The influence of national healthcare regulation on E-health business models

an exploratory comparative case study of four European healthcare markets

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April 5th, 2010

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S0081205

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Management Summary

Motivation

Recently developed e-health services that are to be implemented in the healthcare market show a great potential in increasing the healthcare quality and efficiency. Despite the promising potential of these services, many e-health services are unable to be successfully commercialized after being developed. By using business modeling, e-health services can be better aligned with available resources and the external environment. The external environment is particularly interesting in this instance, because the barriers for e-health services are of a legal nature. This thesis will therefore determine the influence of healthcare regulation on e-health business models.

Methodology

To study the influence of healthcare regulation on e-health business models, a comparative case study has been conducted. The case study has been divided into two stages. The first stage has been used to gather details regarding national healthcare regulations of the participating countries, using an analysis based on a literate study on the effect of national healthcare regulation on e-health services. The second stage has been used to validate the results of the first stage by conducting a set of expert interviews.

Results

Based on the results of the regulation analysis we can determine that the national healthcare regulation has a major influence on the financial domain of the e-health business model. Through the reimbursement methods and the way how treatment tariffs have been set up, the national healthcare regulation influences the financial incentives to adapt an e-health service.

Conclusion

National healthcare regulation has a large influence on the financial domain of e-health business models. It co-determines whether an e-health service can be financially viable. Because of the influence on the financial domain, it may force e-health services to alter their primary money source, also influencing the organizational domain of the e-health business model. Therefore the national

healthcare regulation should already be analyzed in an early stage of the business model design process, in order to anticipate in time to barriers created by national healthcare regulation.

Recommendations

Based on the results of this thesis, the following recommendations can be made:

- Implement the regulation analysis over the entire length of the business model design process.
- Further develop the reimbursement structure of healthcare services.

Regarding this presented regulation analysis, the following recommendations can be made:

- Further research on the influence of national healthcare regulation on other business model dynamics.
- Broaden the scope of the regulation analysis.

Table of content

1. Introduction

This chapter introduces the research question, based on the problem definition and the motivation for this research. Additionally the research approach is presented, along with an introduction of the e-health service that is used throughout this research.

1.1. Problem definition

As in many other sectors, the possibilities and benefits of information technology have not gone unnoticed in the healthcare sector. Under the name of e-health it is believed that information technology will be applied in the healthcare market in the next decade to improve the healthcare quality and efficiency (Piotti & Macome, 2007). E-health refers to all forms of electronic health care delivered using information technology, ranging from informational, educational and commercial products to services offered by healthcare professionals. Examples of such e-health services are e-prescribing and electronic management of chronic diseases, and have a great potential of realizing increased efficiency and quality, and to reduce health care costs and medical errors (Goldsmith, 2000) (Hsu, et al., 2005) (Anderson, 2007). During the development phase of many e-health services, tests indeed show positive results on end user satisfaction and quality improvement. Despite these promising results in the development phase, many e-health services do not succeed to become financial sustainable and successful in the healthcare market. This is substantiated in a recent survey of U.S. primary care physicians, in which 80 percent says that the lack of financial support causes a major barrier to adapt e-health services (Anderson, 2007). In the same survey, over two thirds of the respondents indicated that the lack of a strategic plan for implementing e-health services also forms a major barrier. To fill this hole in the lack of a strategic planning, the concept of business modeling can be used. Studies show that business modeling can be used as a method to bring (e-health) innovations to a successful deployment (Spil & Kijl, 2009) (Itagaki, Berlin & Schatz, 2002). By using business modeling, the e-health service can be better aligned with available resources and the associated stakeholders. This increases the chances of the successful commercialization of an e-health service. Barriers, such as the lack of financial support, can then be identified in time, and solutions can be created to overcome these barriers.

The cause of the lack of financial support can have different origins. In the case of e-health services legal barriers are identified as a major force on the e-health business model. This is recognized by Daly (2000) who states that the barriers for e-health services are essentially legal barriers. Legal barriers can for example be created by healthcare regulations that influence the reimbursement structure and the treatment payment. E-health services may not always fit within the traditional healthcare regulation, making it hard to realize all their potential benefits. This indicates that healthcare regulation hampers the introduction of e-health services in practice. Parente (2000) agrees by stating that regulation is a factor that often creates barriers that influence the success of e-health business models.

Based on this introduction we can state that business modeling offers a useful method that can be used to increase the chance of a successfully deployment of an e-health service. However, adequate attention is needed to potential barriers in the business model design process. Studies show that the legal barriers influence the e-health business model and hamper the success of its deployment. Therefore the research question that drives this study is: *"What is the influence of national healthcare regulations on e-health business models?".* We use the term 'national healthcare regulation' instead of the term 'healthcare regulation', because it allows us to analyze the effect of healthcare regulation on the e-health business model within one healthcare market. Additionally it allows us to conduct a comparative case study as described in the following chapter.

1.2. Research approach and case description

To answer the research question, this thesis will analyze the influence of national healthcare regulation on an existing e-health service. Therefore, a recently developed e-health service has been selected that is on the verge of being brought to the market. The e-health service in question is called Myotel - a feedback system that allows patients with neck and shoulder complaints to monitor their muscle tension. The service consists of two major elements. The first element is MYOfeedback, which allows patients to get feedback based on muscle tension measurements. Studies have shown that patients with chronic neck and shoulder complaints have problems with relaxation of their neck and shoulder muscles. The second element is TELetreatment, which allows the physiotherapist to analyze the measurements via the internet and to allow remote consultation with the patient.

In order to make the Myotel service work, the patient has to wear a harness under his clothes during his everyday activities. The harness has been equipped with sensors that constantly measure the tension of the muscles. A device connected to the harness warns the patient when his muscles are too tense by vibrating. Through a PDA (personal digital assistant), patients are able to get more detailed information on how to change their behavior. The data are also sent to the patient's physiotherapist, allowing the physiotherapist to analyze the data prior to a consult and to give feedback through a teleconsult. The communication flow of the Myotel service has been visualized in Figure 1.

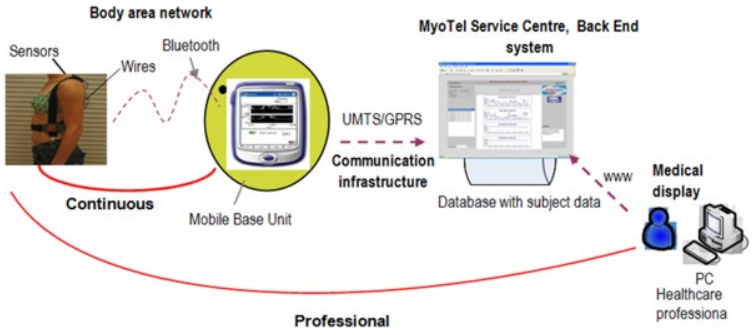

Figure 1 – 'Communication flow of the Myotel concept'

The injuries Myotel has been designed for can have a work related origin as well (for example RSI or a stress related origin). Therefore it can be applied in both the private healthcare as the occupational healthcare.

The Myotel service offers an ideal opportunity for this thesis because it is on the verge of being commercialized. Due to the current status, the potential of the Myotel service is already being investigated in four European countries: the Netherlands, Sweden, Belgium and Germany. This allows this thesis to use the current research that has already been done, and to analyze the influence of national healthcare regulation on the Myotel service in the four European countries. To structure the analysis the following steps have been taken:

1) Conduct a literature study in which the concept of (e-health) business modeling will be explained. Based on this explanation, the business model elements that are of influence on the success of a e-health business model can be identified (chapter 2).

2) Identify the relevant regulatory factors that influence an e-health service, and determine how they relate to e-health business models (chapter 3).
3) Determine and validate the influence of the regulatory factors on the Myotel e-health service in two phases (chapter 4).
    a. The first phase will determine how the generic Myotel value network has to be adapted to the create a fit with the healthcare regulation in the Netherlands, Sweden, Belgium and Germany.
    b. The second phase will validate the suggested changes to the generic Myotel value network.
4) Discuss the results and recognize the regulatory influence in each country (chapter 5).

Finally, this thesis wraps up with a conclusion and discussion to analyze the influence of national healthcare regulation on e-health business models and to answer the earlier formulated research question.

2. Literature review

In the following chapter a short introduction will be given on the term business models. Based on this introduction, the characteristics of e-health business models will be explained. Additionally the elements of the business model that are of influence on the success of an e-health service will be identified.

2.1. What is a business model?

The business model concept was first used in the 1970s to describe IT-related business processes (Konczal, 1975). However, it was not until the 1990s when the concept really started to be used. Not surprisingly, this comes together with the large growth of the internet and the rise of many new IT organizations. Business models have originally been designed to map business processes and information patterns within companies that could be used to build IT systems (Stähler, 2001). However, over time the business model concept has grown to become a method to map a market structure and to make strategic choices regarding the position of the organization within the market structure (Bouwman, de Vos & Haker, 2008). According to Chesbrough and Rosenbloom (2002) these choices lead to a description of how an organization can create value in the market.

To define the term business models, it is important to use a definition that includes the modifications that have been made in the past decades to the business model concept. Osterwalder, Pigneur and Tucci (2005) do this by defining business models as *'a conceptual tool that contains a set of elements and their relationships and allows expressing a company's logic of earning money. It is a description of the value a company offers to one or several segments of customers and the architecture of the firm and its network of partners for creating, marketing and delivering this value and relationship capital, in order to generate profitable and sustainable revenue streams'.*

This definition is particularly useful because it incorporates the most recent development regarding the business model concept. It includes both the approach as suggested by Bouwman et al. (2008) that the business models can be used to map a market structure and to determine the position of the organization within the market, and the approach as suggested by Chesbrough and Rosenbloom (2002), that the use of business models should lead to value creation.

Although the term ‘business model’ has its origin in the IT related businesses it is currently being applied many other branches. One of these new fields of business is e-health.

2.2. E-health business models

First used in 1999 (Eysenbach, 2001), the term e-health is a relatively new term in the family of e-businesses. It is rather difficult to give a proper definition of the term e-health because it covers a lot of ground. E-health is not just the application of e-commerce on healthcare applications, but also the ability of information and communication technologies to improve health and the healthcare system (Alvarez, 2002). In this light, e-health has the ability to compliment and improve existing healthcare services. Therefore e-health business models can be defined as *‘new business models using technology to assist healthcare providers in caring for patients and providing services’* (Sternberg, 2004). Sternberg (2004) defines the business models as ‘new’ because the business models should focus on using technology to assist healthcare professionals in caring for patients and providing services. Through new technological developments or new applications of existing technologies, new products and services are developed to complement existing treatments and services. These new products and services might offer great advantages in theory, but often there is no guarantee whether the commercialization will be a success. This is especially the case in the healthcare market where many barriers exist to new e-health services (Parente, 2000). The barriers are, for example, lack of data standardization and uneven internet access. Another barrier is the financing of new e-health services. E-health services that emerge in the healthcare market are often able to develop their new ideas with external funding. But when the funding dries out and they have to survive on their own, these barriers cause many e-health applications to fail in the commercialization process (Tanriverdi & Iacono, 1999). Itagaki et al. (2002) second that the lack of sufficient revenue is the cause of many failures of e-health projects and state that more research on e-health business models is needed.

2.3. (E-health) business model elements

To go further into the concept of e-health business models, we elaborate on the different elements of a business model. A central element in a business model is value creation (Gordijn, Akkermans & van Vliet, 2000) (Osterwalder et al., 2005). Gordijn et al. (2000) underline the importance of value creation and describe that the focus of a business model is on the main actors and the value exchange

between those actors. Ultimately, this model can be used to map the value creation, expressing the value flow for each participant in the model. However, the scope is of this model is limited because it does not describe any elements other than stakeholders influencing the value creation.

Dubosson-Torbay, Osterwalder and Pigneur (2001) have designed a business model framework that has a wider scope. They agree that a business model is a method to for creating, marketing and delivering value to customers. They designed a business model framework that consists out of four elements that are relevant for the value creation:

1) product innovation, the value a firm wants to offer to its customer;

2) customer management, value creation and exchange patterns between different actors;

3) infrastructure management, the capabilities needed to create and deliver the value;

4) financial aspects, value creation processes and exchange patterns between different actors.

Although Dubosson-Torbay et al. (2001) offer a business model framework with a wide focus on value creation, the focus is only on the internal elements. These internal element are all present in the direct environment of the organization and therefore within the influence of the organization. However, it neglects the external elements that are outside the influence of the organization. This thesis focuses on national healthcare regulation, an external element that essentially influences e-health business models. Therefore a business model framework is needed that not only uses the internal elements as described by Dubosson-Torbay et al. (2001), but also incorporates the external influences. The dynamic STOF model (Bouwman et al., 2008) offers a framework that combines both the internal as the external forces. Bouwman et al. (2008) recognize three external forces:

1) market, influence of suppliers, customers and competitors;

2) technology, influence of technological developments and innovations;

3) regulation, for example licensure and liability regulations.

These external forces influence the four domains of the dynamic STOF model:

1) service, the intended value, delivered value and perceived value;

2) technology, the technological characteristics of the product/service;

3) organization, the actors and roles that are present in the business model and how they interact;

4) finance, cost, revenue and investment sources.

Figure 2 visualizes the relation between the external forces and the dynamic STOF model domains.

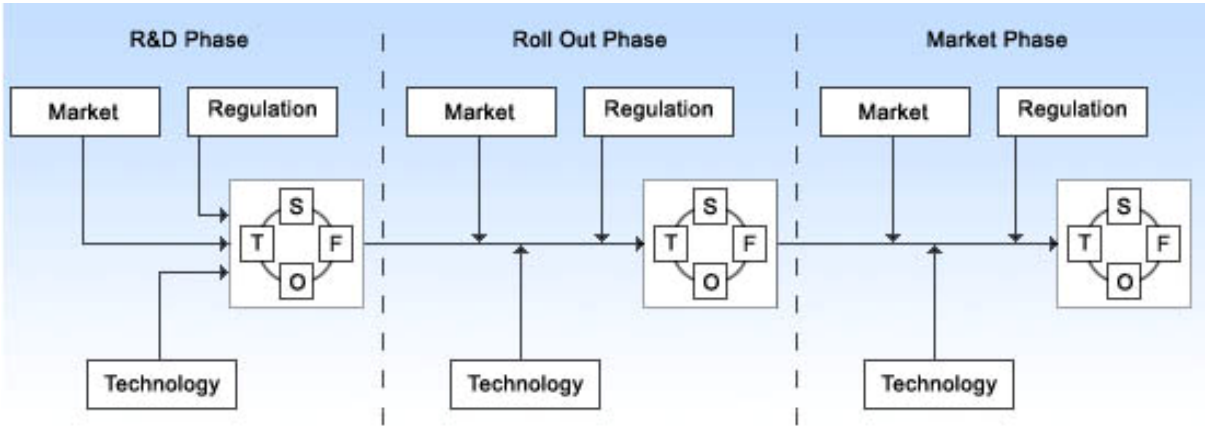

Figure 2 – 'Dynamic STOF model'

As can be seen in Figure 2, the STOF model changes over time, showing that the business model is different for each phase in the product life cycle and visualizing the need for business models to keep adapting towards the changing environment. Every phase experiences different external influences and goals, requiring a different business model to reach those goals. To be able to create a different business model for every phase, it is important to keep a business model dynamic and to keep a fit with the environment (Mason & Rohner, 2002) (Morris, Schindehutte and Allen, 2005).

Most e-health services are technology driven (Broens et al., 2007) and deliver a clear value to the healthcare market. However, despite the value increase, many e-health services fail to commercialize (Tanriverdi and Iacono, 1999). E-health services do well in the *R&D* and *roll out* phase by proving an added value to traditional services, but fail when the e-health service is moved into the *market* phase and needs to become financially independent.

When zooming in on the STOF business model domains, there are few issues concerning the *service* and *technology* domain. In terms of the service domain, e-health offers great opportunities for improving the service quality and efficiency of healthcare (Goldsmith, 2000) (Hsu et al., 2005). Many of these opportunities are made possible by information technology that has already been developed, and can be applied in the healthcare market. However, to successfully implement e-health services, new models for financing these services are needed, requiring to alter the traditional relations between the healthcare providers, insurance organizations and patients. This creates challenges because the new e-health services have to navigate through the web of traditional and new regulations before their economical potential can be determined (Fried, Weinreich, Cavalier & Lester, 2000). Because of the changes in the traditional relations between the healthcare professionals and the patients and the need for new financial models, the focus of this thesis will be on the *finance* and *organization* domain.

To present a practical approach to analyze the two domains we will make use of a value network. A value network is a component of a business model (Hamel, 2000), visualizing the network that surrounds the organization. The value network includes suppliers and partners, showing the main roles and the value flows. This allows us to analyze the *financial* domain of an e-health service. The *organization* domain elaborates on the roles that are present within the value network and how they interact. The interaction of these two domains combined in a value network gives a better view of organizing an e-health service in order to make it financially sustainable.

In this chapter, the concept of a business model has been elaborated on and we have derived that mainly the finance and organization domains of the e-health business model are of influence on the success of an e-health service in the market phase. Because the STOF model includes both these internal domains and recognizes regulation as an external force, this model will be used to structure this thesis.

3. Regulatory environment

In this chapter a literature study is conducted to get a better understanding of the components of the healthcare regulation that influence the financial and organizational domains of the e-health business model.

3.1. National healthcare regulation

To get a better understanding of national healthcare regulation we first have to determine what the term comprehends. According to Saltman, Busse and Mossialos (2002), the influence of national healthcare regulation on a country's healthcare sector can be divided into two different aspects – policy objectives and management mechanisms.

Policy objectives include regulation that is concerned with specific policy goals that influence a broad public. Some examples are: to provide a healthcare system that is accessible for the whole population, to guarantee the safety of healthcare innovation, and to educate citizens about clinical services, pharmaceuticals and a healthy lifestyle. Management mechanisms have a more practical and operational character and target specific regulations that are needed to reach the goals as described in the policy objectives. Saltman et al. (2002) recognize a number of components that affect healthcare management capabilities and are associated with greater operating efficiency and effectiveness of both human and material resources. Other authors mention different aspects of healthcare regulation that influence an e-health service and can be categorized under the management mechanisms recognized by Saltman et al. (2002). They can be categorized into three components:

1) state influence (Saltman & Figueras, 1998) (Colton, Frisof and King, 1997);

2) licensure and liability (Daly, 2000) (Wilson, 2003) (Miller, 2001);

3) financial regulation (Hurst, 1991) (Tanriverdi & Iacono, 1999) (Groll & Wensing, 2004).

Because of the practical and operational character of these components and their influence on the operating efficiency and effectiveness of both human and material resources (Saltman et al., 2002), it is believed that these components have the largest influence on a value network. Therefore these three components will be further used in this thesis to determine the influence of national healthcare regulation on e-health value networks.

3.2. State influence

There are different scenarios concerning how the first component, state influence, is being used (Saltman & Figueras, 1998). One scenario is a situation in which the government controls the healthcare market, where healthcare instructions are managed by healthcare authorities and the system is financed based on taxes. The opposed situation is where the healthcare market is dominated by private profit based organizations in which the government has little influence.

Whether the state influence is high or low does not influence the amount of healthcare regulation. In Europe the healthcare sector is heavily regulated and there is little or no difference in the amount of regulation in the different European countries. This is regardless of the degree of state authority and supervision (Colton et al., 1997). However, what does affect the e-health business model, is the dominant role of either the government or private organizations. This influences the actors present in the value network and how they are organized.

The two different scenario's represent the models that are present within Western Europe. Based on the work of Tajnikar and Bonča (2007) we can recognize two models within the typology of health care systems in Europe. The first type is the social insurance model, a model in which the health insurance funds operate as non-profit entities. Membership of a health insurance fund is compulsory but involves the free choice of a specific fund. The list of services that are guaranteed is standardized and patients can choose their own healthcare provider. The second type is the national health service model in which the healthcare insurer and sponsor functions are integrated into one institution. Hospitals receive a negotiated budget, with a total budget limit for all hospitals, established by the governmental. Healthcare professionals receive fees based on the negotiation between the government and medical societies.

3.3. Licensure and liability

The goals of licensure are to ensure that healthcare professionals meet competence standards and to prevent malpractice (Miller, 2001). Ultimately, proper licensure is believed to reduce the risk of compensating the patient's treatment because of improper healthcare by setting up clear liability rules. When licensure for e-health services is however not fully embedded in the healthcare market, the adoption of e-health services will struggle. E-health changes the traditional relationship between patients and providers, and undermines traditional licensure principles (Kuszler, 1999). Lack of inadequate e-health licensing laws and unclear liability rules fail to give patients adequate protection,

meaning that e-health services will continue to struggle to gain support from healthcare providers and patients. This can cause a loss for both the healthcare providers and the patients (Daly, 2000).

3.4. Financial regulation

The third and last component discusses how regulation influences the financial structure of the healthcare system. To structure this component, the content can be divided into three different elements: ‘reimbursement’, ‘treatment payment’ and ‘different healthcare sectors’. These three elements will give a better insight into the importance and structure of value and money flows within the healthcare markets.

3.4.1. Reimbursement

The first element of the financial regulation of the healthcare sector is whether insurance companies do reimburse e-health services. Hurst (1991) mentions the rising costs of the European healthcare systems in his study on healthcare reforms. To keep the cost increase within limits, Hurst states that healthcare professionals should have the freedom to work with new, cost effective medical and organizational innovations. However, new e-health services need to be financially viable for healthcare professionals to adopt them. This is supported by Tanriverdi and Iacono (1999), who state, in a study on telemedicine, that there has to be an incentive for the healthcare professional when adopting innovations. According to Istepanian, Jovanov and Zang (2004) and Miller (2001), the reimbursement methods have not yet been adapted to acknowledge the new e-health services, meaning that there is no guarantee that an e-health service can be reimbursed. The reimbursement has to be guaranteed to provide the healthcare professional with a (financial) incentive to adapt the healthcare service.

3.4.2. Treatment payment

The second element covers the factors on which the reimbursement is based. Groll and Wensing (2004) define reimbursements as potential financial incentive barriers for adopting new healthcare practices. Reimbursement may be based on a fixed price per treatment or price per hour. Also the ratio of the tariffs has consequences for innovations. In practice, e-health service innovation changes both the amount of treatments as well as the treatment time.

3.4.3. Different healthcare sectors

The third and final element is whether a distinction can be made between different healthcare sectors, based on whether a distinction is made between work related and work unrelated injuries and who is responsible for the costs made. These costs do not only include the treatment costs, but also costs caused by the loss of productivity and the paid sick leaves. This question is relevant because it will determine whether reimbursement for treatments will be handled via employers or via their employees. When an e-health innovation can be considered as a treatment for work related injuries, there might be an incentive for occupational insurance organizations to adopt the innovation in order to realize, for example, a lower paid sick leave. However, when such a distinction is not made, the reimbursement for the treatment will have to come from employees or their insurance organization. Both scenarios result in different money flows. Similarly, such a distinction has an influence on who is responsible for costs caused by the loss of productivity and the paid sick leaves.

3.5. Influence of national healthcare regulation

In this chapter, the components of the national healthcare regulation that influence an e-health value network have been identified. The components have an operational character and influence the operating efficiency and effectiveness of both human and material resources (Saltman et al., 2002). They can therefore be used to analyze the influence of national healthcare regulation on an e-health value network, ultimately to determine the influence of national healthcare regulation on the financial and organizational elements of the e-health business model (as visualized in Figure 3).

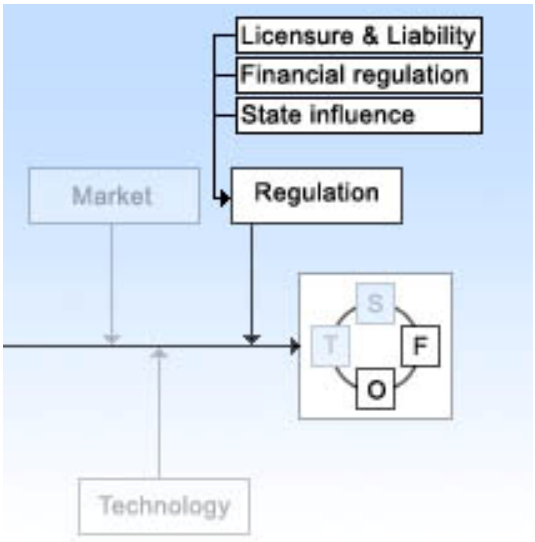

Figure 3 – 'Healthcare regulation components'

4. Methodology

This chapter describes the research plan of action that has been used in this thesis.

4.1. Research Design

As mentioned in the introduction the e-health service Myotel will be used to determine the influence of national healthcare regulation on e-health business models. The Myotel service is on the verge of being introduced onto the healthcare market, enabling this thesis to use research that has already been done for the Myotel project. A second advantage is that the introduction of Myotel is being investigated in four different countries. This allows this thesis to analyze the effect of national healthcare regulation in different settings and to conduct a comparative case study.

As a starting point of this research we will use a generic value network that has been designed for the Myotel service. The generic Myotel value network has been created through three different steps. The first step involves the design of an initial qualitative business model. In order to do so, a workshop has been organized for experts within the field of myofeedback and teletreatments, focusing on which value network would be needed to commercialize the Myotel service and what the related value and revenue streams would look like. In the second step an abstract cost benefit model has been designed to get a better insight into the expected benefits and costs related to the implementation of Myotel. In the third step, the results of the first two stages have been used to set up a generic value network for the Myotel service, visualizing the value and revenue streams and the main actors involved (Figure 4).

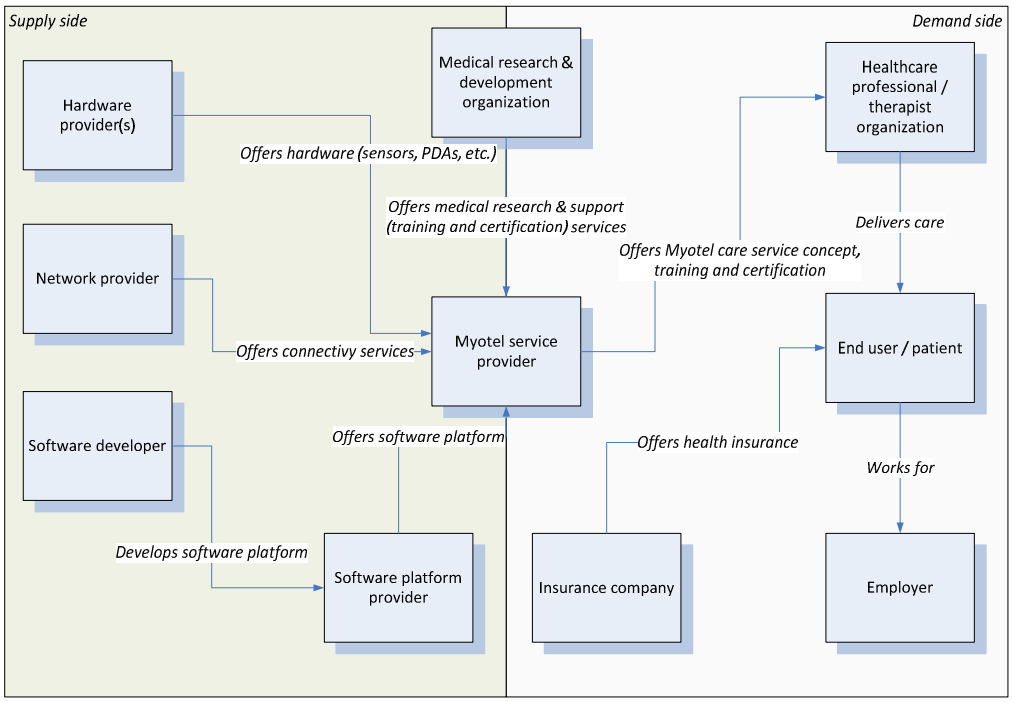

Figure 4 – 'Generic Myotel Value network'

The generic value network visualizes what rolls have to be fulfilled and how they have to interact in order for the Myotel service to function. The goal of this thesis is to determine whether national healthcare regulation influences the way in which the generic Myotel value network is structured and how it ultimately influences the business model design process. This will be done in two phases:

Phase 1) testing the influence of the three regulatory components: state influence, licensure and liability and financial regulation on the Myotel value network;
Phase 2) validating the suggested modifications to the Myotel value network according to the influence of the regulatory components.

In both phases expert interviews will be used to gather and validate the acquired information. Figure 5 visualizes the approach to determine the influence of national healthcare regulation on the Myotel value network. The feedback loop allows us to make changes to the modified value network, based on validation in the second phase.

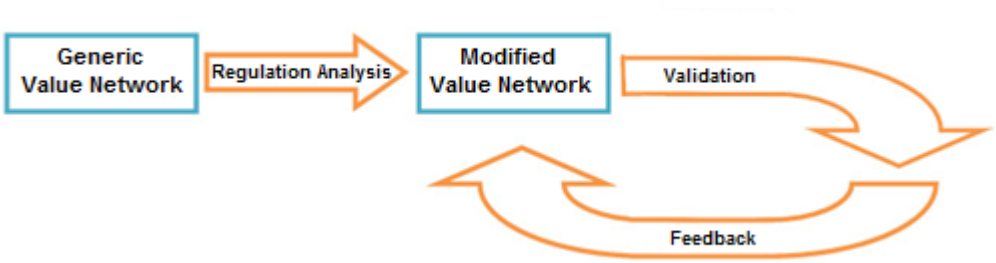

Figure 5 – 'Regulation analysis'

4.2. Selection and Sample

By using the Myotel service in this thesis we are dependent on the participation of the Netherlands, Sweden, Germany and Belgium. However, based on the different types of healthcare models as described in chapter 3.2., we can determine that the two main types are represented in this research. Tajnikar and Bonča (2007) indicate that the Dutch, German and Belgium healthcare market can be defined as a social insurance model and that the Swedish model can be defined as a national health service model. Based on this analysis we can conclude that we are able to determine the influence of national healthcare regulation in both types of healthcare models.

In the first phase, data regarding the national healthcare regulations in the four participating countries will be collected. To do so, this thesis will use four groups from four different universities, known as the centers of excellence (table 1). Each participating country in the Myotel project has a center of excellence that researches the potential of the Myotel service in their country. Because of their participation in the Myotel project, they are familiar with the Myotel concept and already have relevant knowledge regarding the national healthcare system. Because of the knowledge and the network that can be provided by the centers of excellence, they will be used in the first phase to get relevant data regarding the national healthcare regulations. Additionally, the centers of excellence can be consulted throughout this research to obtain extra information. The acquired data will be used to suggest changes to the generic Myotel value network to create a fit with the regulatory environment.

Country	University
The Netherlands	University of Twente
Sweden	Göteborg University
Belgium	University Gent
Germany	Ruhr University of Bochum

Table 1 – 'centers of excellence'

In the second phase the suggested changes will be validated. Since the centers of excellence have been the primary source of data in the first phase, a second group has to be found in order to validate the data. Therefore a group of experts has been selected, based on the specific role they are able to fulfill in the Myotel value network. The experts are already active in the healthcare market. The aim is to conduct interviews on both experts who are active at the supply side and experts who are active at the demand side, to validate the suggested changes to the model and to get insight into the different alternatives.

For provisioning Myotel on a European level, it is not necessary to organize country specific actors for each value network role as distinguished on a national level. Especially the (technological) supply side of the model could be based in one country and serve several European countries in order to increase efficiency and lower operational and maintenance costs. The Netherlands is a leading country with respect to telehealth applications. Within the context of Myotel, there already are organizations who are willing to cooperate within the Myotel project. Therefore, the most crucial roles can be fulfilled within the Myotel value network. As a result, the interviews related to the supply side have been held in the Netherlands.

The demand side is expected to show more discrepancy, therefore the interviews related to the demand side have been held in as well the Netherlands as Sweden. An overview of the interviewees has been given in table 2.

Supply side		**Demand Side**	
Role	*Country*	*Role*	*Country*
System Integrator / Software platform provider	(Netherlands)	Employer	(Netherlands)
Hardware / Technology Provider	(Netherlands)	Insurance Company	(Netherlands)
Healthcare Professional	(Netherlands)	Healthcare Professional	(Netherlands)
Service Provider	(Netherlands)	Occupation Health Service	(Sweden)
		Healthcare Professional	(Sweden)

Table 2 – 'Interviews held'

4.3. Measurements

To obtain useful data in the phases two different questionnaires have been set up.

In the first phase the centers of excellence have been subjected to a questionnaire to get data regarding the healthcare regulation in the four countries. To structure this questionnaire, the three healthcare regulation components, as discussed in chapter 3, have been used. The three healthcare components functioned as categories in the questionnaire. The questions that have been formulated under these categories are based on the literature as provided in chapter three. The questionnaires are based on open questions. According to Stacey (1969) open questions are useful when the issue is complex and when a process is being explored. Because there is little known about the three regulatory components, an open questions based questionnaire is the best option. To prevent that the question becomes too vague, every question has shortly been introduced by or related to a specific example for that country (see appendix A).

The second questionnaire has been used in the second phase for a number of semi-structured interviews that have been held in the Netherlands and Sweden. For these interviews, a number of experts have been selected, based on the roll they are able to fulfill within the Myotel value network. These experts will be confronted with the Myotel value network that has been modified according the results from the first intervention.

The interviews have been focused onto four different topics:

1) Value perception, focusing on getting a better understanding of the value of the Myotel service concept as perceived by the value network actors interviewed;

2) Organization, focusing on getting a better understanding of how the relations between the different value network roles should be arranged;

3) Finance, focusing on determining how Myotel should be financed and by whom;

4) Future perspective, what should be done to implement the Myotel service in the near future.

The questions related to these three topics have been based on the literature provided by Bouwman et al. (2008) (Appendix B). In their book regarding the STOF model, Bouwman et al. describes a list of

relevant topics regarding the organization and finance domain. By including these topics in the expert interviews we can are able to cover all the elements within the organization and finance domain.

4.4. Data collection

Prior to the questionnaires, a workshop with the centers of excellence has been held. In this workshop, many details of the Myotel project have been discussed and it allowed us to get a first discussion on the national healthcare regulation issue. As a result, some interesting topics such as the different reimbursement structures and a discussion regarding the privacy issues have been addressed, forming a base for this research.

To gather the information for the first phase the questionnaire has been sent per email to the centers of excellence. Due to the complex nature of the questions, the centers of excellence were given one week to formulate their answers. The centers of excellence where able to send back an extensive answer and in some cases provide additional literature. In the days after the questionnaire had been returned there has been some communication with the centers of excellence to clarify some ambiguities. The data that had been provided was also a starting point for desk research to obtain additional information. The input of the desk research was mainly complementary information regarding the result of the first questionnaire. It allowed us to get additional data regarding the present healthcare systems within the four participating countries and the rest of Europe**.**

To validate the data that has been gathered in the first phase, expert interviews have been conducted. The interviews with the Dutch interviewees were face to face meetings at the location of the interviewee. The interviews where structured by the questionnaire as discussed in chapter 4.3., but due to the informal character of the interviews it was possible to diverge of the questionnaire and go into a specific subject if needed. All the interviews typically lasted about an hour.

The set up of the Swedish interviews was somewhat different due to the distance. Both interviews where done per phone. The interview with the expert representing the occupational healthcare service was joined by a member of the Swedish centre of excellence to support the interview. Regarding some linguistic issues this turned out to be quite handy. Both Swedish interviews lasted about an hour, similarly to the Dutch interviews.

4.5. Data analysis

The information that has been gathered in the first phase gives insight regarding the influence of national healthcare regulation on a number of different levels. By looking at the state influence the degree of a free market structure can be determined, as can the influence of the government. The licensure and liability component sheds light on potential legal barriers for the Myotel service. Such barriers can hamper the success of the service, because novel aspects of an e-health service might not fit within existing healthcare regulation. The financial regulation gives better insight into the structure of the value delivery within the value network. The data collected on this subject will therefore be used to determine the value streams within each of the participating countries, and what is the most viable scenario.

The second phase validates the suggested changes to the generic Myotel value network. This will be done by analyzing the results of the first phase, based on the expert interviews in the second phase. This allows us to get additional data and, if needed, to alter the value network as presented after the first phase to create a better fit with the national healthcare market.

5. Results

In this chapter the results of the two phases will be presented. The first phase focuses on the influence of national healthcare regulation on the Myotel value network, analyzing the national healthcare regulations in the Netherlands, Sweden, Belgium and Germany. The results allow us to suggest changes to the generic Myotel value network to create a better fit with the current regulatory environment in the specific country. The results of the second phase will be used to validate the suggested changes to the Myotel value network.

5.1. First phase: influence of regulatory components on e-health value network

The results of the first intervention will be presented per country in section 5.1.1. to 5.1.4.. First we give a short description of the three regulatory components as discussed in chapter 3, per country. Secondly, in chapter 5.1.5. we will reflect on the results and compare the regulatory characteristics of the four countries. Based on these characteristics, barriers and opportunities for the Myotel service can be identified. Ultimately the Myotel value network will be adapted, based on the identified barriers and opportunities.

Based on the results, no differences have been found regarding the licensure and liability component. Due to these similarities the results will not be discussed per country, but will be combined in chapter 5.1.5. by determining the effect of licensure and liability on the Myotel service.

5.1.1. The Netherlands

State influence

The Dutch healthcare system is primarily an insurance based model. Not only the state, but the insurance companies as well play an important role in the day to day management of the healthcare market. Every person living in the Netherlands is obligated to obtain a basic health insurance from an insurance company that meets the terms that are set in the Dutch health insurance law. The content of the basic health insurance is set by the Dutch government, but there are some small differences among basic insurances the healthcare insurance companies offer. Additionally, insurance companies

have contracts with local healthcare suppliers. The Dutch patient has the right to choose its own healthcare supplier, but through these contracts the insurance companies can exercise some influence on the patient's choice, for example, by offering a financial reward when the patients uses contracted healthcare suppliers.

Financial regulation

Reimbursement

Physical therapy is reimbursed when the disorder is listed on a legal list of chronic disorders. Reimbursements by insurance companies stop after the ninth treatment. Additional treatments have to be paid by the patient or via the complementary health insurance of the patient.

In the Dutch insurance structure a difference is made between basic insurance and complementary insurances. Customers can increase their healthcare cost coverage by getting a complementary insurance, which allows them to get for example additional treatments. The coverage of what is reimbursed in the basic insurance is, as mentioned earlier, determined by the Dutch government. The success of an e-health service can depend on whether the service is covered by the basic or complementary insurance. An insurance company is exposed to little risk with respect to the basic insurances. Because it is obligatory to accept any application for a healthcare insurance, the costs and thus the risk of the basic insurance are divided among the healthcare insurance companies. However, when it comes to complementary insurances the risk level is higher because insurance companies have to bear the costs on their own. On the other hand, this also means that insurance companies are able to increase margins and profits on these complementary insurances when costs for these extra treatments can be reduced.

Treatment payment

In an attempt to create more free market characteristics within the Dutch healthcare market, the so called *'Diagnose Behandel Combinatie'* (DBC; Diagnosis Treatment Combination) mechanism has recently been developed. This DBC mechanism essentially means that the health care provider is reimbursed with a fixed amount of money for a particular treatment.

In the traditional system, the tariff level for one treatment is the result of a negotiation between the physical therapist and the health insurance company. This is done on both an individual basis as well as via umbrella organizations that represent groups of physical therapists.
Within the new DBC mechanism, all treatments (excluding a number of special cases) are placed within 3000 different DBCs. As a result the costs and workload are homogeneous which creates a more transparent healthcare market. This should result in a situation where healthcare providers are rated based on the quality they deliver, allowing the insurance organizations get more grip on the price and quality of the insurances they offer. (DBConderhoud.nl, 2008)

Within the Dutch occupational healthcare system, a difference can be made between larger organizations that have in-house healthcare services and organizations that have contracts with occupational health organizations that operate externally. Larger organizations have their own healthcare professionals, and are therefore able to negotiate their own tariffs for their services. As mentioned earlier, organizations can also contract external occupational health organizations, which cover over 80% of the Dutch employees (de Valk, Oostrom & Schrijvers, 2007). In this case, organizations pay occupation health organizations a fee for their services, needed for covering costs made to prevent work related injuries and optionally also for covering sick leave costs.

Different healthcare sectors

In the Dutch healthcare system a difference has been made between a private healthcare sector and an occupational healthcare sector. Patients with work related injuries are mostly treated within the regular healthcare system and under control within the occupational healthcare system. This allows an e-health service to be designed for work related injuries as well.

5.1.2. Sweden

State influence

The healthcare market in Sweden is controlled by the state. Private healthcare providers only have limited influence on healthcare policies. However, there are some exceptions. There are, for example, private rehabilitation centers that operate on public contracts, meaning that they are tax financed.

Although the healthcare market is controlled by the state, it is also heavily decentralized. This is due to the fact that healthcare services have been regionalized and are financed through regional taxation. This means that the healthcare service can vary per region, creating different possibilities per region.

Financial regulation

Reimbursement

In Sweden every citizen is covered by general public healthcare insurance. The patient pays a fee for each healthcare visit, the society provides the remaining part to cover the factual healthcare costs. There is a yearly maximum on healthcare costs paid by individuals for treatments as well as for medication. If the maximum is reached, the society takes full coverage for healthcare on a yearly basis. The public healthcare insurance is then obligated to reimburse treatments.

Private insurance companies play a role only when an individual joins a private insurance plan to cover extra treatments or gets treatments from private healthcare providers.

Treatment Payment

A healthcare professional employed in primary healthcare centers gets paid per hour. The tariff level is embedded in the public healthcare insurance and does not differ between physiotherapists. There is no maximum on the number of treatments, but there is a maximum on the personal contribution of the patient. When the personal contribution reaches SEK 900[1], the consults in the twelve months following the date of the first consultation are free of charge.

Different healthcare sectors

In the Swedish healthcare system, there are no differences between work and non work related injuries. However, a company is able to sign a contract with occupational health services (OHS) that determines which services the OHS should provide to employees. The availability of occupational health services is high within the public sector and within larger companies; the conditions are generally defined via negotiations between employer unions and labor unions. In Sweden, about 70%

[1] €88,35, exchange course sep. 9th 2009

of all employees have access to occupational health services. The existence of the OHS makes it possible for e-health services to be designed for work related injuries as well.

5.1.3. Belgium

State influence

The Belgian healthcare system is privately managed and mainly delivered by non-profit organizations. The responsibility for funding and supervision of the Belgian healthcare system takes place on a federal level by a number of public authorities. However, some of the responsibilities have been delegated to smaller communities.

Within the sub-national level of the healthcare system, the flow of services and payments takes place between independent healthcare providers and the insured people. The patient is free to choose among a number of different non profit healthcare providers. An organization that plays a central role in the Belgian healthcare market is the National Institute for Sickness and Invalidity Insurance (INAMI/RIZIV). INAMI/RIZIV is a nongovernmental public body that is most importantly responsible for reimbursement tariffs and the general organization and financial management of healthcare insurances.

Financial regulation

Reimbursement

Insurance companies are obligated to reimburse treatments, although there are, in some cases, limits on the amounts of treatments. When this limit has been reached, the reimbursement of one treatment consult will be less and patients themselves have to pay more.

Treatment payment

The tariffs are based on a payment of about EUR 20 per consult (which takes 30 minutes). These treatments are bounded by some rules, for example, related to treatment duration. The tariff level is usually equal for every physiotherapist, yet some physiotherapists ask more for one consult. In this case the extra costs have to be paid by the patients themselves.

Different healthcare sectors

In Belgium, a distinction is made between the private healthcare and the occupational healthcare. When an injury has been categorized as work related, the costs can be reimbursed by the insurance organizations of employers. However, the injuries that are categorized as work related are only injuries that can be directly related to a profession. Injuries such as RSI are therefore not recognized as work related injuries.

5.1.4. Germany

State influence

In Germany, the main legal framework for the healthcare market is structured by the German Federative State. A number of organizations that influence the structure of the framework are active in the German healthcare market.

One of these organizations is the federal authority, the *Bundesversicherungsamt*, to which health insurance organizations transfer the fees as collected by them. The *Bundesversicherungsamt* is responsible for the collection and allocation of these contributions. A second organization, the *Gemeinsamer Bundesausschuss,* shows that there is also an influence from non-government institutions within the German healthcare market. The *Gemeinsamer Bundesausschuss* is an entity existing of representatives of the umbrella organization of healthcare insurance organizations, representatives of the umbrella organizations of healthcare providers, three independent members, and representatives of patients. This institution negotiates general guidelines of health insurance governance, such as which treatment or drug is implemented and paid for by non-private medical insurances, which treatment is cancelled, or which treatment reimbursements will be reduced. This organization functions without direct involvement of the state. Any decision made concerning a treatment or drug will be added to the *Einheitlicher Bewertungsmaßstab* (EBM). When a treatment is added to the EBM, it has to be reimbursed by all non-private insurances. Private insurances are not restricted by the agreement made in the EBM and are able to make their own decision regarding to what they reimburse.

Financial regulation

Reimbursement

When a treatment is not recognized by the EBM, an insurance company is not obligated to reimburse the treatment. Private insurance companies have the right to refuse a payment regardless of the EBM.

Treatment payment

Tariff levels for treatments are defined in agreements for both private and public insurance companies. For non private companies this is done in the EBM and based on factors such as timeslot, performance, type of contact, qualification of the therapist and, in some cases maximum amounts per case. The situation in case of private insurances is similar; their catalogue is called *Gebührenordnung Ärzte/Psychotherapeuten* (GOÄ/GOP). Which treatment in the catalogue will be paid depends on the individual contracts between patients and insurance organizations.

Different healthcare sectors

In the German healthcare system, a distinction is made between the private healthcare and the occupational healthcare. However, the injury or disease has to be legally defined and accepted as an occupational injury by the employer's liability insurance organization. Injuries such as RSI are nevertheless not recognized as a work related injury.

5.1.5. Reflection

Based on the results from the first intervention, the influence of the national healthcare regulation on the generic Myotel value network can be determined.

State influence

The results show that Sweden clearly has the highest level of state influence. The state influence within the Dutch healthcare market is relatively low due to the responsibilities allocated to the insurance companies. The German and Belgian healthcare markets show a more hybrid approach. Both countries have insurance companies that can operate freely but are more restricted by government controls.

The main differences relate to the structure of the healthcare market. The Dutch healthcare market is more competitive than the German, Belgium and Swedish healthcare market. As a result there is a larger incentive for Dutch healthcare providers to work more cost efficient. In terms of the amount of regulation there are little differences between the four countries

Overall the state influence is a relevant component. Based on the state influence, we can determine whether the government or insurance organizations have to be included into the value network.

Licensure and Liability

In the case of licensure and liability, no significant differences have been found between the four countries. In all four countries there are little constrains considering the licensure and liability rules because the Myotel service is used to complement existing treatments. Therefore rules apply that are already in existence for the traditional treatments.

However, for the novel aspects, such as teleconsults, the licensure and liability regulation has to be adapted to create a fit with the new situation. Since teleconsults are not yet recognized as legitimate consults, the liability of these consults is not regulated. This can hamper the success of an e-health service when services such as teleconsults form a major element of the e-health service.

Licensure and liability can create barriers when e-health services move outside the boundaries of existing treatments, enabling the usage of the e-health service to its full potential. However, it does not influence the structure of the value network nor which value network actor has the largest incentive to adapt e-health services.

Financial regulation

There is a clear difference between Germany and the Netherlands on the one hand and Sweden on the other with respect to financing the healthcare market. In Sweden, most of the costs are covered by taxes, while the healthcare system in Germany and the Netherlands is based on an insurance model (Table 3), meaning that healthcare costs are only partially financed by taxes and for the major part by health insurances. Belgium finances its healthcare system evenly with taxes and health insurances.

	Percentage of total healthcare expenditure from social health insurance	Percentage of total expenditure from taxation	Percentage of total private health expenditure
The Netherlands	73%	5%	22%
Sweden	13%	70%	17%
Belgium	36%	38%	26%
Germany	69%	10%	21%

Table 3 – 'Financial structure healthcare markets' (Mossialos, Dixon, Figueras and Kutzin, 2002) (Wild & Gibis, 2003)

The remaining costs, that are made to cover the healthcare expenses, are the private healthcare expenditures. These are out of pocket costs, costs made by the individual that are paid directly to the healthcare professional and private healthcare insurance companies.

Reimbursement

The results show that there are many differences regarding reimbursement structures, but essentially, in all four countries, insurance companies are obligated to reimburse treatments. This creates possibilities for e-health services. By using an e-health service to reduce the amount of treatments, costs per treatment may be lowered. However, the main problem is within the usage of novel aspects of e-health services such as teleconsults. Teleconsults are not yet equally recognized as face-to-face consults and can therefore not be reimbursed. The possibility of teleconsults is nevertheless a major advantage of many e-health services. The lack of possibilities to reimburse teleconsults indicates that the reimbursement methods have not yet been fully developed.

Since the reduction of treatment time is not enough to make the Myotel service financially viable, other revenue sources have to be located. As a result, the Myotel value network has to be adapted in all four countries to include the additional revenue source. Therefore, the reimbursement structure is of influence on the value network because in all four countries, additional revenue sources have to be implemented in the value network.

Treatment payment

Currently, the Netherlands is the only country where (an increasing subset of) healthcare professionals are being paid for complete treatments instead of for each consult or based on an hourly rate. This creates an incentive for healthcare professionals to work more efficiently. In Belgium,

however, it works the other way around: there, healthcare professionals are paid per hour. When increasing efficiency by adapting an e-health service, there will be a financial disadvantage because less hours will be worked. As a result the payment structure is of influence on the financial sustainability of an e-health service.

Different healthcare sectors

In all four countries a distinction is made between private healthcare and occupational healthcare. However, the structuring of these distinctions differs per country. The injuries described as work related injuries in Germany and Belgium can be categorized as more severe injuries, for example injuries as a result of an accident on a construction site. In the Netherlands injuries such as RSI are considered to be work related. In Sweden, no direct distinction is made between work related and non-work related injuries. However, employers do have the option to contract an occupational health service and negotiate on the injuries that are implemented in the contract.

Because in both the Netherlands and Sweden injuries such as RSI can be defined as work related injuries, it is able to include the occupational healthcare into the Myotel value network.

The main results of the expert interviews can be summarized in table 4, indicating whether there is a relation between the regulatory components and the specific country (+) or not (-).

	The Netherlands	Sweden	Belgium	Germany
Strong state influence	-	+	+/-	+/-
Tax financing	-	+	+/-	-
Reimbursement obligations	+	+	+	+
- Teleconsults reimbursement	-	-	-	-
Payment on a treatment instead of consult basis	+	-	-	-
Occupational healthcare	+	+/-	+	+
- RSI / neck and shoulder complaints defined as occupational hazard	+	+/-	-	-

Table 4 – 'Results influence national healthcare regulation'

Myotel value network

The previous chapter presented the main results regarding the regulatory elements and their influence on the generic Myotel value network. This chapter will determine how the generic Myotel

value network has to be adapted to create a fit with the healthcare regulation in the Netherlands, Sweden, Belgium and Germany.

From the three regulatory elements, the financial element has the most influence on the generic value model. First of all, the reimbursement structure is of influence. Because the reimbursement methods have not yet been fully developed for e-health services, the increase of efficiency of the treatment that can be obtained by using the Myotel service, cannot be used to its full potential. This is due to the fact that teleconsults are not yet reimbursed in any of the four countries.

Because the Myotel service is more expensive than traditional treatments, additional revenue sources have to be included into the Myotel value network. Only in Belgium where the traditional treatment is more expensive, relatively large cost savings can be made, reducing the need for an additional revenue source. In the search for an additional revenue source, a viable option is to determine whether an injury can be categorized as work related. In all four countries, employers benefit by using the Myotel service and thereby lower the loss of productivity. The occupational healthcare can therefore be included into the Myotel value network as an additional revenue source. However, this is not possible in all four countries. In order for Myotel to be used in the occupational healthcare sector, the injuries Myotel has been designed for have to be recognized as work related. Otherwise, patients with these injuries will end up in the regular healthcare. The injuries Myotel has been designed for are only recognized as work related in the Netherlands and Sweden. In both Belgium and Germany only severe injuries are recognized as work related, hampering the success of the occupational healthcare as an additional revenue source in the Myotel value network in Belgium and Germany.

The treatment payment is of influence as well on the success of the Myotel value network. The Dutch healthcare market is different, because of the DBC reimbursement structure it uses. Because a Dutch healthcare professional gets paid for the entire treatment, regardless of the specific treatment, there is an incentive to work more efficiently. In the other three countries, the healthcare professional is paid per hour. As a result, there is no financial incentive to work more efficiently. Only the Belgium healthcare market is unique in this instance, because there, the treatment using the Myotel service is

cheaper than the traditional treatment, providing an incentive for Belgium healthcare professional to adapt the Myotel service.

The state influence affects the structure of the Myotel value network and the actors involved. Because of the highly government-controlled healthcare market in Sweden, the value network will include the government as an important actor. However, in the other three countries, where a more commercial healthcare market is present, the insurance organizations are an important actor in the Myotel value network.

The licensure and liability element is not of influence on the Myotel value network. It does, however, limit the possibilities of using the Myotel service to its full potential due to insufficient licensure and liability regulation.

Table 5 summarizes the effect of the national healthcare regulation on the Myotel service. Pointed out in green are the regulation elements that have positive stimulants for the Myotel service. Red points out the negative effects and blue is indifferent for Myotel. Similarly as in table 3 it also indicates whether there is a relation between the regulatory components and the specific country (+) or not (-).

	The Netherlands	Sweden	Belgium	Germany
Strong state influence	-	+	+/-	+/-
Tax financing	-	+	+/-	-
Reimbursement obligations	+	+	+	+
- Teleconsults reimbursement	-	-	-	-
Payment on a treatment instead of consult basis	+	-	-	-
Occupational healthcare	+	+/-	+	+
- RSI / neck and shoulder complaints defined as occupational hazard	+	+/-	-	-

Table 5 – 'Regulation benefits and constraints'

Overall, based on results regarding the healthcare regulation, the Dutch and Swedish healthcare markets show the best options for the Myotel service. In the Netherlands and Sweden it is possible to include the occupational healthcare in the Myotel value network, adding a much needed recourse to make service financially sustainable. Additionally, the Dutch and Swedish healthcare market have other advantages that could aid the success of the Myotel service. The Dutch healthcare market can

benefit from the DBC reimbursement structure, rewarding the healthcare professional to work more efficiently. The Swedish healthcare market has the advantage of the regional approach, allowing the introduction of an e-health service on a smaller scale. Ultimately, the Dutch and Swedish occupational healthcare approach are the most viable options. There, the Myotel value network can be adapted to include the occupational healthcare in the value network, as visualized in Figure 6.

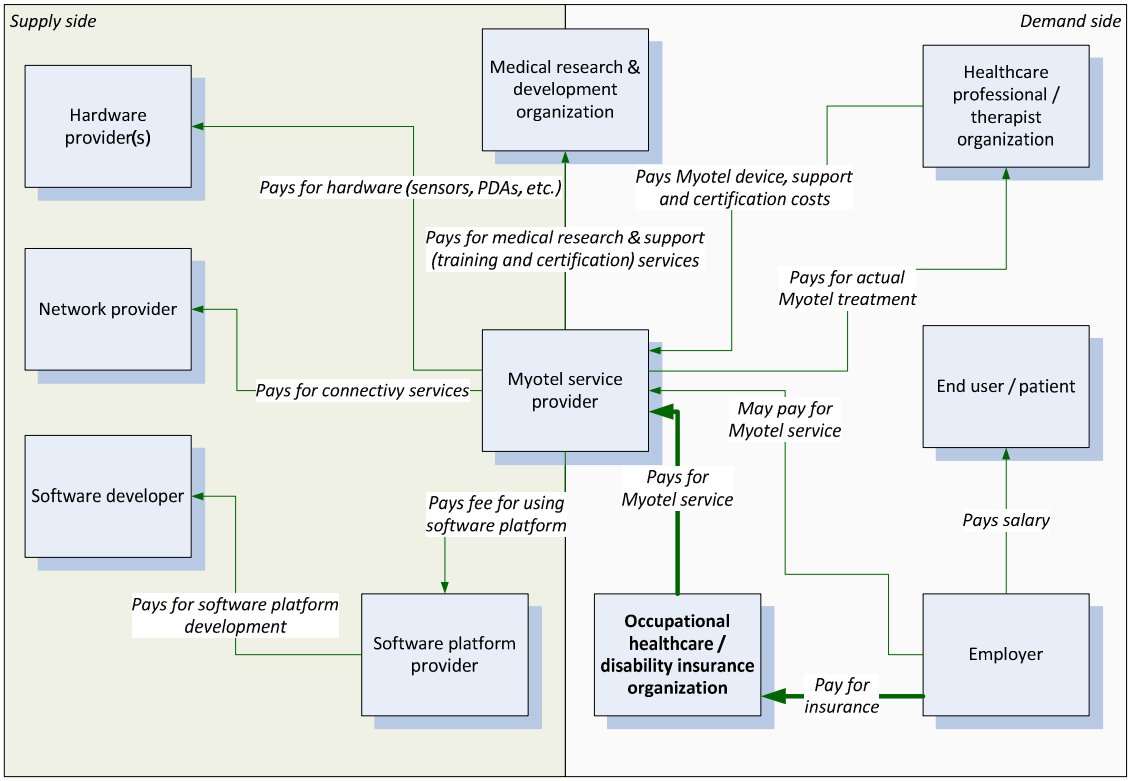

Figure 6 – 'Myotel value network in the market phase'

5.2. Second Phase: Validation and impact on value network

The value network as described in Figure 6 shows the modified Myotel model according to the first intervention. However, it does not necessarily fit into the Dutch and Swedish healthcare market. To validate that the value network will function, a number of semi structured expert interviews with relevant actors have been held.

5.2.1.The Netherlands

The first intervention pointed out that the Myotel value network should have a focus on work related injuries and that insurance organizations should be seen as the primary money source. It is believed that providing Myotel for employees would be the most viable scenario for the next deployment phases of Myotel. A Dutch employer of a large organization emphasizes this and states that, with a lot of deskwork being done in his organization, a lot of neck and shoulder related problems occur. Using Myotel would allow the employees to be aware of their behavior and to improve their behavior leading to improved productivity and less paid sick leave.

One of the interviewees, however, mentions a possible scenario that could cause a threat in the focus on the occupational healthcare system. By using the Myotel service the paid sick leave can be lowered creating a financial incentive. It is on the other hand possible that the Myotel service will be used for a employee who suffers from work related injuries, but who has only minor complaints. In this instance the improvement in productivity is relatively low compared to the costs of the Myotel service. However, because the Myotel service can also prevent work related injuries to worsen, this scenario is unlikely to affect the occupational health as primary money source.

According to the interviewees the financial incentives to use Myotel should therefore preferably come via the occupational healthcare insurance system. This is supported by an insurance company that stated that it is currently unlikely that there will be any direct support to co-finance the purchase of Myotel systems by healthcare professionals. The employer interviewed stressed as well that financial support should come from the occupational insurance organizations, but that, if necessary, there is a high probability that employers are willing to invest directly in Myotel treatments.

Regardless of the reimbursement system, Myotel reduces the total amount of consults needed for a complete treatment, reducing the total costs of the treatment. This is due to the fact that patients are more involved in the treatment when using Myotel, because they constantly get feedback the entire day and can access the historical feedback data at any time they like. However, the reduction of treatments costs are not sufficient to make Myotel financial sustainable. Therefore, additional revenue sources such as the occupational healthcare are needed.

5.2.2. Sweden

The interviews held in Sweden also suggested a clear preference for using Myotel for work related injuries. This shows that Myotel can be provided through the OHS, the Swedish equivalent of the occupational healthcare insurance. Via the OHS there is more time for pilot tests because it is not susceptible to any market pressure. The OHS has the freedom to experiment with and invest in new treatments without any approval from higher governmental bodies. In this way, the OHS can relatively easily start implementing and testing a system like Myotel.

Another advantage is that it is possible to reach a lot of employees without too much effort. For example, the OHS organization that has been interviewed, supports over 52.000 employers and thus has access to a large potential market for Myotel.

The interviewees state that prevention of work related injuries is also an incentive. In Sweden, there is a (large) group of people who already suffer from work related injuries. Myotel allows helping and treating those people before their complaints get too serious. Myotel allows the healthcare professional to give better and more frequent feedback to the patient, which increases the quality of care.

The reduction of paid sick leave is also seen as an important advantage because the distances employees have to travel to their physiotherapist are relatively long in Sweden. Another possibility is that physiotherapists have to travel to the organizations where their clients are working, but in both cases costs have to made that may be partially prevented by using Myotel.

5.2.3. Reflection

The results show that the modifications, that have been suggested for the generic Myotel value network, are applicable in the Dutch and Swedish healthcare market. In the Dutch situation it is clear that an additional revenue source is needed and that the occupational healthcare would be a viable option. However, the results also show that it will take several years to implement the Myotel service in the reimbursement structure of an insurance organization. Therefore a direct contract with large organizations would be a viable option to realize the commercialization of the Myotel service on short term.

The results of the interviews with the Swedish actors do not result in any changes in the Myotel value network. In this case the OHS remains the most viable option for the Myotel service.

6. Discussion

Based on the results of the interviews the research question, *What is the influence of national healthcare regulations on e-health business models?,* can be answered.

6.1. Conclusion

Throughout this thesis, the influence of national healthcare regulation on an e-health value network has been investigated to answer the research question.

We can conclude that the financial regulation has a large influence on an e-health value network. It influences the structure of the value network and creates incentives for the value network actors to adapt the e-health service. The state influence does not have a significant impact on the value network. Also licensure and liability has no influence on the e-health value network, but can nevertheless create barriers for the e-health service when it falls outside traditional legislation.

The results regarding the financial regulation show that the reimbursement methods for e-health services have not yet been fully developed. Novel aspects of e-health services such as teleconsults are not included in the current reimbursement methods, creating a financial barrier for e-health services. The Dutch DBC structure, however, offers a solution because the healthcare professional will receive a fixed reimbursement, regardless of the specific treatment. This creates a large incentive for Dutch healthcare professionals.

With the exception of Belgium, the Myotel service is more expensive than the traditional treatment. In this case additional revenue sources have to be found to make the e-health service financial sustainable.

Due to the specific injuries the Myotel service has been designed for, the occupational healthcare sector would be a viable additional revenue source. Healthcare professionals within organizations have an incentive to adapt the Myotel service to lower, for example, paid sick leave. In the Netherlands and Sweden, the injuries Myotel has been designed for are also recognized as work related injuries. As a result, the occupational healthcare insurance companies also have an incentive to adapt the Myotel service. This indicated that the way in which the occupational healthcare has been regulated influences the value network of an e-health service, leading to different value and money streams.

Whether an e-health service can be placed into different healthcare sectors influences the structure of the value network as well. When, for example, an e-health service is placed into the occupational healthcare instead of the private healthcare, different roles have to be included in the value network, leading to different value and money streams. However, this is not always possible, due to regulation on which injuries are considered to be work-related and which are not.

The state influence element determines the structure of the value network, based on the presence and interference of the government. When there is a strong influence from the government, the government has to be included in the value network. However, when there is little influence from the government, it results in the presence of more market dynamics, and insurance organizations have to be included in the value network.

6.2. Practical implications

Demonstrating the influence of national healthcare regulation, a number practical implications can be presented for the e-health business model. In the case of Myotel, it turns out that from both a financial and a regulatory perspective, the occupational healthcare is more viable in the market phase. First of all, from a financial perspective, it is more viable because the reduction of paid sick leave and the increase of labor productivity of the employee causes a large financial incentive for the employer. Secondly, from a regulatory perspective, it is more viable because the occupational healthcare is attractive, since the injuries the Myotel service has been designed for are recognized as work related injuries. This opens a whole new market for the Myotel service. This information is already of great importance during the research and development phase. The functional characteristics of the Myotel concept change significant when they are designed for either employees or patients at home. When designed for employees, for example, it should not hamper the employee in his work or attract attention from colleagues. To anticipate the regulatory influence on the e-health business model, the national healthcare regulation should be analyzed over the entire length of the business model design process, instead of only analyzing the regulation matching with the current phase (figure 7).

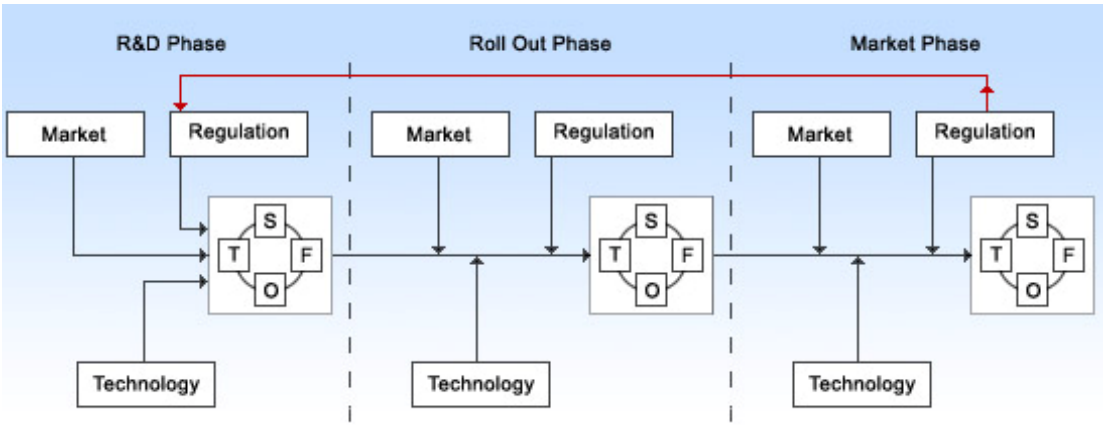

Figure 7 – 'Practical implications for the STOF model'

By doing so the influence of the national healthcare regulation can be determined in the early R&D phase, enabling the developers to adapt the e-health service to the specific circumstances.

6.3. Evaluation

We have analyzed the influence of national healthcare regulation on e-health business models in four European countries. The results have been validated using interviews with various stakeholders. Based on the results of the research presented in this thesis, we can evaluate both the literature that has been used for the regulation analysis, as the performance of the regulation analysis itself.

First we will reflect on the literature used for the regulation analysis. Regarding the first component, state influence, Saltman and Figueras (1998) state that a difference can be made between state controlled and market operated healthcare markets. Colton et al. (1997) mention that, despite this difference, the regulatory density and influence remain the same. The results, that have been presented in this thesis, support this. Although there is a major difference between the heavily government-controlled Swedish healthcare market and the more privatized Dutch healthcare market, the influence of the government on the healthcare market is the same.

Regarding the second component, licensure and liability, Daly (2000), Wilson (2003) and Miller (2001) state that the introduction of e-health innovations is influenced by licensure and liability regulation. However, as long as an e-health innovation stays within the boundaries of existing treatments, the results indicate that this is not an issue. The novel aspects of e-health do nevertheless require additional regulation to guarantee the liability of these consults. The lack of such regulation can prevent an e-health innovation from being fully utilized.

The results regarding the third component, the financial regulation, confirm that the reimbursement methods for e-health innovations have not yet been fully developed, as stated by Istepanian et al. (2004) and Miller (2001). The results indicating that the novel aspects of e-health innovations, such as teleconsults, are not included in the current reimbursement methods, creating a financial barrier for e-health innovations. According to Groll and Wensing (2004), the way the reimbursement is structured is also of influence. The results also confirm this. For example, the Dutch healthcare professional is being paid per treatment, rewarding him when a treatment is done faster. In Belgium, however, the healthcare professional is being paid per hour. An incentive to adapt new e-health services is then taken away because working faster will result in a lower reimbursement indicating that the reimbursement structure is indeed of influence.

Regarding the regulation analysis, as presented in figure 5, there are a number of restrictions of the regulation analysis used in this thesis. First of all, in this research, the Netherlands and Sweden have been selected as the most viable markets for the Myotel service. Therefore, the second phase has been used to validate the suggested changes to the generic Myotel value network in these two countries. They are indeed the most viable markets, based on the regulation characteristics that have been identified in the first phase. From a market perspective, however, Belgium is a viable option because the Myotel service is less expensive than the traditional treatment. Therefore, Belgium is an interesting market as well.

A second restriction is that this thesis has only focused on the healthcare markets within Europe. Although the two different healthcare systems within Western Europe, as identified by Tajnikar and Bonča (2007), are included in the research, it is nevertheless interesting to determine the influence of national healthcare regulation in non-European countries. For example, the American healthcare market is more dominated by private organizations than an European healthcare market, such as in the Netherlands. This is for instance due to lack of regulation to determine the prices of services from private providers (Wangsness, 2009). Due to these differences, different barriers and changes might be found in other more privatized healthcare markets.

The third and final restriction is that Myotel is a rather complex e-health service. As mentioned in the introduction of this thesis in chapter 1, the term e-health includes a very broad perspective of services. The Myotel service uses a physical device, making it quickly more complex than an e-heath service

that, for example, only uses an online platform. Therefore, it would be an interesting addition to use the regulation analysis on a number of different kind of e-health services, to determine whether the same barriers exist.

Overall, the regulation analysis as described in chapter four has been useful to determine the influence of national healthcare regulation on e-health business models. It helps identifying how the value network should be structured to create a fit with the national healthcare regulation. Additionally, this thesis has shown the relevance to get an early insight in the effect of national healthcare regulation. Partly based on these insights, crucial decisions have to be made that influence the development of the e-health business model. Because of the importance to obtain knowledge about the influence of national healthcare regulation on e-health business models, the presented regulation analysis used in this thesis offers a useful analysis to determine this influence.

However, additional research is needed to further develop the regulation analysis. In this thesis, the regulation analysis has been applied to the 'finance' and 'organization' elements of the STOF model. Therefore, as discussed in chapter 3, we focused on the management mechanisms due to the influence of these mechanisms on the financial and organizational elements. However, it would be interesting to broaden the scope of the regulation analysis and to apply it on the 'service' and 'technology' elements as well. Relevant issues such as privacy and safety can then be included in the analysis. Although the major barriers for e-health services are of financial nature, these issues might reveal barriers as well.

6.4. Recommendations

Based on the results of this thesis, the following recommendations can be made:

- Implement the regulation analysis over the entire length of the business model design process.

  By identifying the regulatory influence on an e-health service in an early stage, proper actions can be taken to adjust the e-health service.
- Further develop the reimbursement structure.

  To fully support the benefits of e-health services, the reimbursement structure has to be further developed to make the e-health services financially viable.

In this research we also presented a regulation analysis for the development of e-health business models. Regarding this analysis the following recommendations can be made:

- Further research the influence of national healthcare regulation on other business model dynamics.

  In this thesis the focus has been on the 'finance' and 'organization' dynamic of the STOF business model. An interesting addition would be to focus on the 'service' and 'technology' dynamic as well.

- Broaden the scope of the regulation analysis.

  This thesis has focused on the influence of national healthcare regulation on a complex e-health service in the different typologies of healthcare markets in Europe. It would be a viable addition to the regulation analysis to broaden the scope of the analysis and to test it on different kind of e-health services and also in other, non-European, healthcare markets.

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Appendix A - Questionnaire on national healthcare regulation

The purpose of this questionnaire is to obtain a better understanding of how the healthcare market is regulated and how these regulations influence the adoption of technological innovations.

Please note that it is not our goal to retrieve specific laws that 'demarcate' healthcare markets. Rather the purpose is to get a better understanding of how the healthcare market is regulated and how these regulations work out in practice. We would like to ask all Centers of Excellence to fill in this questionnaire and return the filled-in questionnaires to j.ooijevaar@rrd.nl ***before March 31, 2009***

You can easily fill in your answers in the special grey areas (YOUR ANSWER) after each question. Any relevant extra information in the form of e.g. pictures, graphs or PDF documents can be sent to the e-mail address mentioned above as well.

Could you please include any resources / references used in answering the questions?

Many thanks for your collaboration!

State influence

1. What is the degree of state influence in your country: is the healthcare market fully controlled by the state or is it mostly a liberalized market? Could you provide us with a brief description of how the state influences the healthcare market?

   A healthcare market fully controlled by the state can be characterized by for example organizations with full state ownership and financed with taxes, while a liberalized

market can be characterized by for example the presence of private for-profit companies, medical supply companies and for-profit private insurance companies.

(YOUR ANSWER)

2. Myotel is targeting on work related complaints. Are there differences in regulations regarding the treatment of work related or non-work related complaints?

Finance

The following questions are meant to obtain a better understanding of regulations regarding the financial structure of the healthcare market in your country. If you mentioned any differences between work related injuries and non-work related injuries in question 2, please include those differences in the following question

3. Are insurance companies obligated to refund every treatment, or is there a maximum per treatment?

(YOUR ANSWER)

4. Are healthcare professionals paid per time slot, per patient or per treatment?

(YOUR ANSWER)

5. How is the tariff for one treatment/patient constructed? And does the tariff differ per physiotherapist? Are there any regulations that influence the tariff structure?

(YOUR ANSWER)

When answering the following questions I would like you to base your answers on similar projects that have been rolled out in **the Netherlands** in the past. For example, how did privacy and accountability regulation influence these projects? Did they fail or succeed because of any of these regulations? Examples used in the question are derived from deliverable D4.04.

Privacy

6. Are there any privacy regulations that obstruct the collection/registration of medical information? Are there for example any privacy regulations that formed a barrier for the Eletronic Health Record (EPD) that might form a similar barrier to the Myotel concept.

(YOUR ANSWER)

7. Are there any known cases where the privacy issues resulted in a rejection of healthcare innovation by the end user?

(YOUR ANSWER)

Accountability / Liability

8. The teletreatment aspect of the Myotel concept does have a number of limitations, for example the lack of face-to-face and physical contact. Who is responsible when this leads to insufficient care and how is guaranteed that the patient is really speaking with a certified healthcare professional? Are there any healthcare product that ran into the same issues? For example with the introduction of the national infrastructure for healthcare (AORTA)[2] that allows the exchange of medical information. Are there any similar accountability regulation that affect both AORTA as Myotel?

(YOUR ANSWER)

9. Related to the same example in last question: who is responsible when a consult fails because of a technical malfunction? Does the healthcare professional still get paid, and by whom?

[2] http://www.ringholm.de/docs/00980_en.htm

(YOUR ANSWER)

Finance

10. Are there any known cases of healthcare innovations that required a change in the financial system of the healthcare market? Could you describe these cases? Did they succeed in doing so? And if not, why?

(YOUR ANSWER)

Experience

11. Are there any other examples of healthcare innovations regarding the regulation of the healthcare market you consider to be relevant?

(YOUR ANSWER)

When answering the following questions I would like you to base your answers on similar projects that have been rolled out in **Sweden** in the past. For example, how did privacy and accountability regulation influence these projects? Did they fail or succeed because of any of these regulations? Examples used in the question are derived from deliverable D4.04.

Privacy

6. Are there any privacy regulations that obstruct the collection/registration of medical information?

   For example, the Patient Data inquiry[3] has drawn up regulation that should result in greater patient safety while ensuring continued protection of patient privacy. Does the regulation influence the Myotel project? And are there any similar products that have been influenced by these (or other) regulations?

(YOUR ANSWER)

7. Are there any known cases where privacy issues resulted in a rejection of healthcare innovation by the end user?

(YOUR ANSWER)

Accountability / Liability

8. The teletreatment aspect of the Myotel concept does have a number of limitations, for example the lack of face-to-face and physical contact. Who is responsible when this

[3] http://www.carelink.se/dokument/nationellt/doc_200659091625.pdf

leads to insufficient care and how is guaranteed that the patient is really speaking with a certified healthcare professional? Are there any healthcare product that ran into the same issues (for example the reliability of E-Prescription[4], a system that allows physicians to digitally prescribe medicine to patients)? How do you think such a project and related projects are influenced by accountability and liability regulation?

(YOUR ANSWER)

9. Related to the same example in last question: who is responsible when a consult fails because of a technical malfunction? Does the healthcare professional still get paid, and by whom?

(YOUR ANSWER)

Finance

10. Are there any known cases of healthcare innovations that required a change in the financial system of the healthcare market? Could you describe these cases? Did they succeed in doing so? And if not, why?

(YOUR ANSWER)

[4] https://www.frost.com/prod/servlet/market-insight-top.pag?docid=102824378&ctxixpLink=FcmCtx1&ctxixpLabel=FcmCtx2

Experience

11. Are there any other examples of healthcare innovations regarding the regulation of the healthcare market you consider to be relevant to the Myotel concept?

(YOUR ANSWER)

Appendix B – Expert interview

Myotel

Myotel is een medisch feedback systeem dat in staat is om mensen gedurende de dag feedback te geven op het aanwezig zijn van voldoende ontspanning in de spieren. Onvoldoende ontspannen spieren kunnen een voorbode zijn van nek- en schouderklachten of deze klachten verergeren. Daarnaast is voldoende ontspanning van de spieren ook belangrijk voor het herstel van mensen met een whiplash.
Het aantonen hiervan is mogelijk door sensoren die constant de spierspanningen meten. Deze sensoren zijn in een hesje verwerkt welke onder de kleren gedragen kan worden waardoor het gemakkelijk in het dagelijks leven toe te passen is. De gegevens die de sensoren opleveren kunnen worden gebruikt om via een klein mobiel apparaatje (bijvoorbeeld een PDA) de gebruiker te informeren over zijn/haar spiergebruik en houding.
De gegevens die worden verzameld worden vervolgens naar de betrokken fysiotherapeut gestuurd. De fysiotherapeut kan vervolgens de gegevens analyseren en mogelijk ook op afstand een consult geven. Op deze wijze hoeft patiënt zijn werkplek niet te verlaten waardoor tijd bespaard kan worden.

Voordelen (waardepropositie van Myotel)

Deze eigenschappen van het Myotel feedback systeem leveren een aantal voordelen op:

Preventie
- Doordat mensen tijdig gewaarschuwd worden bij een verkeerde houding kunnen door het gebruik van Myotel verbeteringen worden aangebracht aan de houding. Op deze wijze kunnen nek en schouderklachten voorkomen worden.

Reductie ziekteverzuim
- Doordat patiënten met nek- en schouderklachten niet de werkplek hoeven te verlaten voor een consult wordt het ziekteverzuim teruggedrongen. Daarnaast heeft de preventieve werking ook een positieve invloed op het omlaag brengen van het ziekteverzuim.

Efficiëntere werking
- Doordat fysiotherapeuten de beschikking krijgen over gedetailleerde gegevens is het mogelijk om doelgerichter te werken. Dit resulteert in een snellere en efficiëntere behandeling waardoor het aantal behandelingen gereduceerd kan worden.

I - Algemene vragen (value perception)
De onderstaande vragen zijn bedoeld om een perceptie krijgen van het waardeoordeel over de service die Myotel aanbiedt.

- In de bovenstaande inleiding staan een aantal voordelen van Myotel omschreven. Ervaart / ziet u zelf deze voordelen?

- Welke voordelen verwacht u nog meer van Myotel? En welke nadelen? Wat weegt zwaarder denkt u?

- Ziet u Myotel als een waardevolle toevoeging op de huidige behandelmethodes. Waarom wel/niet?

- Zou u Myotel gebruiken/aanbieden wanneer het beschikbaar is? Waarom wel/niet?

Rollen

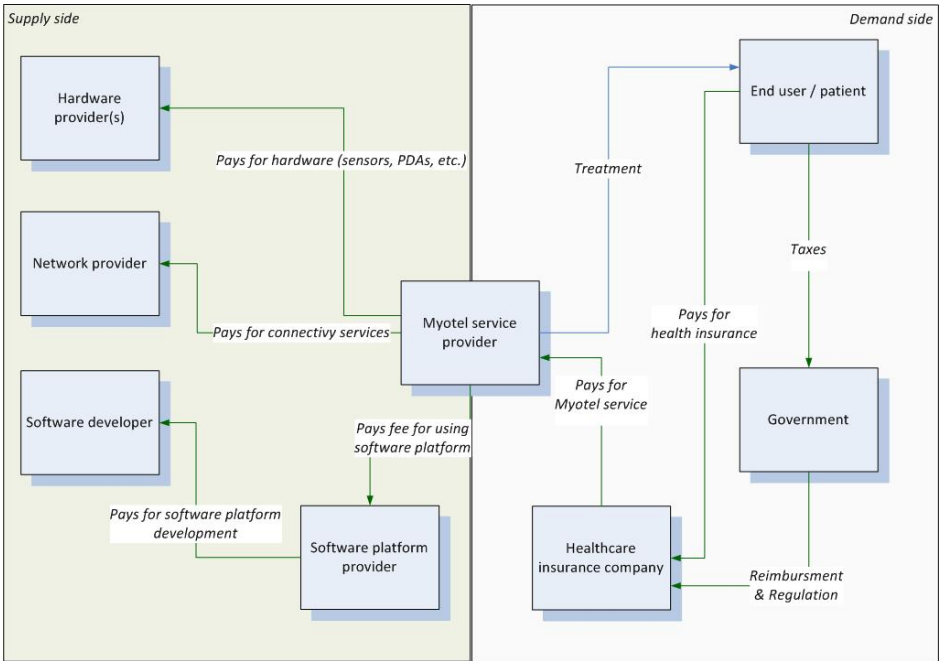
Om dit systeem te laten werken zijn er meerdere partijen nodig die samen dienen te werken. Onderstaande tabel geeft een overzicht van de verschillende rollen die onderscheiden kunnen worden en welke mogelijke partners deze rollen kunnen vervullen.

Network Provider	Hardware Provider	Sofware developer / platform provider	Myotel Service proivder
- KPN - Vodafone - T-Mobile	- Relex	- Mobihealth - Relex	- Roessingh - Telezorg centrum

Employer	Insurance company	Occupational Insurance company
- Gemeente Enschede	- Menzis - Achmea	- Arbo Unie - Arboned - Achmea arbo - Commit BV - ArboDuo - Maetis Arbo

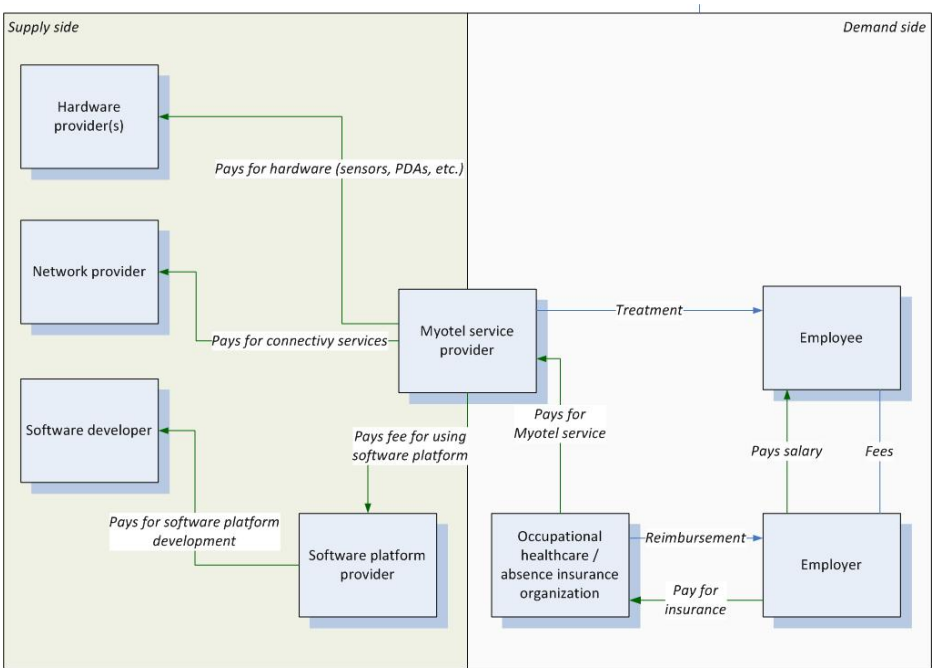
De wijze waarop deze partijen met elkaar verbonden zijn, is op verschillende manieren weer te geven. In de onderstaande twee figuren zijn twee scenario's weergegeven.

Scenario 1 - Myotel in de reguliere gezondheidzorg



In dit scenario wordt er van uitgegaan dat Myotel wordt aangeboden in de reguliere gezondheidzorg en dat de zorgverzekering deze behandeling (deels) vergoed.

Scenario 2 - Myotel als behandelmethode voor werkgerelateerde aandoeningen



In scenario twee wordt er vanuit gegaan dat Myotel wordt toegepast als behandelmethode voor werk gerelateerde aandoeningen. In dit geval wordt Myotel aangeboden door de werkgever of de verzekering van de werkgever.

II – Organisatie / Financiering
De onderstaande vragen zijn bedoeld om een oordeel te krijgen over de organisatie de financiering van Myotel. Onder andere door het behandelen van de voorgestelde rollen verdeling en de geschetste scenario's.

- Welke rollen ontbreken of zijn uw mening overbodig in het voorgestelde model?
- Welke actoren zijn, naast de genoemde actoren in het bovenstaande tabel, geschikt om deze rollen te vervullen?
- Zijn de relaties tussen de verschillende rollen, zoals geschetst in de twee scenario's, naar uw mening juist? Naar welk scenario gaat uw voorkeur?
- Waar (bij welke actor/rol) moet naar uw mening de investering in Myotel vandaan komen?
- Welke actor/rol profiteert naar uw mening het meeste van Myotel?

III – Implementatie / toekomst vragen
De onderstaande vragen zijn bedoeld om te achterhalen welke concrete stappen er nog genomen dienen te worden om Myotel in de markt te zetten en te achterhalen in welk tijdsbestek dat zou kunnen.

- Op welk termijn zou Myotel in gebruik genomen/geleverd kunnen worden? Waarom?

- Welke stappen dienen er genomen te worden om Myotel in gebruik te nemen. Wat ziet u als de belangrijkste volgende stappen in verdere commercialisatie?

- Wat zou er buiten de organisatie om moeten veranderen om projecten als Myotel meer kans te geven (Bijvoorbeeld de onlangs ingevoerde diagnosebehandelingcombinatie (DBC))?
