of a "patient" can be different to a "customer" with regard to responsibilities of this role. A user centric system based on PSS typically has the goal to minimise the responsibility for the customer, by having the provider take care of certain responsibilities associated, for example, with product ownership. In the health care sector, focus on the end user may mean focus on the patient, which typically means that the patient has more involvement and responsibility about health-related decisions. This requires patients to be prepared for this new role by being educated and provided with the required infrastructure, providing for example accessibility to relevant data.

6.4.5 Life cycle scope

Life cycle is not a well-defined terminology in health care. It can be related to terms like “care cycle” or “course of disease”, however, the definitions of those terms are not consistent and vary depending on the context. The concept is often associated with sustainability and with value generation as means to define the time period considered for assessing long term benefits or patient value.

6.4.6 Product Ownership

There was no paper found in this analysis discussing “Product ownership concepts” as proposed as an integral part of PSS in other industries, which led to the conclusion that PSS as a concept is not established as a framework in health care.

6.4.7 Continuous Improvements

The code “continuous improvement” was also strongly linked to the “sustainability” and “network” codes, but not in publications with the topics around sustainability and patient-centric care or networks, which seems contra-intuitive. Continuous improvement is a goal in health care well aligned with potential benefits of PSS.

6.4.8 Network aspects

Network aspects have been discussed in many different contexts within health care. As networks are considered to be a prerequisite for well-functioning PSS, those enhanced networks may serve as required infrastructure to implement PSS in health care.

6.5 CONCLUSIONS

While PSS adoption in health care is considered low, there was no data available on the adoption of certain aspects of PSS in this market. The adoption of PSS in health care was analysed by inductive and deductive content analysis of literature to provide an objective analysis of adoption.

The analysis showed that single aspects of PSS are implemented in solutions offered by health care companies, however there is no systematic approach for PSS design and implementation. The results discussed on existing adoption of PSS confirm that PSS can address needs in the market and can be applied in practise, however there is a certain resistance to utilise the full potential of PSS by applying it as a concept, which can be explained with the barriers identified and the fact that there is no tailored PSS design method available.

The hypothesis evaluated in this objective was that certain aspects of PSS actually are implemented within the health care sector, but the degree of adoption is obscured by the inconsistency of terminologies used to describe PSS and health care. To a certain degree this was confirmed by the analysis of this work.

The analysis showed that adopted concepts, methods, business models and other tools used in the health care sector are partly aligned with PSS characteristics and goals. However, those adopted concepts are not necessarily integrated with each other, and, within health care, PSS is not established as a framework to link those concepts. Rather than proactively adopting an overarching approach like PSS, implementations of certain isolated concepts can be found, sometimes driven by technological advances, such as availability of digital patient data and data connectivity.

The health care market includes several stakeholders that define value from their own perspective and are driven by incentives set by the system they operate in, rather than optimising the system itself towards an overall increase of value. This may be one reason for the lack of integration between separate efforts to increase efficacy and decrease costs in the system.

Another system-related reason might be the fact that the health care sector is highly regulated, which causes inertia for system-wide changes. Concepts like

dematerialisation or product ownership may not fit into regulatory pathways available to players in the sector, so adoption of those concepts may not be feasible.

The concepts identified in the analysis also have to be interpreted in the light of their meaning in PSS, which may be different from their conceptual meaning in health care. Value generation, sustainability and life cycle scope may have a clear definition in PSS, but within the health care context, those terms are less well defined, which hinders adoption.

In addition, the lack of objective measurement may be a reason for reluctant adoption of PSS in this sector. While in consumer markets, value, life cycle und sustainability can be defined fairly clearly, this can pose a challenge in the context of healthcare.

In the case of customisation, this analysis identified a significant difference in how this concept would affect the market. Rather than taking away responsibility from a user, it increases the responsibility of a patient in the context of health care. While in many instances this may simplify relationships in a consumer market, it poses new requirements on patients and patient education in the health care sector. Those requirements can affect the required infrastructure in the system, leading to higher degree of necessary system changes compared to consumer markets. While this may slow down the initial adoption of PSS, there is also potential to incorporate the provision of the required infrastructure and patient education in PSS offerings.

The PSS aspect of “network aspects” typically describe the infrastructure needs for PSS implementation, while “continuous improvement” is a likely result of a successfully implemented PSS. The fact that those aspects are discussed in health care shows that PSS could be implemented on existing foundation of existing networks and long term goals would be aligned as well.

To stimulate adoption of PSS in healthcare, however, the definitions and goals have to be adjusted for the health care market, in order to describe a system that can be successfully implemented.

Results of the analysis contributed to the development of the proposed design method as the identified aspects of PSS were used as a guideline for PSS ideation.

7 ASSESSMENT OF CLINICAL UTILITY OF PSS

7.1 LITERATURE REVIEW

The ability of a company to identify their customers' needs and translate those into innovative product or service offerings determines the success of such an enterprise (Chong & Chen 2010). Concepts like quality function deployment (QFD) have been developed to address the issue of translating customers' requirements into product specifications (Mallon & Mulligan 1993). However, the output quality of such methods highly depends on the quality of the input data and hence the identification of users' needs (Verworn et al. 2008). While this is valid for any market, companies active in the health-care market are likely to face challenges in identifying customers' needs, as the market features a complex network of actors, and some of their actions are impinged upon by a high degree of market regulation.

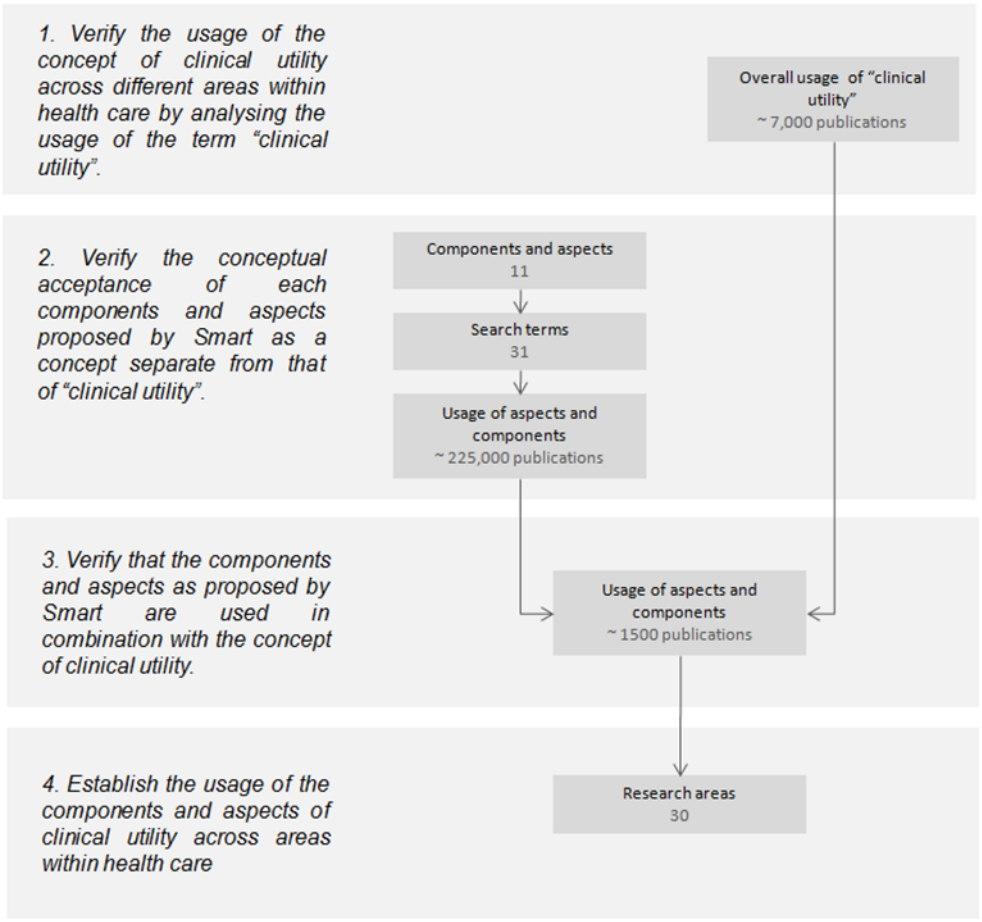
The term "clinical utility" is becoming a frequently used term to describe the wide range of aspects that determine the usefulness of medical approaches. This is despite the lack of a formal definition of the term (Lesko et al. 2010). It has been proposed that "clinical utility" possesses several dimensions which describe the usefulness of medical innovations (Smart 2006). These dimensions are appropriateness, accessibility, practicability and acceptance.

7.2 METHOD

Evaluating the potential utility of offerings such as PSS, can be challenging for companies in the health care sector as there is no simple, direct and exclusive relationship between a company and a customer. The market distinguishes itself from other markets by a rather complex stakeholder structure and a decoupling of receiver of a product or a service and payer of such service. Many different aspects need to be taken into account to fully assess the usefulness of an offering. Smart developed a multi-dimensional view on clinical utility, which was adopted for the assessment of PSS offerings in health care (Smart 2006).

To verify the hypothesis that the multiple dimensions of clinical utility form an appropriate framework for customer requirement definition in one or more areas of medical innovation, where appropriate, the guidelines set forth in the PRISMA statement were used (Liberati et al. 2009). A small number of steps in the process, purely related to statistical analysis of medical data were not performed, as such data were not the focus of the review. No language, or status restrictions were imposed. Publications between 2001 and 2011 were included in the search. Studies were identified by searching the US National Library of Medicine (PubMed) and the Web of Science (WoS) citation index (Thomas Reuters).

Figure 7-1: Methodology for systematic review



Error! Reference source not found.gives an overview over the four-stage search methodology implemented to verify the hypothesis:

1. Verify the usage of the concept of clinical utility across different areas within health care by analysing the usage of the term “clinical utility”.

In both databases, the search term “clinical utility” was used to identify the total number of publications related to the search term. The databases offer different tools for data analysis. To be able to use both databases for further analysis, the number of publications from 2001-2011 were compared against each other by year to validate consistency between both sources.

The WoS database allows classifying results according to research areas. Such classification was used to identifying the top ten research areas the respective search term is used in.

2. Verify the conceptual acceptance of each components and aspects proposed by Smart as a concept separate from that of “clinical utility”.

To determine applicable search terms for this 2nd stage of the methodology, the components and aspects of clinical utility as defined by Smart were used as a starting point. Synonyms for such terms as provided by the thesaurus of Microsoft Word 2010 (language English, US) were combined with the term “clinical” or “clinically” where applicable. Synonyms were excluded from further search, if one of five predefined exclusion criteria applied. Those five exclusion criteria are listed in Table 7-1 below:

Exclusion criteria	Example
Term is not applicable in the clinical context	Source term: accessible Synonym: near by
Term has a too broad meaning in the clinical context	Source term: knowledge Synonym: (“clinical”) data
Term has a different meaning in the clinical context	Source term: training Synonym: (“clinical”) education
Term is redundant, because included of other aspects listed	Source term: functional Synonym: efficient
The term is an antonym.	Source term: practicable Antonym: impossible

Table 7-1: Exclusion criteria for terms used in subsequent research

Additional terms related to components and aspects of clinical utility and also cited and used by Smart were included if applicable, like “clinical decision making”.

3. Verify that the components and aspects as proposed by Smart are used in combination with the concept of clinical utility.

Publications were identified containing at least one of the defined search terms in combination with the term “clinical utility”, for the entire publication in Pubmed, and as publication topic in the WoS database respectively.

4. Establish the usage of the components and aspects of clinical utility across areas within health care.

The areas within health care were taken from the research areas as predefined in the WoS database. The WoS database allows analysing the data with regard to the research areas the search results are related to. This tool has been used to analyse the usage of dimensions proposed by Smart in combination with “clinical utility”. For each search term that returned more than 20 results in the previous search the top ten research areas were considered in the analysis. As a threshold, a minimum of two publications was defined to be included in a top ten list of research areas.

7.3 RESULTS

The concept of clinical utility as an assessment model for PSS was verified in four steps described in the section before:

7.3.1 Usage of the Term Clinical Utility

In the first stage, the acceptance of the concept of clinical utility across different areas within health care was analysed. The search term "clinical utility" returned in the broadest possible search setting for each database, 7,099 publications, containing the term "clinical utility" in Pubmed and 7,631 publications in the WoS database considering "clinical utility" as a topic of the respective publication.

Figure 7-2**Error! Reference source not found.** shows the number of publications from 2001-2011 which either contained the term clinical utility in the "all fields" search (Pubmed) or the "topic" search (WoS).

Figure 7-2: Number of publications from 2001-2011 related to clinical utility

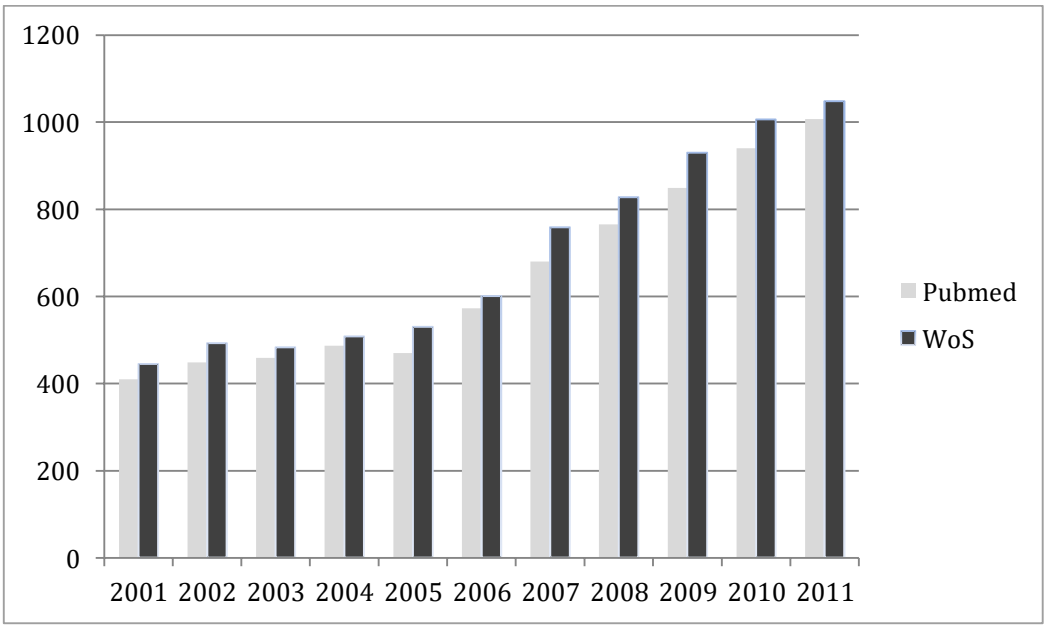


Table 7-2**Error! Reference source not found.** shows the distribution of publications returned in the WoS database search by research area, only considering the top ten areas based on the number of publications.

Research Areas of Clinical Utility	Number of Publications in WoS
ONCOLOGY	851
NEUROSCIENCES NEUROLOGY	756
CARDIOVASCULAR SYSTEM CARDIOLOGY	618
PHARMACOLOGY PHARMACY	604
PSYCHOLOGY	582
RADIOLOGY NUCLEAR MEDICINE MEDICAL IMAGING	428
PSYCHIATRY	424
GENERAL INTERNAL MEDICINE	412
SURGERY	395
GASTROENTEROLOGY HEPATOLOGY	344

Table 7-2: Top 10 research areas of publications with "clinical utility" as topic of paper (WoS database)

7.3.2 Acceptance of the Term Clinical Utility

For the subsequent search, search terms have been defined, as outlined in **Error! Reference source not found.**, by following the methodology, section 2, with the source terms taken from Smart (Smart 2006). At the base of the table the footnotes indicate the exclusion parameters for search terms, as detailed in the methodology.

To take the example of “appropriate”, this can be directly transformed into the search terms of “clinically appropriate” and “clinical appropriateness”. “Clinical suitability” is a search term, because it’s a synonym of “appropriate” and none of the exclusion criteria apply. However, “fitting” is excluded as a search term because it is not applicable within a clinical context. 32 search terms are obtained by that method (see Table 7-3)

Component	Aspect	Synonyms & Antonyms	Search term
appropriate			Clinically appropriate OR clinical appropriateness
		suitable	clinically suitable - N/A [4]
		fitting	N/A [1]
		apt	N/A [1]
		proper	N/A [1]
		apposite	N/A [1]
		right	N/A [1]
		correct	N/A [1]
		inappropriate (antonym)	N/A [5]
			Clinical evidence [6]
			Clinical impact [6]
			Clinical decision making [6]
			Clinically meaningful [6]
	effective		Clinically effective OR clinical effectiveness
		effectual	N/A [1]
		efficient	Clinically efficient OR clinical efficiency
		successful	Clinically successful OR clinical success
		useful	N/A [4]
		helpful	N/A [1]
		of use	N/A [1]
		valuable	Clinically valuable OR clinical value
	relevant		Clinically relevant OR clinical relevance
		pertinent	N/A [1]
		applicable	Clinically applicable
		germane	N/A [1]
		related	N/A [2]
		appropriate	clinically appropriates - N/A (4)
		significant	Clinically significant OR clinical significance
		importance	Clinically important OR clinical importance
		unrelated (antonym)	N/A [5]

accessible			Clinical accessibility
		easy to get to	User friendliness [6], ease of use [6]
		nearby	N/A [1]
		available	Clinically available OR clinical availability
		reachable	N/A [1]
		easily reached	N/A [1]
		handy	N/A [1]
		to hand	N/A [1]
		within reach	N/A [1]
			Cost efficiency OR cost effectiveness [6]
	Resource implication	supply	N/A [1]
		source	N/A [1]
		store	N/A [1]

practicable			Clinically practicable OR clinical practice
		feasible	Clinically feasible OR clinical feasibility
		realistic	N/A [1]
		possible	N/A [1]
		workable	N/A [1]
		practical	N/A [1]
		viable	N/A [3]
		doable	N/A [1]
		impossible (antonym)	
	functional		Clinical functionality
		useful	Clinically useful OR clinical usefulness
		practical	N/A [4]
		handy	N/A [1]
		purposeful	N/A [1]
		efficient	N/A [4]
		well designed	ease of use [6]
		serviceable	N/A [1]

	worthless (antonym)	N/A [5]
suitable		Clinically suitable
	appropriate	N/A [4]
	apposite	N/A [1]
	fitting	N/A [1]
	fit	N/A [1]
	apt	N/A [1]
	inappropriate (antonym)	N/A [5]
	proper	N/A [1]
	right	N/A [2]
Training		Clinical training
	Preparation	Clinical preparation
	Teaching	N/A [2]
	Guidance	Clinical guidance
	Education	N/A [3]
	Schooling	N/A [1]
	Instruction	N/A [2]
	Exercise	N/A [1]
	Working out	N/A [1]
Knowledge		Clinical knowledge
	Information	Clinical information
	Facts	N/A [2]
	Data	N/A [2]
	Acquaintance	N/A [1]
	Familiarity	N/A [1]
	Awareness	Clinical awareness
	Understanding	Clinical understanding
	Comprehension	N/A [1]
acceptable		Clinically acceptable OR clinical acceptance

satisfactory	N/A [1]
suitable	N/A [4]
good enough	N/A [1]
adequate	Clinically adequate
up to standard	N/A [1]
tolerable	N/A [1]
okay	N/A [1]
all right	N/A [1]

Notes:

[1] Excluded from search, as the term is not applicable in the clinical context

[2] Excluded from search, as the term has a too broad meaning in the clinical context

[3] Excluded from search, as the term has different meaning in this field

[4] Excluded from search, as the term is included in other aspects

[5] Excluded from search, as the term is an antonym

[6] Source: Smart (Smart, 2006)

Table 7-3: Search terms

Error! Reference source not found. Table 7-4 shows the number of publications returned for each search term as listed in Table 7-3**Error! Reference source not found.**.

Component	Aspect	Synonyms & Antonyms	Search term	Pubmed	WoS
appropriate			"Clinically appropriate" OR "clinical appropriateness"	321	281
			"Clinical evidence"	9802	7214
			"Clinical impact"	3978	4292
			"Clinical decision making"	4476	4187
			"Clinically meaningful"	2839	2656
	effective		"Clinically effective" OR "clinical effectiveness"	5302	4519
		efficient	"Clinically efficient" OR "clinical efficiency"	2307	337
		successful	"Clinically successful" OR "clinical success"	6914	2836
		valuable	"Clinically valuable" OR "clinical value"	4601	3993
	relevant		"Clinically relevant" OR "clinical relevance"	39282	38771
		applicable	"Clinically applicable"	995	956
		significant	"Clinically significant" OR "clinical significance"	32515	33289
		importance	"Clinically important" OR "clinical importance"	12447	11658
accessible			"Clinical accessibility"	11	13
		easy to get to	"User friendliness" OR "ease of use"	3204	6067
		available	"Clinically available" OR "clinical availability"	1018	936
	Resource implication		"Cost efficiency" OR "cost effectiveness"	19141	33893
practicable			"Clinically practicable" OR "clinical practice"	56408	53744
		feasible	"Clinically feasible" OR "clinical feasibility"	1122	1118
	functional		"Clinical functionality"	17	18
		useful	"Clinically useful" OR "clinical usefulness"	8115	7529
	suitable		"Clinically suitable"	57	46

	Training		"Clinical training"	983	847
		Preparation	"Clinical preparation"	35	32
		Guidance	"Clinical guidance"	185	149
	Knowledge		"Clinical knowledge"	769	647
		Information	"Clinical information"	6012	5331
		Awareness	"Clinical awareness"	278	222
		Understanding	"Clinical understanding"	192	171
acceptable			"Clinically acceptable" OR "clinical acceptance"	1497	1388
		adequate	"Clinically adequate"	0	52
			TOTAL	**224823**	**227192**

Table 7-4: Number of publications by search term

7.3.3 Usage of Dimensions of Clinical Utility

The Pubmed search for publications containing "clinical utility" and a respective search term returned results as outlined in Table 7-5**Error! Reference source not found.**. A comparable search in the WoS databases was conducted identifying publications that have two topics, "clinical utility" and the respective search term.

Component	Aspect	Synonyms & Antonyms	Search term	Pubmed	WoS
appropriate			"Clinically appropriate" OR "clinical appropriateness"	2	1
			"Clinical evidence"	32	34
			"Clinical impact"	34	33
			"Clinical decision making"	63	64
			"Clinically meaningful"	36	35
	effective		"Clinically effective" OR "clinical effectiveness"	30	31
		efficient	"Clinically efficient" OR "clinical efficiency"	12	3
		successful	"Clinically successful" OR "clinical success"	34	12
		valuable	"Clinically valuable" OR "clinical value"	72	73
	relevant		"Clinically relevant" OR "clinical relevance"	194	191
		applicable	"Clinically applicable"	7	5
		significant	"Clinically significant" OR "clinical significance"	151	163
		importance	"Clinically important" OR "clinical importance"	56	53
accessible			"Clinical accessibility"	0	0
		easy to get to	"User friendliness" OR "ease of use"	25	27
		available	"Clinically available" OR "clinical availability"	10	10
	Resource implication		"Cost efficiency" OR "cost effectiveness"	85	105
practicable			"Clinically practicable" OR "clinical practice"	375	356
		feasible	"Clinically feasible" OR "clinical feasibility"	16	17
	functional		"Clinical functionality"	1	1
		useful	"Clinically useful" OR "clinical usefulness"	218	215
	suitable		"Clinically suitable"	0	0
	Training		"Clinical training"	1	1

		Preparation	"Clinical preparation"	0	0
		Guidance	"Clinical guidance"	1	1
	Knowledge		"Clinical knowledge"	0	0
		Information	"Clinical information"	36	30
		Awareness	"Clinical awareness"	0	0
		Understanding	"Clinical understanding"	1	1
acceptable			"Clinically acceptable" OR "clinical acceptance"	8	9
		adequate	"Clinically adequate"	0	0
			TOTAL	**1500**	**1471**

Table 7-5: Number of publications by search term combined with the term "clinical utility"

7.3.4 Usage of Clinical Utility across Areas of Health Care

Out of the 30 search terms, 14 returned more than 20 hits in the WoS search shown in Table 7-6**Error! Reference source not found.**.

Research areas are ordered by the absolute number of publications in the top ten across all search terms, starting with the highest number.

As shown in Table 7-6**Error! Reference source not found.**, those 14 search terms were found in 30 different predefined WoS research areas. Out of those 30 research areas, 22 research areas appeared in the top ten list of multiple search terms. None of the research areas was listed in every search, however 6 research areas appeared 10 or more times in a search.

Component	Aspect	Synonyms & Antonyms	Search term	ONCOLOGY	PHARMACOLOGY PHARMACY	NEUROSCIENCES NEUROLOGY	CARDIOVASCULAR SYSTEM CARDIOLOGY	PSYCHIATRY	PSYCHOLOGY	GENERAL INTERNAL MEDICINE	RADIOLOGY NUCLEAR MEDICINE MEDICAL IMAGING	SURGERY	GASTROENTEROLOGY HEPATOLOGY	GENETICS HEREDITY	HEMATOLOGY	RESEARCH EXPERIMENTAL MEDICINE	MEDICAL LABORATORY TECHNOLOGY	UROLOGY NEPHROLOGY	PATHOLOGY	PEDIATRICS	OBSTETRICS GYNECOLOGY	ORTHOPEDICS	INFECTIOUS DISEASES	PUBLIC ENVIRONMENTAL OCCUPATIONAL HEALTH	ENDOCRINOLOGY METABOLISM	IMMUNOLOGY	HEALTH CARE SCIENCES SERVICES	MICROBIOLOGY	BIOCHEMISTRY MOLECULAR BIOLOGY	NURSING	ALLERGY	ENGINEERING	OPTICS	TOTAL
			total number of publications for "clinical utility"	851	604	756	618	424	582	412	428	395	344	232	268	280	285	239	225	200	170	80	175	110	244	210	75	149	319	36	34	116	35	8896
appropriate			Clinically appropriate OR clinical appropriateness																															
			Clinical evidence (6)	4	2	6	2		2	3						2		2										2						25
			Clinical impact (6)	3	3	2	3			5	5		4			5	3									2								35
			Clinical decision making (6)	12		4	7	8	5	6				3	3		3						3											54
			Clinically meaningful (6)	6	5	7		3	6	3						2				2					2									36
	effective		Clinically effective OR clinical effectiveness		5	2		3	2	4			2	2		2							2				4							28
		efficient	Clinically efficient OR clinical efficiency																															
		successful	Clinically successful OR clinical success																															
		valuable	Clinically valuable OR clinical value	13			4			4	7	7	4		6		6	4			4													59
	relevant		Clinically relevant OR clinical relevance	26	20	14	11	11	12	13	14	13										12												146
		applicable	Clinically applicable																															
		significant	Clinically significant OR clinical significance	24	12	15		22	19			9						11	9	11	8													140
		importance	Clinically important OR clinical importance	6	5	6	5	4	3	5		4													3				3					44
accessible			Clinical accessibility																															
		easy to get to	User friendliness (6), ease of use (6)	2		2	2	4		3							2		2											2		2	2	23
		available	Clinically available OR clinical availability																															
	Resource implication		Cost efficiency OR cost effectiveness (6)	6	13		15	5		6	11			12		7			5					6										86
practicable			Clinically practicable OR clinical practice	31	44	36	29	30	25	31	17		17	15																				275
		feasible	Clinically feasible OR clinical feasibility																															
	functional		Clinical functionality																															
		useful	Clinically useful OR clinical usefulness	25	16	16	26	17	18		12	13	12		12																			167
	suitable		Clinically suitable																															
	Training		Clinical training																															
		Preparation	Clinical preparation																															
		Guidance	Clinical guidance																															
	Knowledge		Clinical knowledge																															
		Information	Clinical information	2	2	2	4			4			2										2			3		2			2			25
		Awareness	Clinical awareness																															
		Understanding	Clinical understanding																															
acceptable			Clinically acceptable OR clinical acceptance																															
		adequate	Clinically adequate																															
			TOTAL	**160**	**127**	**112**	**108**	**107**	**92**	**87**	**66**	**46**	**41**	**32**	**21**	**18**	**14**	**17**	**16**	**13**	**12**	**12**	**7**	**6**	**5**	**5**	**4**	**4**	**3**	**2**	**2**	**2**	**2**	**1143**

Table 7-6: Number of publications in research areas for respective search terms

7.4 DISCUSSION

7.4.1 Usage of the Term Clinical Utility

The search confirmed that the term "clinical utility" became a more popular term within medical publications to describe the usefulness of medications, medical devices, clinical practices or guidelines and other medical innovation over the last decade. **Error! Reference source not found.** shows the increase of publications with "clinical utility" as a topic between 2000 and 2011 based on the search results in the WoS Database and Pubmed. Distribution of publications among different areas within the medical field appeared to have a low variability, ranging from 851 to 344 within the top ten areas as provided by WoS database data analysis tools (see **Error! Reference source not found.**).

Neither any particular focus, nor any obvious exclusion of areas, was detected in the data analysis. The term "clinical utility" is used across different research areas of health care. It is used in therapeutic and diagnostic context to discuss treatment guidelines, medical devices, therapeutic (e.g. oncology) and diagnostic (e.g. radiology) approaches as well as drugs (e.g. pharmacy).

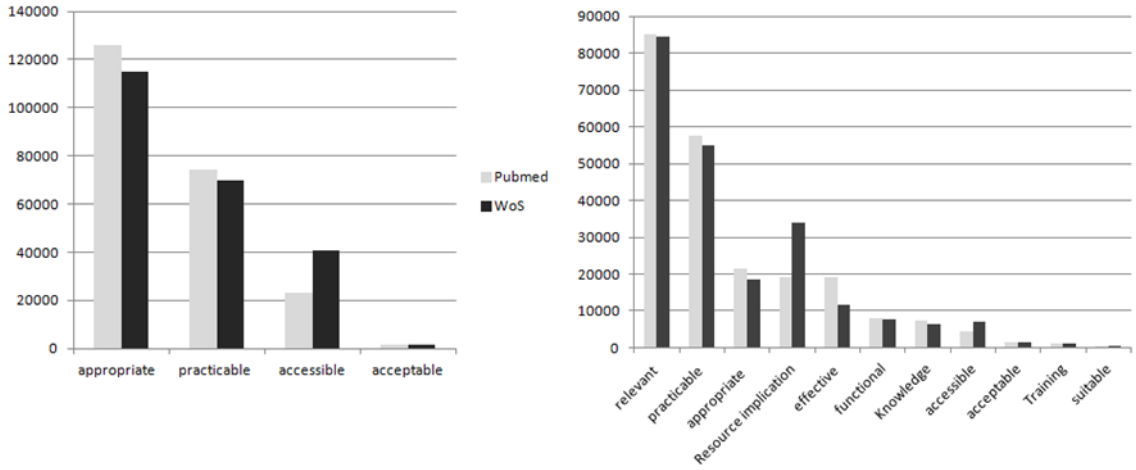
Smart showed that despite the increase in using "clinical utility" to describe and discuss medical innovation, there is no rigorous concept of what clinical utility implies and therefore proposed a multidimensional model covering all aspects of clinical utility. The lack of a clear definition may be the reason for the broad usage across very different areas in health care.

7.4.2 Acceptance of the Term Clinical Utility

When aggregated to the Smart dimensions the distribution of publications still shows an emphasis on the top three components (appropriate, practicable, accessible) (see Figure 7-3**Error! Reference source not found.**). However, a substantial number of publications was found for all areas. The fact that a difference between the two databases was detectable most likely due to a slight shift from the medical focus in the WoS database, including adjacent areas such as social sciences, arts, and humanities. The analysis showed that all of the aspects and dimensions outlined by Smart are

considered in research, however, with a significant variation in frequency, hence numbers of publications using particular aspects and dimensions. The fact that Pubmed returned more results for the individual search terms as compared to WoS, while WoS consistently for every year included retuned more hits for “clinical utility” as compared to Pubmed, may be an indication that the use of search terms are not necessarily linked to the concept of “clinical utility”.

Figure 7-3: Number of publications by components and aspects



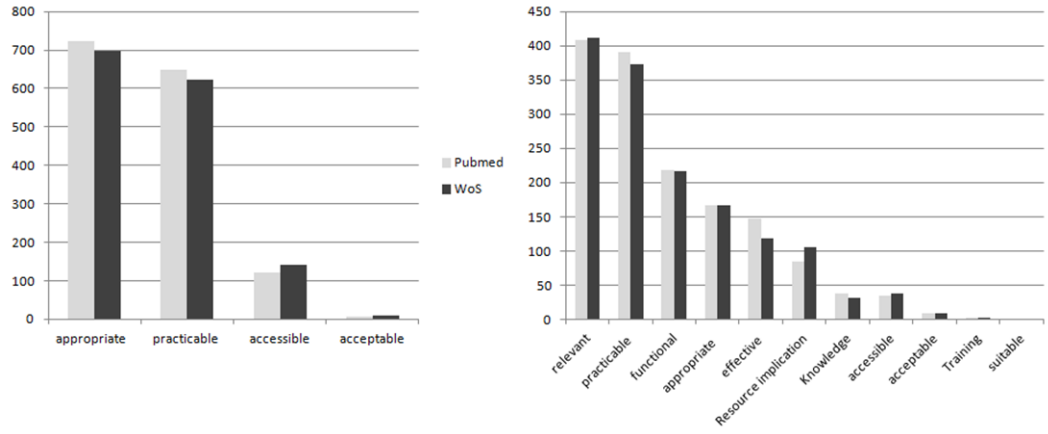
7.4.3 Usage of Dimensions of Clinical Utility

The results of combining the search terms denoting the dimensions of clinical utility with the term “clinical utility” are summarised in Figure 7-4. Comparing those numbers to the results of the previous search, it becomes obvious that publications with search terms combined with “clinical utility” on average account for less than 1% of those which only contain at least one of the search terms. This indicates that there is a relatively weak tendency to consider “clinical utility” as a broad concept, when using one of the components and aspects. At the same time, approximately 20% of publications talking about “clinical utility” also contain at least one of the search terms, which shows on the other hand a tendency to consider one or more components and aspects if the concept of “clinical utility” is applied.

The only aspect, gaining importance in combination with “clinical utility” was “functional”, driven by a high number of search hits for the search terms “clinically

useful” or “clinical usefulness”. With 218 results in Pubmed and 215 in WoS, this aspect also had the 2nd highest number of publications, after "clinically practicable" OR "clinical practice" with 375 and respectively 356 search hits. As “functional” is an aspect of the component “practicable”, those two are the main drivers for the strong focus on the components “appropriate” and “practicable” for the combination of “clinical utility” with one or more of the search terms.

Figure 7-4: Number of publications by components and aspects combined with "clinical utility"



7.4.4 Usage of Clinical Utility across Areas of Health Care

The results showed that, based on the WoS data analysis tool with predefined research areas, search terms derived from dimensions of clinical utility as proposed by Smart were used in combination with the concept of clinical utility. The distribution of search results among research areas indicates that there are no specific areas in which the concept of clinical utility was predominantly used in combination with a specific dimension proposed by Smart, nor any area in which the concept cannot be used.

The search, however, did reveal that the weighting of dimensions and the focus on specific aspects of clinical utility can vary between different fields of health care. As an example, cost effectiveness is a focus topic in areas of clinical routine such as medical imaging (ranking: 2) or areas of chronic conditions such as cardiovascular diseases (ranking: 1), but less of a focus in more acute conditions like in the field of oncology (ranking: 8).

The research areas in which most of the dimensions proposed by Smart where used were oncology, general internal medicine, neuroscience, pharmacology and cardiovascular/cardiology. This focus is likely caused by the general focus on those research areas.

7.4.5 Data Analysis

Databases used for this research returned results consistent with each other. In the majority of cases, Pubmed returned a slightly higher number of results for each search terms, especially if the focus of the search term was clearly health-care related. WoS tended to return more results for search terms that indicated another focus outside heath care, like “cost effectiveness” and “user friendliness” as well as for terms that had at least an implicit economic component like “clinical impact”, “clinical accessibility” and “clinically adequate”. This bias is most likely caused by the database itself, as WoS also includes publications social sciences, arts, and humanities. In contrast to this observation, the initial search on the term “clinical utility” consistently returned more hits on WoS over all publication years included in the search than Pubmed.

7.5 CONCLUSIONS

As PSS is aiming to increase the value for a customer, determining this value is crucial to develop and assess PSS. Determining the value in health care is more complex than in other markets, as a network of market actors are involved in the process of health care service provision.

Since no commonly accepted approach for determining the value and clinical utility was available, an approach proposed by Smart (Smart 2006) was identified as a potential mechanism to be implemented in the proposed design method. To confirm the validity of the approach, its practical application across different segments of the health care market was studied, by analysing data on scientific publications reporting on clinical utility of health products, procedures and services.

This analysis confirmed that the dimensions for clinical utility proposed by Smart provided a useful framework for PSS design in health care. A holistic view on clinical utility that takes into account the value generation for all market actors and the society in total is required to open up the scope of development projects.

The hypothesis investigated in this objective was that a multi-dimensional model of clinical utility, as proposed by Smart, forms an appropriate framework for customer requirement definition and design in one or more areas of medical innovation. To address this hypothesis, a systemic literature review was conducted. The four-stage research design to verify this hypothesis assumes that appropriateness can be determined by the current acceptance of the components and aspects of clinical utility in the peer-reviewed literature. It also assumes that current acceptance can be quantified by the presence or absence of those dimensions in the literature.

1. Verify the usage of the concept of clinical utility across different areas within health care by analysing the usage of the term “clinical utility”.

As more than 7000 publications contain the term “clinical utility”, the term appears to be an accepted concept with the field of health care. The growing importance of clinical utility as a concept is shown by the increasing number of publications per annum since 2005. Across the top ten research areas in which the term is used, the variability in usage is quite low: a maximum of 851 papers in oncology vs. a minimum of 344 papers in gastroenterology hepatology.

2. Verify the conceptual acceptance of each components and aspects proposed by Smart as a concept separate from that of “clinical utility”.

Over 225,000 publications contain one or more of the proposed dimensions of clinical utility. For each dimension examples of publications were found, indicating that all dimensions are used separately from the concept of clinical utility. However, the usage with those dimensions varies significantly - by three orders of magnitude (13 publications on “clinical accessibility” vs. 53744 publications on “clinical practice”).

3. Verify that the components and aspects as proposed by Smart are used in combination with the concept of clinical utility.

Approximately 1,500 publications were found for the combination of the term clinical utility with at least one of the proposed dimensions. Several components and aspects, however, have low numbers, especially for the component of “acceptability” and the

aspect of “training”. The highest numbers were found for the aspects of relevance and functionality as well as the component of practicability

4. Establish the usage of the components and aspects of clinical utility across areas within health care

To analyse the usage of components and aspects of clinical utility across different fields, the top ten research areas were analysed with regard to the number of publications for each component and aspect. Clinical utility and its components and aspects are used across many, very different areas within heath care. However, the distribution is very inhomogeneous. While areas like oncology, pharmacology and neuroscience are highly represented in our analysis – with over 100 related publications considering components and aspects of clinical utility, other research areas such as allergy or nursing are only sporadically connected to clinical utility dimensions.

These findings indicate a selective use of components and aspects of clinical utility. The rationale for this may be that different players in the health care market are stakeholders for different components and aspects of clinical utility. Rather than looking at optimisation of clinical utility in total, a focus on specific aspects and components may result from addressing concerns of stakeholders in the market. While new technologies may initially focus on increasing acceptance and addressing specific concerns in the health care field, to secure funding for research, well established and highly utilised methods may face pressure on reimbursement rates and therefore focus more on cost aspects.

While the theoretical concept, if used in its entirety, has the potential to bridge gaps between different adjacent areas such as economics, health care, social and ethical considerations, etc., the current practical realisation, with its selective and sequential focus on certain aspects has an inherent risk of developing and maintaining suboptimal solutions.

8 DESIGN GUIDELINES FOR PSS IN HEALTH CARE

8.1 LITERATURE REVIEW

8.1.1.1 Requirements for PSS Design Methodologies

Five papers were identified as key contributions regarding general requirements for PSS design methodologies. Those papers reviewed other literature in the field as well as earlier reviews published. Reviewing content and references helped identify those publications as the ones summarising existing research on PSS design methodologies in a complete fashion, in particular with regard to requirements for design methodologies. The publications identified span from 2007 to 2012. This timeframe is consistent with later observations by Qu et al. (2016) showing a peak of published research on design methods in PSS between 2008 and 2012, which a significant drop after that period (Qu et al. 2016a). Each of the requirements listed in Table 8-1**Error! Reference source not found.** below was mentioned at least in one publication.

General Requirements for PSS	Reference
1. Integrated approach *A PSS development process model shall allow for developing integrated solutions for products and services that considers the overall functionality to be delivered.*	(Vasantha et al. 2012)
2. Common terminology *A PSS development process model shall establish common terminology to communicate progress and identify stages of the development within the development team and stakeholders.*	(Müller et al. 2010)
3. Strategic analysis *A PSS development process model shall include a strategic analysis of business goals and stakeholders*	(Maussang et al. 2009)
4. Process description *A PSS development process model shall describe the sequence and iterations of activities during the development in a process model*	(Müller et al. 2010)
5. Schema/Visualisation *A PSS development process model shall include a good schema for representing PSS concepts with appropriate notation that avoids misinterpretation*	(Vasantha et al. 2012)
6. Project planning *A PSS development process model shall form a framework for task specific method application and be the basis for project planning, including milestone deliverables.*	(Müller et al. 2010)
7. Communication *A PSS development process model shall allow to share information to synchronise with internal and external project stakeholders (especially for requirements engineering purposes)*	(Müller et al. 2010) (Berkovich et al. 2011)
8. Value generation *A PSS development process model shall include characterisation of actors and identification of value generated for them by the PSS*	(Nicolas et al., 2007)
9. Concept evaluation *A PSS development process model shall include a method for comprehensive evaluation of developed PSS concepts.*	(Vasantha et al. 2012)
10. Requirements identification *A PSS development process model shall include a method for identification of the requirements of stakeholders involved in the PSS and how these change over time.*	(Vasantha et al. 2012) (Nicolas et al. 2007) (Berkovich et al. 2011)

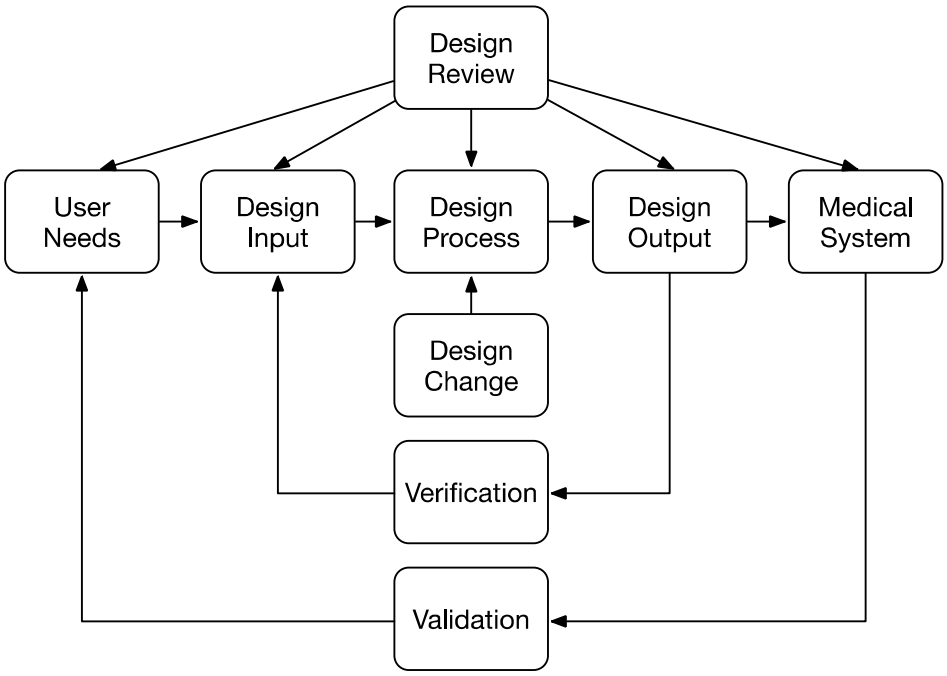
11. Traceability *A PSS development process model shall provide procedures for requirements traceability*	(Berkovich et al. 2011)
12. Requirements documentation *A PSS development process model shall provide procedures for requirements documentation*	(Berkovich et al. 2011)
13. Modularisation *A PSS development process model shall provide support of modularisation by requirements engineering*	(Berkovich et al. 2011)
14. Requirements concentration *A PSS development process model shall provide procedures for requirements concretisation*	(Berkovich et al. 2011)
15. Requirements management *A PSS development process model shall provide procedures for identification and resolution of conflicts between the requirements.*	(Berkovich et al. 2011)
16. Change management *A PSS development process model shall provide procedures for changes in the requirements.*	(Berkovich et al. 2011)
17. Life cycle management *A PSS development process model shall include a method to understand and identify influences, compromises and differences between products and services throughout their lifecycle.*	(Vasantha et al. 2012)
18. Specification development *A PSS development process model shall include a method to translate requirements into detailed specifications.*	(Nicolas et al., 2007)
19. Validation *A PSS development process model shall provide procedures for requirements validation.*	(Berkovich et al. 2011)
20. Verification *A PSS development process model shall include a process to define acceptance criteria for specifications.*	(Nicolas et al., 2007)
21. Implementation/Design transfer *A PSS development process model shall include preparation for implementation.*	(Maussang et al., 2009)

Table 8-1: Requirements for PSS design methodologies

8.1.1.2 Design Process in Health Care

Within the health care sector, the design process is subject to regulatory requirements in the US (FDA 2006) as well as in Europe (European Parliament and of the Council 2007). Companies are obliged to follow those regulations in order to enter specific markets. To enter the market in the United States, the FDA (Food and Drug Administration) sets forth regulations that need to be fulfilled to obtain approval for a particular product (see Figure 8-1). FDA 21 CFR § 820.30 in particular regulates the design process. In European countries, notified bodies clear products for the market based on industry standards such as ISO 9001:2015 (Iso.org 2015) and ISO/DIS 13485:2016 (ISO/TC 210 2016).

Figure 8-1: Regulatory guideline for design process of medical devices (FDA 2006)



Another important cornerstone in any design process in health care is risk management (FDA 2006; European Parliament and of the Council 2007). ISO 14971:2013 Medical devices - Application of risk management to medical devices further defines the requirements for risk management during the design process in the medical device industry. Table 8-2 summarises mandatory requirements for the design process set forth in ISO 14971(ISO/TC 210 2013):

Regulatory requirements for design phases in the medical device/system design process

1. Design and development planning
   Plans shall be established and maintained describing or referencing activities and responsibilities in the design process. This includes descriptions of interfaces different groups or activities in the design process.

2. Design input
   Procedures shall be established and maintained to ensure that requirements are appropriate and address the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements.

3. Design Phase
   Procedures shall be established and maintained to ensure system or device is designed according to the design input following the design plans set forth for the project.

4. Design output
   Processes shall be established and maintained for defining and documenting design output allowing adequate evaluation of conformance to requirements defined in the design input. Acceptance criteria shall be defined to evaluate the conformance.

5. Design review
   Formal, documented design reviews shall be conducted at appropriate milestones throughout the design process, including appropriate members of the design team.

6. Design verification
   Processes for design verification shall be established and maintained to verify the design. Design verification shall confirm that the design output meets the design input requirements.

7. Design validation
   Processes for design verification shall be established and maintained to validate the design under operating conditions. Design validation shall ensure conformance to defined user needs and shall include testing of production units under actual or simulated use conditions.

8. Design changes
   Processes shall be established and maintained to identify, document, validate or where appropriate verify, review, and approve design changes before their implementation.

9. Design history file (documentation)

A DHF (design history file) shall be established and maintained. The DHF shall demonstrate that the design was developed in accordance with the approved design plan and the requirements.

10. Design transfer
    Processes shall be established and maintained to ensure that the design is correctly translated into production specifications.

11. Risk Management
    Processes shall be established and maintained to carry out risk management activities throughout the development and document those in a risk management file as part of the DHF.

Table 8-2: Regulatory requirements for design phases in the medical device/system design process as set forth in ISO 14971

8.2 METHOD

The attempt of this objective was to establish requirements to develop a PSS design methodology specifically in the field of health care. Input from two areas "product service systems" and "health care" had to be considered. In order to provide a structured approach for the requirements identification, the process was broken down in five steps.

In the first two steps, requirements identified in literature of both areas were identified separately. Sources for the requirements showed no overlap. (General PSS design methodology requirements are mainly discussed in scientific publications, while due to the maturity of the field of design in health care, requirements for this sector are largely incorporated already in regulatory standards.)

The relationships between PSS requirements and health care requirements were analysed to understand the applicability of PSS requirements in the context of the development process in health care/medical device design. With this applicability established, the actual list of requirements for a PSS design methodology in health care was developed considering both the PSS requirements and the health care requirements as sources.

In a last step, the developed list of requirements was validated against the initial requirements for design methodologies in health care, to ensure that, collectively, the

new requirements did meet and were not in conflict with any mandatory requirements derived from regulatory standards.

The detailed methodology for each of these steps is given below.

Step 1 - Identification of general requirements for PSS design methodologies. Literature on PSS design methodologies has been reviewed to develop a list of requirements generally applicable for PSS design methodologies (general PSS requirements = gPSSR). To identify relevant publications, a search was conducted for papers with a title or topic related to "design methodologies for/in PSS", "requirements/requirements engineering for PSS design". The identified papers were checked for cross-references to identify the key papers summarising and referencing earlier publications. The requirements proposed in those publications have been reviewed for overlapping content (see step #1 in Figure 8-2**Error! Reference source not found.**) and a consolidated list of requirements was generated (see Table 8-2).

To structure the list and improve the context for further analysis, the requirements were regrouped into clusters based on overarching topics:

- Project Management
- Documentation
- Traceability
- Requirements Engineering
- Design Verification and Validation
- Design Implementation

Step 2 - Identification of requirements for PSS design methodologies in health care. The high-level design process in health care is driven by regulatory requirements (FDA 2006). Applicable standards and regulations provide guidance for the development of medical devices and respective documentation to prove compliance with regulatory requirements (health care design requirements = hcDR). Those guidance documents have been considered to establish the high-level requirements outlining the distinct phases in the design process of medical devices/systems (see step #2 in Figure 8-2**Error! Reference source not found.**)**Error! Reference source not found.**.

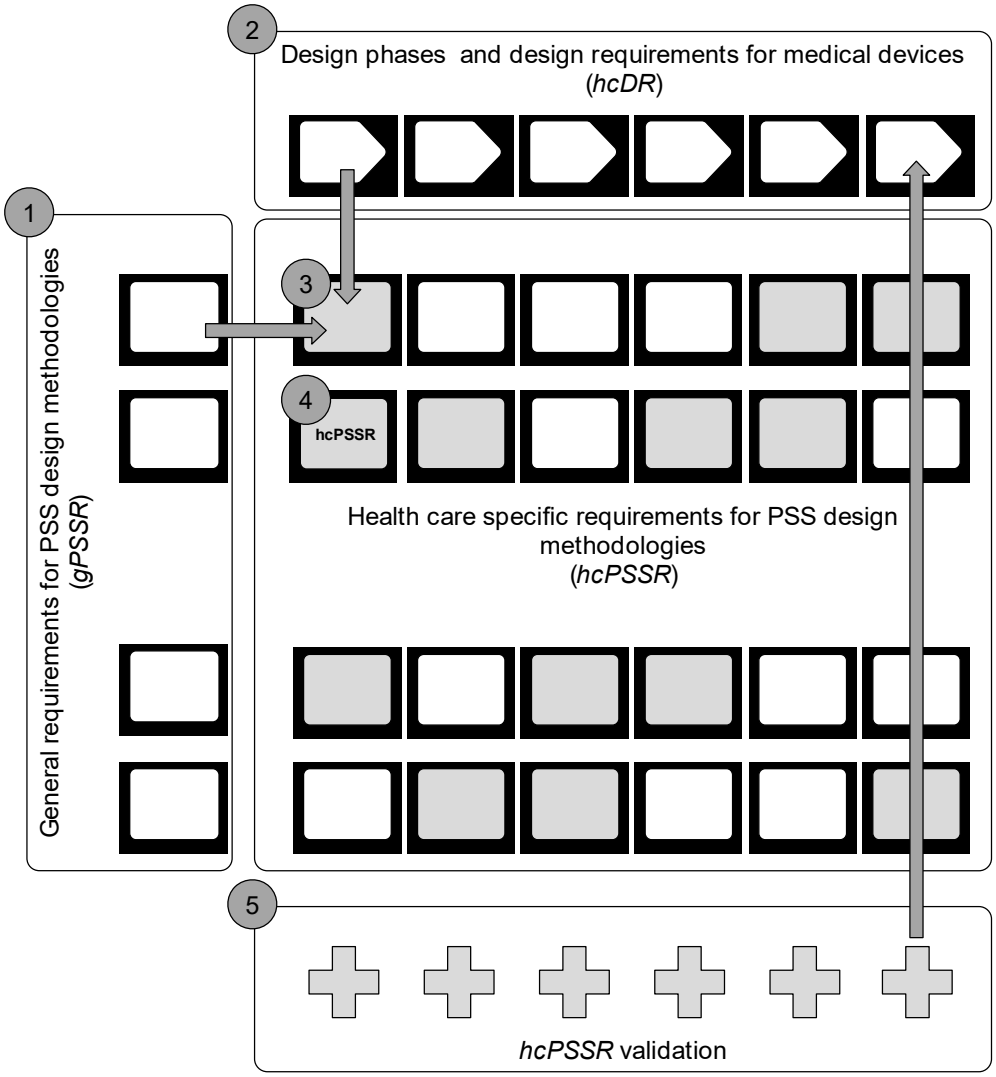
Step 3 - Identification of relationships between requirements. In order to define the scope of a useful list of requirements for PSS design in health care (health care PSS requirement = hcPSSR) and to analyse the relationships between requirements, general PSS requirements (gPSSR) were mapped against the high-level requirements to have a

particular sequence of design phases in the development process (hcDR) in a matrix. This exercise allowed identifying areas of applicability of general PSS requirements within the medical device design process (see step #3 in Figure 8-2**Error! Reference source not found.Error! Reference source not found.**).

Step 4 - Development of requirements for PSS design methodologies in health care. In this step, specific PSS design methodology requirements (hcPSSR) are developed within the applicable scope defined in the previous step (see step #4 in **Error! Reference source not found.**). Requirements were derived from a PSS perspective.

Step 5 - Confirmation and validation of requirements. Fulfilling the regulatory requirements is mandatory for any medical system (Kaplan et al. 2004). Therefore, for every design phase, all newly developed requirements were reviewed to confirm that the fulfilment of those single requirements also fulfils the respective regulatory requirements for each design phase (see step #5 in Figure 8-2**Error! Reference source not found.Error! Reference source not found.Error! Reference source not found.**). This validation step ensures the set of requirements (hcPSSR) does meet all regulatory needs.

Figure 8-2: Requirements definition for PSS design methods in health care



8.3.1 Overview

The proposed method for PSS design is built around traditional design processes that are executed in companies in health care. Medical device companies as well as pharmaceutical companies typically have well established design processes compliant with respective regulatory requirements. As PSS consists a combination for products and services, certain components can and should be developed under existing processes. This approach also allows an easier implementation into a company's quality system, as existing standard operating procedures and implemented processes can stay in place.

The proposed design methodology for PSS in health care starts with an extensive design input phase. The quality of the design input information is crucial for the subsequent work in the design process.

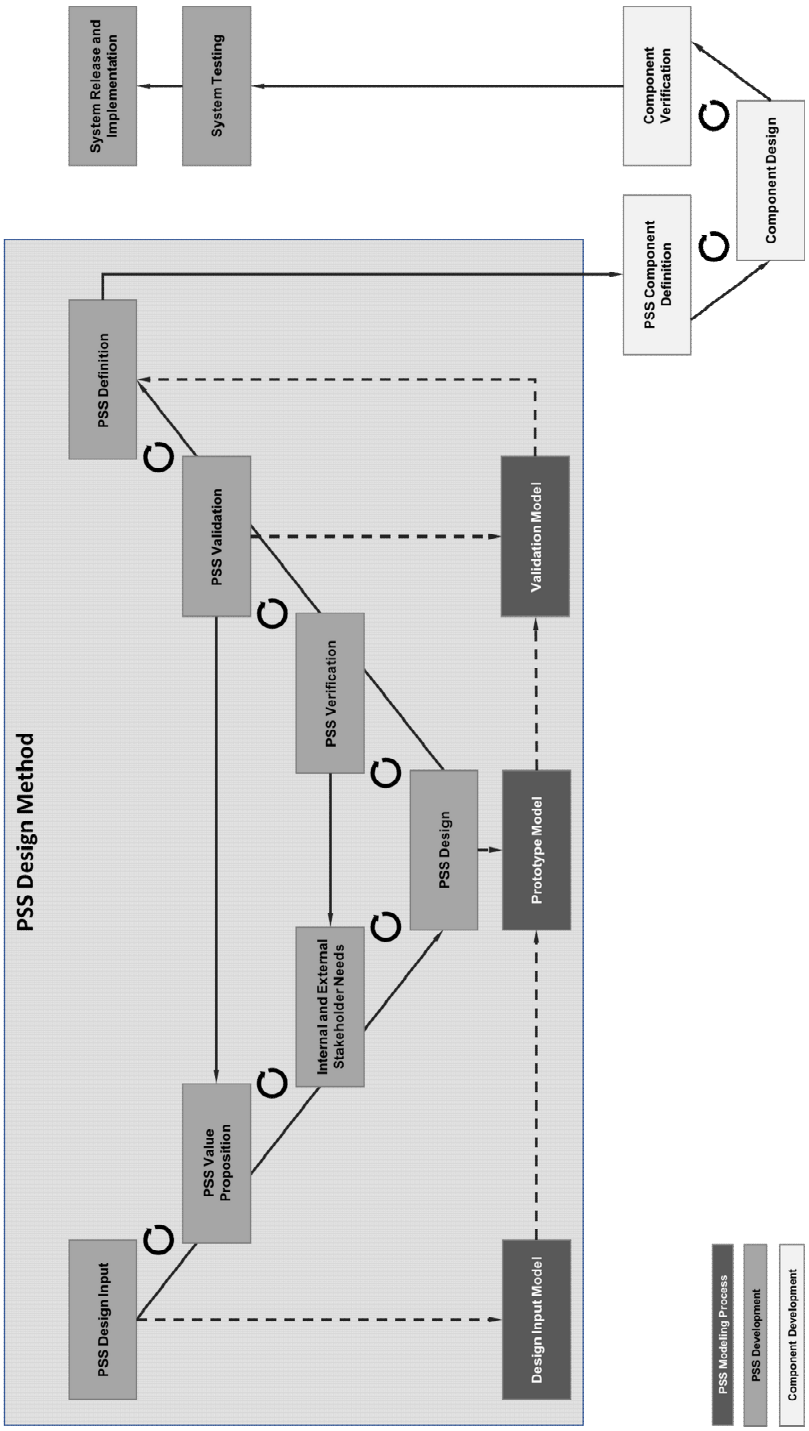
As a new PSS development project is typically initiated in the context of a company's strategy, these considerations as well as potential limitations regarding, budget, timelines and resources have to be defined. In contrast to traditional product development projects, this information however is considered design input from internal stakeholders (that also can be challenged by a design team), rather than predefined boundary conditions, to give development teams the required freedom to PSS design.

On a high level, the proposed PSS design process is following development processes implemented medical devices to ease implementation of the method in a company. The PSS design is also de-coupled from the components design for several reasons. It allows to keep existing design processes in place, which enables companies to implement PSS design as an addition rather than a change in their processes and quality systems. It also allows to have separate, yet collaborating teams working the PSS design and the component design, as PSS design teams need a different skill set than traditional product design teams.

To achieve the goal to develop a more specific method for PSS design in health care and offer practical solutions for companies, every high-level process step in the method (see

Error! Reference source not found.), is detailed out and design guidelines tailored to health care are provided.

Figure 8-3: PSS Design Process for Health Care



8.3.2 PSS Design Input

The success of a development project highly depends on the focus of the team. Explorations of design options hat are not relevant to the business objectives, the market

to be addressed or the real-life scenario the user will utilise a PSS, are costly in time and resources. The quality of the design input defines the quality of the design output.

8.3.2.1 Business Needs

Internal stakeholders are the driving force behind development projects. While fulfilment of customer needs should be the mission and goal for a development project, business needs often dictate the boundaries of the solution space for design and therefore the scope of a PSS. Arriving at a common understanding of those limitations ahead of the development is important to focus a PSS development towards a feasible goal. While in traditional development projects, those limitations are pre-defined, PSS requires a more flexible approach to avoid missing opportunities in the development phase. Business needs should be evaluated right at the beginning of a project to get an understanding of the design solution space and the project scope. PSS requires a change in the mind-set of almost all functions and divisions in a company, however changing the mind-set and culture of an entire company is not feasible most of the time. For PSS design teams to cope with this situation, business needs should be treated as such, meaning that those needs should not be pre-defined limitations, but rather design input requirements from internal stakeholders for the PSS design. Those needs have to be challenged and weighted against needs from external stakeholders, such as patients, health service providers and other market actors. Table 8-3**Error! Reference source not found.** outlines different internal stakeholders and their likely concerns in regards of new PSS developments.

Internal Stakeholders	**Areas for Business Needs**
General Management	• *Overall company budget and long term financial planning* • *Product strategies*

	• *Sales strategies*
Research and Development	• *Budget planning* • *Resource planning* • *Relative priorities between R&D projects*
Sales	• *Sales model* • *Sales cycle* • *Pricing strategy*
Marketing	• *Marketing strategy* • *Marketing claims*
Quality Management and Regulatory Affairs	• *Regulatory pathways* • *Regulatory approvals of components* • *Development process*
Finance	• *Business model* • *Pricing and accounting model*
Product Service	• *Serviceability of product components*
Customer Service	• *Feasibly of services to customers*

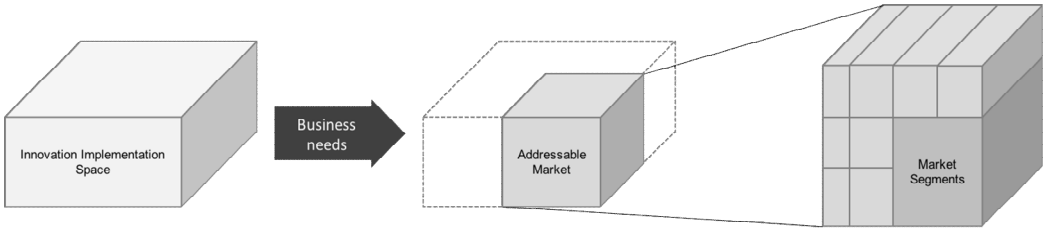
Table 8-3: Concerns of internal stakeholders

8.3.2.2 Market Analysis

8.3.2.2.1 Addressable Market

Defining the addressable market, is a first step focus on the potential scope of a PSS. A certain technology, product or service as core of a PSS may add value in different geographical markets or in different clinical indications. However, a company may not be able to harvest the full potential of an idea in all those areas, but will have to focus on an addressable market for which the company has the resources to analyse the market, develop and implement a PSS (see **Error! Reference source not found.**).

Figure 8-4: Market definition



8.3.2.2.2 Market Segmentation

The addressable market is typically not a homogeneous market for which one design solution will sufficient. Obvious market segmentation along geographical markets, clinical indications or patient groups, clinical workflows or regulatory requirements may already be obvious at this early stage of the development which may later be refined as the understanding of market dynamics, actors and workflows is growing (see Table 8-4).

Market Segmentation	**Rationale**
Geographical	• *organisational reasons (for example to line up with the sales organisation),* • *political reasons* • *intellectual property (IP) reasons (if existing IP in certain countries prevents the company from entering the market)*
Regulatory	• *internal expertise:* • *regulatory risk* • *regulatory timeline*
Clinical Indication	• *Customer: different customers* • *Regulatory pathway: Different indications for use require different regulatory approvals*
Patient groups	• *Different sales call points*
Clinical workflow	• *Different call points for sales*
Payment mechanisms	• *Different payment processes*

Table 8-4: Dimensions of Market Segmentation

8.3.2.3 Workflow and User Analysis

With the initial definition of the target market, a PSS design team can focus on the workflows, networks and actors involved the current clinical practice ("gold standard") for this market.

Workflows and roles of actors in health care are typically more standardised that in other industries due to regulations. Clinical workflows are often well documented. The same is true for actors involved in those workflows, as roles and responsibilities for medical personnel are clearly defined.

8.3.2.3.1 The Full Health Cycle

Traditional medical device or drug developments do focus on the diagnosis and the treatment of a patient and therefore focus on the clinical workflows involved in those phases.

PSS design should not be limited to those phases, as often value is created for the patient before and after the immediate diagnosis and treatment.

Error! Reference source not found.Error! Reference source not found. provides a health cycle model, which can serve as a template for a full analysis of workflows. While not in all instances all six phases may be applicable as the right scope for PSS design, the phases offer a view on the entire timeline extending before diagnosis and after treatment, which may be too narrow for PSS development as in other phases value may be generated and outcomes can be positively influenced.

In a pre-disease phase, a patient would not have any symptoms that would prompt the patient to seek any medical care. In this phase, certain risk factors or predictors may already indicate that a patient is likely to suffer from a certain disease. This may even be true for acute health issues such as injuries, if those injuries or the outcome are influenced by certain risk factors or preconditions of the patient.

During the disease manifestation phase, symptoms are manifesting themselves and may start to decrease the quality of life for a patient. As symptoms increase in this phase, the quality of life will reach a level at which a patient would seek medical attention.

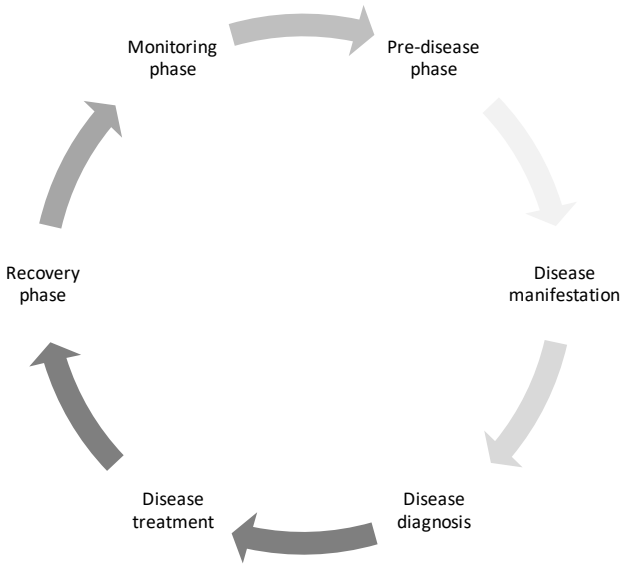
As a patient enters into the medical system, the next phase is the disease diagnosis. Information from medical histories and diagnostic testing is gathered to identify the cause of symptoms.

Once the diagnosis is determined, treatment of symptoms and the underlying disease can be initialised and progress is monitored till the patient's quality of life is back to a minimal achievable level.

In the recovery phase, the goal is to get the quality of life back to the maximal achievable level (ideally a "normal" level).

The following monitoring phase may be required to ensure that a relapse of a disease can be detected early or new health risks resulting from the disease can be managed.

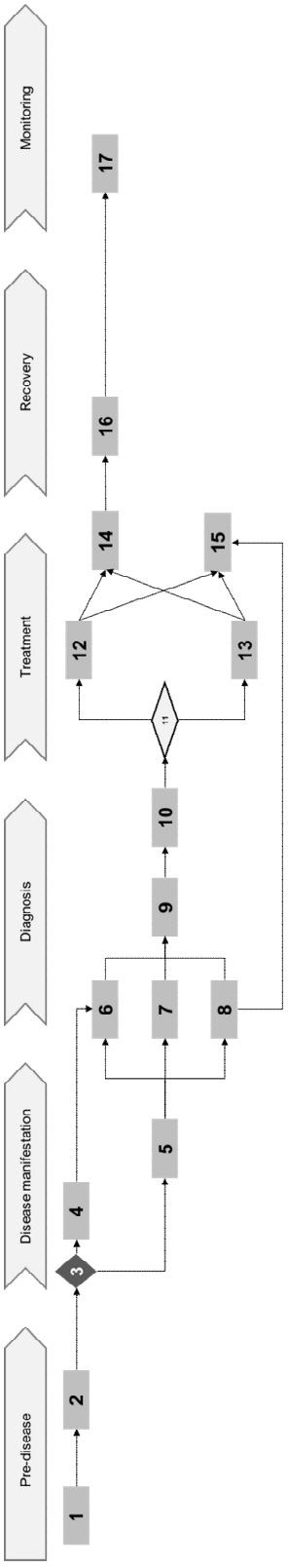
Figure 8-5: Health cycle for holistic PSS development



Considering the entire health cycle allows to consider the value for the patient based on long term effects and outcomes. Workflows along the health cycle typically are not one linear process. Depending on where they enter health care system (e.g. general practitioner, emergency department, specialist) and different referral patterns, patients may follow different pathways for diagnosing and treatment through the system. Pre-conditions of a patient may require alternative diagnosing or treatment and treatment outcomes and recovery schedules may be very different.

Figure 8-6 illustrates a theoretical workflow along the health cycle with typical patterns for referral, diagnosis and treatment options.

Figure 8-6: Example workflow along the six phases of a health cycle

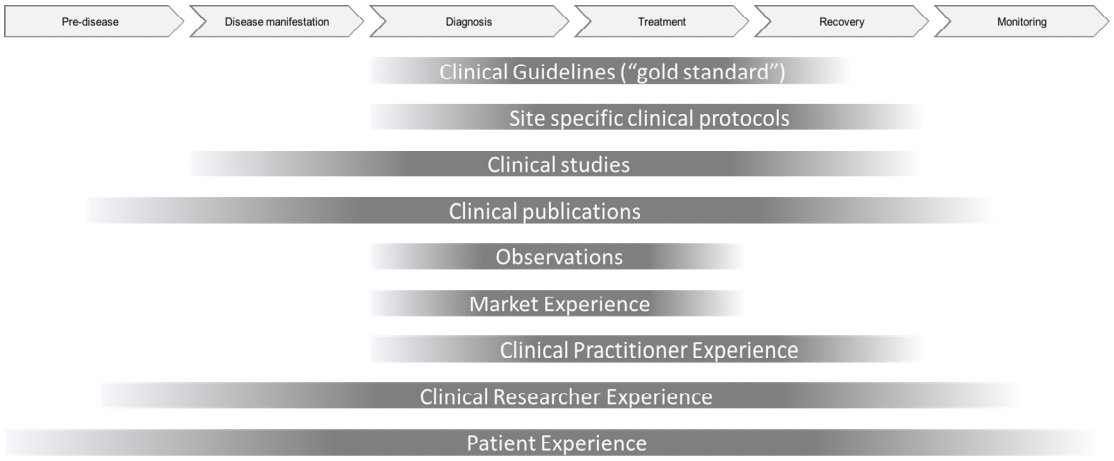


8.3.2.3.2 Information Sources for Workflow Analysis

As a first approximation for a clinical workflow, guidelines for disease diagnosis and disease treatment published by medical associations and payers can be utilised. Health service providers, such as hospitals may have more specific standardised procedures or clinical protocols based on high level clinical guidelines. Besides reviewing of literature, published clinical guidelines and standardised procedures, PSS designers should also utilise others experience and interview and observe health service providers and if possible patients to get more insight on the flow of events and actors involved. Existing experience in the market can also contribute to the workflow analysis, however the potential bias of existing design solutions needs to be observed.

Error! Reference source not found.Error! Reference source not found. illustrates the different information sources and their likely information content and value along the health cycle phases. Scientifically solid data typically can be found for the diagnosis, treatment and some of the recovery phase. The experience of patients going through all phases is the most complete information, yet data may be biased based on individual characteristics of a patient.

Figure 8-7: Information Sources for PSS development

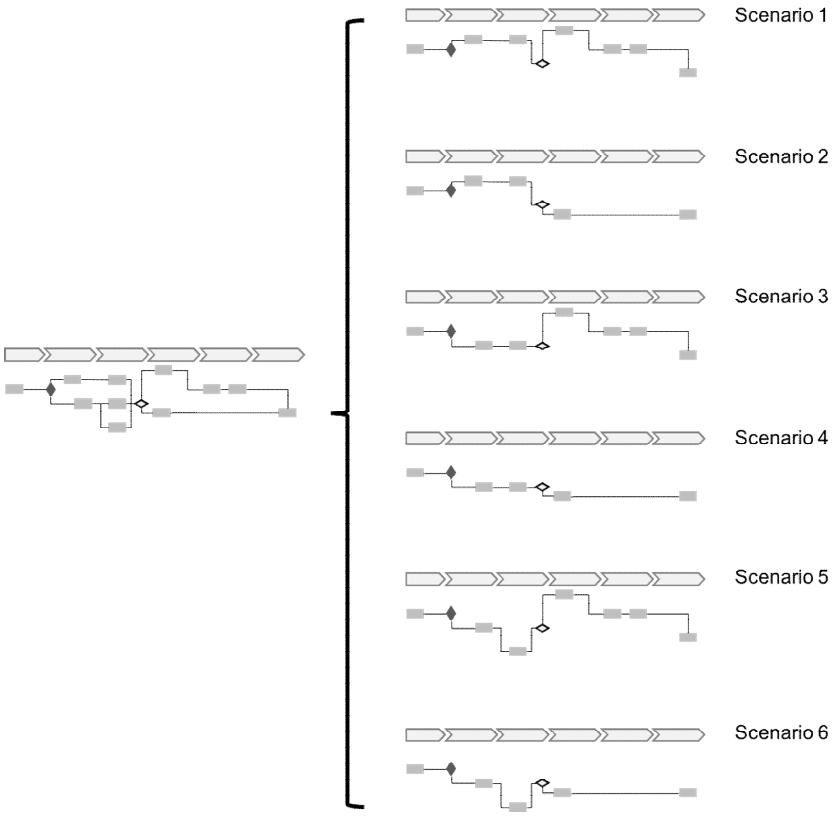


8.3.2.3.3 Patient Journeys and Episodes

The flow of events along the health cycle can become extremely complex, as many decisions are involved along the process and also other bifurcations are caused by different outcome scenarios.

To focus the analysis, every pathway should be studied separately (see **Error! Reference source not found.Error! Reference source not found.**). Focusing on specific pathways allows to investigate the workflow in more detail, with regard to process steps and time required, resources involved, value provided, cost generated, as well as risks generated for patient or health service provider.

Figure 8-8: Scenario development



Scenarios should describe the entire patient journey throughout all health cycle phases. Patient journeys can be documented in formal workflow diagrams, text based descriptions or sketches.

To prepare scenarios for further in depth analysis, it may also be useful to divide scenarios up into episodes. This is particularly useful for further development of PSS and components of PSS, as different episodes of a patient journey can take place in different locations.

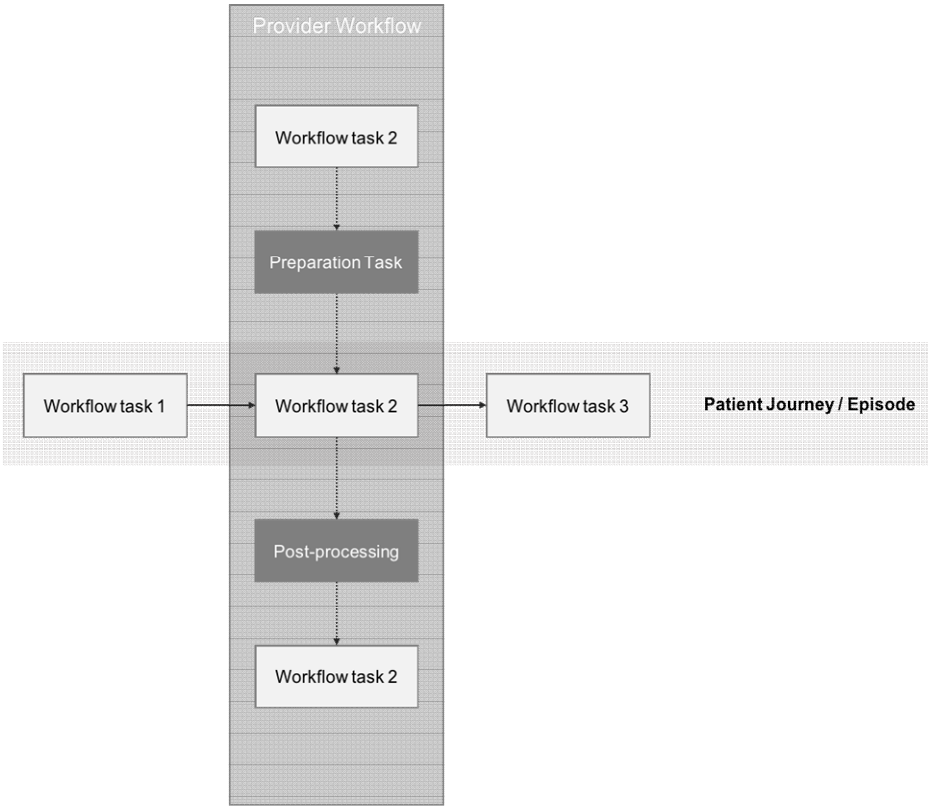
The patient journey or an episode forms the framework to organise additional information relevant for PSS development, discussed in the following sections.

8.3.2.3.4 Provider Workflows

Due to the regulations in health care, roles of health service providers (nurse, general practitioner, radiologist, neurologist, etc.) are very well defined, so solid assumptions can be made about the capabilities, education and training for a specific role in the workflow.

Along a patient journey, several health service providers in different roles may interact with the patient as part of their daily routine. Some providers may only be involved in one particular phase along the patient journey, others may be crossing a patient journey several times long the workflow. The interaction with a patient often involves some preparation of post-processing tasks (see **Error! Reference source not found.Error! Reference source not found.**). Depending on the situation, non-professional providers, such as care-givers like family members, may cross patient journeys as well.

Figure 8-9: Provider Workflow versus Patient Journey

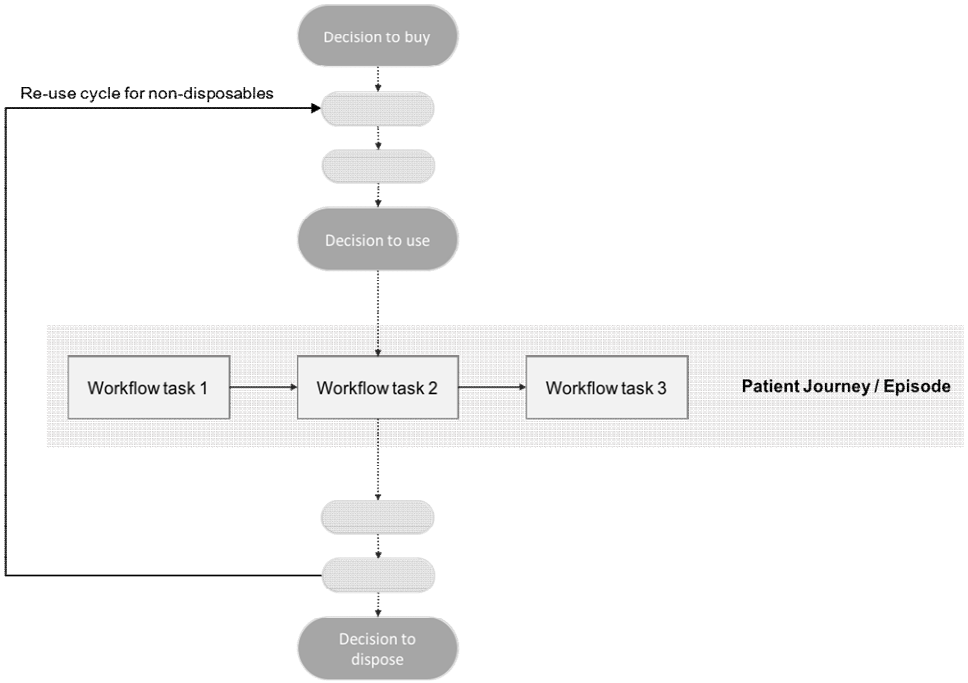


8.3.2.3.5 Product Life Cycles

Like health service providers, different tangible products do cross patient journeys, as they are necessary to carry out certain tasks (see Figure 8-10). As products can be

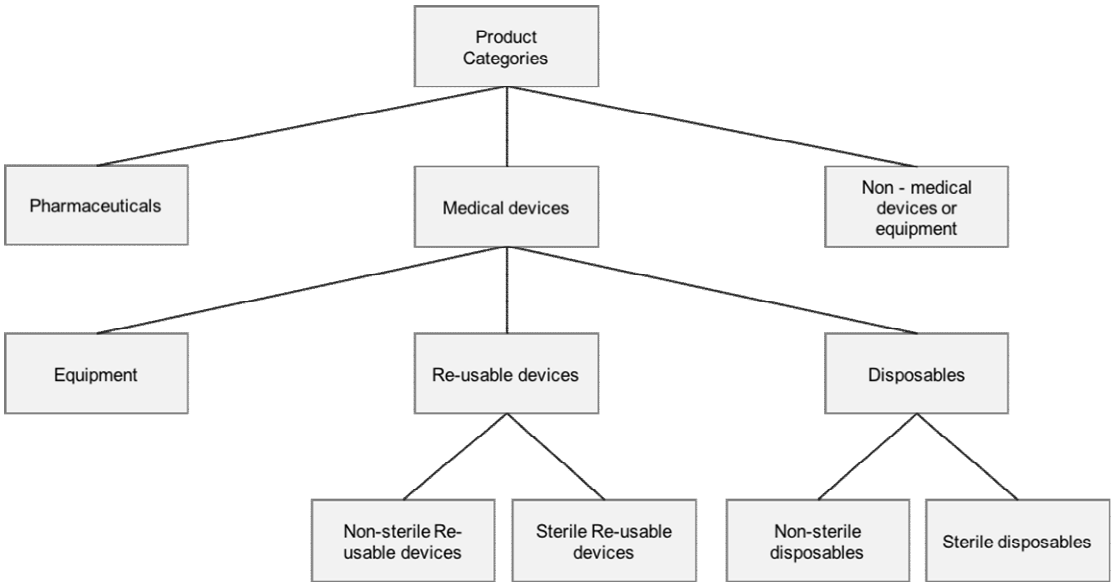
classified into distinct groups (see Figure 8-11**Error! Reference source not found.**), PSS design teams can develop and reuse template product life cycles for different product categories, including services associated with the product life cycle. For instance, re-usable sterile products require certain predefined steps in their product life cycle like cleaning, sterilisation, re-packaging, etc. Several decision points are relevant to all product categories, like the decision to buy, the decision to use and the decision to dispose a product.

Figure 8-10: Product life cycle



Tangible resources (products) can also be easily classified in a health care setting into four different categories: Pharmaceuticals (e.g. Ibuprofen), equipment (e.g. computer tomography scanner), re-usable medical device (e.g. stethoscope) and disposable medical devices (e.g. syringes) and other non-medical device tools (e.g. a lamp). Re-usable devices and disposables can be further categorised into sterile and non-sterile products.

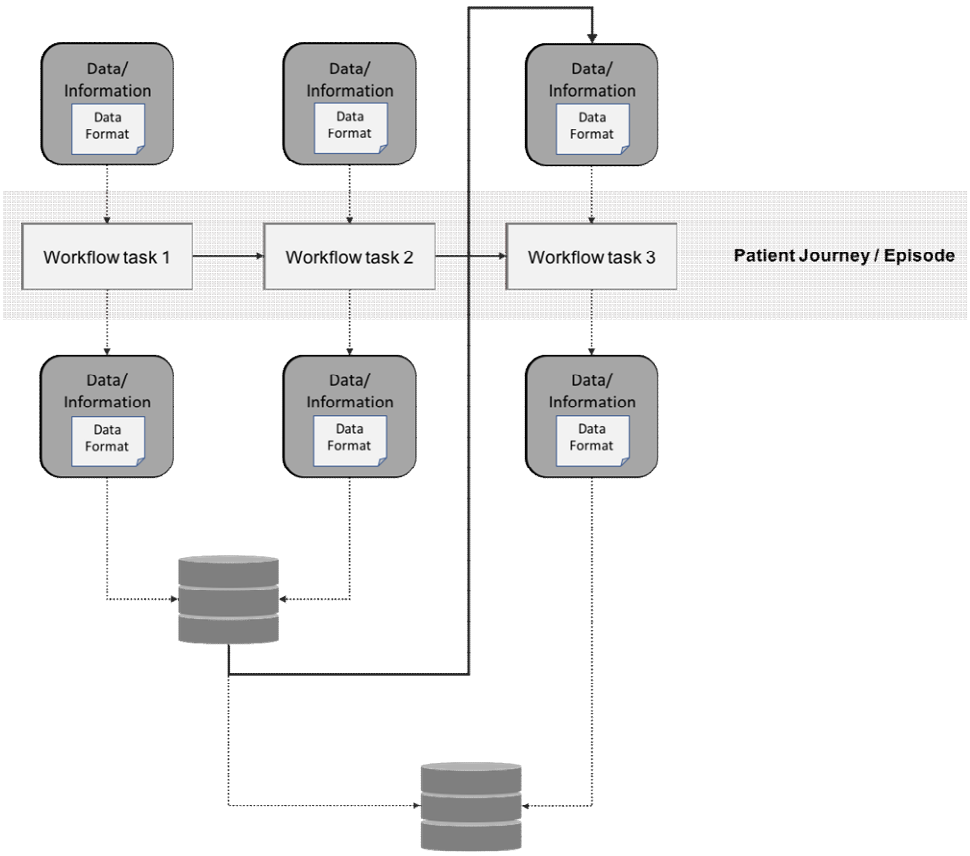
Figure 8-11: Product Categories



8.3.2.3.6 Data and Information Layer

Many steps along a patient journey, a provider workflow or a product life cycle require and create data, which may be used immediately for decisions, stored, processed, analysed, shared and transferred. Data and information is provided, outputted, processed and stored in different formats, which may not necessarily be digital, as paper based documentation is still very common in health care (see **Error! Reference source not found.**).

Figure 8-12: Data Flow Analysis along a patient journey



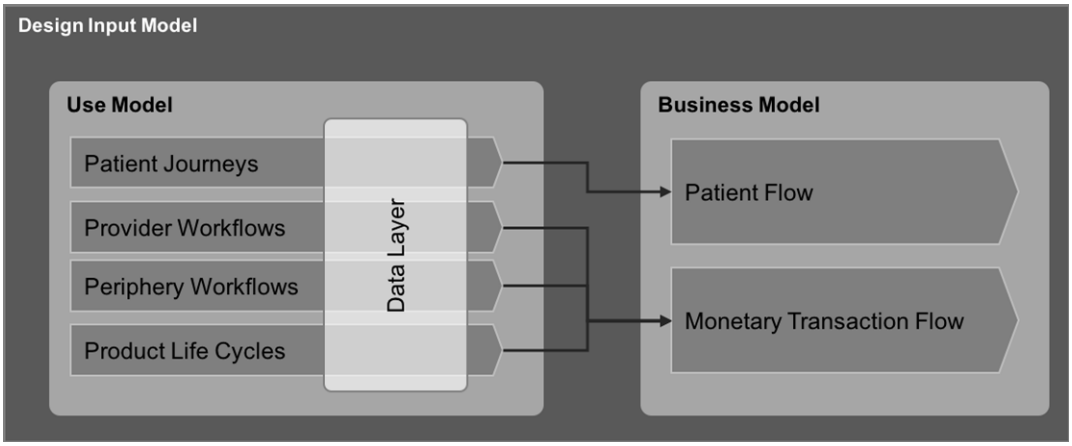
8.3.2.3.7 Periphery Workflows

Provider workflows, product life cycles and data flows are analysed from a patient journey perspective, however several peripheral tasks may have to be worked on, in order to create overall clinical value. Those tasks are part of workflows that may be carried out by service providers not directly in contact with the patient. Products are also utilised in those workflows that do not appear in a patient centric perspective, as they do not cross the patient journey directly. Data and information may also be required and created along those periphery workflows, or may even be the purpose of the workflow.

8.3.2.4 Design Input Model

To develop a baseline for prototype testing and system validation, but also to organise the design input a design input model can be put together in which the current status in the addressable market with regard to patient journeys, provider workflows, periphery workflows, product life cycles and data flows is described. To integrate the design of the business model into the PSS design, the business model is also included in the design input model. Information gathered in the use model allows building a patient flow model, which illustrates how many patients go through specific patient journeys. The workflow analysis in the use model also identifies the workflow steps related to billing and payment, so the monetary flow can also be derived from the use model and be used in the business model (see **Error! Reference source not found.Error! Reference source not found.**).

Figure 8-13: Design Input Model



8.3.2.4.1 Use Models

The information collected during the design input phase summarised and documented in use models for different scenarios. Patient journeys, provider workflows (and periphery workflows), product life cycles and data/information flows describe the current situation within the scope of a PSS solution. This is an important resource for ideation, detailed design development and prototype testing (see
).

Figure 8-14: PSS Use Model

patient Journey
provider Workflows
product Life Cycles
Data /Information Flows

8.3.2.5 Business Model

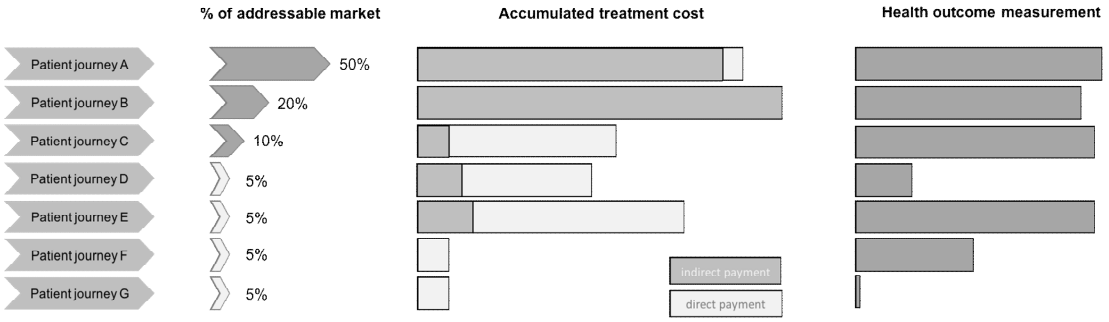
Like use models, an understanding of the current business models in place is an important design input for PSS,as developing the business model for a PSS should be integrated in the development process. Compensation or reimbursement for health services provided is depending on the funding model used in a health care system (see chapter 2.1.2.2). Many systems however apply combined models, which results in more complex payment mechanisms. The compensation for services provided along a patient journey may include combinations of coverage provided by public insurance and private insurances, as well as out-of-the-pocket payments by the patient. From the use model, the reimbursement or payment workflow can be identified. Often, this billing process is managed in a periphery workflow, collecting data on reimbursable tasks, creating a bill according to defined reimbursement codes, sending the bill to the payer followed by the collection of the reimbursement.

To evaluate the value of a certain patient journey, the outcome needs to be measured to be able to compare it to the cost accumulated to achieve that particular outcome for the patient (see Figure 8-15**Error! Reference source not found.**). An appropriate outcome measurement needs to be selected for the addressable market.

Besides all monetary transactions, the business model needs include information about the market size and patient flows. In traditional projects, the business plan is often disconnected from the development process and planned in a top down approach. Information about market size, patient flows, market shares and other parameters are based on either external information or internal experience.

The use models allow a bottom up planning based on patient journeys, as long as information is collected about how frequently certain patient journeys are occurring.

Figure 8-15: Key Parameters in the Business Model



8.4 PSS VALUE PROPOSITION

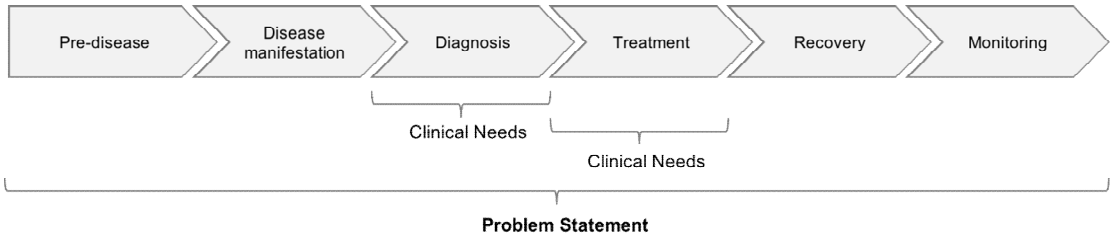
8.4.1 Clinical Needs

Unmet clinical needs are describing a particular shortcoming in a clinical workflow. This can be the lack of an appropriate treatment option or a diagnosis. An unmet clinical need often is the trigger for development projects and therefore is either pre-defined, or relatively easy to define for a development team, due to the focus on a particular problem in the workflow.

8.4.1.1 Problem Statement

Developing a problem statement is crucial for PSS development, as this helps identifying the actual value proposition of a PSS in the next step. While a clinical need describes the shortcoming within a clinical workflow, the problem statement should consider the entire patient journey throughout all health cycle phases (see **Error! Reference source not found.Error! Reference source not found.**). A clinical need may be addressed with (most likely) product components, the analysis of the actual problem along the patient journey allows to increase the scope of a PSS development project to a point where a PSS solution can generate customer value.

Figure 8-16: Problem Statement versus Clinical Needs



8.4.1.2 Value Proposition

The value proposition for the PSS describes what is needed to address the problem statement or a meaningful part of the problem statement. Depending on business needs, a company may not be in the position to develop a PSS that addresses the entire problem, however, by starting with the problem statement the design team starts with the broadest possible scope for the PSS to be developed. Value is defined in health care by health outcome per cost (Porter & Teisberg 2006). The PSS therefore has to improve the health outcome or minimise the cost over the entire health cycle for the entire population. While health outcome is the main interest of the patient and also the provider, the associated cost to achieve the health outcome and its impact of the health care system is of interest for the payer and the policy maker.

All market actors' needs have to be considered in the value proposition (see Table 8-5**Error! Reference source not found.**).

Market Actor	Value proposition consideration
Patient	• *How does the PSS improve state of health of patients?* • *How does the PSS improve quality of life of patient throughout the health cycle?*
Provider	• *How does the PSS improve the clinical workflow for providers?* • *How get providers compensated for services provided?*
Payer	• *What are the direct cost savings of applying a PSS?* • *What are the indirect cost savings through improved outcome?*
Policy Maker (Regulatory Authorities)	• *Is the PSS and it components safe and effective?* • *Is the PSS accessible to patients?* • *Is the PSS affordable to patients/cost effective for the health care system?* • *Is the quality of the PSS consistent and sufficient?*
PSS Provider	• *Who is paying for the PSS or components of the PSS?*

Table 8-5: Value considerations by market actors

8.4.2 Internal and External Stakeholder Needs

8.4.2.1 User Needs

User stories are a valuable tool to translate customer value and user needs into requirements. PSS requirements engineering should focus on customer value. Typical semantics for requirements, like "<*Component*> shall <*function*>", does not give any context with regard to the value generated by fulfilling the requirement. The user story format captures the value for and the role of the customer and helps design teams to focus on value:

As a <*user*>, I want <*function*>, so that <*value*>.

The format also provides a description of the function, without defining a component providing the function. In the context of PSS, this is beneficial to allow teams to openly develop and evaluate service and product design solutions for the same functions. User

stories also provide a very useful basis for discussions between users and developers, as several iterations may be required to actually get to the function and the value definition.

8.4.2.2 Business Needs

The consolidation of such business needs is typically not part of the design process. From a PSS design team perceptive, those business needs are however part of the design input. PSS design teams do need to understand the link between business needs leading to requirements in their projects and the strategic considerations by internal stakeholders. To increase the transparency for design teams to the underlying rationale and strategy, business needs should be documented in the form of user stories, like customer needs.

As <*function*>, I want <business *need*>, so that <*value/rationale*>

This format also captures the origin of a business need, namely which function is creating the particular business need. Defining business needs at this stage also allows to address conflicting needs early in the design process, which typically leads to a clearer focus and commitment of design teams.

8.4.2.3 User Stories

The output of this design phase is a comprehensive list of user stories of internal as well as external stakeholders in the format outlined above. User stories have been used in agile software development and enable a conversation between the developer and the user on a non-technical level.

User stories will be used for several steps in the subsequent design process. First of all, it serves as input to generate ideas for design PSS solutions. The defined user stories are also used in the PSS verification. In this phase, a PSS design solution will be verified against the functions and user values defined in the user stories. In the requirements engineering phase for the component development, requirements should link back to user stories to ensure traceability in the design process.

8.4.3 PSS Design

In the design process, all information gathered in the design input phase should be utilised to develop design solutions that fulfil the user needs and provide the most optimal solution for the problem defined in the problem statement.

8.4.3.1 Ideation and Concept Design

To generate ideas and initial concepts for a PSS the design team can leverage the information provided gathered in the design input.

User stories and the use model should be reviewed for aspects of PSS in mind:

PSS aspects	Design considerations
Dematerialisation	• *Can products in the workflow be replaced by services achieving the same value?* • *Can disposable products be replaced with reusable products?*
Value generation	• *Can a product or service be added that improves the long-term outcome for the patient?* • *Can a product or service be added that decreases cost along the health cycle?*
Sustainability	• *Can disposable products be replaced with reusable products?* • *Can a product or service be added that improves the long-term outcome for the patient?* • *Can a product or service be added that decreases risk factors for the patient?* • *Can a product or service be added that decreases cost along the health cycle?*
Customer/Customisation	• *Would a customised product add value in the process?* • *Would a customised service add value to the process?*
Life cycle scope	• *How can the PSS design solution develop over time?* • *Does the PSS change patient journeys and workflows in a way that the PSS offering needs to be adjusted to a new established clinical standard?*
Product ownership	• *Can a product be offered on a prescription basis rather than be sold?*
Continuous improvement	• *What information and data generated along the patient journey and workflows can be utilised for improving the offering?*
Network	• *Who needs to be connected along a patient journey or workflow?* • *What information or data can be utilised at other points of the workflow?*

Table 8-6: Aspects of PSS and design considerations in health care

8.4.3.2 Detailed Design

To maximise the value of a PSS, all market actors have to be considered. Fulfilling an individual user need or even a set of user needs of different market actors, may not necessarily lead to optimal clinical utility. Clinical utility takes a higher-level view on a system, that subsets of user needs may not cover entirely. For a PSS design solution

to be clinically useful, the solution has to be appropriate, accessible, practicable and acceptable. As PSS architecture and PSS components are developed, PSS designers can utilise clinical utility as guidance in the design process.

8.4.3.2.1 Design for Appropriateness

PSS design solutions and components of PSS need to be safe and effective. Both aspects need documented for regulatory purposes. For safety, regulatory risk management guidelines have to be incorporated in the design process, in particular for system components that fall under medical device or pharmaceutical classification. PSS and PSS components need to address a user need, this needs to happen in a repeatable manner and work for all users with the particular need addressed. Clinical effectiveness often is shown in controlled clinical studies, and can also be monitored in post market surveillance efforts. A design solution has to be effective in all use scenarios, as defined in the design input.

The second aspect of appropriateness is the relevancy of a design solution. Unlike an isolated design solution for a particular clinical need, PSS have to create value for a customer. Solving a clinical need within a patient journey may only shift an issue downstream or result in another unmet clinical need, without creating any value. Design team should focus on relevancy and challenge design solutions by asking the simple question “So what?”. If a design solution fulfilling a particular need still results in a better outcome, hence a higher value, the design solution passes the test of relevancy. For example, a newly developed treatment method may suffer from fact that a sufficiently accurate diagnosis is not available. The extended scope of PSS taking into account the entire patient journey makes it less likely to develop design solutions with limited clinical utility due to a lack of relevancy.

8.4.3.2.2 Design for Accessibility

A main criterion for evaluating health care systems and therefore any offerings within this market segment is accessibility. A PSS design needs to take into account cost effectiveness considerations as well as the availability of other resources required. This includes tangible products as part of the design solution as well as not tangible resources like knowledge or experience. An imaging method for example that requires on site and

on demand production of radioactive contrast agents, may provide superior results in imaging, however may not be accessible to a large group of patients that would benefit from such superior imaging. A component of a pharmaceutical agent may be highly efficient, but if such component cannot be produced in required quantities, required quality or at reasonable cost, the clinical utility is significantly decreased by the lack of accessibility. If a method for diagnosis requires high skill level or a level of experience that is only achieved by a small number of health service providers, its clinical utility is also minimal. PSS design may allow to overcome limitations especially on the non-tangible side by adding training and education services, or by solution to allocate resources.

Design for accessibility also means design for affordability. Financial processes between manufacturer and PSS buyer, as well as reimbursement processes for PSS components have to be considered. Value is defined as (clinical) benefit divided by cost. If the cost component is out of proportion, the value and therefore the clinical utility is diminished.

8.4.3.2.3 Design for Practicability

PSS design solutions in health care have to perform in practice as intended by the designer. PSS components have to be integrated and work seamlessly in clinical practice. As clinical practice is typically operating in relatively tight boundaries set forth by regulatory guidelines and reimbursement mechanisms, roles of market actors, stakeholders and users of PSS are often strictly defined. Design solutions ignoring those boundaries lack clinical utility, as they may not be used in a real-life market setting.

As practicability in traditional product offerings is often reduced by training and knowledge issues, the ability to add service components to handle those issues in PSS offers options to overcome those limitations.

8.4.3.2.4 Design for Acceptability

Lack of acceptance for a PSS design solution can minimise the clinical utility despite otherwise well designed systems. A design solution needs to be acceptable to all market actors, stakeholders and users of PSS, but also to the society. Ethical or legal concerns may prevent utilisation of a health care PSS, but also social or psychological concerns.

Services offered by companies to analyse DNA to evaluate the likelihood for the person to get certain diseases in the future for example are not adopted as much as expected, as psychological concerns regarding knowledge of risk for future diseases are still not addressed adequately. There are also social concerns, as people are potentially becoming patients, before they get a disease. Legal issues about ownership of such information and data are also still a concern for patients and the society as a whole.

8.4.3.3 Prototype Modelling

During the design phase, several PSS design solutions will be developed and should be tested in a prototype stage. PSS components developed should be inserted into the design input model and the model should be updated accordingly. This allows developers to identify potential issues in a virtual setting.

8.4.4 PSS Verification and Validation

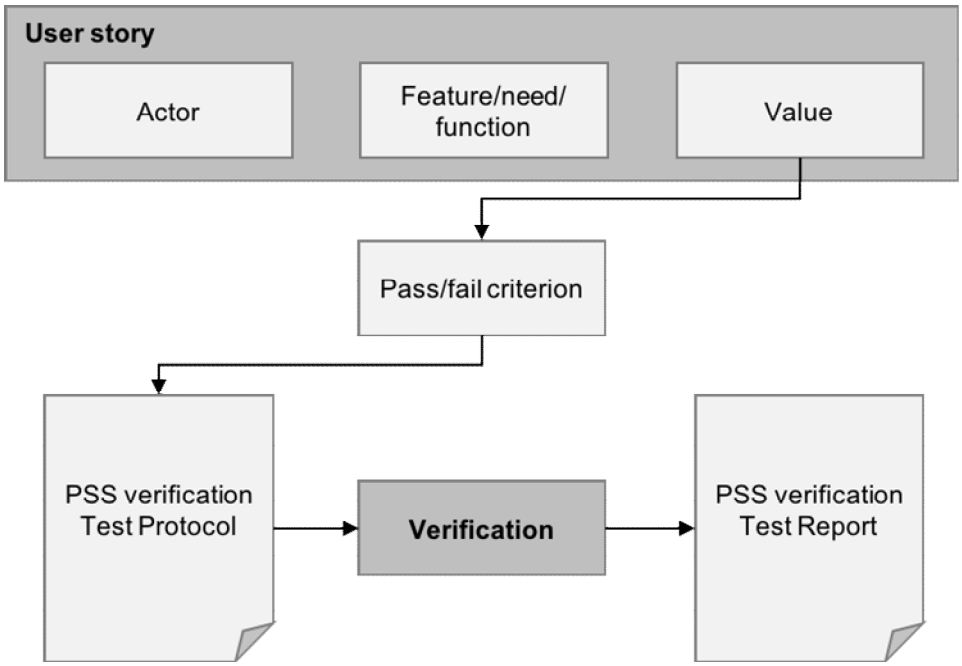
8.4.4.1 Verification Process

A PSS or a PSS concept has to be verified against the predefined user stories of both internal and external stakeholder. A PSS is passing the verification, if all user stories are addressed by a PSS. In contrast to verification on product component level, the verification cannot be carried out as a technical test against product specifications, with measurable success criteria (see **Error! Reference source not found.**).

User stories contain the feature, function or need of an internal or external stakeholder, and in addition the underlying value, which is the pass/fail criterion for the PSS verification. If the value as defined in the user story is not quantifiable, a pass/fail criterion needs to be defined in a verification test protocol for each user story to enable traceability and consistent documentation.

The question to be addressed in the verification process is, if the PSS as described by the user stories has been developed correctly and does actually fulfil the individual values of each user story.

Figure 8-17: PSS Verification Process



8.4.4.2 Validation Process

The question addressed by the validation is if the "correct" PSS has been developed to fulfil the value proposition and to solve the problem it attempts to address.

This requires a holistic view on the entire PSS and a judgement if the actual value proposition is met by the system and the problem stated in the problem statement is appropriately solved.

A prototype model describing the entire PSS, as it is planned to be developed, can be used to virtually validate the system, by reviewing it with users involved in the usage of the final PSS.

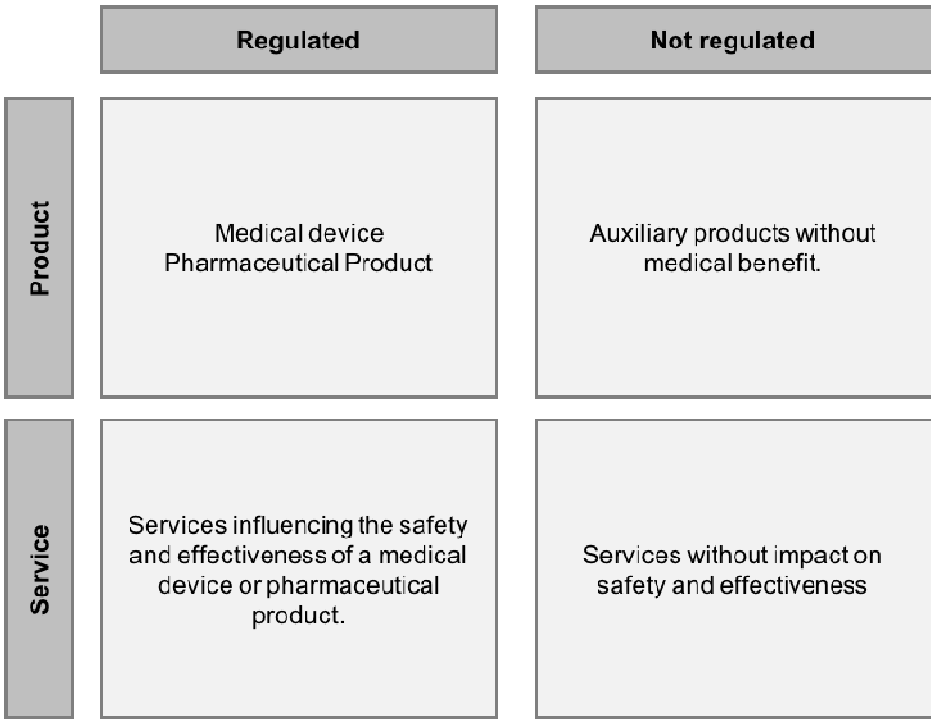
8.4.5 PSS Definition

The process of PSS design for health care is divided into a PSS design level and a component design level. The link between both is the PSS definition.

After a PSS has successfully passed the verification and validation on a system design level the components of PSS have to be defined and classified to apply the appropriate component design process to each part of the PSS.

PSS components divide into products and services. In a health care setting, each product and service has to be categorised as either a regulated component (e.g. medical device, pharmaceutical product, services that impact the safety or efficacy of a medical device or pharmaceutical product) or a not-regulated component that does not fall under the definition of a medical device (see **Error! Reference source not found.**).

Figure 8-18: Categories of PSS components in health care



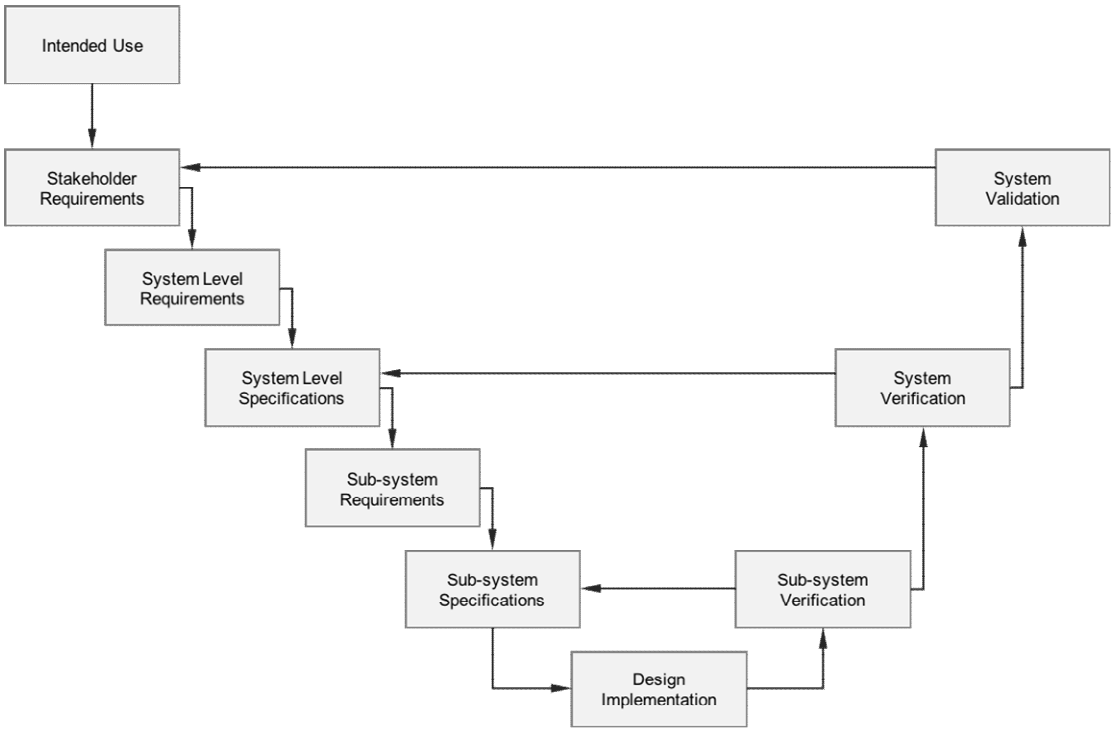
The component definition serves as design input to the component design.

8.4.6 PSS Component Design

After components of the PSS are defined, those components are specified enough to be developed independently. This allows companies to keep existing development processes or to outsource the development of components that are not in their expertise.

Regulated product and services would have to be developed along a traditional development process for medical devices (see **Error! Reference source not found.Error! Reference source not found.**).

Figure 8-19: Medical Device Design Process based on regulatory guidelines (e.g. FDA)



Components defined as not regulated can also be developed following other, more agile design methods for products and services.

9 VALIDATION

The proposed method was developed based on validated observations, conclusions and results of the research objectives set forth at the beginning of the research and field observations in an inductive research approach. Much care was put in the validation of results of each research objective.

The proposed method was developed to show that PSS can be designed in health care. To further validate the feasibility of the method, a case study was carried out, in which the most relevant part of the design method, namely the design input phase was applied to a real-life scenario.

9.1 CASE STUDY SELECTION

To validate the feasibly of the design input phase of proposed design methodology, an innovative technology currently under development was chosen to provide a real-life scenario on which the method could be tested. The scenario was chosen for several reasons:

- Novelty of technology: Products using this technology are not marketed yet. This scenario allowed testing the method with minimal bias with regard to existing offerings in the market.
- Application spectrum: The technology has the potential to lead to products in different clinical applications.
- Market spectrum: The technology has the potential to be applied in the medical field as well as the consumer product field.
- Access: The researcher was involved in the development and therefore had access to information relevant for testing the method.

The access to the development project was most relevant for the study selection. This allowed to apply action research approach in which observations made in project related meetings helped validating and refining the proposed design guidelines. Observations were logged to document relevant issues that validated the proposed guidelines or led to adjustments. References to the respective observations in the numbered observation log were included in the case study below.

An action research approach was chosen to minimize the bias. Questionnaires were considered, however the hierarchical structure between researcher and engineering team was expected to have a risk of bias.

Observations were made in meetings at Jan Medical, between June 2015 and February 2017. The core project development team included a project manager, a hardware engineer, software engineers, a marketing manager, as well as a regulatory and quality management expert.

The team of the structure covered a wide range of viewpoints on the development project at hand.

9.2 GOAL AND LIMITATIONS

The goal of this validation was to evaluate the feasibly of the proposed method, with focus on the design input phase. The case study provided a realistic scenario a PSS design team would face and the background information on the company, the core technology and the market. The available information and data was to determine the feasibly of the design guideline for design input and PSS ideation.

The case study presented is only utilising data of an existing case scenario. This limitation of the case study setup does not allow for a validation of the effectiveness of the method, as the output of the method cannot be evaluated against an endpoint like economic success of a PSS.

The case study also was limited to engineering design input. Business model considerations have been excluded.

A single case study has inherent limitations with regards to the generalisation. The unique combination of the target market, technology and team structure does not allow for a general validation of proposed guidelines and further research is required to refine the methods discussed herein.

9.3 CASE STUDY BACKGROUND

9.3.1 Technology

The core technology of the Company (Jan Medical, Inc.) was based on very sensitive accelerometer sensors that are positioned around the head, held in place by a headset. The accelerometers are able to pick up minute acceleration of the scull. Within the scull, the brain is oscillating driven by the pulsatile flow of blood into the brain with every heartbeat. The acceleration data collected by the sensors shows signal features that alter with structural changes of the brain, caused by brain pathologies. Changes in the signal features therefore can be used to develop algorithms that help in diagnosing or monitoring of brain pathologies, such as stroke, concussion, aneurysms and other pathologies that change either the structure of the brain or the vascular flow of blood through the brain.

9.3.2 Company

The Company is a start-up company in Silicon Valley with 8 employees. The Company is funded through private investors and a strategic lead investor (medical device company). Besides administrative functions, the Company has a clinical team to carry out clinical studies for data collection and product validation, an R&D team to develop or oversee external development projects for hardware, software and algorithm development, and a quality and regulatory team to coordinate the approval processes for products and maintain a quality management system.

The team also had expertise in marketing, sales and business development in the respective markets, although the product was not on the market at the time of the data collection for this case study.

9.3.3 Markets

Driven by the product and the fact that it is a medical device company, the Company was focusing on the neuro market. The main geographical focus was on North America.

The technology has potential in different indications, but the focus was on concussion and stoke at the time of the data collection.

9.4.1 Business Needs Analysis

The following customer needs have been identified (Table 9-1):

Internal Stakeholders	Concerns and Needs
General Management	• *The Company was funded based on development milestones. It therefore was crucial to meet development milestones within the planned timeframe.* • *The Company was seeking additional funding. Increasing company value by showing measurable progress was very important.* • *As the Company was seeking additional funding, focusing on short term projects and tasks that increased the value of the company within one or two quarters were of higher priority than long term projects, for which the value increase would only be measurable after a timeframe longer than three quarters.* • *As the Company was based on milestone funding, it was necessary to focus on one specific indication for development. In this case, the detection and monitoring of concussion.* • *The goal of the Company was to sell distribution rights to other companies with an existing sales force in the relevant field.*
Research and Development	• *To minimise cost and to reduce the burn rate of the Company, only a core team for the development was internal. Many resources needed to accomplish the defined goals and milestones were pooled from consultants.* • *R&D team members were not located in the same office, but distributed over different locations in the US and Europe.* • *The development was highly depended on clinical data* • *The technology (product) included hardware, application software and algorithm development.*
Sales	• *The market to be addressed with a first product was very price sensitive.*

	• *The call points for a sales force were diversified. Customers potentially interested*
Marketing	• *Potential long term effects and health risks related to concussion are in the public focus in North America, mainly because of the popularity of contact sports such as American Football. Parents of young athletes from age 7 to 18 are concerned about the safety of their children, therefore Marketing identified parents are driving force for the adoption of the technology.* • *As the technology was placed as a medical device, marketing claims had to be matched with the indication for use of the product as approved by regulatory authorities (FDA)*
Quality Management and Regulatory Affairs	• *Due to the novelty of the technology, the regulatory pathway was a "de-novo" process (FDA approval process for novel technology), which can be used to obtain approval of a new, but low risk technology.* • *Components of the product have been approved by the FDA under a "de novo".* • *Clinical data was required for regulatory approval*
Finance	• *The prepared business model from a finance perspective was a "razor/razorblade" model, in which equipment components are sold with low revenue or loss, but the main portion of the revenue is created by selling, products and services per use or per user. In this case, licensing models were preferred, in which there is a charge for either every data analysis preformed or for every patient measured till recovered, not considering the number of actual recordings.*
Product Service	• *The Company had experience with product service for product components, as the product was utilised in clinical trials*
Customer Service	• *The Company has limited customer service resources or experience*

Table 9-1: Concerns and needs of internal PSS stakeholders

9.4.2 Market Analysis

9.4.2.1 Addressable Market

The technology has the potential to add value in several clinical indications related to the brain. The company focused on concussion as an indication at the time of the data collection. The addressable market therefore was defined driven by the clinical indication, focusing on concussion (see OBS-020).

9.4.2.2 Market Segmentation

With the addressable market defined an analysis of potential market segments was performed. Since the clinical indication was defined in the prior step, other market segments were derived from the pre-defined clinical indication (concussion).

Concussion is mainly a concern in North America (USA) due to the popularity of contract sports such as American football (see OBS-010). In fact, the topic is in the public focus as professional athletes with a history of concussions over their career showed long term effects leading to depression, post-traumatic stress disorder and dementia, leading to cases of suicides (see OBS-040 and OBS-050).

Due to this focus, there was no need to further segment the market geographically. Given the geographic focus, also no further segmentation related to regulatory jurisdictions was necessary as the FDA (Food and Drug Administration) is the only relevant regulatory authority for this market (see OBS-030).

The market analysis showed that the concussion market can be segmented further along different clinical patient groups and clinical workflows.

Concussions are mainly caused by falls, assaults, motor vehicle accidents and sports related hits to the head. Sports related concussions can be seen as a separate market segment for several reasons. The main difference however is the fact that athletes are a known group with an increased risk for concussion. This allows access to this particular group prior to an injury, which opens the possibility to extend the scope of a PSS design solution across the entire health cycle, despite the fact that the indication is triggered by an injury event, which often prohibits to extend PSS into the pre-disease or even the disease manifestation phase of the health cycle.

Another identified segment is the field of paediatric cases of new-borns or small children suffering from a concussion in a fall.

Persistent concussion syndrome was identified as another market segment within patient groups, which is a subgroup of about 20% of patients that continue to have symptoms after a concussion after two to three weeks, that are severe enough to impact their quality of life.

Along the clinical workflow, the market can be divided into two different clinical workflows. The detection of concussion is taking place after a concussive event or after symptom onset caused by an impact to the head.

Monitoring of concussion is taking place after the diagnosis of a concussion and is necessary to determine when it is safe for a patient to return to activity or for an athlete to return to play. This process is crucial as too much activity in the recovery period can lead to an increase in symptom severity, prolongation of symptoms. A second concussion during the recovery period can be fatal (secondary concussion syndrome), which is relevant for athletes.

Segmentation Criteria	**Market Segmentation**
Geographical	*North America (USA)*
Regulatory	*FDA approval*
Clinical Indication	***Concussion***
Patient groups	• *Concussions (all concussions)* • *Persistent concussion syndrome patients* • *Sports Concussions (focus on young athletes)* • *Paediatric (new-borns)*
Clinical workflow	• *Detection of concussion* • *Monitoring of concussion*
Payment mechanisms	*Depending on patient group*

Table 9-2: Market Segmentation within Concussion Market

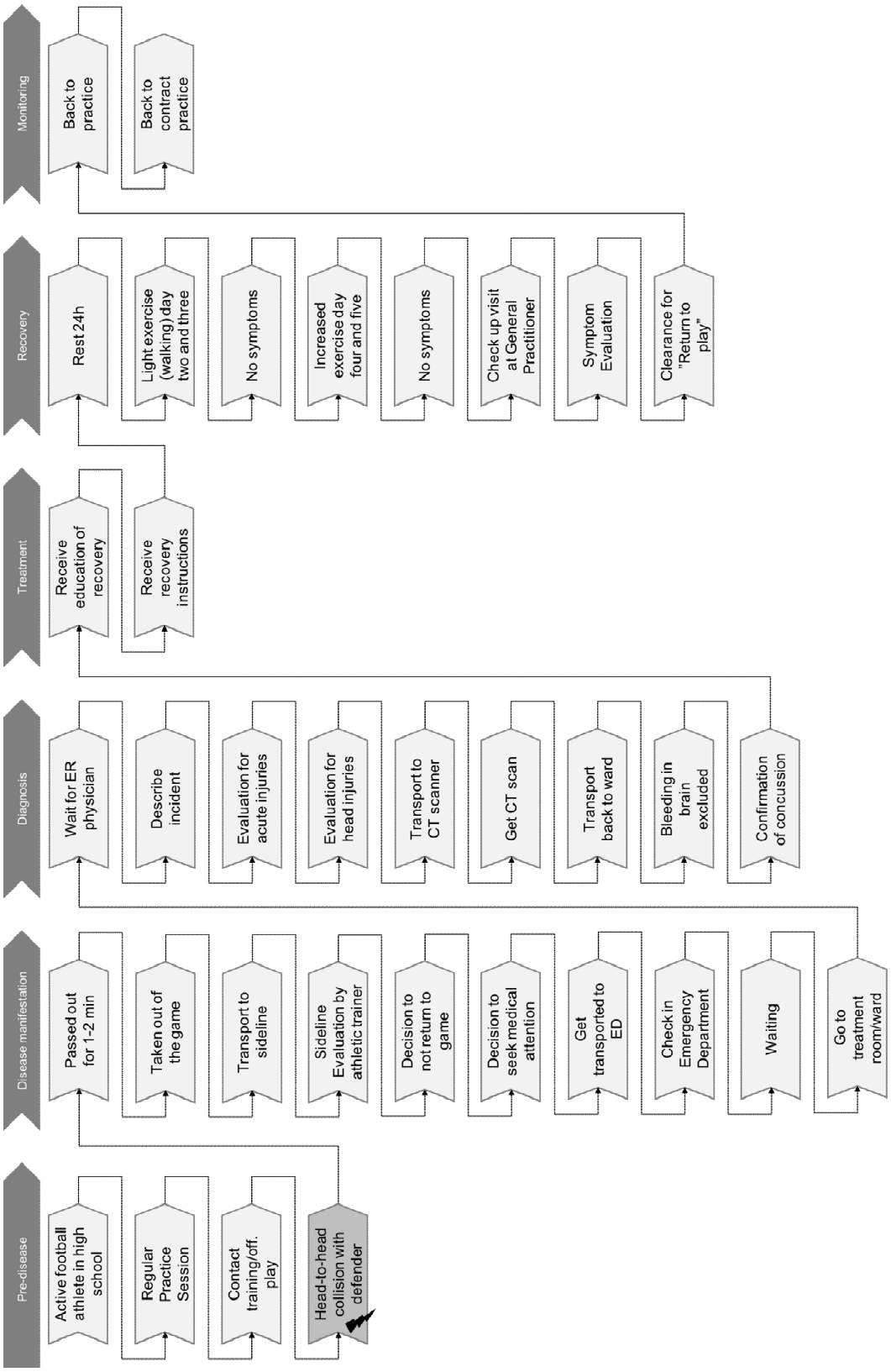
9.4.3 Workflow Analysis

9.4.3.1 Patient Journeys

Patient journeys have been developed utilising information gathered in interviews with medical professionals and researcher in the field of concussion. In addition to those interviews, published protocols for side-line assessment protocols developed for athletic trainers, clinical protocols and hands on experience from a prior data collection study was used to develop patient journeys.

Patient journeys have been discussed and reviewed and updated in brain storming meetings with a team of engineers, clinical specialists and regulatory specialists. **Error! Reference source not found.** Figure 9-1 shows an example for a patient journey along the health cycle.

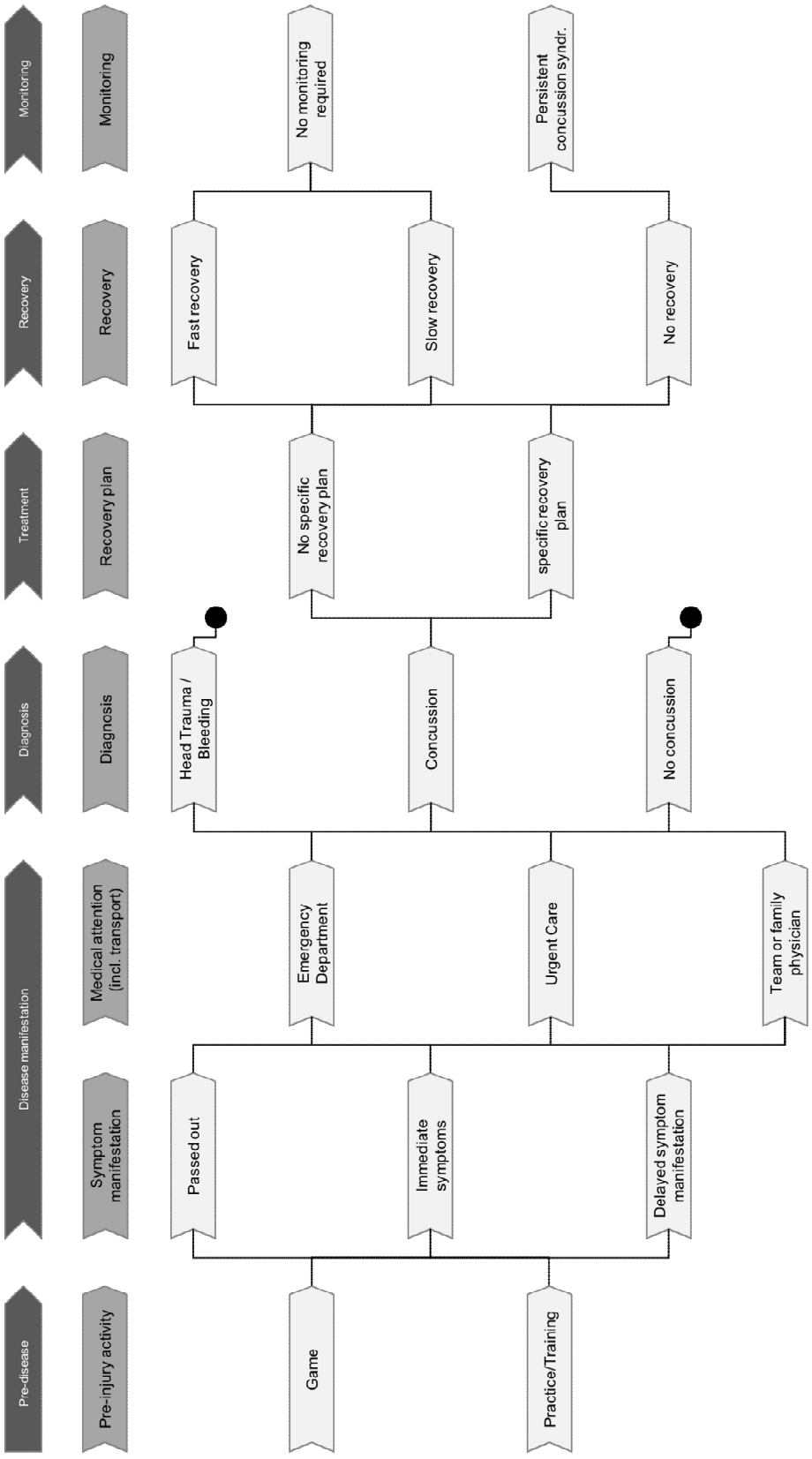
Figure 9-1: Example for patient journey after a sports concussion injury



In discussions and reviews, often alternative paths for a patient journey are identified. This allowed developing an understanding of the decision points that ultimately lead to the different patient journeys and scenarios (see **Error! Reference source not found.Error! Reference source not found.**).

Mapping the decision points along the health cycle improved the generation of different scenarios and ensure that all scenarios were captured in the analysis. This mapping also led to subdivisions of health cycle phases. This structure also was utilised to identify reasonable patient episodes that allowed a more focused approach in identifying provider workflows, product life cycles, periphery workflows and data/information flows.

Figure 9-2: Pathway map outlining decision points and different scenarios throughout the health cycle



9.4.3.2 Provider workflows

Provider workflows were analysed for different patient episodes. As an example, **Error! Reference source not found.** Figure 9-3 shows the workflow for a scenario in which a medically training athletic trainer is managing the patient episode from injury to transport to emergency department. **Error! Reference source not found. Error! Reference source not found.** describes the workflow during the diagnosis episode in a scenario where the patient is brought into an emergency department.

Figure 9-3:Provider workflow during symptom manifestation of concussion

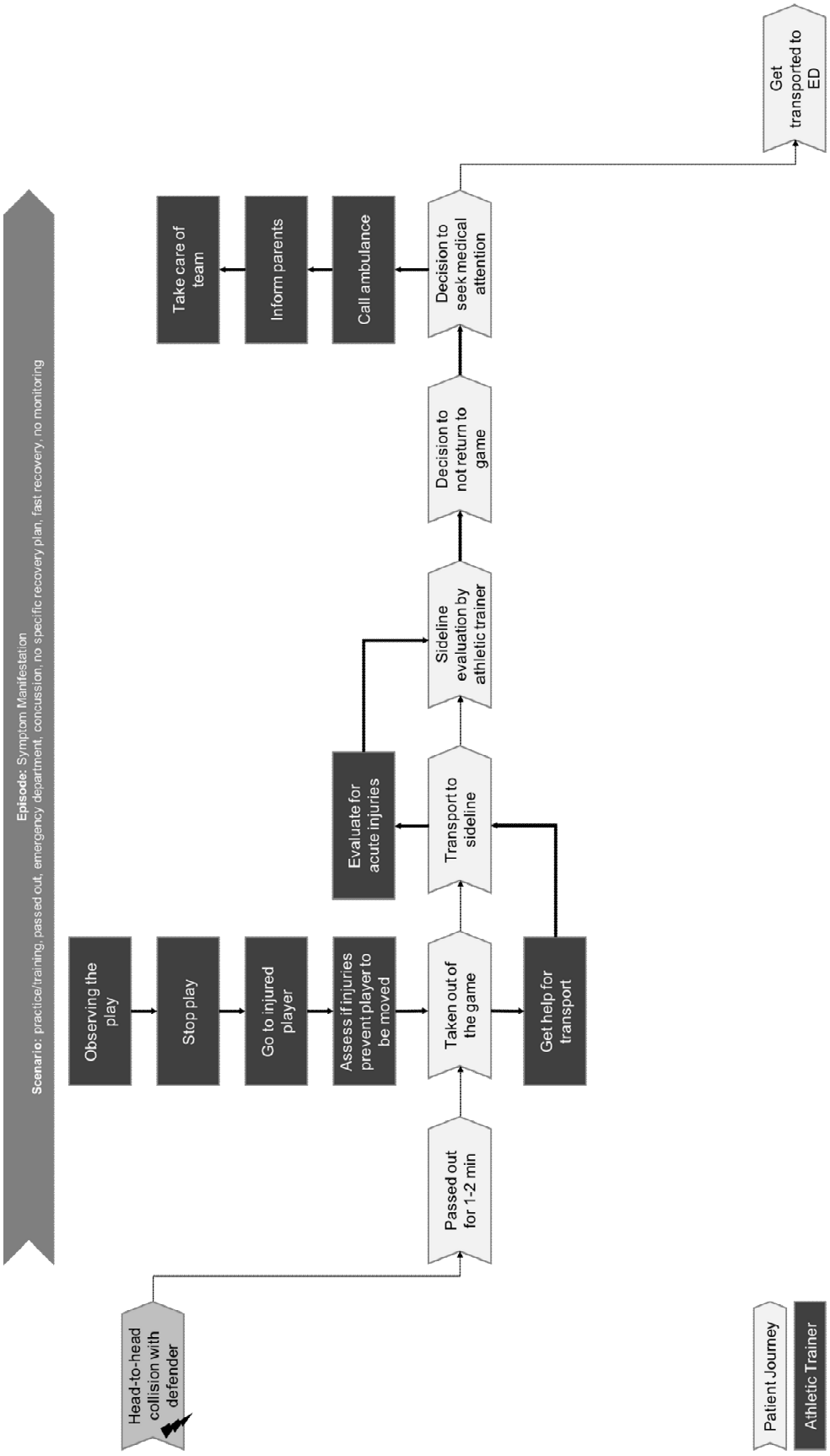
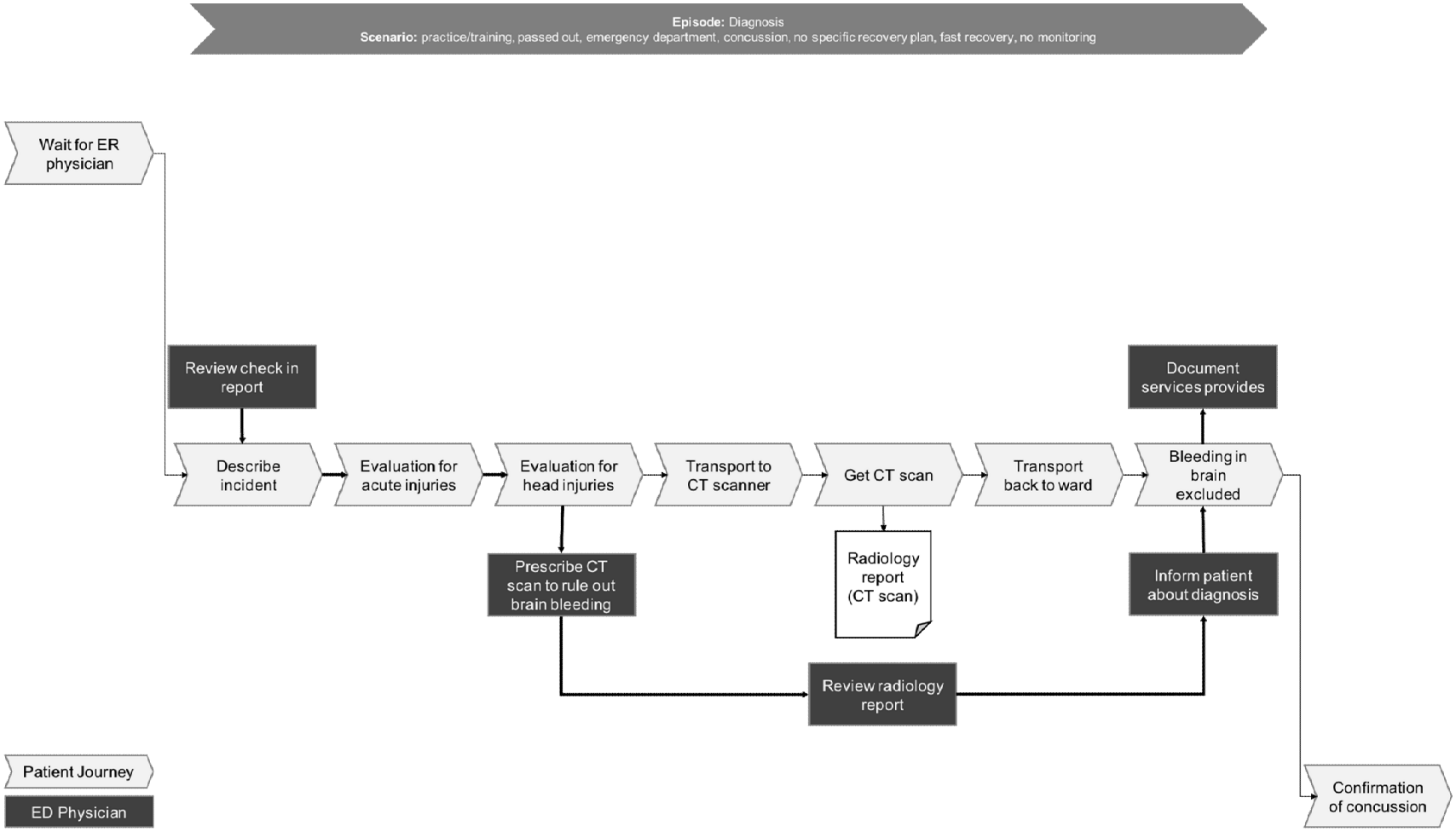


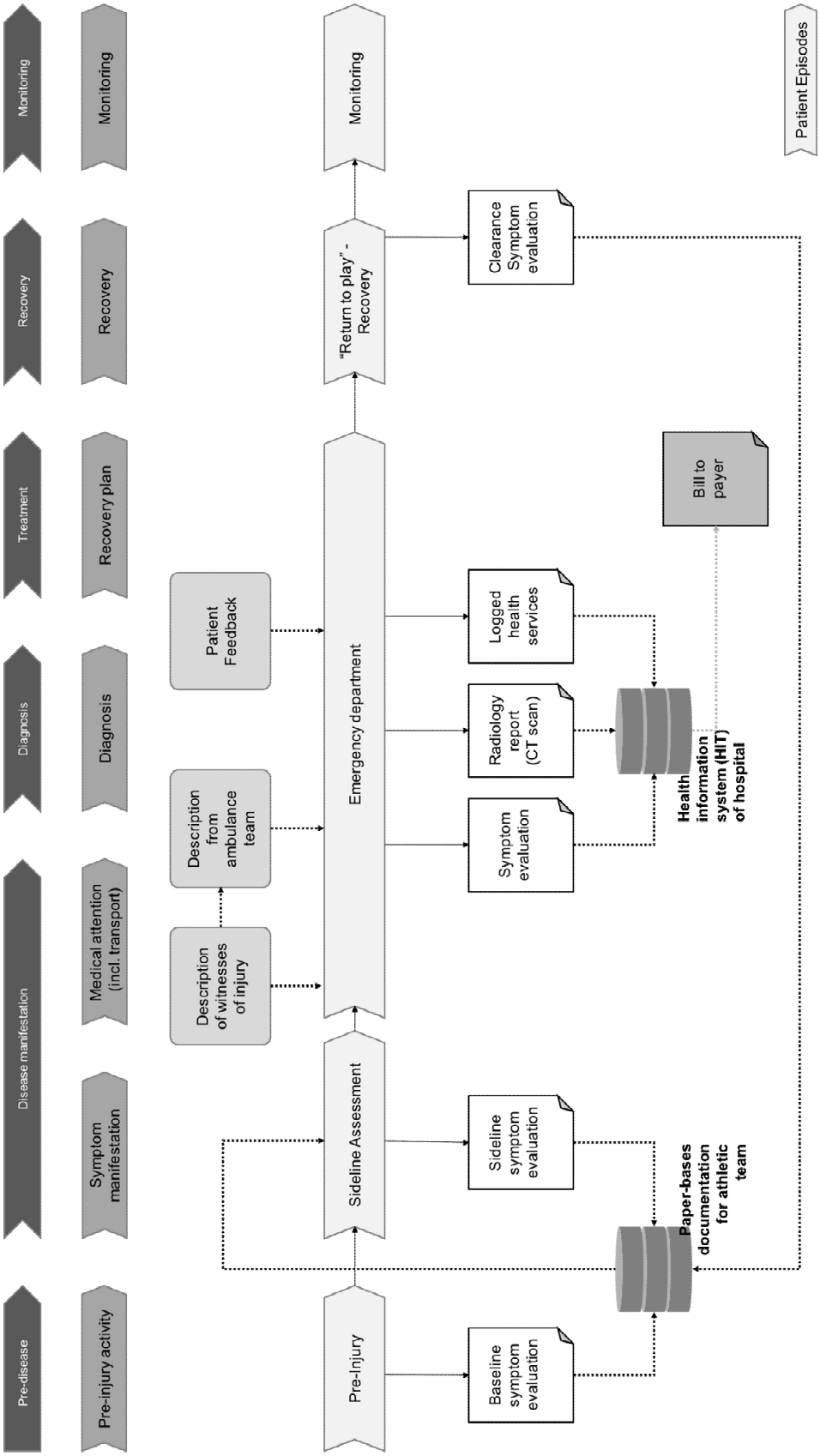
Figure 9-4: Provider workflow during diagnosis of concussion


Episode: Diagnosis
Scenario: practice/training, passed out, emergency department, concussion, no specific recovery plan, fast recovery, no monitoring
Wait for ER physician
Review check in report
Describe incident
Evaluation for acute injuries
Evaluation for head injuries
Transport to CT scanner
Get CT scan
Transport back to ward
Bleeding in brain excluded
Document services provides
Prescribe CT scan to rule out brain bleeding
Radiology report (CT scan)
Inform patient about diagnosis
Review radiology report
Confirmation of concussion
Patient Journey
ED Physician

9.4.4 Data Flow

Figure 9-5 shows the data flow along the entire health cycle for a scenario in which an athlete is injured, assessed at side-line and brought to an emergency department for further diagnosis and treatment. This scenario also includes a recovery period, after which an athlete who suffered a concussion, needs to be cleared for “return-to-play” in by a physician.

Figure 9-5: Data flow along the health cycle for concussion



9.4.5 Value Proposition

The value proposition was discussed among the team, after review of literature, interviews with clinicians (emergency departments, concussion clinics, sports clinics), concussion researchers and observations from clinical studies.

The following clinical needs have been identified (see **Error! Reference source not found.**):

Figure 9-6: Clinical Needs along the health cycle

Health Cycle Phase	Clinical Need
Pre-disease	*n/a*
Disease manifestation	*Diagnosis of concussion on the field/side-line*
Diagnosis	*Objective diagnosis of concussion*
Treatment	*Treatment of concussion to shorten recover periods and minimise long term effects*
Recovery	*n/a*
Monitoring	*n/a*

The problem statement was defined as follows:

> *"Objective detection and assessment of severity, as close to point of injury as possible and throughout the recovery is key to enable physicians assessing the brain injury to initiate appropriate treatment for a successful recover after a concussion. Current approaches only evaluate symptoms subjectively or are not feasible from a cost perspective. Under-diagnosing concussion can lead to serious health risks for the patient, such as second impact syndrome. Over-diagnosing of concussions does increase the cost of care, as patients may be treated or monitored that do not require the care."*

Bases on the problem statement, a value proposition was formulated for a PSS:

> *"The system will generate value in preventing, diagnosing and monitoring athletes who suffered a concussion, by*

- *including an objective, non-invasive test to determine the state of the brain with regard to effects from impacts to the head*
- *providing a platform to handle any data across health phases*
- *streamlining the diagnostic and recovery process"*

The value for market actors will be (see Figure 9-7):

Figure 9-7:Value propositions for market actors involved in concussion

Market Actor	Value
Patient	• *Better health outcome due to* *(i) objective diagnosis* *(ii) non-invasive diagnosis* *(iii) objective evaluation of severity of concussion during recovery* *(iv) streamlined diagnostic process allowing to start recovery earlier and minimise discomfort*
Provider	• *Easy access to data relevant for diagnosis* • *Fast diagnostic test*
Payer	• *Cost savings due to shorter recovery periods*
Policy Maker (Regulatory Authorities)	• *Objective diagnosis* • *Cost effective and accessible to patients* • *Quality is monitored and improved with use data*
PSS Provider	• *Payment through subscriptions model* • *Pay per patient*

9.4.6 Internal and External Stakeholder Needs

User needs were collected from interviews with clinicians, concussion researchers and observations from clinical studies and documented in a user story log to allow traceability. **Error! Reference source not found.** Figure 9-8shows a segment of logged user stories. User stories where associated with the respective health cycle phase.

Figure 9-8: Segment of user story log

US #		Role		Function		Value	Health Cycle Phase
USI-0010	As	an athlete	I want to	know if it save for me to play	so that	I do not have to worry about any long term effects.	pre-disease/monitoring
USI-0020	As	a parent	I want to	know if it save for my child to participate in a game or practise session	so that	I do not have to worry about any long term effects.	pre-disease/monitoring
USI-0030	As	an athletic trainer	I want to	make sure that my players are save	so that	I can minimize the injury rate in the team.	pre-disease/monitoring
USI-0040	As	an athletic trainer	I want to	be able to determine quickly, if a player should be taken out of the game due to an increased health risk	so that	so that I can minimize the injury rate in the team and keep players save.	disease manifestation
USI-0050	As	an athletic trainer	I want to	be able to determine quickly, if a player can be put back in a game	so that	so that I can increase the team success.	disease manifestation
USI-0060	As	a parent	I want to	know immediately, if my child is injured	so that	so that I can make a decision to request taking my child off the game.	disease manifestation
USI-0070	As	a parent	I want to	know immediately, if my child is injured	so that	so that I can pick up my child, in case I am not present.	disease manifestation
USI-0080	As	a parent	I want to	be able to contact the athletic trainer, in case I am not present	so that	I can discuss next steps with her/him.	disease manifestation
USI-0090	As	an athletic trainer	I want to	to be able to contact the parents	so that	I can discuss next steps with her/him.	disease manifestation
USI-0100	As	an athletic trainer	I want to	have documentation of any concussion side-line assessment	so that	I can justify my decision to take out or keep a player in the game.	disease manifestation
USI-0110	As	an athletic trainer	I want to	be able to get medical assistance quickly, if I deem necessary	so that	an improved outcome for my player more likely.	disease manifestation
USI-0120	As	an athletic trainer	I want to	be able to estimate, when a player may be fully recovered	so that	I can adjust my team planning accordingly.	recovery
USI-0130	As	ED physician	I want to	get information about the incident as early as possible	so that	I can take this information into account for planning next steps in the diagnostic process.	diagnosis
USI-0140	As	ED physician	I want to	evaluate the severity of the traumatic brain injury	so that	I can take immediate action in the treatment process, if necessary.	diagnosis
USI-0150	As	an athlete	I want to	leave the emergency room as soon as possible	so that	I can rest and avoid situations that cause increased symptoms like noise, light, dizziness, etc.	diagnosis
USI-0160	As	an athlete	I want to	recover as fast as possible	so that	I can be active in the team.	recovery
USI-0170	As	ED physician	I want to	know that the recover process is monitored	so that	I can be sure that the patient recovers as expected	recovery
USI-0180	As	ED physician	I want to	know that the recover process is monitored	so that	any signs of a persistent concussion syndrome are identified early.	recovery
USI-0190	As	a parent	I want to	know that the recover process is according to plan	so that	I can react if there are deviations from the recovery plan.	recovery
USI-0200	As	a parent	I want to	know how to react, if the recovery is not progressing as planned	so that	I know when it is appropriate to take action.	recovery
USI-0210	As	an athlete	I want to	know how I am doing in my recovery	so that	I stay motivated to comply with the recovery plan	recovery
USI-0230	As	ED physician	I want to	know about any history of concussions for the athlete	so that	so I can take this into account in my diagnosis and treatment considerations.	diagnosis
USI-0240	As	ED physician	I want to	know about any medical history that is relevant to the injury	so that	so I can take this into account in my diagnosis and treatment considerations.	diagnosis
USI-0250	As	ED physician	I want to	know about any medical history that is relevant to the diagnosis	so that	so I can take this into account in my diagnosis and treatment considerations.	diagnosis
USI-0260	As	ED physician	I want to	know about any medical history that is relevant to the treatment	so that	so I can take this into account in my diagnosis and treatment considerations.	diagnosis
USI-0270	As	ED physician	I want to	know about any medical history that is relevant to the recovery	so that	so I can take this into account in my diagnosis and treatment considerations.	diagnosis
USI-0280	As	physician	I want to	know about any medical history that is relevant to the recovery	so that	so I can take this into account in my return-to-play consideration.	recovery
USI-0290	As	physician	I want to	know about any data collected since injury	so that	so I can take this into account in my return-to-play consideration.	recovery

Internal stakeholder user stories were logged similar to user stories (see Figure 9-9):

Figure 9-9: Key internal stakeholder user stories

US #		Role		Function		Value
USE-0010	As	general management	I want to	to enable other distribution partners to sell the system	so that	I can minimize the cost for commercialisation.
USE-0020	As	R&D	I want to	incorporate continuous data analysis into the system	so that	the system provides a more accurate diagnosis and therefore better value for the patient
USE-0030	As	sales	I want to	be able to offer the system at very competitive pricing	so that	I can achieve a high market penetration quickly
USE-0040	As	marketing	I want to	collect data that can be used in post market publications	so that	I can win over key opinion leaders as customers
USE-0050	As	marketing	I want to	collect data that can be used in post market publications	so that	I can start building a body of literature for a reimbursement strategy.
USE-0060	As	finance	I want to	base the system on a licensing model	so that	I can charge the customer for the actual value generation (analysis of recording data) rather than the hardware components
USE-0070	As	general management	I want to	to outsource the service components of the system	so that	so that I do not have to build up the resources internally

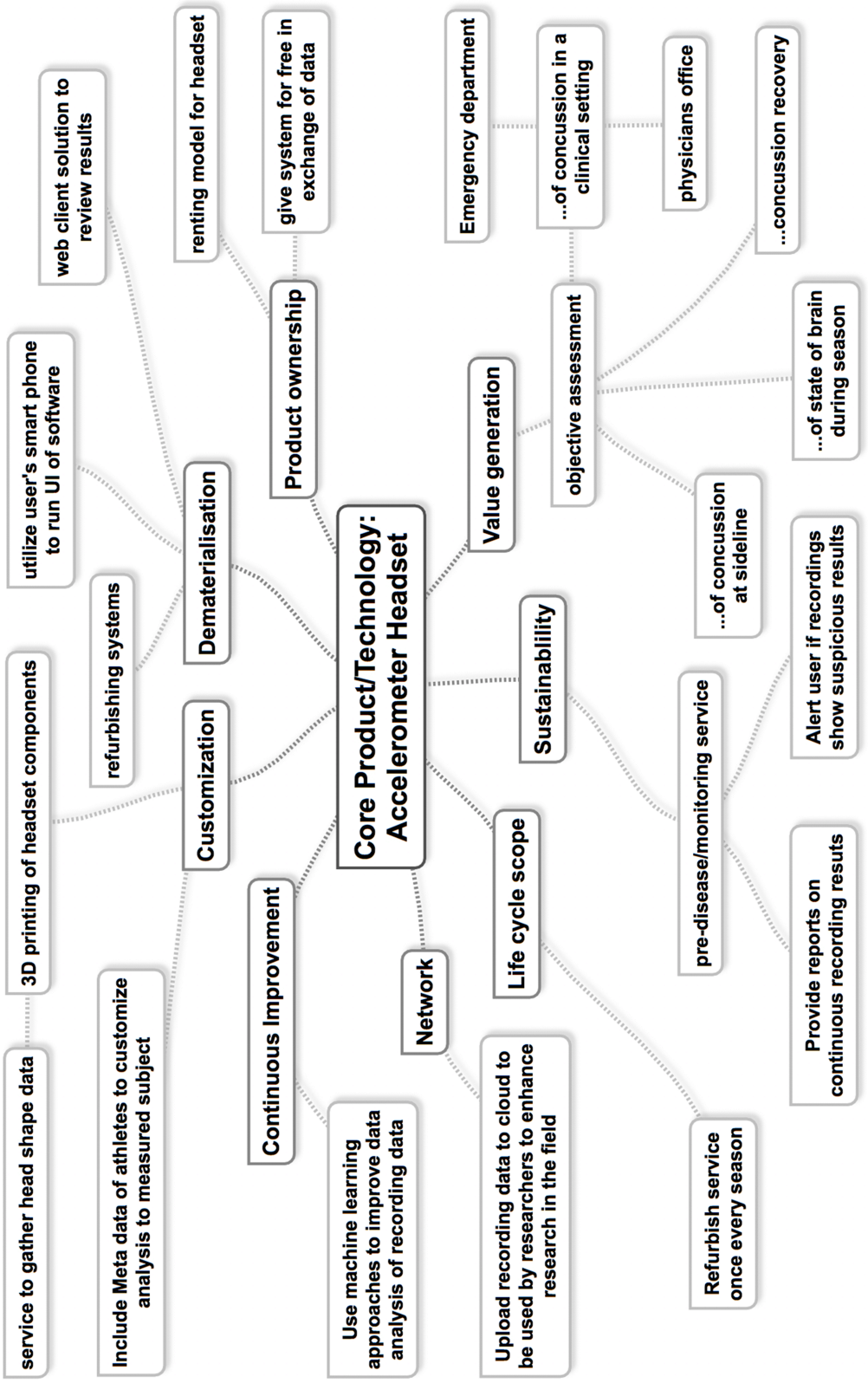
9.4.6.1 Ideation

To create ideas and concept for a PSS, three different creative approaches were followed utilising the proposed design guideline.

9.4.6.2 PSS Aspect Consideration

Starting with the core technology, ideas were generated along aspects of PSS. The mind map shown in **Error! Reference source not found. Error! Reference source not found.**captures the idea generation.

Figure 9-10: Mind map summarising ideas generated by applying PSS aspects to core technology (brainstorming)



9.4.6.3 Review of Design Input Model

Reviewing the design input model in the light of strengths and weaknesses also allowed to generate ideas for PSS design (see **Error! Reference source not found.**).

Observation in Design Input Model	PSS Design Idea
Data generated along the patient journey is not connected.	*Digitise data gathering and provide cloud services for data storage, analysis and sharing.*
Recovery period is not agile	*Provide feedback loop: Enable recordings every day (provide system for recovery as part of a suspicion), provide data analysis, provide service (trained personnel) to help manage the recovery process with the patient and adjust if necessary.*
Diagnosis is not objective	*Provide tool for objective measurement (core technology)*
No (consistent) treatment available	*Provide service to follow patients that opt for a treatment suggested by a health service provider.*
Not much funding available on team side	*Provide subscription offerings for PSS, so that the technology can be utilised more widely.*
Other diagnostic information is not integrated	*Provide integration service to feed results of other diagnostic testing into cloud service*

Table 9-3: PSS design ideas generated from Design Input Model

9.4.6.4 Review of User Stories

Reviewing user stories allowed generating further ideas for PSS design (**Error! Reference source not found.**).

User Story	PSS Design Idea
(*USI-0020*) As a parent, I want to know if it is safe for my child to participate in a game or practise session, so that I do not have to worry about any long-term effects.	*Provide recording history to parents.* *Provide "medical consulting" service to parents, to discuss concerns regarding long term effects of concussion.* *Provide service to update parents on research results with regard to long term effects.*
(*USI-0110*) As an athletic trainer, I want to be able to get medical assistance quickly, if I deem necessary, so that an improved outcome for my player more likely.	*Provide "concierge" service to call trainer, when recording is detected that indicated a concussion, to help with getting an ambulance, finding location of next ED or concussion clinic.*

(*USI-0280*) As a physician, I want to know about any medical history that is relevant to the recovery, so that so I can take this into account in my return-to-play consideration.	*Provide data access to history of patient recording though web interface.*

Table 9-4: Examples for PSS ideas developed from user stories

9.5 CASE STUDY OBSERVATIONS

Several project meetings have been observed. Besides the results presented in prior sections of this chapter, additional observations have been made.

The scope of development projects is often limited by circumstances like overarching strategic goal (OBS-020) or the need to produce cash flow (OBS-010). While ideally PSS are developed in a green field approach, many restrictions apply in a real world setting (OBS-070). This may influence the development process and the result.

As medical devices are regulated, many downstream activities like sales and marketing (OBS-040), risk analysis (OBS-050) and validation strategy (OBS-060) are depending on the wording of the indication for use. The proposed design guidelines are focusing on the problem statement and value proposition, which is appropriate for PSS development, however in reality, the wording on the indication for use may have a significant impact on the scope of the PSS and therefore the freedom to operate for a design team (OBS-150 and OBS-160).

Another significant issue is bias towards technology or core products. Companies are often founded around an idea, a core technology or a key product (OBS-080). At the same time services may not be an expertise in a development team of a technology focused company. This causes product focused solutions, if no active change in company culture and mix of expertise is facilitated through management.

Quality of the outcome of a PSS project will always depend on communication between stakeholders (OBS-090 to OBS-010). Information loss can occur vertically, if for example high level strategy goals are not broken down and communicated to business units or projects (OBS-170). At the same time, information can be lost horizontally, if

divisions like sales, R&D and Regulatory Affairs are not aligned and no common terminology is established.

The proposed guidelines call for the definition of the value proposition and the underlying problem statement. Partly due to the technology/product bias described above, teams may struggle with those steps (OBS-120). Investing the time for a team to be able to look at the bigger picture can minimize the bias (OBS-180).

The core technology available to a company may solve a particular problem, often referred to as an “unmet clinical need”, while not actually increasing the value for a patient (OBS-130). If for example a diagnosis can be provided through a new technology, but there is no treatment available yet, the value for a patient is very limited and may even be negative. A value driven approach like PSS and the proposed guidelines can help avoiding development with limited scope leading to limited value.

User stories proved to be very helpful to associate a customer value with requirements (OBS-0190). This also helps increasing transparency and collaboration between divisions that typically do not work on the requirements engineering in parallel.

The complexity of workflows can be overwhelming for development teams decreasing the efficiency the process (OBS-210). Breaking down workflows and changes of perspective (e.g. patient view, physician view, etc.) is mandatory to handle the complicity. More detailed methods and tools especially for visualization and documentation have to be developed in the future to facilitate efficient communication about complex clinical workflows.

10 DISCUSSION, CONCLUSIONS AND FURTHER WORK

10.1 MAIN RESEARCH OUTCOME

The research questions asked at the beginning of this thesis was:

> *"What is the status of product-service systems (PSS) adoption in health care and how can future PSS adoption be facilitated?"*

As the literature review confirmed, benefits of PSS are well understood and discussed in research, however those benefits have not been linked to specific challenges in the health care market in much detail. The first step towards answering the research question was to develop a better understanding of if and how PSS can be a feasible and useful approach to address challenges in the health care market. Benefits of PSS were identified from literature and compared to challenges in the health care market to confirm in a systematic way that PSS can add value to the market. The focus on the user, value generation and continuous improvement of systems is in line with the need in health care to produce high quality at lower cost, overall increasing the value in health care for the patient, the provider and the system as a whole. To confirm the not only the theoretical usability, but also the practical feasibility a generic PSS design method was applied to a specific case study that allowed to develop a business-to-customer as well as a business-to-business scenario. The case study showed that for both scenarios PSS can be developed and PSS solutions can increase the value of offerings.

After the usefulness was established for the current setup in the health care market, trends in health care where identified to evaluate if PSS was also relevant for this market in the future. The three meta trends identified were digitalisation, personalised medicine and demographic changes. From those meta trends, likely effects have been derived and analysed for their impact on PSS adoption. In the future, there will be an increased demand for cost effective solutions in health care and patients will be more demanding as they are increasingly educated on health topics. The increasing complexity will also

drive more inter-disciplinary collaborations. Those effects will likely act as drives for PSS adoption, as PSS offers helpful approaches to for these challenges. Inertia within the system, like regulatory or legal requirements may however slow down PSS adoption and act as barriers. Using, sharing and analysing digital health data is already a topic of public concern. Artificial intelligence and data mining needs regulatory guidance to ensure self-learning algorithms are continuing to be safe and effective as they alter with additional data. While barriers are significant and will increase the risk companies need to take implementing PSS to ultimately profit from the benefits, especially the cost pressure on health care systems will drive adoption of PSS as a viable approach to increase quality of care while keeping control of cost.

PSS involves fairly drastic changes in culture and process landscape of a company. While changing to a completely new business model, development approach and sales strategy may be overwhelming, many companies actually have aspects of PSS already implemented in their business. Partial adoption of PSS may allow to develop strategies to extend from that status quo and develop a business towards a full PSS provider. The extend of partial PSS adoption was therefore studied in this thesis. PSS can be broken down in different aspects, many of which are integral parts of the business model of health care companies today. Value generation, dematerialisation (digitalisation), customisation and continuous improvement are important cornerstones of business strategies already, from which companies can grow into full PSS provides. An interesting observation in this analysis was that product ownership by itself does not play a major role in health care today. Given the need to safe cost and better align cost and care services provided, this area of PSS is expected to see growing adoption in health care.

An important prerequisite for adoption of a concept like PSS is the ability assess the success of such implementation and to be able to benchmark results against offerings of competitors. The health care market with its complex network of market actors and indirect mechanisms to compensate providers through tax funded, insurance funded, and out-of-pocket payments does typically not allow for a straight forward valuation of a PSS system by only looking at the commercial success. PSS inherently aims to optimize value, which in health care can be distributed between actors throughout the system. A multidimensional approach capturing different aspects of value (clinical utility) was evaluated for applicability in PSS assessment. The multidimensional

approach allows to assess the impact of a PSS on the system in its entirety, giving companies the opportunity for focused development, improvement and benchmarking of their PSS offering.

Based on the observations and concussions derived from the research aims described above, design guidelines where proposed to offer companies a framework for PSS development in health care. As market access in health care is highly regulated, design processes have to follow closely all relevant standards and regulations. Based on processes outlined in such regulations, guidelines have been developed to facilitate the development of PSS, rather than only products. Those guidelines have been applied to a real life scenario to evaluate the feasibility, however further validation and adjustments will be required to develop a generic, but detailed enough guideline for companies to follow as a PSS design process.

10.2 ADDITIONAL OBSERVATIONS

10.2.1 Value as Driver and Barrier for PSS in Health Care

All research objectives contributed to a deeper understanding of drivers and barriers for PSS in health care.

PSS is focusing on value generation and sustainability, which is very much in line with the increasing focus on value in health care. Health care systems have to focus on value to maintain financial sustainability, therefore PSS do address the market need from a health care system or society perspective.

For companies to be incentivised to develop PSS, it is necessary that customers do demand an increase in value. This is not necessarily the case in health care for two reasons:

- **Value Determination**: The value (outcome) for a patient can be hard to determine. Diagnoses and treatment interventions may have long term effects that influence the overall value of an intervention, however long term outcome data is not always available and can be influenced by other factors.

- **Value Appreciation**: Even when outcome data is available and the value can be determined, a health care system may not pass that information on to market actors as effective as in other markets. Regulations handling indirect compensation for health care services through tax and insurance premiums may prevent the market from appreciate value generation by PSS.

Due to the digitalisation in health care as well as mobile health devices and applications, data for outcome based reimbursement becomes more available and the health care market will become more appreciative of value generation. PSS offerings can become enabler in value based medicine, as they can offer products and services to solve a clinical problem but also add other products and services to collect data prior and after a medical intervention, which can be used for value based reimbursement for the intervention. PSS can also be connected to payers as data provided by a PSS may be used to adjust premiums based on risk profiles.

10.2.2 Scope of PSS in Health Care

Due to its complexity and special characteristics compared to other markets, the health care market is typically addressed by specialised companies such as medical device companies. Implementation of PSS in health care will extend the scope of offerings by companies in the field and part of the design solution may be outside the traditional scope of health care. Certain components of a PSS may be in the consumer market area and fall outside the regulations of health care. This will require companies in health care to either cooperate with partners outside the health care field or develop this expertise themselves.

On the other side, there will be pressure from companies outside the health care sectors, especially in the area of wearables and 3D bio-printing to enter the health care market as some of their products will have to be regulated as medical devices.

Building PSS capabilities in the health care sector can help companies to handle this blurring of sector boarders.

10.3 FUTURE RESEARCH DIRECTIONS

The research presented in this thesis should be interpreted as a first pass towards a tailored PSS design methodology in health care. The goal was to confirm that PSS can be designed and implemented in health care. Further research is required to address the limitations of this work and improve the methodology, ideally on real-life data.

10.3.1 Prospective Evaluation and Method Improvement

The research was limited by the fact that testing the method in a real-life setting was only possible in a retrospective fashion. A case study provided data to be used as a starting point to execute the proposed method and validate its feasibility.

Future research should evaluate the method prospectively and improve the method based on those results. In particular, different use cases may allow to develop templates for patient journeys, product life cycles and data flows that can enhance the granularity of the method provided in this work.

An economic evaluation of the method in a real-life setting would also provide information about the efficiency of the method with regard to input of resources versus the design output and the economic success.

10.3.2 Modelling, Visualisation and Tool Development

The observations in the case studies showed that efficiency in the PSS development process likely can be increased by improving tools for documentation and visualisation. This would allow a more streamlined process and a higher degree of consistency in both the documentation and visualisation, which as a consequence would enhance the communication within a development team and between the development team and internal and external stakeholders.

Better visualisation of patient journeys and flows, provider workflows, product life cycles and data flows will very likely lead to faster and better creation of PSS solutions. More sophisticated tools may also allow to enhance the virtual testing of a PSS, by modelling a design solution into the model of current flows.

10.3.3 PSS Team Organisation and Qualification

The users of a method do play a major role in the successful application of the proposed approach. The issue of required qualifications for PSS designers, required capabilities within PSS design teams, as well as the internal structure of such teams as well as their position within a company's organisational structure needs to be further researched. The proposed method may serve as input, as it highlights the tasks and challenges that PSS designers and their teams face in the development of PSS in health care.

APPENDIX

Observation Log

ID	Source	Observation Notes
OBS-010	Design Input Meetings (traditional, product oriented, software and hardware)	The scope of development projects is often driven by the need to release a new product or product generation by a certain date. The stakeholder responsible for this prioritisation typically is sales.
OBS-020	Design Input Meetings (traditional, product oriented, software and hardware)	Projects typically are in the context of a long-term product strategy, defined in upper management. Scope and timelines are often not variables a typical design team has influence on.
OBS-030	Regulatory strategy meetings (traditional, product oriented, software and hardware)	The Intended Use is the starting point for a development project. The Intended Use is defined in regulatory standards and defines the risk classification of a device and subsequently the regulatory pathway. The decision therefore has a major impact on potential project timelines.
OBS-040	Regulatory strategy meetings (traditional, product oriented, software and hardware)	The Intended Use is also defining, how a product can be marketed.
OBS-050	Regulatory strategy meetings (traditional, product oriented, software and hardware)	Internal stakeholders are influencing the definition of the Intended Use. Regulatory/Quality will try to minimise project risks (regulatory risks) by opting for conservative approaches (being as close as possible to an existing Intended Use). Marketing is interested in addressing a market as broad as possible and wants to market the product as aggressive as possible, pushing for broader Intended Use definition.

OBS-060	Regulatory strategy meetings (traditional, product oriented, software and hardware)	Developing a device for an Intended Use that already exists, allows to validate a product by comparison to an existing, already approved product [4] or a self-certification. New indented uses require a clinical validation to prove safety and efficacy of a product. The scope of a regulatory market approval is limited to the intended use and therefore the marketing and advertising scope.
OBS-070	Business Development Meetings (evaluation of other companies)	Limitation of resources and funding may prevent teams from developing the optimal solution, even if a solution is technically possible, because progress needs to be shown to the outside. Taking more time to develop a full system, may not result in significant milestones, that can be associated with increasing company value.
OBS-080	Business Development Meetings (evaluation of other companies)	Companies may not have visibility or access to technology or services that would complement their core technology or products. This is especially true for companies that are driven by core technology or IP (intellectual property).
OBS-090	Design Input Meetings (traditional, product oriented, software and hardware)	Strategic goals and context for a project may be not clear to a design team for different reasons. This may be caused by systematic, or personnel specific issues in the communication of strategic goals. Lack of interest or lack of strategic understanding within the design team.
OBS-100	Design Input Meetings (traditional, product oriented, software and hardware)	In typical project plans, no time for clarification of strategic goals and context for a project is allocated.

[4] in the USA regulated in 21 CFR 807.81

OBS-110	Design Input Meetings (traditional, product oriented, software and hardware)	The process of defining the user need is often limited to existing sales models, company structures and available capabilities in a team
OBS-120	Design Meeting, Brain Storming on value proposition	Defining the value proposition of a product, service or a PSS, or in other words the final customer need is challenging for a design team, if there is already a core product or core technology available or developed. Teams are biased as they want to confirm that what has been developed is useful and tend to make the value proposition fit to existing work products (products and services).
OBS-130	Design Meeting, Brain Storming on value proposition	Design teams (and this includes R&D and Marketing) tend to utilise what is called “unmet clinical need” in the market as the customer need. The unmet clinical need typically is not taking into account downstream workflows or patient flows and may therefore guide a team in the wrong direction. The unmet clinical need for a “definitive diagnosis of Alzheimer’s Disease” does not take into account that such a diagnosis only adds value, if that information can be used for an improved treatment.
OBS-140	Design Input Meeting	In health care, there are typically more than one “user”, namely other market actors.
OBS-150	Design Input Meeting	Deciding on a geographical market also defines the regulatory and policy setting. This decision needs to be made early in the development process, and helps to be more specific on the interactions between actors with regard to expectations of actors and especially payment methods.
OBS-160	Design Input Meeting	Payment methods are not only defined by the country/jurisdiction. Many systems allow a mix of different payment models, in which case the team needs to evaluate, which ones are the applicable payment mechanisms for the PSS.
OBS-170	Design Input Meeting	Starting a project without giving strategic guidance, design teams do not know what the project boundaries are and tend

		to fall back into “traditional” project scopes, to be “on the safe side”
OBS-180	Design Input Meeting	The term “service” in traditional development projects is limited to servicing a product. The term should be discussed in a team to clarify how it is used in a project. A project may include “cloud-services” and other components that can confuse the terminology for a team.
OBS-190	Design Meeting(s)	Traditional semantics for requirements lack information regarding the rationale behind the requirement.
OBS-200	Design Meeting(s)	Handling the entire workflow is too complicated. Teams need to break down a workflow into scenarios (only one path) and episodes (only short sections of a path)
OBS-210	Design Meeting(s)	Workflows traditionally cover chains of events, which each event associated with a person responsible for the event. This view neglects that a person being part of the workflow (such as a patient) may also have needs, while inactive (e.g. waiting for a test results for a long time can increase unnecessary concerns)
OBS-220	Design Meeting(s)	Product or a service in the health care system needs to address the needs of the customer (who is buying?), but also needs to address needs and expectations between other market actors
OBS-230	Design Meeting(s)	PSS systems are likely to extend outside the regulated design process. While parts of a PSS may have to follow regulations, other parts may not qualify as a “medical device” and therefore be not regulated.

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