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Hydra

Networked Embedded System middleware for Heterogeneous physical devices in a distributed architecture

D10.7 Business models in Healthcare

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1. Introduction

1.1 Background

The Hydra project develops middleware for networked embedded systems that allows developers to create ambient intelligence applications. System developers are thus provided with tools for easily and securely integrating heterogeneous physical devices into interoperable distributed systems.

The Hydra middleware is based on a Service Oriented Architecture (SOA), to which the underlying communication layer is transparent. The middleware includes support for distributed as well as centralised architectures, cognition and context awareness, security and trust and will be deployable on both new and existing networks of distributed wireless and wired devices that typically are resource constrained in terms of computing power, energy and memory.

The middleware is being validated in three application domains: building automation, healthcare and agriculture.

1.2 Purpose and context of this deliverable

An integral part of the Hydra project is the analysis and development of realistic business models for developer users and service providers. New research into defining and measuring value creation in dynamic constellations based on Hydra middleware was needed. This work has led to innovative business structures involving content providers, service providers, device manufacturers, and system integrators in collaborative efforts. The goal of the work is thus to provide the business models, which can be used for customers and users of the Hydra middleware, and to instantiate them in realistic, sustainable business cases in the selected domain. A further aim is to analyse and possibly derive new technical requirements for the Hydra middleware and feed such requirements back to the iterative requirements engineering process.

The present deliverable provides internal and external documentation of the work undertaken in WP10 of the Hydra project. Moreover, it acts as an internal communication vehicle to the Hydra consortium partners, in order to make our business modelling work transparent among all partners and to arrive at a mutual understanding of the proposed process.

1.3 Methodology

In order to secure the widest possible foundation for the business cases, the Hydra project has conducted one-day high-level workshops in each domain with a group of experts in the field.

To shed light on the possible business models in healthcare, a workshop was organised in Berlin, Germany, on 8 June 2009. Invited for the workshop were experts from a range of different stakeholders in Germany, Denmark, Italy and the UK. The participants represented diverse viewpoints such as clinicians, solution providers, system integrators, component manufacturers, and healthcare economists. The agenda has been attached as Appendix 1: Workshop agenda. The experts appear from Appendix 2: List of participants. Finally, the scenarios that where presented to the workshop participants are presented in Appendix 4: Three healthcare scenarios.

The workshop was initiated with a lecture on Networking systems and devices – visions and possibilities in the Internet of Things and Services. The lecture described how the Hydra middleware could facilitate advanced, networked services for monitoring and interaction with patients in their homes. A set of healthcare scenario was also presented as lead-in to the discussions that followed.

The scenarios covered 1) Multi-parametric monitoring of health parameters in out-patients with chronic diseases, 2) Self-management and personalised risk assessment for people at risk and 3) Therapy, rehabilitation and exercise monitoring.

After the presentations, the rest of the day was devoted to expert discussions on three topics:

Firstly, the experts discussed scenarios for innovative healthcare applications & provisioning of e-health services. During this discussion the limitations and opportunities of networked healthcare applications were discussed from a clinical point of view and attempts were made to identify how the technology could best be used to serve medical purposes.

The discussion then turned to identification of the business framework, actors and stakeholders in healthcare management. The experts identified a series of early adaptors of networked eHealth services. These early adaptors will later be used for the development of business models for Hydra enabled applications.

Finally, the experts attempted to estimate the potential value and revenue streams, pricing models and cooperation strategies in eHealth applications. Not surprisingly, this area is very complex and no definitive answer could be found. However, the Hydra business modelling tool will be able to perform various simulations under different conditions allowing us to assess the potential revenue streams in future services.

The outline of the discussion is presented in the form of mind-maps in Appendix 3: Mind maps from the workshop. The discussion yielded important input to the business cases presented in this deliverable.

1.4 Content of this deliverable

In this document, we will describe two business cases for the deployment of Hydra based services for telemonitoring of patients with chronic conditions.

It is important to note, that the business cases are not unfolding the business of selling the Hydra middleware or the development tools. Rather they are describing the business of providing services, which could be developed with the help of the Hydra middleware. Our chosen methodology is first to understand how the business of a Hydra Service Provider is performing and then to analyse how the Hydra tools can optimise the ROI for the Service Provider. In this deliverable, we demonstrate that with a certain level of investment for application development, a profitable business case can be constructed. In the Hydra exploitation plan, we will demonstrate how business cases in all the domains (Building Automation, Healthcare and Agriculture) can become even more profitable by using the Hydra middleware.

We will develop business models and instantiate them with realistic economic data thereby arriving at realistic business cases and cost-benefit valuations for the relevant stakeholders. The work will be based on suggested revenue and pricing models for the services and will be rounded off with as simple process model for the Hydra Service Provider. The theoretical foundation of business modelling and the different methods available; value models, process models, revenue models, etc. have been described in *D10.5 Business modelling concepts*.

Firstly, chapter 3 provides a short introduction for the new reader of the Hydra products and the healthcare services than can be envisioned using Hydra middleware to develop the applications.

In chapter 4, a simplified survey of the healthcare market in Europe is presented in order to present an overview of the unique market conditions in selected Member States. This is followed by a summary of recent European directives and regulations, action plans and standards. The following chapters reflect the results of the discussion with experts in the workshop. In chapter 6 an overview of telemonitoring is presented. The chapter describes the state-of-the-art, which diseases are relevant for telemonitoring and how the implementation should be planned. In chapter 7 the different stakeholders are described and grouped in primary, secondary and tertiary stakeholders. The finally in chapter 8, drivers and inhibitors for the roll-out of telemonitoring services are discussed and early adopters and market entry points are identified. The chapter also deals with the deployment process and potential revenue streams.

Having thus prepared the foundation for the business modelling work, chapter 9 briefly introduces the methodology to be used and the real business cases are presented in chapters 10 through 12. Chapter 13 provides a comprehensive bibliography and references and chapter 14 a list of figures and tables.

2. Executive summary

An integral part of the Hydra project is the analysis and development of realistic business models for developer users and service providers based on innovative business structures involving content providers, service providers, device manufacturers, and system integrators in collaborative efforts.

The Hydra middleware is not intended to be deployed directly to healthcare providers. Rather, it is a tool for *developers* of healthcare applications. By using the Hydra development tools in the development of new products and applications, producers of devices and components can provide higher value-added intelligent solutions for their customers. The goal for the producers is to be able to build cost-efficient services with reduced time to market and faster deployment.

The goal of the work documented here is to provide an overview of the business models and business cases in the healthcare domain, which can be used for the customers and users of the Hydra middleware. Effective Hydra exploitation strategies and plans can only be developed, if the needs and the business of the targeted customers are completely understood.

2.1 The products

The Hydra middleware is aimed at providing interoperability of networked embedded systems, supporting distributed as well as centralised intelligent architectures. To facilitate the development, a series of development tools is available: A Software Development Kit (SDK), a Device Development Kit (DDK) and an IDE (Integrated Development Environment).

The Hydra healthcare application areas are almost unlimited and specific implementations will be determined by actual customer requirements at the time of deployment. However, due to its generic nature, the business modelling work will focus on telemonitoring applications using the Hydra middleware to create the monitoring platform that connects sensors and devices in the patients' sphere with healthcare professionals and informal carers as well as emergency and crisis management teams in the carers' sphere. It also connects to Health Information Systems (HIS) and external medical knowledge repositories and security providers.

The Hydra middleware will provide tools for overcoming the deployment obstacles inherent in previous remote monitoring and case management programmes by providing easy to use middleware tools that allow developers to design and implement advanced solutions based on existing or new home medical devices.

2.2 Market conditions

In order to understand the market opportunities for the development tools, we first need to understand the market for the healthcare applications, which are to be developed by developer users. Understanding the market conditions, the stakeholder dynamics, and the business models in this market allows us to position the Hydra products successfully in this market.

Public health is a key priority for the EU Member States and Europe is facing serious challenges in the near future of delivering quality healthcare to all its citizens, at an affordable cost. Prolonged medical care for the ageing society, the costs of managing chronic diseases, and the increasing demand by citizens for best quality healthcare are major factors.

The structures of European healthcare systems are diverse and it is therefore necessary to be aware of fundamental differences in order to be able to commercially exploit Hydra enabled solutions successfully across Europe.

National health legislation and healthcare policies are the responsibilities of the governments of the EU Member States. National governments also set the overall financial framework for the healthcare sector, albeit with varying degrees of control of the management of the allocated financial resources for healthcare services.

The healthcare system in the EU Member States described here is decentralised to various degrees. France and Italy have begun to move towards a decentralisation of the healthcare system from state to regional level. Healthcare services are provided mainly by public sector. In Germany, there is a trend towards increasing privatisation of healthcare service provisioning; however, the private sector still provides less than 10% of healthcare services.

It is possible to distinguish between A) tax-based systems (based on the so-called Beveridge Model) where healthcare services are funded through general national tax revenue and provided by the public sector free of charge, and B) statutory health insurance systems (based on the Bismarck model) where healthcare services are funded through non-risk related insurance contributions and provided by a greater mixture of public and private providers. The UK, Italy, Spain, Denmark and Sweden have tax-based healthcare systems, whereas Germany and France have social health insurance based healthcare systems.

A general trend in Europe is to put emphasis on providing for the chronically ill and old patients in their own home in response to patients' and their families' wishes. In France, "hospitalisation at home" has been introduced and in the UK some rehabilitation care is being carried out at community level or at home rather than at hospitals. Such developments not only meet the needs and wishes of the patient, in addition, they may also reduce hospital costs significantly.

Overall, the provisioning of long-term healthcare and home-care differs between the EU Member States. Some EU Member States (e.g Sweden, Denmark and UK) have well-developed systems which ensures that the patient is provided with the appropriate home-care, usually free of charge. These services are generally under the responsibility of the municipalities or local communities, and may combine healthcare services with social services and with the private sector in order to meet patients' needs.

All Member States have developed national strategies and plans for the deployment and use of ICT technologies in healthcare and are carrying out various activities towards eHealth.

In Denmark, the National IT Strategy for the Danish healthcare service was published in the late '80ies, which provided a common framework for the full computerization of the health sector for the period 2003-2007. The implementation of electronic health records (EHR) and the spread of EHR within the health system were among the initiatives. Today, Denmark consistently ranks in the top-three OECD countries when measured on the use of ICT services in healthcare.

In France, eHealth has been implemented at both local and regional levels and a national eHealth virtual community has been created. Some of the eHealth implementations include the Health Professional Card.

Germany has also taken steps towards implementing eHealth services. First of all, the implementation of an Electronic Health Card, which allows patients and healthcare professionals universal access to information, started in 2008. A German eHealth Strategy was published in 2005 which focuses on improving the ICT infrastructure.

The Italian eHealth Strategy aims to improve the efficiency and effectiveness of the healthcare systems as a whole, to assure the fundamental levels of healthcare services throughout the country, and to speed up the technological innovation in patient-centered social and health care services. In 2004, an eHealth Board was established whose main responsibility is to help the implementation of national and regional eHealth policies and action plans.

In 2006, an eHealth Roadmap and Action Plan was approved in Slovakia. Some of the aims include the development of a National Healthcare Information System, electronic health/identification cared, an Electronic Multimedia Record, telemedicine and independent living, and ICT supported home care systems.

In Spain, eHealth services such as electronic health records, medical appointments through the Internet, ePrescribing, telemedicine systems and the patient health card are therefore being implemented – to differing extents – in all Spanish Regions.

In December 2000, Carelink was established to develop the use of IT in healthcare in the Sweden. Carelink also runs a national IT infrastructure for data and telecommunications in healthcare, called

Sjunet, which includes various forms of telemedicine. eHealth strategies with the aim of improving the conditions for ICT in health and elderly care were published in 2006.

The UK healthcare systems, NHS, is presently implementing "Connecting for Health", an integral agency of the Department of Health which is responsible for delivering the National Programme for IT (NPfIT) for the NHS in England, This programme aims to provide authorised access to patient information whenever and wherever it is needed.

Over the years the EU has established laws on the protection of people's health. The main thrust of EU public health policy is to help EU Member States pool their expertise on health, and to identify and share best practice.

In order to foster the development, deployment and implementation of eHealth, the Commission has produced various action plans and strategic frameworks. In June 2005, the Commission published a strategic follow-up to the eEurope 2005 Action Plan, the i2010 – A European Information Society for growth and employment. The i2010 framework defines a package of proactive policies to harness the potential of the digital economy to deliver growth, jobs and modern, on-line public services. i2010 has a particular focus on the further development of ehealth strategies and it sets out a interoperability roadmap for greater use of technologies, new services and systems, to create a "European e-Health Area".

In June 2006, the Commission's ICT for Health Unit adopted an updated strategy, "Transforming the European healthcare landscape" in line with the Commission's new policy framework i2010. This strategy builds upon the Action Plan for eHealth with the vision of building a "*new healthcare delivery model, based on preventive and person-centred health systems, which can only be achieved through proper use of ICT*". The i2010 strategy was reviewed again in 2008 and a new set of actions for 2008-2009 was defined. In relation to healthcare, the Commission recommended a continued promotion of the development of innovative eHealth technologies as a key to better and more efficient healthcare, particularly acute in the light of the needs of Europe's ageing population.

Both the Action Plan and updated Strategy for eHealth emphasise interoperability between health systems, services and technologies. eHealth interoperability is a complex issue, involving more than simply technical factors. It also has legal, ethical, economical and organizational implications which need to be resolved.

The strategic frameworks and action plans call for standardisation as a prerequisite for the successful deployment of eHealth services. Another aspect of regulation is the area of medical devices, where strict rules govern the safety of medical devices in issues of patient safety as well as employee safety.

2.3 Telemonitoring

Telemonitoring can support patients and health professionals. Its use can allow symptoms and abnormal health parameters to be detected earlier than during a routine or emergency consultation, and corrective measures thus to be taken before more serious complications appear. Telemonitoring has already been acknowledged as valuable tools in disease management in several clinical areas. A large potential for Hydra enabled telemonitoring applications is believed to exist in:

- CHD/CHF (Coronary Heart Disease / Failure)
- COPD (Chronic obstructive pulmonary disease)
- Diabetes
- Metabolic Syndromes
- Back pain
- Medication compliance

Today's "successful" telemonitoring services are, to a large extent, not really services aimed at new clinical practice but rather services aimed at workflow improvement, organisational efficiency and cost savings. In the future, there will be more focus on actually improving clinical practice. Telemonitoring is particularly useful in the case of individuals with chronic illnesses. Telemonitoring with personalised feedback is expected to have positive impact on self-management of chronic conditions such as COPD and diabetes.

Another aspect to be carefully considered is the cultural practice prevailing in the community, region or Member State, in which the service is being deployed. To a large extent, the patients' cultural background determines their interest in the diseases and their ability and willingness to take on the responsibility for managing their disease. In the same frame of mind, one must also carefully analyse the ethical aspects of the planned telemonitoring service and how it will fit to the culture prevailing among the target groups. Ethical concerns relate to justice and fairness, rights and discrimination, participation and privacy, dignity and body integrity, somatic surveillance, human experiments and informed consent, as well as loneliness and isolation.

Adequate and correct funding of the conceived telemonitoring service is of fundamental importance for its success and sustainability. Today, most telemonitoring services are still limited to the status of temporary projects without clear prospects for wider use and proper integration into healthcare systems. Commitment by healthcare providers and concerted action between all stakeholders are needed in order to ensure wider deployment of these types of services throughout the EU.

Cost effectiveness of telemonitoring services can be undermined by high cost of devices or logistical problems in getting devices from central repositories to the patients' homes. Will the service then be based on the patients' buying devices themselves? But the patients' willingness to pay or co-fund the telemonitoring service is deeply rooted in tradition and, since healthcare provisioning in Europe is mostly a national concern, the funding systems vary considerably among the Member States.

A fundamental paradigm in the provisioning and payment of healthcare services is the question of what added value is created for whom. Even when the funding is exclusively provided for by healthcare commissioning bodies, the telemonitoring service still must have an added value to the beneficiary. It also must present added values to the other stakeholders in the value chain. It is thus essential to fully understand the value creation process for each stakeholder and the possible constellations that exist in this highly complex ecosystem.

2.4 Stakeholders

Before a new eHealth service can be analysed and its business potential can be assessed, it is necessary to have a complete overview of all possible stakeholders, their motivation and their interaction. Stakeholders have been organised in groups (classes) according to their primary motives, expectations and behaviour in a telemonitoring environment.

Primary stakeholders are found in the social (private) domain. Here we find stakeholder classes such as patients, relatives, friends, neighbours, maids, and even patient organisations. They are all actors involved in a social context. The primary stakeholders have certain expectations and it is up to the service designer to live up to these expectations so that it has a clear value proposition.

Secondary stakeholders are actors that are directly accountable for the end-user experience. The secondary stakeholders are thus creating the value object, and primarily include national or regional healthcare providers and to some extent also healthcare provisioning bodies.

Tertiary stakeholders are all other actors supporting the primary and secondary stakeholders. This level of actors is very broad and of less significance for the business models since the actors do not enter the business model per se.

2.5 Telemonitoring services

The experts have identified several drivers for widespread use of telemonitoring services. The medical benefits of telemonitoring have been demonstrated in many studies. There is evidence of improved quality of treatment in CHD, hypertension, diabetes, treatment of wounds, and many other diseases. Patients benefit from being treated at home and do not have to come into the healthcare systems, which tends to stigmatise some patients or patient groups. Further, it provides increased comfort to the patients, mobility and significant savings in time. From an organisational point of view, telemonitoring unquestionably offers increased efficiency in ward or in General Practitioners' (GP) office workflows. The number of people in the work force is rapidly decreasing, so there is more work to be done by fewer hands.

But there are also inhibitors. There is still a lack of *definitive* evidence for clinical effectiveness and the acceptance by patients is not universal; in particular, ethical and privacy concerns have not been satisfactorily addressed. Another great inhibitor is the reluctance of professionals to embrace the new technology and adjust to the new roles and the lack of a regulatory framework that can facilitate integration of telemonitoring services in national healthcare systems. Finally it is difficult to create convincing business models.

In order to be successful, the design and implementation of telemonitoring system architectures must go beyond the technical functionality and fulfil clinical, organisational, legal, and patient requirements. First of all, the design and setting up of schemas for monitoring must be able to be designed and modified by the carers. The schemas must be designed to report exceptions and identify events, but the medical interpretation of events must be directed to healthcare professionals. In order to secure correct medical intervention and monitoring, the healthcare professionals must be in full charge of vital elements such as schema definition, diagnosis and change of regime. Routine monitoring, filtering and event tracking can be left to the ICT systems.

The monitoring task must be designed based on clinical significance. This monitoring can be combined with filtering of data, so that only those outside the normal range will be alerted to the healthcare professionals. Filtering can also be combined with event detection and handling. Other useful feature of the telemonitoring service is the ability to collect and store massive amount of data and analyse trends.

2.6 Early adopters and partnerships

With the aim of securing early and successful entry into the market, it is essential that the exploiter aligns with partners in the healthcare system, who are willing to take the role as early adaptors and can act as ambassadors for the services.

The group of healthcare commissioning bodies and healthcare providers includes national and regional healthcare authorities, hospitals and clinics. They are prime customers for telemonitoring services as part of the overall healthcare system. The primary healthcare providers (GPs and outpatient clinics) cannot be regarded as early adopters of telemonitoring services.

Strategic health authorities are in some Member States identical to the healthcare provisioning bodies, but in some cases they are separate entities. The strategic health authorities may decide to support telemonitoring as a strategic tool, because it supports their plans for disease management.

Some Member States have statutory insurance contribution-based systems where there is a mixture of public and private providers and where some services must be paid for at the point of use. The statutory health insurance groups have a direct interest and influence on any cost containment effort or efficiency improving methods, including telemonitoring.

Patient organisations are generally very aware of the key global issues surrounding health technologies. The patient organisations are keen to understand the various systems that are already available or which are under development, and to assist in designing and implementing eHealth solutions.

Finally, it is seen as essential for the successful deployment process that the proposer of the telemonitoring service represents a professional, reputable and convincing partnership, since it is unlikely that a single organisation or enterprise can master all the technologies or services involved.

The partnerships are particularly important in the value configuration. Who is actually creating the value for the various stakeholders? The need for partners becomes evident during the development of the business models based on value creation. The ability to enter into successful partnerships is one of the core capabilities that must be possessed by the firm or organisation in order to develop sustainable business models for telemonitoring services.

2.7 Business models and cases

Having thus discussed the basic market conditions and the clinical, social, regulatory and economic frameworks defining the market place, we now turn to proposing sustainable business models and business cases for the Hydra enabled telemonitoring healthcare services. The overall analysis is carried out based on the methodology described in deliverable *D10.5 Business modelling concepts.*

2.7.1 Diabetes hypertension monitoring

The first business case evolves around diabetes monitoring & self-management. The service will initially be offered in Denmark as a service to control hypertension in diabetes management. Each patient enrolling in the system will be provided with a home medical device (initially blood pressure monitors, but other relevant sensors may be added later). The service will allow GP's or hospital clinics to monitor a large number of diabetes patients with high risk of hypertension and a history of non-compliance. The aim of the service is to provide personalised feedback that will help and motivate patients to better control their blood pressure thus reducing the risk of additional conditions.

A value based business model has been used to identify value objects and value exchanges between stakeholders. The organisation "Connected Digital Healthcare in Denmark" has been chosen to be the most likely early adopter in the Danish healthcare system for a Hydra based telemonitoring service. Digital Health already has agreed on an action plan in which telemedicine is used to increase patients' participation in disease management through monitoring at home and self-care.

A Hydra Service Provider will provide primary and secondary healthcare providers in the regions access to the telemonitoring platform.

The revenue model is based on a mix of fixed subscription fees, fees per user and transaction fees. It has a relatively small fixed fee and the majority of the revenues for the service provider coming from activity based fees.

Both primary and secondary healthcare providers benefit form the services, but the business case aggregates all savings in the Ministry of Health. With the set of assumptions, the business case shows that there are additional costs for new reimbursement fees to the GPs for telemonitoring of patients, but that these fees are by and large compensated by savings in the secondary healthcare system stemming from significantly reduced admissions to hospitals.

Setting up the service platform at the Hydra Service Provider is assumed to cost 600 k€ of which 100 k€ is for software including the cost of the Hydra DDK and IDE. The business case shows a rapid return of investment with 18 months payback and ROI of 135%.

The outstanding issue is how the purchase of sufficient numbers of medical devices to be used in the telemonitoring is going to be financed. This issue must await discussions with real stakeholders.

2.7.2 Epilepsy seizure monitoring

The second business case takes place in Germany and involves continuous monitoring of persons with epilepsy. Epileptic seizures are detected using Electromyography electrodes attached to the patient's skin surface with plasters. When an epileptic tonic-clonic seizure is detected, an alarm state is triggered. The alarm state is transmitted to the patient's registered emergency service centre together with GPS based location information. After the alarm is send, an instructive animation with voice-over is automatically downloaded to the mobile devices and launched. The animation video explains in voice and pictures to bystanders what is happening and how they can help the patient.

A value based business model has been used to identify value objects and value exchanges between stakeholders. Two organisations have been identified as early adopters: The German Epilepsy Association (DE - Deutsche Epilepsievereinigung gem. e. V) and the Malteser emergency service (MHD) organisation. The business case will be based on a cooperative venture, where DE funds the creation of the monitoring platform and provides its name, expertise and access to the specialist medical network, whereas the Malteser Emergency Service organisation operates the service for epilepsy patients and handles emergency alarms. A health insurance company is co-funding the new telemonitoring services through reimbursements. The Hydra Service Provider will provide Emergency Service organisations access to the telemonitoring platform.

The revenue models are based on a mix of fixed subscription fees, fees per user and transaction fees. They have a relatively small fixed fee and the majority of the revenues for the service provider coming from activity based fees. The service will initially be launched in cooperation with one Emergency Service organisation only. After 3 years, the service may be extended to other organisations.

Both patients and insurance companies benefit form the services, but in short term monetary terms, the patients and the health insurance company are funding the new services. A small contribution is also coming from the German Epilepsy Association.

The main source of funding for the new services is coming from patients subscribing to the service. Additional funds are derived from the health insurance schemes and the German Epilepsy Association.

Both the Emergency Service organisation and the newly established Hydra Service Provider have a net increase in profits whereas the epilepsy specialists are declining due to a decreasing number of visits to their offices.

The budget for the Hydra Service Provider shows a nice income and reasonable EBDIT of 247 k€ corresponding to 15% of recurrent earnings. The business case shows a rapid return of investment with 10 months payback and ROI of 104%.

The budget for the Malteser Emergency Service organisation also shows a nice income and reasonable EBDIT of 634€ mainly coming from the alarm emergency services.

3. Hydra products

The Hydra middleware has a significant potential for being used to design cost-effective and easy to deploy applications for ICT supported healthcare, i.e. eHealth. Through its unique combination of Service oriented Architecture (SoA) and Model Driven Architecture, the Hydra middleware will enable cost-effective development of intelligent, networked healthcare services.

The Hydra product consists of the middleware itself (in the form of software libraries) and accompanying development tools: Software Development Kit (SDK), Device Development Kit (DDK) and Integrated Development Environment (IDE).

The Hydra middleware is based on a Service-oriented Architecture, to which the underlying communication layer is transparent, and which include support for security and trust, distributed as well as centralised architectures, reflective properties and model-driven development of applications.

The Hydra middleware is not intended to be sold/deployed directly to healthcare providers. Rather, it is a tool for *developers* of healthcare applications. By using the Hydra development tools in the development of new products and applications, producers of devices and components can provide higher value-added intelligent solutions for their customers, where the complexity is hidden behind user-friendly interfaces. The goal for the producers is to be able to build cost-efficient Ambient Intelligence (AmI) systems with high performance, high reliability, reduced time to market and faster deployment and still build on the assets of the installed base.

This chapter will briefly discuss the Hydra products to allow the reader to understand the various healthcare scenarios and business models that will be developed in subsequent chapters and the business rationale related to the creation of value through new services, transactions and interrelations among the stakeholders.

3.1 Middleware

The Hydra middleware is aimed at providing interoperability of networked embedded systems, supporting distributed as well as centralised intelligent architectures.

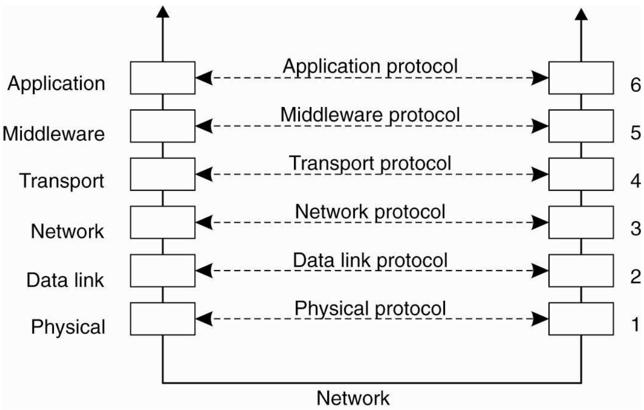

Figure 1: Middleware Layers

The concept of middleware in distributed systems is often taken to mean "the software layer that lies between the operating system and the applications on each site of the system" (Krakowiak, 2003). Another characteristic in terms of the ISO OSI stack (Day and Zimmerman, 1983) is that middleware provides protocols that run on top of the transport layer and that provides services to the application layer (Tanenbaum and Van Steen, 2007, p. 123) as shown in Figure 1 Middleware Layers. Thus, application services such as graphical user interface support or domain-specific application functionality and transport-level services such as sockets are most often thought not to be part of middleware.

The desired functionality is implemented through various layers and components in the Hydra middleware as visualised in the following architecture:

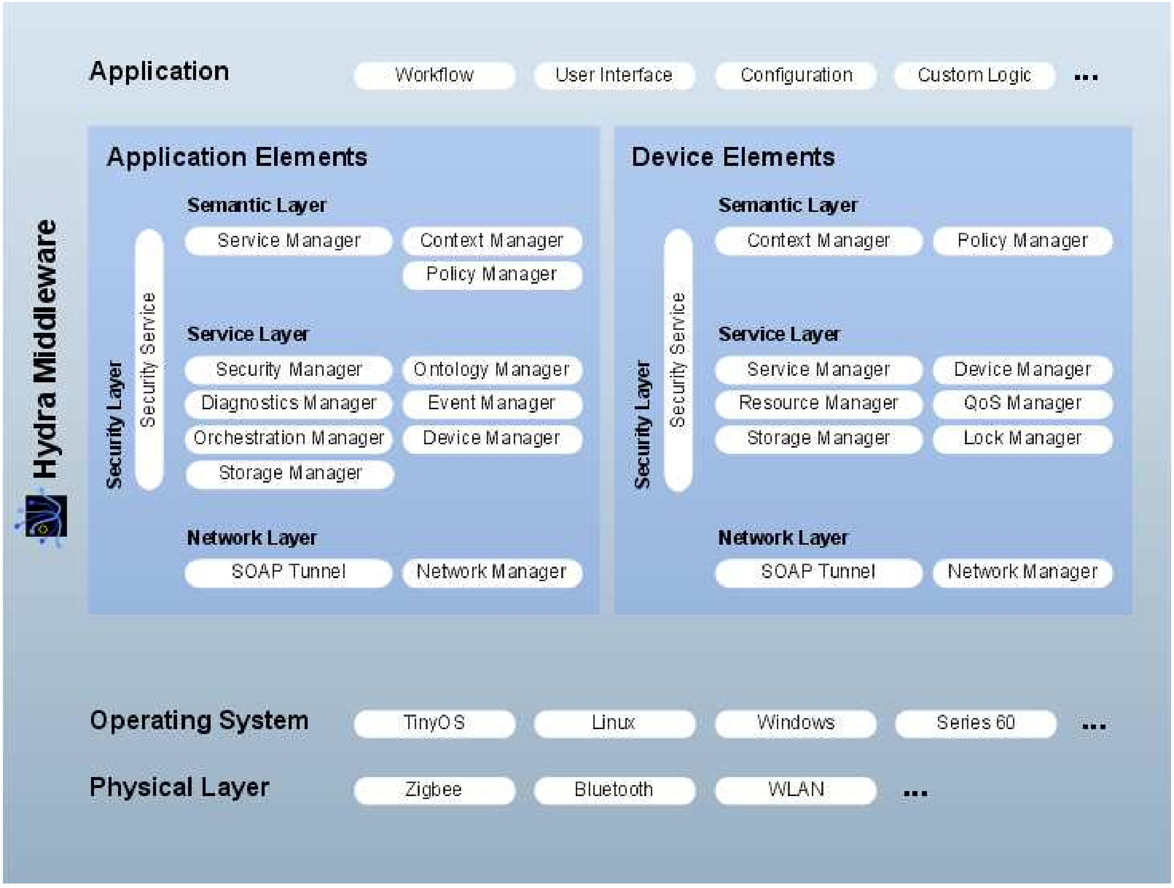

Figure 2 Software Architecture Layers

The Hydra middleware elements are enclosed by the physical, operating system and the application layer shown at the bottom and at the top of the diagram respectively.

The physical layer realizes several network connections like ZigBee, Bluetooth or WLAN. The operating system layer provides functionality to access the physical layer and manages many other hardware and software resources and provides methods to access these resources. The application layer contains user applications. These layers are not part of the Hydra middleware.

The middleware itself consists of three layers - the network, service and semantic layer. Each layer holds elements according to their functionality and purpose. It should be noted, that some device elements have similar and thus similar named, counterparts among the application elements. Both, device and application elements, have a Security Manager. To express that this manager is an orthogonal service, it is depicted in a vertical format and covers all three middleware layers. The device and application elements are described in detail in D3.9 Updated System Architecture Report.

By incorporating semantic web services at the device level, the Hydra middleware opens up for interoperability of networked embedded systems and provides provision for creating AmI services and systems through a model-driven, semantic approach. Every device, sensor, actuator enabled with Hydra middleware will be able to be considered as a unique service. Support for dynamic reconfiguration of devices will allow for self-configuration of applications. The middleware thus has provision for monitoring systems, discovering failures, reasoning about failures, and reacting to failures within the Hydra middleware environment.

The Hydra Middleware is strongly focused on wireless objects and aims to hide the complexity of the underlying infrastructure while providing open interfaces to third parties for application development and ease of use for end-users. The communication layer is thus not part of the middleware.

In order to solve the rapidly growing challenges of privacy, identity theft and trust, the Hydra middleware addresses security goals such as confidentiality, authenticity, and non-repudiation by a particularly trustworthy design and implementation of personalised agents.

3.2 Development tools

To facilitate the development, a series of development tools are available: A Software Development Kit (SDK), a Device Development Kit (DDK) and an Integrated Development Environment (IDE).

The SDK and DDK are two different views on the middleware. The SDK will allow developers to develop the innovative software applications with embedded ambient intelligence computing using the middleware, while the DDK will allow device developers to enable their devices to participate in a Hydra network.

The SDK consists of the managers and associated tools (compilers, archivers, debuggers, documentation, etc.), which are used to develop an application, together with the associated programming interface. In contrast, the DDK consists of the managers needed to Hydra-enable a specific device. Both the SDK and the DDK offer Hydra functionality but at a low programming level.

The IDE will provide solution developers with a high-level interface for developing networked embedded AmI applications. The IDE is integrated with IDE's such as Eclipse and Visual Studio.

3.3 Typical healthcare application

The Hydra healthcare application areas are almost unlimited and specific implementations will be determined by actual customer requirements at the time of deployment. However, due to its generic nature, an attempt has been made to identify a typical telemonitoring application using the Hydra middleware as visualised in Figure 3.

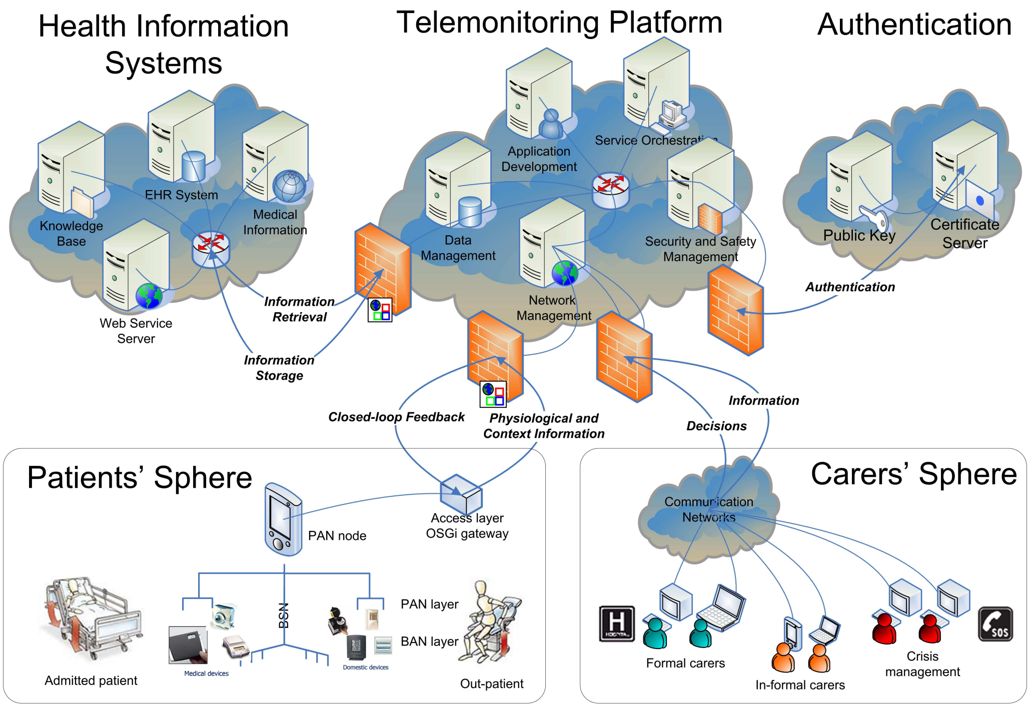

Figure 3 A telemonitoring platform concept

The telemonitoring platform consists of subsets of production servers for data management, security, application execution and communication. All servers interoperate on the basis of web services and are thus completely platform agnostic and scalable. A Hydra SDK toolkit allows for rapid development of the telemonitoring applications. The telemonitoring platform connects to sensors and devices in the Patients' Sphere and to healthcare professionals and informal carers as well as emergency and crisis management teams in the Carers' Sphere. It also connects to Health Information Systems (HIS) and external medical knowledge repositories and security providers.

The Patients' Sphere

Wearable medical sensors are connected in a Body Area Network (BAN) for multi-parametric recording of vital physiological parameters. The BAN interconnects with other sensors in the environment that can record contextual information about the other vital parameters and the patients' activities. Data is pre-processed and formatted in the access layer active nodes/ gateways, which operates personalised software bundles in an OSGi (Open Service Gateway initiative) framework. The gateway can also handle simple episode monitoring and alarm handling and other services, which are needed during periods of non-connectivity.

The gateway also manages personalised feedback from health professionals adapted to the available user terminals, as well as self-monitoring and autonomous regulation of the connected devices in the BAN. For devices not capable to operate web services (due to resource constraints or proprietary concerns), the gateway also dubs as a platform for virtualisation of devices. Data are transmitted securely to and from the platform through fixed or mobile public or proprietary networks.

The telemonitoring platform

The telemonitoring platform is the central production environment for the deployment of telemonitoring services. It consist of five subsets each responsible for their part of the functionality.

The Data Management subset is central to the high level functioning of applications and services deployed on the platform. It implements the model-driven architecture for application development and deployment, the service oriented architecture for core service functionalities, data manipulation, data fusion and event handling. It also manages data transfer to and from stakeholders in the telemonitoring environment. A Service Orchestration subset will orchestrate the different services available in a pre-described sequence for execution. This component introduces higher abstraction mechanisms and makes the application developer independent of using a specific programming environment to orchestrate telemonitoring applications. It will also eliminate the interdependencies of services.

The Network Management subset is responsible for the physical communication between devices, persons and external repositories.

The Security Management subset will perform mapping and brokering between security models, user and client devices profiling management, mapping and usability between trust domains, and semantic standards and generalisation ontologies development.

The Application Development subset is the SDK toolkit for model-driven development of services that use the telemonitoring platform.

The Carers' Sphere

The telemonitoring platform connects to a broad range of stakeholders and provides multiple ways of feedback to the patient or to any object in the Patient's Sphere, including actuators. Data and knowledge are transmitted in personalised form from the Data Manager to various stakeholders.

3.4 Scenarios

Scenarios of end-user behaviour and interaction with platform functionality is an extremely useful instrument for identifying key technological, security, socio-economic and business drivers for future end-user requirements. Scenarios have been used extensively in Hydra to visualise functionalities, opportunities and constrains. The scenarios are constructed from a varied background of knowledge and guesswork about the relevant environment and the trends and discontinuities likely to happen in the future and affecting the users operations and way of work.

4. Market descriptions – European healthcare systems

In order to understand the market opportunities for the development tools, we first need to understand the market for the healthcare applications, which are to be developed by developer users. Understanding the market conditions, the stakeholder dynamics, and the business models in this market allows us to position the Hydra products successfully in this market.

4.1 The healthcare domain

The emerging situation in Europe, of delivering quality healthcare to all its citizens, calls for a change in the way healthcare is delivered and the way medical knowledge is managed and transferred to clinical practice. eHealth may offer useful capability to open new opportunities in health and disease management, improve illness prevention, facilitate chronic disease management through active participation of patients and enable personalisation of care that contributes to improving the productivity of healthcare provisioning.

The Hydra middleware will provide tools for overcoming the deployment obstacles inherent in previous remote monitoring and case management programmes by providing easy to use middleware tools that allow developers to design and implement advanced solutions based on existing or new home medical devices. eHealth services and the development of sophisticated personal wearable and portable medical devices can improve the management of chronic conditions considerably. It is important, however, that sophisticated and intelligent medical devices, which can be used by people at home or on the road, are developed according to the needs and demands of both patients and healthcare professionals. Intelligent devices must be interoperable allowing them to interact with other devices and services. When these basic requirements are fulfilled, eHealth and medical devices will allow patients and healthcare professionals to become more mobile, as well as enabling a more efficient monitoring and management of diseases. A limited number of eHealth applications devoted to self management programmes and intelligent monitoring of patients in their homes is available today as well as a larger number of individual medical devices with interfacing capabilities.

The structures of European healthcare systems are diverse and it is therefore necessary to be aware of fundamental differences in order to be able to commercially exploit Hydra enabled solutions successfully across Europe.

We have chosen to focus on the countries of the Hydra consortium (but including also France) as these will be the main targets for exploitation.

4.2 Denmark

Denmark implemented a structural reform in 2007, which had implications for the structure of the healthcare system. All residents enjoy free access to health services. The main feature of the Danish health system is a decentralized responsibility for primary and secondary health care. There are three administrative levels: the State, the regions and the municipalities, each with clearly defined responsibilities. The state (as in the Ministry of Health) is responsible for national health policy, financing of the health system, and health insurance. The new regions will be overall responsible for the healthcare system. Regions own and run hospitals, and partly or fully finance private practitioners, e.g. general practitioners (GPs), specialists and physiotherapist. The municipalities are responsible for disease prevention, health promotion long-term care, rehabilitation, and social care.

The financing of the healthcare system is obtained through earmarked proportional taxation at the national level. 80% of this revenue is redistributed to the regions via block grants, based on objective criteria (social and demographic indicators), and 20% is redistributed to the municipalities which use these funds to co-finance regional hospital services for the respective population. Self-employed practitioners are reimbursed by taxes and user charges. There a very few private hospitals and clinics in Denmark. These are reimbursed by taxes, private insurance and user charges, and pharmacies licensed by the State.

There is an increasing level of user payments for health care (mainly for pharmaceuticals, dental care and physiotherapy), mainly as a result of a growing private health insurance market, which has been partly established through labour market agreements for groups of employees. In addition, a current trend shows support for introducing more co-payments, such as patient fees for GP consultations. Also, the increasing demand for new health care technologies, the aging of the population, and the growing number of patients with chronic diseases might promote political initiatives to reduce access to publicly funded services through new financial and structural reforms.

Trends within the national healthcare provisioning, point towards a decrease in the length of hospitalised treatment and an increase in out-patient treatment at clinics or at home.

Notably, there is also a trend pointing towards patients becoming more involved with their own healthcare treatment; a development not least due to the increased access to health related information on the Internet, such as the Danish eHealth Portal. (Strandberg-Larsen et al., 2007)

ICT in Healthcare

A National Strategy Group has been established for the development of an IT strategy in Health. The National IT Strategy for the Danish health care service was later published, which provided a common framework for the full computerization of the health sector for the period 2003-2007. The implementation of electronic health records (EHR) and the spread of EHR within the health system were among the initiatives (European Commission, 2007)

4.3 France

Jurisdiction in terms of health policy and regulation of the healthcare system is divided between the state (parliament, the government and various ministries) and the statutory health insurance funds. The structure of the public healthcare system can be divided as follows: the state, regional level, departmental level (local communities) and statutory health insurance.

The state regulates the quality of health service organisation, monitors safety, regulates the volume of health services supply and oversees social protection and regulates healthcare system. The state also sets the ceiling for health insurance spending, approves a report on health and social security trends and amends benefits and regulation. The Government decides the methods of financing and sets tariffs.

The regional hospital agencies (ARH) are responsible for hospital planning (for both public and private hospitals), financial allocation to public hospitals and adjustment of tariffs for private for-profit hospitals (within the framework of national agreements). They bring together, at the regional level, the health services of the state and health insurance funds, which previously shared management of this sector.

The Regional Unions of the Health Insurance Funds (URCAMs) bring together the three main health insurance schemes at the regional level. They coordinate the work of the funds and give impetus to a regional policy of risk management. In relation to the ARHs, whose role is operational, their function is more to influence and stimulate and they do not have authority over the regional and local funds.

The three main health insurance schemes are: 1) The general scheme (Régime general) which covers employees in commerce and industry and their families (about 84% of the population) and CMU beneficiaries (about 1.6% of the population), 2) the agricultural scheme (MSA) which covers farmers and agricultural employees and their families (about 7.2% of the population), and 3) the scheme for non-agricultural self-employed people (CANAM) which covers craftsmen and self-employed people, including self-employed professionals such as lawyers etc (about 5% of the population).

France's health system is based on a national social insurance system complemented by elements of tax-based financing (especially the General Social Tax) and complementary voluntary health insurance. The Ministry of Finance and Ministry of Social Affairs and Employment holds authority over finances, including the financial administration of the French healthcare system.

The National Health Insurance System (NHIS) guarantees universal access to healthcare for the whole population resident in France. The CNAMTS (Caisse National d'Assurance Maladie des Travailleurs Salaries) accounts for 80% of the NHIS. It covers mainly employees in the commercial and industrial sectors, as well as their families. The remaining 20% of the NHIS consists of funds for agricultural workers, independent professions, civil servants, doctors and students.

The national funds of the three main health insurance schemes also conclude agreements with self-employed healthcare professionals practicing privately: general practitioners, specialists, dental surgeons, nurses, physiotherapists, biologists, midwives, speech therapists, orthoptists and ambulance personnel. These agreements concern the conditions and level of charges for treatment. Home care is delivered by self-employed professionals or by specialised home care services (European Commission, 2007).

ICT in healthcare

The French eHealth strategy focuses on using ICT for optimisation and reengineering of the healthcare system. eHealth has been already implemented at both local and regional levels. A national eHealth virtual community has also been realised through the national mapping of all eHealth initiatives. Some of the eHealth implementations include the CPS (Carte de Professionnel de Santé – Health Professional Card), a microprocessor card whose functionalities include identification, authentication and electronic signature of health professionals, and a microprocessor card (carte Vitale) which contains health insurance data for the insured and their beneficiaries. In the near future, the Vitale card will be replaced by a new one, the Vitale 2 (European Commission, 2007)

4.4 Germany

The healthcare system has a decentralized organization, characterised by federalism and delegation to non-governmental corporatist bodies as the main actors in the social health insurance system: the physicians' and dentists' associations on the providers' side and the sickness funds and their associations on the purchasers' side.

The Ministry of Health and Social Security proposes the health acts that - when passed by parliament - define the legislative framework of the social health insurance system. It also supervises the corporatist bodies and - with the assistance of a number of subordinate authorities - fulfils various licensing and supervisory functions, performs scientific consultancy work and provides information services.

The 292 sickness funds collect contributions and purchase proactively or pay retroactively for health and long-term care services for their members. Since 1996 almost every insured person has had the right to choose a sickness fund freely, while funds are obliged to accept any applicant.

According to figures from 2002, public funds cover 79% of the health expenditure. Of total expenditure, 57% of the funds came from statutory health insurance, 7% from statutory long-term care insurance, 4% from other statutory insurance schemes and 8% from government sources. Private health insurers financed 8%, employers 4% and non-profit-making organizations and households (families) 12%. Most out-of-pocket payments cover purchases of over-the-counter drugs and co-payments for prescribed drugs. On 1 January 2004, co-payments were introduced for outpatient visits and raised for virtually all other benefits.

A survey conducted in Germany in 2002 demonstrated that an efficient remote patient management can save approximately 20% of yearly treatment costs and between 50-60% of costs due to late stage diseases (Busse & Riesberg, 2000).

ICT in healthcare

Germany has already taken steps towards implementing eHealth services. First of all, the implementation of an Electronic Health Card, which allows patients and healthcare professionals universal access to information, started in 2008 and is ongoing. Moreover, a German eHealth

Strategy was published in 2005 which focuses on improving the ICT infrastructure. In particular, an online verification of insurance status including availability of all data for an electronic European Health Insurance Card and the implementation of a private electronic patient record are emphasized in the report (European Commission, 2007).

4.5 Italy

The Italian National Health Service (NHS) provides universal health care coverage. Pursuant to the 2001 reform of the Italian constitution, the NHS has become more decentralized, and the state and the regions share responsibility for healthcare. The Ministry of Health is responsible for health care planning and financing, framework regulation, monitoring, and general governance of the National Institutes for Scientific Research. Regional governments are responsible for meeting the national objectives set by the National Health Plan at the regional level. Regions are also responsible for legislative and administrative functions, for planning health care activities, for organising the supply in relation to population needs and for monitoring the quality, appropriateness and efficiency of the services provided. Local health units (public health enterprises legally independent from the regions) are responsible for delivering healthcare services at the local level. Local health units are organised into health districts responsible for ensuring the accessibility, continuity and timeliness of care.

The Italian healthcare system is mainly financed by indirect taxes. The Ministry of Health is responsible for proposing the amount of public resources to be dedicated to health care and how these resources should be allocated among levels of care. The Ministry manages the National Health Fund and allocates resources to regions from the global national budget. The allocation aims to ensure uniform availability of resources in the regions. The regions have to finance the remaining health care expenditure from their own sources

Throughout the 1990s social health insurance contributions represented more than 50% of total public financing of the healthcare system. In 1998, a regional business tax replaced social contributions. This tax is supplemented by a national grant financed with revenues from the value-added tax to ensure adequate resources for each region. Out-of-pocket payments refer to cost sharing for public services, such as co-payments for diagnostic procedures, pharmaceuticals and specialist consultations (Donatini et al., 2001).

ICT in Healthcare

The Italian eHealth Strategy aims to improve the efficiency and effectiveness of the healthcare systems as a whole, to assure the fundamental levels of healthcare services throughout the country, and to speed up the technological innovation in patient-centered social and health care services. In 2004, an eHealth Board was established whose main responsibility is to help the implementation of national and regional eHealth policies and action plans (European Commission, 2007).

4.6 Slovakia

The health care system in Slovakia is based on a mixture of decentralized and centralized structures. The Ministry of Health is responsible for proposing principal directions and priorities of state health policies. The Ministry also controls the health insurance companies.

Until 2003, the Ministry of Health owned, ran and controlled the vast majority of inpatient facilities. Today, due to decentralisation only few specialised inpatient care providers and few major regional and teaching hospitals are still under state ownership and centralised management. Decentralization has given the regions more autonomy in health service organisation and management, and has allowed regions to participate more fully in the ownership of health care establishments. Regions are, among other things, responsible for issuing licences for the provision of health care in various non-state health care establishments, e.g. home care agencies and polyclinics.

As part of the decentralisation process, municipalities have also gained self-governing administration responsibilities. Since 2001, municipalities have, among other things, established outpatient centres, specialised outpatient facilities and home care agencies. Long-term inpatient care, social services for the elderly, and patients with chronic conditions all form part of social care services. Health insurance finance nursing and rehabilitation.

Health care is funded by a mix of public and private sources. The state budget provides a basis for annual financial planning for health care expenditures from taxes. Public expenditure includes resources to fund the operation of the Ministry of Health, capital investments and the state contributions to the health insurance system.

There are two types of health insurance: the mandatory public health insurance scheme and a voluntary health insurance scheme. The former is based on the principle of solidarity and provided by health insurance companies on the basis of a permit issued by the Office for Supervision in Healthcare. It is used to finance a basic benefit package, the solidarity package. The voluntary health insurance scheme is used to cover out-of pocket payments for health care provided outside the framework of the solidarity package.

The health insurance companies represent third-party payers who contract with individual health care providers. A health care provider may contract with any or all health insurance companies and vice versa. The health insurance companies reimburse services delivered by both the state and private health care providers. There is no separate system to cover private health care providers (Hlavačka, 2004).

ICT in Healthcare

In 2006, an eHealth Roadmap and Action Plan was approved in Slovakia. Some of the aims include the development of a National Healthcare Information System, electronic health/identification cared, an Electronic Multimedia Record, telemedicine and independent living, and ICT supported home care systems (European Commission, 2007).

4.7 Spain

Spain's healthcare system is tax-based, and during the past two decades the responsibility for healthcare has largely been devolved to Spain's 17 regions, the autonomous communities. The Ministry of Health and Consumer Affairs establishes norms that define the minimum standards and requirements for healthcare provision, has regulatory power, sets up information systems and assures cooperation between national health authorities and the autonomous communities. The autonomous communities decide how to organize or provide health services and implement the national legislation. The inter-territorial council (Consejo Interterritorial del Sistema Nacional de Salud) is composed of representatives of the autonomous communities and the state administration and is in charge of promoting the cohesion of the health system. The role of municipalities is limited to complementary public health functions linked to hygiene and the environment.

Private insurance companies provide complementary healthcare coverage and increasingly play a role in covering services not included in the basic package and designed to avoid waiting lists.

The healthcare system is financed out of general taxation such as value-added tax and income tax but also regionally raised taxes. The regions may modify the rate of taxation at the regional level up to a threshold fixed by the national government. Some autonomous communities also receive grants from the state. Private healthcare financing complements public financing with out-of-pocket payments to the public system (such as co-payments for pharmaceuticals). Patients also pay directly for outpatients appointments. If they have signed with a private insurance scheme, they will receive part or full amount of money paid, depending on the type of insurance (Durán et al., 2006).

ICT in Healthcare

The national programme for the healthcare system in Spain is defined in the Plan for Quality in the National Health System. The strategic goals of the Plan for Quality include improving citizen participation in their own healthcare, increasing patient safety through improved quality of care, intensifying healthcare ICT security by continuous assessment, and increasing the use of ICT by adapting the human resources policy to the changing service needs. Within the national health system framework, the regional health authorities are also developing numerous initiatives for improving their healthcare services based on use of new ICT. eHealth services such as electronic health records, medical appointments through the Internet, ePrescribing, telemedicine systems and the patient health card are therefore being implemented – to differing extents – in all Spanish Regions (European Commission, 2007).

4.8 Sweden

The responsibility for health and medical care is divided between the state, county councils and municipalities.

The state, operating on national level, is responsible for overall health and medical care policy through laws and ordinances. The Ministry of Health and Social Affairs is responsible for ensuring that the healthcare system runs efficiently and it is responsible for developments in healthcare.

The 21 county councils are responsible for providing, organising and financing healthcare services. The county councils own and run the hospitals, health centres and other health institutions, even if these institutions are supplemented by private providers which, in most cases, have contracts with the county councils to supply certain services. The county councils decide on the allocation of resources to the health services and are responsible for the overall planning of these services.

The 290 municipalities are responsible for long-term care, care of the elderly and social welfare services. They deliver and finance welfare services such care for the elderly and people with disabilities. They operate public nursing homes and home care services. Half the municipalities in the country have agreed with the county council to take over responsibility for elderly and disabled people living at home. In the other municipalities, such care remains the responsibility of the county councils.

Healthcare in Sweden is mainly financed by local taxation, i.e. municipal, county and parish taxes. The county councils and the municipalities have the right to levy income tax on their residents and to decide the rates of taxation. Local taxes are proportionate to income. Other important revenue sources for the country councils are grants and payments for certain services received from central government. Patient fees amount to 4% of county council revenue.

The National Healthcare System provides coverage for all residents of Sweden and no substitute private coverage is available. However, it is possible to take out a supplementary voluntary insurance which is mainly done by employers on behalf of their employees. It is most often taken out to cover payments for employees' long-term sick leave and/or in order to have faster access to treatment (Glenngård et al., 2005).

ICT in Healthcare

In December 2000, Carelink was established to develop the use of IT in healthcare. Carelink also runs a national IT infrastructure for data and telecommunications in healthcare, called Sjunet. Sjunet is the infrastructure for communication of healthcare data and services in Swedish healthcare, including various forms of telemedicine. Sjunet started as a regional project and today, practically all Swedish hospitals and primary care centres are connected. Sjunet is as much a cooperative network as it is a technical communicative platform. EHealth strategies was published in 2006, which aims at improving the conditions for ICT in health and elderly care, and improve eHealth solutions and adapting these to patients' needs (European Commission, 2007).

4.9 The United Kingdom

The United Kingdom has devolved responsibility for healthcare to its four constituent counties. The four health services operate independently, but there is close cooperation and collaboration. The Department of Health is responsible for the National Health Service (NHS). The Primary Care Trusts (PCTs) are both providers and commissioners for different healthcare services. The PCTs provide primary healthcare services such as district nurses, specialist treatment, health visitors and community nurses. These primary care health teams (including GPs) are responsible for providing home-care as well. In general, the district nurse, who works closely with a GP but who is provided (i.e. salaried by) the PCT, assists the GP with providing relevant home-care for patients. As a commissioning body, the PCTs commission healthcare services from the public, private and voluntary sector in order to meet national delivery and service requirements.

An increased number of conditions are being dealt with in the community to reduce the costs, reduce distress of patients, improve outcomes and empower patients. Hypertension, diabetes, CHD, COPD and other chronic conditions are targeted for home care management

The NHS is mainly funded through general taxation: direct taxes, value-added tax and employee income contributions. Local taxation provides further funding for social services. Private funding can be broken down into out-of-pocket payments for prescription drugs, ophthalmic and dental services and private medical insurance premiums.

In England, budgets for healthcare are set every three years through negotiations between the Chancellor of the Exchequer and Department of Health. In the rest of the United Kingdom, the devolved administrations set budgets separately (World Health Organisation, 2004).

ICT in Healthcare

NHS Connecting for Health is an integral agency of the Department of Health and is responsible for delivering the National Programme for IT (NPfIT) for the NHS in England. The NPfIT, launched in 2002, is one of the largest public sector health ICT projects in the world and aims to provide authorised access to patient information whenever and wherever it is needed. Some of the initiatives include creating a NHS Care Records Service to improve the sharing of consenting patients' records across the NHS and also provide patient access to their own health records, making it easier and faster for general practitioners (GPs) and other primary care staff to book hospital appointments for patients, and providing a system for electronic transmission of prescriptions (European Commission, 2007).

5. Policy framework

The national governments in Europe are responsible for deciding on the organization of national healthcare service provisioning. This includes developments in the area of eHealth in accordance with the eEurope Action Plan. European Health Ministers have already shown eHealth leadership in their Ministerial Declaration 53 at the 2003 eHealth Ministerial conference. The ministers welcomed Commission initiatives to explore the possibilities to promote co-ordination at a European level. They proposed to meet the targets and objectives laid down in the eEurope Action Plan and in the Programme of Community Action in the field of Public Health (2003-2008) set out in decision 1786/2002, and liaise with other Community initiatives.

The EU Members States have already showed their commitment to promote eHealth strategies and initiatives (European Commission, 2003). By the end of 2005, each Member State developed national or regional roadmaps for eHealth. In the eHealth High Level Conference Declaration of May 2008, Member States' representatives acknowledged the urgency of ensuring wider deployment of telemedicine services and innovative ICT tools for chronic disease management. The EU Commission followed with its Communication (European Commission, 2008) setting out a range of actions to be undertaken.

This chapter will look more closely at the EU policies and action plans that will influence the national eHealth strategies in the years to come.

5.1 European directives and regulations

Over the years the EU has established laws on the protection of people's health. The Health and Consumer Protection Directorate General has the task of keeping these laws up to date, to check what is really happening and that the rules are being applied properly in all EU Member States. However, it is national, regional or even local governments in EU Member States who actually apply the EU's health and consumer protection laws.

Most of the national laws of data protection and privacy issues are mainly relevant to operational and business policies rather than to the architectural design of a telemonitoring platform. Specific requirements of encryption and traceability of information transactions (Denmark and Spain) are, however, relevant for the security architecture.

The main thrust of EU public health policy is to help EU Member States pool their expertise on health, to identify and share best practice and to help coordinate the EU wide response to health threats such as infectious disease outbreaks. Fostering cooperation between EU Member States' healthcare systems is also becoming an increasingly important area of activity. Together with the Member States, the EU works to protect and promote the health of European people.

5.2 European action plans

In order to foster the development, deployment and implementation of eHealth, the Commission has produced various action plans and strategic frameworks. The first important action plan for eHealth was **eEurope 2005 Action Plan**. It was later followed up by the **i2010 – A European Information Society for growth and employment** which was part of the Lisbon strategy. In the sections that follow, we look closer at the most important action plans and strategic frameworks related to the commercial exploitation of the Hydra Middleware in the healthcare domain.

5.2.1 eEurope 2005

The development of eHealth has long been promoted within the EU as a part of *e*Government initiatives in Europe. An important strategic initiative was the publication of the eEurope 2005 Action Plan, which set out a number of policies and targets for both the European Commission and the EU Member States (European Commission, 2002). The action plan focused on three priority areas:

- creating a common framework to support eHealth, including interoperability of health information systems and of electronic health records, patient identifiers and mobility of patients and health professionals;
- accelerating deployment by improving information on health education and disease prevention and promoting the use of cards in health care; and
- working together and monitoring best practice.

The Action Plan advocates the development of interoperability approaches for patient identifiers, medical data messaging and electronic health records. The ultimate goal is to enable access to the patient's electronic health record and emergency data from any place in Europe, even outside a citizen's country of origin or residence, whenever this is required.

It also called specifically for new regulation and legislation to be introduced by Member States by the end of 2009 that will:

- Set a baseline for a standardised European qualification for e-Health services in clinical and administrative settings;
- provide framework for greater legal certainty of e-Health products and services liability within the context of existing product liability legislation;
- improve information for patients, health insurance schemes and providers regarding the rules applying to the assumption of the costs of e-Health services;
- promote e-Health with a view to reducing occupational accidents and illnesses as well as supporting preventive actions in the face of the emergence of new workplace risks.

As the points above illustrate, it is important to consider the issue of personal data protection in relation to the development of eHealth. The Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 applies to the protection of individuals with regard to the processing of personal data and on the free movement of such data. The Directive applies "to the processing of personal data wholly or partly by automatic means, and to the processing otherwise than by automatic means of personal data which form part of a filing system or are intended to form part of a filing system".

The Action Plan also includes a number of detailed specific targets for member states and is further discussed in the deliverable D2.3 Initial regulatory-standards watch.

5.2.2 i2010

In June 2005, the Commission published a strategic follow-up to the eEurope 2005 Action Plan, the **i2010 – A European Information Society for growth and employment** (European Commission, 2005). The i2010 framework defines a package of proactive policies to harness the potential of the digital economy to deliver growth, jobs and modern, on-line public services. It is a key component of the EU's renewed "Lisbon" competitiveness strategy. i2010 states that "ICT can contribute strongly to improvements in the **quality of life**. ICT are capable of improving the health of our citizens via new ICT enabled medical and welfare services. In light of the demographic challenges facing Europe, ICT can help make public health and welfare systems more efficient and effective".

i2010 has a particular focus on the further development of ehealth strategies and it sets out a interoperability roadmap for greater use of technologies, new services and systems, to create a "European e-Health Area". The roadmap identifies the various steps involved in order to:

- Recommend a set of guidelines to facilitate Member States' decision-making on eHealth interoperability, and to assess what aspects of interoperability are most urgent (e.g., Electronic Health Records, health messaging and patient identifiers);
- Develop and establish mechanisms for assessing good practice in eHealth interoperability;

- Assess rapid international (US, Canada, Australia, etc) developments in eHealth interoperability in order to strengthen the competitiveness of EU industry in the eHealth field;
- Reinforce appropriate collaborations by/with industrial players and public-private partnerships;
- Propose possible legislative or regulatory approaches to eHealth interoperability, including aspects relating to data privacy and security.

The eHealth components of Member States' national health systems must be interoperable to ensure that European citizens can enjoy their right to live, work, and visit other European countries knowing that their health needs will be met safely and affordably.

The issues of security, confidentiality and liability are crucial elements of *e*Health development and are some of the major challenges of eHealth. The document **e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area** defines several security issues (European Commission, 2004). Firstly, the confidentiality and protection of patient data is governed by the general EU rules of data protection, as well as by the requirements of ePrivacy legislation regarding communications infrastructure. The requirement for confidentiality makes health information systems security critical. There is a provision within the general data protection directive to create a code of conduct for special domains such as health, but this has not yet been taken forward.

Another important legal issue is liability in the event of problems - such as technical malfunctions of the system, network, or provision of the service itself - that result in serious harm to a patient. While there are currently no specific guidelines or liability rules, as with any emerging or growing area of practice, only the increased use of e-Health applications and the performance of eHealthcare will make its potential fully visible as well as raising any remaining legal uncertainties. The electronic commerce Directive which creates a legal framework for the provision of information society services, also applies to the provision of online health services. The Directive, principally by virtue of its internal market clause, contributes to the legal certainty and clarity needed for the provision of online information society services throughout the entire Community. In particular, its provisions on information and transparency requirements, commercial communications, the liability of intermediary service providers, and the basic principles it establishes regarding electronic contracts, provide for high standards in the provision of online services in all Member States, thus also increasing consumer confidence.

Updates to i2010

In June 2006, the Commission's ICT for Health Unit adopted an updated strategy, "Transforming the European healthcare landscape" in line with the Commission's new policy framework i2010 (European Commission, 2006). This strategy builds upon the Action Plan for eHealth with the vision of building a "*new healthcare delivery model, based on preventive and person-centred health systems, which can only be achieved through proper use of ICT*". It provides greater emphasis on interoperability, the shift to preventative healthcare and more effective management of health risks, and also aligns eHealth under the EC's broader i2010 policy framework.

ICT for Health is a main force in supporting this paradigm shift in healthcare delivery in Europe from symptom-based to preventative healthcare, and from hospital-centred to person-centred health systems to secure a seamless, mobile and personalised healthcare delivery system. The deployment of interoperability of eHealth systems across Europe will ensure continuity in healthcare as it enables access to a patient's medical data and history from anywhere at anytime. Moreover, ICT can empower citizens to become actively involved in managing their own health status, improve prevention and early diagnosis of many diseases, enhance patient safety, facilitate active ageing and independent living for the aging, and enable cost-effective management of chronic diseases.

The i2010 strategy was reviewed in 2008 by the Commission and a new set of actions for 2008-2009 were defined. In relation to healthcare, the Commission recommended a continued promotion of the development of innovative eHealth technologies as a key to better and more efficient healthcare, particularly acute in the light of the needs of Europe's ageing population. The Commission has also published recommendations on the cross-border interoperability of electronic health record systems and on the general advantages of telemedicine. Telemedicine services include distant diagnosis, treatment and monitoring which will greatly benefit patients; they can receive specialist diagnosis without having to travel far distances and patients with chronic diseases can be monitored closely in the comfort of their own home (European Commission, 2009).

Building further on the emphasis on the advantages of ICT for health, the Commission published the "Communication on telemedicine for the benefit of patients, healthcare systems and society" in 2008 (European Commission, 2008). The communication stresses that the EU economy, and in particular small and medium-sized enterprises engaged in the telemedicine industry, will also benefit significantly from the development and deployment of telemedicine in European healthcare systems. In this regard, it is crucial that interoperability and standardisation are in place in order to fully explore the single market and to ensure the widespread use of the technologies.

The communication identifies various action points to help foster the deployment of telemedicine as an integral part of healthcare systems. The action points are divided into three strategic sets of actions: 1) Building confidence in and acceptance of telemedicine services, 2) Bringing legal clarity and, 3) Solving technical issues and facilitating market development. Member states and their health authorities are called upon to engage actively to integrate telemedicine into their healthcare systems. Some of the key action points defined in the communication are:

- The Commission will continue to contribute to European collaboration between health professionals and patients in key areas with the potential for greater application of telemedicine, in order to make specific recommendations on how to improve confidence in and acceptance of telemedicine, also taking into account ethical and privacy related aspects
- Member States are urged to assess their needs and priorities in telemedicine by the end of 2009. These priorities should form part of the national health strategies to be presented and discussed at the 2010 eHealth Ministerial Conference
- In 2009, the Commission will establish a European platform to support Member States in sharing information on current national legislative frameworks relevant to telemedicine and proposals for new national regulations
- By the end of 2010, the Commission will invite industry and international standardisation bodies to issue a proposal on the interoperability of telemonitoring systems, including both existing and new standards
- By the end of 2011, Member States should have assessed and adapted their national regulations enabling wider access to telemedicine services. Issues such as accreditation, liability, reimbursement, privacy and data protection should be addressed
- By the end of 2011, the Commission, in cooperation with Member States, will issue a policy strategy paper on how to ensure interoperability, quality and security of telemonitoring systems based on existing or emerging standards at European level.

5.2.3 Together for Health: A Strategic Approach for the EU 2008-2013

In order to clearly define the Community's role in health, and to develop a new health strategy, the White Paper - Together for Health: A Strategic Approach for the EU 2008-2013 – was published in 2007 (European Commission, 2007b). It identifies four core principles:

1. A strategy based on shared health values
2. "Health is the greatest wealth"
3. Health in all policies
4. Strengthening the EU's voice in Global Health.

These four principles underpin three overall objectives for improving healthcare services in Europe:

1. Fostering good health in an ageing Europe
2. Protecting citizens from health threats
3. Supporting dynamic health systems and new technologies.

Objective 2 and 3 are particular relevant to the Hydra middleware. As the White Paper emphasises, new technologies are an important tool for meeting the future challenges facing Europe's healthcare systems. eHealth has the potential to improve prevention of illness, delivery of treatment and support a shift from hospital care to prevention and primary care. Interoperability of healthcare systems across borders, patient mobility and safety, and better citizen-centred care can all be made possible with eHealth services. The Commission will therefore support the implementation and interoperability of eHealth solutions in health systems.

5.3 Interoperability requirements

Both the Action Plan and updated Strategy for eHealth emphasise interoperability between health systems, services and technologies. This is clearly of great importance to Hydra, but there is little yet in the way of clear guidance and regulation. eHealth interoperability is a complex issue, involving more than simply technical factors. It also has legal, ethical, economical and organizational implications which need to be resolved.

A useful paper, "Connected Health: Quality and Safety for European Citizens", has been produced by the Commission in September 2006 which provides an overview of activities in this area (European Commission, 2006b). This paper emphasizes the importance of compliance with emerging international technical standards for healthcare, including HL7 (see ISO section below).

5.4 Standardisation

The strategic frameworks and action plans described above all call for standardisation as a prerequisite for the successful deployment of eHealth services. The standardisation of system components and services is necessary for the interoperability of different healthcare systems across national borders (European Commission, 2002). Interoperable standards are also generally emphasised in member states' ICT for health strategies and objectives (European Commission, 2007).

5.4.1 eHealth standards

CEN (European Committee for Standardization) in a recent feasibility study declares that there is a considerable interest in European standardisation activities related to the provision of healthcare services (CEN BTTF 142/N43, 2004). It is likely that European standards could be developed and beneficial to the citizens, healthcare providers and governments for a growing number of issues in this very large and complicated sector, accounting for some 7-12% of the Gross Domestic Product in Europe. However, this is also a very sensitive area where national governmental regulation traditionally dominates.

The World Health Assembly in May 2005 adopted resolution WHA58.28[1], recognising that a WHO eHealth strategy could serve as a basis for WHO's activities in eHealth as well as encouraging Member States to consider creating their own long-term strategic plans for developing and deploying eHealth services. It also requests WHO to provide technical support to Member States and facilitate integration of eHealth in health systems and services, including in training. This strategy from WHO should be positive for Hydra as it encourages convergence of international adoption of eHealth technologies and associated standards compliance.

The table in Appendix 5: Relevant eHealth standards summarises the key international standards and TC projects relating to eHealth.

5.4.2 Medical devices regulation

Another aspect of regulation which may apply to Hydra-enabled products is the area of medical devices. Strict rules govern the safety of medical devices as issues of patient safety as well as employee safety apply. The key European regulation in this area is the Medical Device Directive (MDD) Directive 93/42/EEC (European Commission, 2009b). The MDD covers the placing on the

[1] http://www.euro.who.int/telemed/20060713_1

market and putting into service of Medical Devices that do not require invasive procedures with the patient (other directives cover these products). The MDD nonetheless covers an extremely wide range of products, including, for example:

- first aid bandages;
- tongue depressors;
- hip prostheses;
- X-ray equipment;
- ECG;
- heart valves;
- spectacles; and
- dental materials.

However, the relevance at present of this legislation to Hydra would be limited to any devices requiring direct connection to the patient, and it is likely that such sensors would be developed by experienced medical equipment suppliers.

5.4.3 Emerging regulations for software development for medical devices

ISO TC 215 has prepared two documents on "Risk evaluation and management in the deployment and use of health software" and "Application of risk management to the manufacture of health software" (Rolands, 2007).

Through these papers, ISO is proposing a new product category called "health software" defined as software which has a "possible influence" on patient health. Under this definition, software with influence on patient health may either be software classified as a medical device (either as part of a medical device, controlling a medical device, or software which by itself is a medical device), or software not classified as a medical device.

If mandated, software developers may have to follow medical device standards and regulations including IEC 60601 (Medical electrical equipment – General requirements for basic safety and essential performance) (IEC, 2007), ISO 14971 (medical devices: application or risk management to medical devices) (ISO, 2000) and in the future IEC 62304 (medical device software: software lifecycle processes) (IEC, forthcoming). This IEC standard specifies a life cycle framework for medical device software in terms of processes, activities and tasks to be adopted for medical device software development.

6. Telemonitoring provisioning

It is generally acknowledged that telemonitoring can support patients and health professionals. Its use can allow symptoms and abnormal health parameters to be detected earlier than during a routine or emergency consultation, and corrective measures thus to be taken before more serious complications appear. It may also result in less frequent visits to healthcare facilities, thereby increasing the quality of life for patients.

Telemonitoring has specific characteristics (European Commission, 2008):

- It can contribute to re-organisation and re-deployment of healthcare resources, for instance by reducing hospital visits, thus contributing to the greater efficiency of healthcare systems.
- It has proven to increase quality of care for patients, in particular chronically ill patients. In the context of an ageing population and an increasing burden of chronic diseases, the benefits its wider deployment can provide are crucial.
- It requires a coherent approach and partnership involving patients, health professionals, healthcare providers, payers and the industry, to ensure sustainability of the services.

It is generally acknowledged that eHealth can deliver significant improvements in access to care, quality of care, and the efficiency and productivity of the healthcare sector and it is a key priority of the European Union's eEurope strategy. In this chapter we will take a closer look at trends and drivers for the special form of eHealth applications called telemonitoring.

6.1 Status of telemonitoring

The demographic trend across Europe means that life expectancy is increasing every year, partly thanks to good economical and social conditions and good services. Extended life expectancy coupled with decreasing birth rates in recent decades will lead to a general ageing of the population in Europe. Of course elderly people need more healthcare services. As the European population grow older, the demand for healthcare will rise accordingly. Information and Communication Technologies can be very useful in managing the flows of supply and demand, just as it could be for waiting lists. Electronic "brokerage" of healthcare services will link excess supply in one place with excess demand in another, thus, increasing access.

The term eHealth has been used in the literature to refer to a variety of applications including telemedicine, electronic patient records (EPRs), consumer health websites, teletraining for health professionals and electronic referrals and bookings that might be categorised as using information and communication technologies (Oh et al., 2005). Telemedicine may be described as the use of these technologies by healthcare professionals to practice medicine at a distance, and again numerous definitions have appeared in the literature. One that is favoured by many researchers is that by Reid (1996, p.14): "Telemedicine – the use of advanced telecommunications technologies to exchange health information and provide healthcare services across geographic, time, social and cultural barriers". It emphasises the potential of telemedicine to improve access to healthcare for those who do not live within the reach of high-rated or specialist hospitals and medical centres.

Telemonitoring can be seen as a subcategory of telemedicine. Telemonitoring is a telemedicine service aimed at monitoring the health status of patients at a distance. It entails the electronic monitoring of physiological measurements in a setting other than a hospital, such as a patient's home, or a community setting such as a residential or nursing home. Physiological measurements can include heart rate, blood pressure, ECG, SpO2 (oxygen saturation of the blood), temperature, respiration and weight. Telemonitoring is defined as: "The electronic monitoring of physiological measurements of patients not confined to hospital, using information and communication technologies to transfer data over geographical distances" (adapted from Bratan & Clarke, 2005).

Telemonitoring overlaps with telecare, which is defined as the monitoring of non-medical data such as general behaviour patterns, falls and, and is referred to as "social alarms", as the response is most commonly by a non healthcare professional.

Success and sustainability factors for telemedicine have been extensively researched (e.g. Yellowlees, 1997 and 2005; Doolittle, 2001; Watson et al., 2001; Saligari et al., 2002; Whitten & Adams, 2003), but so far no studies have been carried out to compare the different approaches in terms of implementation in order to identify common elements that would inform the design of a generic architecture for an RPM system. There have also been no studies that have optimised current implementations.

Coughlan et al. (2006) developed a new approach for evaluating telemedicine services, which focuses on clinical and organisational aspects and uses patient pathways and simulation modelling ('patient pathway simulation'). The use of the patient pathway as a tool for comparing traditional healthcare and telemedicine is promising and forms an important aspect of developing the generic architecture. Patient pathways show the patient's journey through the healthcare system and are usually represented diagrammatically.

Telemonitoring can also lead to better clinical outcomes (e.g. Hopp et al., 2006; Clarke et al., 2005) and be more convenient and cost-effective (Finkelstein et al., 2006; Hersh et al., 2001) than traditional institutional care, since it enables patients to remain in their usual environment whilst being looked after professionally. However, not all reviews of cost-effectiveness have proven conclusive, which has been blamed on the poor design of projects (Whitten et al., 2002).

Telemonitoring is particularly useful in the case of individuals with chronic illnesses (such as diabetes or chronic heart failure). Many of these patients - who are often elderly people - need regular monitoring because of the prolonged duration of their disease, the nature of their health condition and the drugs that they are using.

There is therefore great potential for the commercial exploitation of Hydra middleware tools to develop telemonitoring services capable of meeting these challenges.

However, telemonitoring remains to be integrated into mainstream healthcare (Barlow et al., 2006; Yellowlees, 2005), despite its potential for improving health outcomes and effective use of resources, and the efforts of government, industry and academia. This can be seen in the relatively low utilisation and success rate of many projects, and the lack of routine services. A number of contributing factors have been identified:

- Lack of definitive evidence for cost-effectiveness when applied wide-scale (Whitten et al., 2002).
- Lack of definitive evidence for clinical effectiveness (Wootton, 2001).
- Lack of funding to establish services (Hopp et al., 2006).
- Lack of experience (Richards et al., 2005).
- Technical issues, especially with the early equipment (Hopp et al., 2006).
- Absence of a well-established industry (Craft, 2003).
- Uncertainty due to the lack of standards (Loane & Wootton, 2002), guidelines (Stanberry, 2006) and service models (Barlow et al, 2006).

Some authors argue that the design and implementation of system architectures (beyond technical) is often given insufficient consideration when establishing a telemonitoring service, which not only leads to poor design and difficulties in implementation, but, more importantly, also results in the development of a service that does not fulfil technical, clinical, organisational or user requirements. The inclusion of design considerations such as ethical acceptance, inclusion, privacy, and ease-of-use is thus extremely important for the successful design of telemedicine services.

There should be no doubt of the long term advantages of eHealth developments, patients' compliance is high and some healthcare authorities have already acknowledged the need for telemonitoring services. In France, "hospitalisation at home" has been introduced; in the UK rehabilitation care is increasingly being carried out at community level or at home rather than at hospitals; and Kaiser Permanente in the US, one of the earliest adaptors of telemedicine, has developed the concept of "Home as the Hub". Just to name a few of the many healthcare organisations working with remote monitoring and telemedicine, who have realised sustainable business cases for achieving acceptable cost-benefit ratios with these new services. However, greater commitment by healthcare providers and concerted action between all stakeholders are needed in order to ensure wider deployment of these types of services throughout the EU.

In conclusion, telemonitoring services have not yet reached the stage of massive penetration in European Member States, which is partly due to the lack of cohesive attempts by providers and partly due to poor performance of the prototype services. However, there are many signs that the market is beginning to change and that more and more eHealth and telemedicine services are being successfully deployed.

Thus having laid the ground for a better understanding of the nature of eHealth services, we will continue to look at the likely provisioning systems and identify the actors and stakeholders in the eHealth ecosystem. This part will be partly based on the discussion in the high-level expert workshop organised by the Hydra project.

6.2 Diseases relevant for telemonitoring

Telemonitoring has already been acknowledged as valuable tools in disease management in several clinical areas. A large potential for Hydra enabled telemonitoring applications is believed to exist in:

- CHD/CHF (Coronary Heart Disease / Failure)
- COPD (Chronic obstructive pulmonary disease)
- Diabetes
- Metabolic Syndromes
- Back pain
- Medication compliance

CHD/CHF (Coronary Disease / Hearth Failure)

Coronary heart disease (CHD) refers to the failure of coronary circulation to supply adequate circulation to cardiac muscle and surrounding tissue. Congestive heart failure (CHF), or heart failure, is a condition in which the heart can't pump enough blood to the body's other organs.

CHD is already the most common form of disease affecting the heart and an important cause of premature death in Europe, the Baltic States, Russia, North and South America, Australia and New Zealand. It has been predicted that all regions of the world will be affected by 2020. Moreover, it is by far the most expensive disease in European healthcare systems today.

Over six million people in Europe suffer from CHF. The burden on patients' quality of life and mortality and on healthcare systems' costs is considerable. Telemonitoring services for patients with chronic heart disease enable closer monitoring of their disease and contribute to treatment at the earliest possible stage. Dyspnoea (difficulty in breathing) and/or rapid increase in weight, which are key parameters to monitor on a daily basis, often signify aggravation of the disease. Early modification of treatment based on the monitoring data may stabilise the condition, make consultations unnecessary and avoid or shorten hospital stays.

Louis et al (2003) concluded in a review study of available data that telemonitoring might be an effective strategy for disease management, especially in high-risk heart failure patients. Chaudhry et al (2007) performed six studies, which suggested a reduction in all-cause and heart failure hospitalizations (14% to 55% and 29% to 43%, respectively) or mortality (40% to 56%) with telemonitoring. However, in both cases the evidence base for telemonitoring in heart failure was currently quite limited but the authors concluded that telemonitoring may be an effective strategy for disease management in high-risk heart failure patients.

Of patients which have experienced cardiac events, only 30-40% attend rehab groups on a regular basis, 20% are just hanging in and an alarming 40-50% do nothing to manage their disease (from the Hydra workshop discussion).

The Hydra middleware can be effectively used to develop simple and/or advanced telemonitoring services that automatically monitor weight, physical activity, blood pressure, and pulse rate; all parameters of importance for the assessment of patients status and adherence to their clinical pathway.

COPD (Chronic obstructive pulmonary disease)

Chronic obstructive pulmonary disease (COPD) refers to chronic bronchitis and emphysema, a pair of two commonly co-existing diseases of the lungs in which the airways become narrowed. COPD is caused by noxious particles or gas, most commonly from tobacco smoking.

Chronic obstructive pulmonary disease (COPD) is one of the most common respiratory conditions in adults in the developed world and poses an enormous burden to society, both in terms of direct cost to healthcare services and indirect costs to society through loss of productivity. According to the World Health Organization (WHO), 80 million people suffer from moderate to severe COPD and 3 million died due to it in 2005. The WHO predicts that by 2030, it will be the 4th largest cause of mortality worldwide (WHO – COPD, 2007). Since COPD is not diagnosed until it becomes clinically apparent, prevalence and mortality data greatly underestimate the socio-economic burden. In the UK, COPD accounts for about 7% of all days of sickness related absence from work (Kumar, 2005).

Although COPD is not curable, it can be controlled in a variety of ways such as pharmacotherapy (medication) and/or change of occupation. A good prognosis of COPD relies on an early diagnosis and prompt treatment. Most patients will have improvement in lung function once treatment is started, however eventually signs and symptoms will worsen as COPD progresses. The median survival is about 10 years if two-thirds of expected lung function was lost by diagnosis.

Clinical monitoring of COPD patients is highly labour intensive. Respiratory nurse specialists are dispatched to see patients who are unable to attend hospital appointments, and to act as a liaison between primary and secondary care. With a typical caseload of 150 patients per nurse and about half requiring home visits on a regular basis, it is becoming increasingly problematic to monitor patients effectively and, subsequently, to keep them out of hospital.

COPD can be remotely monitored with sensors for measuring $pC0_2$, $Sp0_2$ as well as highly sensitive pressure sensors and accelerometers for use in acoustic measurements on hearts and lungs. These are promising candidates for telemonitoring COPD patients. Telemonitoring systems can be set up to ensure that the correct treatment protocols are followed while documenting the clinical care pathway for each patient.

Commercial systems are available, such as the Excelicare Direct, a software programme developed by AxSys Technology, is in operation in East Elmbridge & Mid Surrey PCT and by the Glasgow Royal Infirmary. The system works by patients placing a call to the system whenever their symptoms change but could be enhanced with automatic data collection. Moreover, the system can be linked to the acute sector to give other clinical staff instant access to patients' up-to-date records. It seems eminently sensible to have all professionals associated with the care of patients joined up on the same platform. Using the Hydra middleware, sensors could be automatically attached to the data link and provide data collection. Smart filtering techniques could be developed for continuous data monitoring for detecting deterioration in the patient's condition.

In East Elmbridge & Mid Surrey PCT the telemonitoring system has been in operation since 2001 and hospital admission for patients seen at home has fallen by 40% and the average length of stay in hospital; has been reduced to 5.9 days, representing a 26% reduction in bed days. Moreover, considerable cost savings were made through the outpatient nurse-led clinics. In the first eight months of the Service starting £28,620 was saved for the PCT by moving the clinics to community hospitals from the acute trust (Davey, 2007)

Diabetes

Diabetes mellitus is a metabolic disorder characterised by hyperglycaemia (high blood sugar) resulting from defects in the production of or in the body's response to insulin. The disease has two main forms: type 1 and type 2. Type 1 disease is characterised by diminished insulin production resulting from the loss of beta cells in the pancreatic islets of Langerhans, in most cases caused by immune-mediated cell destruction. Disease management entails administration of insulin in combination with careful blood glucose monitoring. Type 2 diabetes sufferers in contrast exhibit both reduced insulin production and resistance or reduced sensitivity to insulin.

Type 2 diabetics are typically over 50 years old with additional health problems, especially cardiovascular disease (CVD). Management principally involves the adjustment of diet and exercise level and the use of oral anti-diabetic drugs (OADs) and insulin to control blood sugar.

Diabetes mellitus has reached epidemic proportions in western countries (Zimmet, 2001). Diabetes type 2 is one of the fasted growing chronic conditions in the developed world. In Britain, a total of about 3% (1.3 million) of the population has diagnosed diabetes. It is estimated that an additional 2% of the population have undiagnosed diabetes. Type 2 diabetes is very closely linked to the emerging epidemic of obesity and life style, which is now a major cause of preventable health problems.

The associated morbidity and mortality of diabetes represents a major healthcare burden. Diabetes can cause many complications if the disease itself and associated risk factors (e.g. blood pressure and hyperlipidemia) are not adequately controlled. These complications include Cardio Vascular Diseases (CVD), chronic renal failure, eye disease leading to blindness and neuropathy. Thus, diabetes increases CVD risk 2-3 fold, which is the most common cause of renal failure and blindness, and increases the risk of amputation by 20-30%.

There is abundant evidence that shows tight control of the blood glucose level to be vital for good diabetes management and insulin therapy. Good glucose control requires frequent measurement of blood glucose levels and complicated algorithms for assessing the insulin dose needed to adjust for short term variations in activity, diet and stress.

On the other hand, good control of diabetes, as well as increased emphasis on blood pressure control and lifestyle factors, may improve the risk profile of most complications and attain future good health. Hence, self-management of diabetes is an area that offers exceptionally good prospects, both in clinical terms and in economical terms.

The overall health status of type 2 diabetics can be improved by adequate treatment of diabetes and of the associated risk factors. Self-management of diabetes in which the patient measures blood glucose several times a day and uses the resultant data to gauge the required insulin dosage is a promising modality.

Blood glucose is typically measured in a drop of capillary blood using a disposable dry chemical strip and reader device, an uncomfortable and slow process. Tight Glucose control (TGC) requires almost continuous measurements and different sensors for continuous blood glucose measurement have been under development for the last two decades.

Minimally invasive sensors able to measure glucose in interstitial fluid, and thus more suitable for self-monitoring, have also been developed. To date, however, none of these has delivered a level of performance sufficient for use in routine glucose monitoring. Robust, clinically acceptable devices are however widely expected to become available in the near term. New Hydra based telemonitoring services can be developed integrating new promising transcutaneous and minimally invasive continuous glucose sensors.

Metabolic Syndrome

Metabolic syndrome is a combination of medical disorders that increase the risk of developing cardiovascular disease and diabetes. It affects one in five people, and prevalence increases with age. Some studies estimate the prevalence in the USA to be up to 25% of the population.

The pathophysiology is extremely complex and has been only partially elucidated. Most patients are older, obese, sedentary, and have a degree of insulin resistance. The symptoms of Metabolic Syndrome are hyperglycemia (high blood sugar), high blood pressure, central obesity (apple-shaped), decreased HDL cholesterol, and elevated triglycerides.

Telemonitoring solutions would include regular blood pressure measurements, regular glycaemic control, physical exercise and information about diet. Several studies have shown the benefits of using telemonitoring for blood pressure control. In one study (Santamore, 2007), the accuracy of home blood pressure measurement and telemedicine transmission was tested in an underserved population. Percent error was <1% and ability to use the home equipment was not an issue. The study concluded that contribution of telemonitoring to underserved patients could overcome considerable problems of access, and ability of patients to interact with electronic tools.

The aim of a Danish study was to compare the quality of life and cost effectiveness of hypertension treatment based on telemonitoring of medical home blood pressure in hypertension treatment compared with the usual blood pressure checks in the doctor's office (Madsen, 2008). The study found that patients whose treatment was based on usual check of blood pressure in the doctor's office were more inclined to assess their health as deteriorated over the past year, compared with patients monitored remotely. The analysis of cost effectiveness showed that the consultation and medication costs were lower in the telemonitoring group than in the control group. However, this was offset by the costs of telemonitoring equipment.

The Hydra middleware could significantly reduce the cost of the telemonitoring programme because a wider range of blood pressure gauges are available. Further, networked applications support higher mobility so that devices can be circulated among patients thus reducing the overall costs of the programme.

Back pain

Back pain (also known "dorsalgia") is pain felt in the back that usually originates from the muscles, nerves, bones, joints or other structures in the spine. Back pain is one of humanity's most frequent complaints. In the U.S., acute low back pain (also called lumbago) is the fifth most common reason for physician visits. About nine out of ten adults experience back pain at some point in their life, and five out of ten working adults have back pain every year.

Physical therapy consisting of manipulation and exercise, including stretching and strengthening (with specific focus on the muscles which support the spine). Exercises can be an effective approach to reducing pain. Generally, some form of consistent stretching and exercise is believed to be an essential component of most back treatment programs.

Regular physical exercise and prescribed rehabilitation are extremely important prerequisites preventing back pain. The need for regular physical exercise is undisputed, but there is a large need for prescribed exercise.

A Hydra enabled service could be developed to support needs for regular physical exercise and physical and psychosocial rehabilitation such as:

- Monitoring of physical rehabilitation at home or mobile (recreational or work)
- Contextualised education of patients in their current state (feedback)
- Self-management programs for lifestyle changes (exercise, diet, weight loss)

In a typical back pain prevention telemonitoring application, the patient carries wearable sensors for physiological monitoring: Myographic sensors (bio-feedback), sensors for pulsoxymetry, blood pressure, etc. External measuring devices (e.g. ergo meters or weight scales) may also be connected as well as terminals for possibly patient interaction. The Hydra enabled service will take care of data collection and inference, context aware situation analysis, personalised feedback, and event handling and will continuously inform patients in a personalised way about their progress or shortcomings. Data will also be logged allowing healthcare professionals to monitor the adherence to prescribed therapy.

Medication compliance

Problems of non-compliance with prescribed medicine (insulin) plans are wide spread and cause unnecessary medical complications as well as high costs. For example, it is estimated that more than one in five patients with diabetes type 2 does not take medication on a regular basis, even when they have been told about the dire consequences. Non-compliance can be attributed to various behavioural factors, including mild dementia.

Hydra enabled telemonitoring applications can measure compliance and evaluate the impact on the patient's health status. Electronic drug dispensers can log the time when patients are talking their medication (assuming that they actually administer it) and provide feedback and personalised incentives for the patients and statistical pharmacologic information to the clinicians for assessment of patient cases.

6.3 Implementation of telemonitoring

6.3.1 Clinical practice

When contemplating new telemonitoring services and applications, it is important to understand that technology does not drive the clinical process. There is a widespread view that technology can only support existing clinical services and clinical practice.

Today's "successful" telemonitoring services are, to a large extent, not really services aimed at new clinical practice but rather services aimed at workflow improvement, organisational efficiency and cost savings. Many of the services would be equally effective if deployed in building maintenance or service industries. But even in this field, there is limited evidence of the effectiveness and cost-effectiveness of telemedicine services on a large scale. Awareness, confidence and acceptance by health authorities, professionals and patients still need to be strengthened and commonly accepted methodologies for assessing effectiveness, such as those used to assess pharmaceutical products, must be further developed.

In the future, there will be more focus on actually improving clinical practice. Telemonitoring is particularly useful in the case of individuals with chronic illnesses. Telemonitoring with personalised feedback is expected to have positive impact on self-management of chronic conditions such as COPD and diabetes. Properly designed (i.e. user oriented) services providing personalised feedback and risk assessment has the potential to motivate lifestyle changes and thus reduce prevalence of lifestyle induced diseases, which are different from other diseases because they are potentially preventable.

Telemonitoring can never replace the direct contact between patient and the GP. It can only augment it. Besides, patients like to have face-to-face consultations about their disease. However, the increasing caseload is somewhat obstructing this relationship.

Hence every telemonitoring application must be based on a sound clinical practice and a thorough understanding of the clinical workflows involved and with due regard to the cultural setting in which the telemonitoring service shall be implemented.

6.3.2 Cultural practice

Another aspect to be carefully considered is the cultural practice prevailing in the community, region or Member State, in which the service is being deployed. Cultural diversity can affect the way people perceive the services and how willing they are to use them.

To a large extent, the patients' cultural background determines their interest in the diseases and their ability ad willingness to take on the responsibility for managing their disease. Healthcare providers and pharmaceutical companies (e.g. GSK and Novo Nordisk) spend large amounts on creating awareness of diseases among patients and foster prevention, but in some cultures it is not effective at all. The patients firmly believe that any disease related activity has to come from the healthcare system.

Some ethnic and demographic communities also have a strong paternalistic tradition and will not accept any advice or recommendation not coming from the proper medical professional in the hierarchy. This tradition impedes the move from doctor to nurse or from nurse to paramedics, not to mention replacing humans with a "thing". Other groups express a strong aversion against what is perceived to be a top-down controlled healthcare system and would always seek alternative methods for managing illnesses. The sentiments can be very strong and can render an otherwise well-conceived telemonitoring service completely useless.

In the same frame of mind, one must also carefully analyse the ethical aspects of the planned telemonitoring service and how it will fit the culture prevailing among the target groups. Ethical concerns relate to justice and fairness, rights and discrimination, participation and privacy, dignity and body integrity, somatic surveillance, human experiments and informed consent, as well as loneliness and isolation. All this ethical aspects are thoroughly covered by the SENIOR project for elderly patients and well documented in the SENIOR Discussion Paper for European Ministerial e-Inclusion Conference in Vienna (SENIOR, 2008).

But it is not only the cultural traditions of patients that hinder the deployment of telemedicine. Also the healthcare professionals need to overcome a cultural barrier in order to embrace widespread use of telemonitoring. An important factor for ensuring the confidence and acceptance of health professionals is enhanced dissemination of the evidence base regarding the effectiveness of telemedicine services, their safety features and user-friendliness.

In conclusion, sensitivity to cultural attitudes is essential for successful telemonitoring services. Achieving the full potential of telemonitoring depends on patients and healthcare professionals alike being convinced of its ability to satisfy their healthcare needs. Acceptance by patients depends crucially on acceptance by the health professionals treating them.

6.4 Funding schemes

Adequate and correct funding of the conceived telemonitoring service is of fundamental importance for its success and sustainability. In subsequent chapters we will look much more detailed into the funding schemes and business models of telemonitoring services. At this point we will just highlight a few points that demonstrate the need for individual approaches to each specific service.

Today, most telemonitoring services are still limited to the status of temporary projects without clear prospects for wider use and proper integration into healthcare systems. Commitment by healthcare providers and concerted action between all stakeholders are needed in order to ensure wider deployment of these types of services throughout the EU.

The development and implementation of ICT in healthcare, in general, requires willingness to invest large sums without expecting to see the economic benefits immediately. In fact, an EU project, eHealth-Impact[2], has demonstrated that there is at least a 4 years payback period of ICT investments in eHealth. After this period, there will be a 2:1 ratio between benefits and costs, thus illustrating the overall benefits of investing in ICT in healthcare. Most governments are adapting this view and beginning to see ICT investments as long term investments a major priority in order to ensure an efficient and cost-effective healthcare system in the future.

Telemedicine industry players, in particular SMEs, do not have the financial capacity to engage alone in large-scale telemonitoring trials. Stronger intervention by the public sector seems to be necessary. Public-private partnerships can also be an instrument for the deployment of large-scale projects.

Cost effectiveness of telemonitoring services can be undermined by high cost of devices or logistical problems in getting devices from central repositories to the patients' homes. Will the service then be based on the patients' buying devices themselves? But the patients' willingness to pay or co-fund the telemonitoring service is deeply rooted in tradition and, since healthcare provisioning in Europe is mostly a national concern, the funding systems vary considerably among the Member States. For example the UK, Italy, Spain, Denmark and Sweden have tax-based healthcare systems, whereas Germany and France have social health insurance based healthcare systems. Each funding domain has a different attitude towards user-contributions to healthcare. The payment modalities must be critically analysed before the telemonitoring service is conceptualised.

A fundamental paradigm in the provisioning and payment of healthcare services is the question of what added value is created for whom. Even when the funding is exclusively provided for by healthcare commissioning bodies, the telemonitoring service still must have an added value to the

[2] The eHealth-Impact project, funded under FP6, www.ehealth-impact.org

beneficiary. It also must present added values to the other stakeholders in the value chain. It is thus essential to fully understand the value creation process for each stakeholder and the possible constellations that exist in this highly complex ecosystem.

The value creation process and value modelling is described in details in deliverable D10.5 Business modelling concepts. The term "value" is defined as follows: *Value is co-produced by actors who interface with each other. They allocate the tasks involved in the value creation process among themselves and to other actors*. Hence, it is essential for the understanding of the funding possibilities for telemedicine services that the value creation is seen in the dynamic interaction between several stakeholders.

Examples of added values for patients in telemonitoring are: Tighter control and follow-up compared to infrequent visits to clinics, improved outcome of therapeutic treatment, convenience by not having to go to the doctor's office, and feeling of safety and security for medical incidents.

Examples of added values for healthcare providers and commissioners are: Cost effectiveness, avoiding routine work, less workload/greater throughput, optimising workflow, support fiscal incentives, improved disease management, and, ultimately, improved health of the population.

In order to implement telemonitoring services and accompanying businesses models, it is essential that reimbursement systems be analysed and adapted to the new type of services. Today, most reimbursement systems are related to numbers in some combinations: Number of visits to the General Practitioners office, number of patients in the clinic, number of admissions in the hospital. With telemonitoring services the "number of" paradigm looses its meaning, because the patient is always being monitored and the "number of contacts" is dynamically adjusting to the status of the patient.

In conclusion, a sustainable telemonitoring service can only be built, if its transactions are creating true, lasting values for all the stakeholders. If there is no added value for one stakeholder, the business will eventually disappear. New models of business constellations should be explored including private public partnerships, collaboration pharmaceutical companies as innovation drivers and bringing together payers, providers and patients in new constellations with new reimbursement paradigms.

The Hydra business modelling methodology is precisely developed for modelling of such complex services as shall be witnessed in the ensuing chapters.

7. Telemonitoring stakeholders

Before a new eHealth service can be analysed and its business potential can be assessed, it is necessary to have a complete overview of all possible stakeholders, their motivation and their interaction. In this chapter we aim to identify all stakeholders in the telemonitoring market. Attention will be made to the fact that each national healthcare system is different within the European Union and must be taken into account in the actual business cases.

7.1 Actors and stakeholders

The target stakeholders of the Hydra products and services consist of all active or potential manufacturers, developers, customers and users of an application or a service. Some will be developing devices and applications (developer users) whereas others will be using the devices and applications (end-users) in either private or professional settings. All of them are stakeholders in the Hydra world, but with very different needs and requirements, which must be taken into account when defining the business environment.

In the present deliverable we will focus on the end-user experience, the telemonitoring service, and thus confine ourselves to stakeholders that are actors in the telemonitoring services.

In deliverable *D10.5 Business modelling concepts* we introduced a suitable taxonomy for classifying end-user stakeholders using the "seamless experience environment". It focuses on people and their interaction with each other, with devices in their personal near-field environment and with their contextually related global (far-field) environment. Stakeholders have been organised in groups (classes) according to they primary motives, expectations and behaviour in a telemonitoring environment. Figure 4 shows the three stakeholder levels and their relationships.

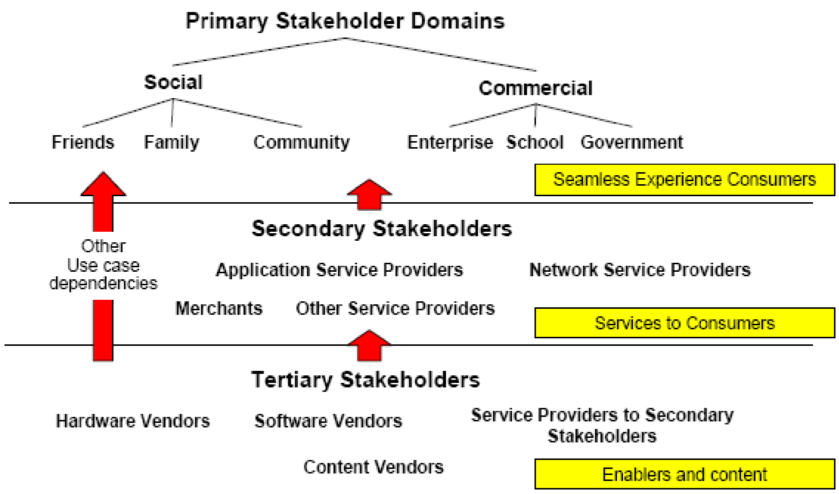

Figure 4 Stakeholder domains (Lee, 2007)

Telemonitoring stakeholders are those who carry the value activities of delivering and living the seamless experience (telemonitoring) as modelled in the business model.

Primary stakeholders

The primary stakeholder level consists of end-users of the telemonitoring services.

One group of primary stakeholders is in the social (private) domain. Here we find stakeholder classes such as patients, relatives, friends, neighbours, maids, and even patient organisations. They are all actors involved in a social context. In our value model, all social actors have access to various assets provided by the telemonitoring service. Assets can be paid services such as monitoring by health professionals or social caretakers, or it can be a physical asset such as a lamp, a blood pressure device, a TV set. Further, an asset can be a logical asset in the form of context aware information extracted and combined from external repositories such as health profiles or health articles. How the free and the commercial assets are exchanged and how they turn into sustainable business for the stakeholders is the subject of the business modelling work.

Another group of primary stakeholders is found in the professional care provider domain. Here we find classes of professional end-users such as doctors and nurses, hospitals, health clinics, private or public rehab centres and local health agencies and municipalities. The actors are also known as "workers" and their task is to carry out professional activities defined by their employers. The professional end-users can control devices in the Hydra enabled services and they can access information repositories and perform configuration and monitoring of patient states.

There is a great deal of overlap between the professional primary stakeholders, as defined here, and the primary healthcare system, which is usually the point of contact between the patient and the healthcare system and is provided in the community by general practitioners (GPs), local health clinics, district nurses and primary care specialists (e.g. physiotherapists).

The primary stakeholders have certain expectations of what the seamless experience can do for them and it is up to the service designer and developer to live up to these expectations so that it has a clear value proposition.

Secondary stakeholders

Secondary stakeholders are those actors that are directly accountable for the end-user experience. The secondary stakeholders are thus creating the value object, which is requested by the end-user. Whether this value object has a sound value proposition or not, depends on the nature of the value object, how it is presented and delivered, and its price.

Secondary stakeholders can be identified by the following simple characteristics: An actor, who has a value interface with a primary stakeholder in the scenario or assume liability for a value object being exchanged, can be regarded as a secondary stakeholder.

Secondary stakeholder classes primarily include national or regional healthcare providers and to some extent also healthcare provisioning bodies. Secondary stakeholders provide ambulatory medical services and hospital care (inpatient and outpatient services), thus offering the care services that are generally provided through referral from primary care providers. Secondary stakeholders also include local municipalities, which are often responsible for long-term care and home-care. The healthcare providers may operate telemonitoring services in connection to their Electronic Patient Records systems or other data management systems or as part of their outpatient services.

Other secondary stakeholder classes include commercial *Service Providers* like facility firms providing social and home healthcare service i.e. in Private-Public Partnerships, health management companies, etc. The commercial service providers are carrying out services, which are deemed to be more effectively carried out by private enterprises, but could have been performed by public service providers.

Healthcare commissioning bodies are also to be seen as secondary stakeholder classes. Healthcare commissioning entails the appropriation of funds for providing healthcare services to citizens or to selected groups of citizens. The structure of the commissioning system varies from Member State to Member State, and sometimes even from Region to Region as can be seen from Chapter 4 above. Some typical stakeholders at the public level are health ministries or health agencies (i.e. Primary Care Trusts in the UK), regional or specialised commissioning bodies responsible for packages of services, Health Maintenance Organisations, municipalities responsible for personalised care. Other organisations may also provide commissioning services such as public and private health insurance organisations. Healthcare commissioning bodies may operate telemonitoring services as part of their health portals or backbone healthcare service networks.

Finally, some service providers may specialise in offering the telemonitoring platform and services exclusively from at technical point of view, whereas the population of data and medical content and the primary stakeholders are fully embedded in the healthcare system. This specialised role will typically be performed by commercial companies like large telecom companies, ISP's (Internet

Service Providers), ICT consulting firms etc. We term these stakeholders for "Service Aggregators" because the typically aggregate several eHealth services on the same communication platform.

The flow of services can be visualised using the following generic figure of the eBusiness ecosystem:

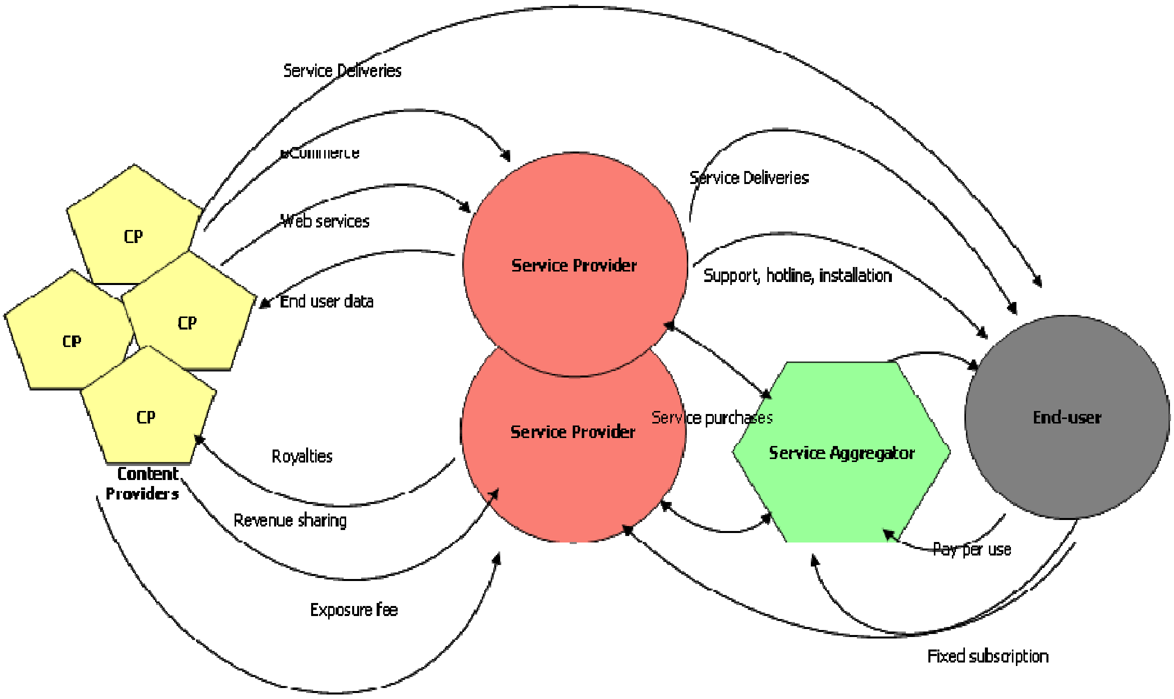

Figure 5 Primary and secondary stakeholders and generic value exchanges

The primary stakeholders are represented on one hand by End-users (patients, relatives) and on the other hand by "Content Providers" (doctors, nurses, care providers). The telemonitoring services are provided by Service Providers (hospitals, regional healthcare authorities, PCT) or by Service Aggregators that run a number of services (telecom, consulting).

Tertiary stakeholders

Tertiary stakeholders are all other actors supporting the primary and secondary stakeholders. This level of actors is very broad and of less significance for the business models since the actors do not enter the business model per se. Their role and activities are not affected by the dynamism of the model so for simplicity, we will often regard them as static actors and not dynamic stakeholders.

The developer user target group, consisting of manufacturers, developers, system integrators, etc., are important for the exploitation of Hydra products and services, but they are neither primary nor secondary actors in the "seamless experience environment", except for some cases where a system integrator or developer also acts as service provider for the telemonitoring service. As such, they are tertiary stakeholders. Other tertiary stakeholders are device manufacturers, system integrators, data processing and storage centres, maintenance organisations, sales distributors, etc. The device manufacturer, for example, has the sole role of providing medical devices for the telemonitoring service. No matter how the services are constructed and what value proposition is defined, the device remains the same. In such a case, moving the device manufacturer from a stakeholder domain to the cost structure would considerably simplify the business model. Unless, of course, the device manufacturer takes active part in the business ecosystem and provides the device as a service paid for at a click-fee. In such case the device manufacturer has a direct interaction with the "seamless experience" user and becomes a secondary stakeholder.

Finally, to complete the picture, Hydra exploitation actors are also seen as tertiary stakeholders in this sense, since they do not interact with primary stakeholders, but only with secondary or even other tertiary stakeholders.

8. Telemonitoring services

In this chapter we will identify a series of potentially exploitable eHealth services and their motivation (drivers and inhibitors). We will also assign tasks to the different stakeholders. From the discussion of the experts, we have identified likely entry points (early adopters) for the services and the most effective procedures for deploying such services.

8.1 Drivers and inhibitors

As previously discussed, the market for telemonitoring services is emerging. From a technological point of view, the infrastructure and the services exist or can be easily developed. From a clinical point of view, the evidence base is growing, although it is still not fully penetrated in the medical professional community. Even patients have, in most pilots, valued the technology positively. The main reason for the lack of successful services is rooted in lack of organisational acceptance and insufficient acceptance among healthcare commissioning bodies so that funding and appropriate reimbursement schemes are missing. In this section we will look deeper into the drivers and inhibitors of telemonitoring services.

8.1.1 Drivers

The experts have identified the following drivers for widespread use of telemonitoring services:

- Medical
- Patient
- Organisational
- Demography
- Financial

Medical

The medical benefits of telemonitoring have been demonstrated in many studies. There is evidence of improved quality of treatment in CHD, hypertension, diabetes, treatment of wounds, and many other diseases. A survey of 24 telemedicine project in CHF suggests that telemonitoring; used either alone or as part of a multidisciplinary care program, facilitate early detection of deterioration and reduce hospital bed-days occupancy (Louis et. al., 2003).

Teleradiology, i.e. service involving the electronic transmission of radiographic images from one geographical location to another for the purpose of interpretation and consultation, is an area of telemedicine which is in an advanced stage of deployment. Its benefits include: helps dealing with peak workloads, ensures 24-hour services, reduces waiting list for specific examinations and cuts costs (European Commission 2008).

Patient

The study referenced above also shows that patient acceptance of and compliance with telemonitoring is high. Patients benefit from being treated at home and do not have to come into the healthcare systems, which tend to stigmatise some patients or patient groups. Further, it provides increased comfort to the patients, mobility and significant savings in time. Finally, telemonitoring offers, or is perceived to offer, good health and better quality of living.

Organisational

From an organisational point of view, telemonitoring unquestionably offers increased efficiency in ward or GP office workflows. Provided with good, intelligent filtering capabilities, telemonitoring applications have the potential to drastically increase the number of patients that can be monitored during treatment or rehab. On top of offering reduced admissions, the services even offer better controlled admissions and thus better resource utilisation.

The interoperability of systems and devices would have a positive effect on patient safety issues. Evidence shows that hundreds of thousands Europeans are affected by the incidences of avoidable deaths due to medical intervention, adverse drug effects and preventable injuries. Research into these issues has been carried out in the USA; however, it is widely believed that one can find similar deficiencies in the vast majority of European health delivery contexts.

Findings from the USA showed that more than one million patients suffer injuries each year as a result of broken healthcare processes and system failures. Also, an estimated thirty to forty cents of every United States' dollar spent on healthcare, or more than a half-trillion dollars per year, is spent on costs associated with 'overuse, underuse, misuse, duplication, system failures, unnecessary repetition, poor communication, and inefficiency'. According to the United States Institute of Medicine, over a half million people are injured each year because of adverse drug events, many of which could be avoided if healthcare providers had complete information about which drugs their patients were taking and why (European Commission 2006b).

Demography

The population of Europe is growing older and requiring more care and the number of people with chronic diseases is increasing. At the same time, the number of people in the work force is rapidly decreasing, so more work to be done by fewer hands. This inevitable trend spells havoc for healthcare systems and quality of life for European citizens as we know it today. There is no other way than to automate and substitute human work tasks with machine or ICT technology wherever possible, if we want to maintain our quality of life and a working healthcare system.

Financial

Although not clearly recognised yet by the healthcare commissioning bodies, the financial drivers are certainly real. There is undoubtedly a potential large, positive cost-benefit from introducing telemonitoring services.

8.1.2 Inhibitors

The experts also identified the following inhibitors for widespread use of telemonitoring services:

- Medical
- Patient
- Organisational
- Regulatory
- Financial

Medical

There is still a lack of *definitive* evidence for clinical effectiveness (Wootton2001). Some failures can be attributable to technical issues, especially with the early equipment (Hopp2006).

Patient

The acceptance by patients is not universal. In some cases, patients have readily accepted the service and find it useful. Other cases are less successful. Some failures can be attributable to technical issues, poor interface design and complicated operations. Moreover, ethical and privacy concerns have not been satisfactorily addressed.

Organisational

A formidable inhibitor for introduction of telemonitoring services is the reluctance of professionals to embrace the new technology and adjust to the new roles, i.e. supervisor of filtered telemonitoring data rather than front-end enquirer in front of the patient. Also delegation of responsibilities between professional groups is a strong inhibitor.

Regulatory

The biggest organisational inhibitor for telemonitoring services is the lack, in practically all Member States, of a regulatory framework that can facilitate integration of telemonitoring services in national healthcare systems. Moreover, there are unresolved issues of liabilities for malpractice and mea culpa for malfunctioning services and equipment.

Also, more work needs to be done to investigate the whole range of legal issues relevant to the use of ICT tools and services in healthcare and to draw conclusions about the regulatory needs which may exist in a European-wide or cross-border environment (European Commission 2006b).

Financial

The financial inhibitors are equally worrying. Since different groups benefits from and pays for telemonitoring services, it becomes difficult to create convincing business models. Although in theory it is possible, moving budgets between sectors is in real life almost impossible. Or at least, it has to be decided at a very high level, typically at government level and in ministries of health. In order to really facilitate telemonitoring services, and thus fully utilising the medical and demographic benefit, requires a total revamp of the reimbursement systems in most countries.

8.2 Tasks in telemonitoring services

It is universally accepted that in order to be successful, or even marginally successful, the design and implementation of telemonitoring system architectures must go beyond the technical functionality and fulfil clinical, organisational, and patient requirements.

Hence the experts were asked which tasks would need to be included in a successful telemonitoring service and how the tasks would be shared between the healthcare professionals and the ICT system.

8.2.1 Healthcare professionals

Healthcare professionals are needed in any telemonitoring application or service in order to secure the medical and clinical integrity of the service and to minimise risk of malpractice. There are several tasks that require deep involvement of the healthcare professionals.

First of all, the design and setting up of schemas for monitoring must be designed and modifiable by the carers. The schemas must be designed to report exceptions and identify events, but the medical interpretation of events must be directed to healthcare professionals. If the system involves feedback loops, the clinical analysis and change of regime must be under the control of the medical professional. Finally, a telemonitoring service may be a support for healthcare professionals in better managed admissions.

In conclusion, no telemonitoring service can be left to operating on its own. In order to secure correct medical intervention and monitoring, the healthcare professionals must be in full charge of vital elements such as schema definition, diagnosis and change of regime. Routine monitoring, filtering and event identification can be left to the ICT systems.

8.2.2 ICT systems

Thus having identified the roles of the humans, a large number of routine tasks can be better left to the ICT systems.

Firstly, the routine monitoring of physiological parameters can very well be left to the telemonitoring service: Frequent checks for blood pressure, blood glucoses level, pulse, oxidation, heart rate, skin temperature, etc. Also more complicated monitoring e.g. of continuous electro-myography, electro-cardiography and electro-encephalography can beneficially be left to a telemonitoring service. Also constant monitoring for event or epochs, including early warning and short term predictions of e.g. hyper and hypo-glycaemia, seizures, etc. are critical services. The services can be made at different intervals from weekly or daily to several times a day. Measurements are either performed automatically, with wearable sensors, or manually by patients performing the measurement and reporting the results to the system.

However, the monitoring task must be designed based on clinical significance. For example, there is no need for monitoring blood glucose levels in type 2 diabetes patients on a daily basis. The best way to control type 2 diabetes is to test for glycosylated hemoglobin every two weeks. The Hb_{A1c} level is proportional to the average blood glucose concentration over the previous four weeks to three months and will thus represent an aggregated quality measure of the patient's level of glycaemic control.

This monitoring can be combined with filtering of data, so that only those outside the normal range will be fed on the healthcare professionals. Data can further be analysed, aggregated, linearised, modified and condensed using advanced medical algorithms thus leading to better and easier to digest medical information.

Filtering can be combined with event detection and handling. An event occurs when a *transition* (change of state) take place and alarm responses can be initiated by the occurrence and detection of events corresponding to a pre-defined schema. The alarm handling can take the form of a simple, predefined feedback to the patient: "Your blood sugar level is slightly elevated. You need to adjust your insulin dose at next injection" or more complex medical feedback to healthcare professional or crisis management teams.

Other useful feature of the telemonitoring service is the ability to collect and store massive amount of data and analyse trends, both in populations and in individual patients. Automated data collection and storage in ERP systems means great savings in time and resources in healthcare organisations.

Finally, it was pointed out that telemonitoring services must take an end-to-end approach. In order to be acceptable and easy to deploy, they must include the entire chain from sensors and devices to user terminals and interoperability with legacy Hospital Information Systems. The overall design must be user friendly and adapted to the workflow of the healthcare professionals. It must be easy to use and present an intuitive and logical user interface. And last, but not least, the telemonitoring service must offer a high level of privacy and data security.

8.3 Early adopters and market entry points

With the aim of securing early and successful entry into the market, it is essential that the exploiter aligns with partners in the healthcare system, who are willing to take the role as early adaptors and can act as ambassadors for the services. The following entry points have been identified:

- Healthcare commissioners and providers
- Strategic health authorities
- Payers, insurance groups
- Patient organisations

8.3.1 Healthcare commissioners and providers

The group of healthcare commissioning bodies and healthcare providers includes national and regional healthcare authorities, hospitals and clinics. They are prime customers for telemonitoring services as part of the overall healthcare system. The primary healthcare providers (GPs and outpatient clinics) cannot be regarded as early adopters of telemonitoring services.

Public bodies often act as both providers and commissioners (purchasers) of health services. In the UK there is a strict separation between commissioning and providing healthcare services in the NHS; commissioning indicates a strategic planning function, which in the UK is the responsibility of health authorities, such as the PCTs. Although, other EU Member States with tax-based healthcare system may not have a similar strict separation between commissioning and providing, the following UK definition of commissioning is useful for a general understanding of the strategic underpinnings of commissioning responsibilities:

"Commissioning is the process by which PCTs identify the health needs of their population and make prioritised decisions to secure care to meet those needs within available resources. It includes longer

term strategic planning (three year Local Delivery Plans) and the shorter term agreement and performance management of Service Level Agreements."

Pilot projects are carried out by healthcare providers. They are very useful, sometimes required, entry points for introducing telemonitoring services into the healthcare system. Pilot projects allow medical and organisational teams to gain hands-on experience with the services and the potential benefits and may, if they are sufficiently comprehensive, provide medical evidence as to their effectiveness in disease management.

After successful execution of the pilots, the commissioning bodies may decide to include the telemonitoring service in their strategic planning.

Pilot projects usually do not require approval at the highest level, but can be instated at the department level. However, it is very depending on the local culture. For example in Denmark, it is strongly recommended to start introducing concepts for pilot services at the highest levels in the regional healthcare systems, i.e. healthcare or ICT directors. The capital's regional healthcare organisation has app. 70 m€ annually for investments in equipment and ICT systems and has entered into more than 400 cooperation agreements with commercial companies through their innovation unit Tectra (Sørensen, 2009).

8.3.2 Strategic health authorities

Strategic health authorities are in some Member States identical to the healthcare provisioning bodies, but in some cases they are separate entities. In France, the state regulates the quality of health service organisation, monitors safety, regulates the volume of health services supply and oversees social protection and regulates healthcare system. In Denmark, the National Board of Health is the supreme healthcare authority in Denmark assisting the minister for Health and Prevention within the administration of the healthcare service. They also have information responsibilities vis-a-vis citizens on specific health issues. They follow the population health status through monitoring and evaluation and endeavour to be at the cutting edge of knowledge and expertise. It is their task to set the best possible frames within the healthcare system for the prevention and treatment of illness and provide national guidelines for disease management.

The strategic health authorities may decide to support telemonitoring as a strategic tool, because it supports their plans for disease management. The Danish Agency for Health, for example, is hosting the Danish Centre for Digital Healthcare (www.sdsd.dk). The centre has published the first Danish strategy for digital healthcare: "National Strategy for Digitalisation of the Danish Healthcare Service 2008 – 2012 – to promote public health as well as prevention and treatment.

The strategy calls for a common infrastructure to be established as a foundation for exchanging and sharing data across healthcare sectors. At the same time, a number of specific shared services are to be developed, making data and/or functionality available across the healthcare sector.

In most cases, the shared services will provide both data and functionality – either directly to users, for example via sundhed.dk (the public health portal in Denmark), or via integration with the local solutions of the individual players, which can then make them available to users (for example via integration with EPR, ECR or practice systems). In addition to shared services making data available, it may be relevant to establish shared services making functionality available. For example, "*shared services could make certain telemedicine solutions available to all relevant healthcare users"*. (Digital Health, 2007).

As can be seen from this example, some strategic health authorities see eHealth services, which include telemonitoring, as a strategic investment in healthcare which needs to be addressed at the national level rather than by the individual regional healthcare providers. The eHealth platform could also be used to enforce certain national clinical protocols, which are part of a national plan for disease management, and for collecting health data on a massive scale as part of a national programme for monitoring prevalence of e.g. certain chronic diseases.

In any case, it is to be expected that the investment needed to commission and install the service will be born by the government (i.e. Ministry of Health or similar) and the healthcare providers may use the service, either for free or with a calculated usage fee to be decided as part of the annual budget negotiations.

8.3.3 Payers, insurance groups

Some Member States have statutory insurance contribution-based systems where there is a mixture of public and private providers and where some services must be paid for at the point of use. This is true for Germany, France and, to some extent, Greece. The statutory health insurance schemes mainly act as purchasers of healthcare services from both public and private providers, albeit they may provide some healthcare services as well (as in Greece). In France, statutory health insurance funds approximately three quarters of total health expenditure, while in Germany statutory health insurance funded approximately 57% in 2002, with other statutory insurance funds contributing 10%.

The issue of cooperation and communication between various healthcare providers, and in-between the public and private sector, plays an important role for the efficiency and quality of healthcare services to the patients.

The statutory health insurance groups have a direct interest and influence on any cost containment effort or efficiency improving methods, including telemonitoring. They have a history of funding large scale pilots to achieve these goals or even carrying out the pilots themselves. Their role in the pilots is often to involve the user groups (patients and healthcare professionals) and recruit patients for the trials and, of course, analyse and evaluate the results.

In the case of telemonitoring, the health insurance groups will be interested to deploy services with a potential for large cost-benefit gains. They may fund both the pilots and, if successful, a collective investment in operational services, perhaps in cooperation with the strategic health authorities.

8.3.4 Patient organisations

Patient organisations have emerged worldwide in the last decades. They are present in every region and country in the Western world and work to represent and support patients, their families and carers in a wide range of diseases. A patient is a person with any chronic disease, illness, syndrome, impairment or disability.

The Alliance of Patients' Organizations (IAPO) is a global alliance representing patients' organizations working at the international, regional, national and local levels. In Europe alone, more than 625 patient associations are members of the IAPO.

Patient organisations are generally very aware of the key global issues surrounding health technologies. IAPO emphasizes the important issues for patients, giving the patients' perspective. They are normally aware of the potential of eHealth and telemonitoring to patient health outcomes but also advocate the concerns such as privacy of personal medical information and that, in addition to patients' rights, patients also have responsibilities in their self-management.

The patient organisations are keen to understand the various systems that are already available or which are under development, and to assist in designing and implementing eHealth solutions.

Patient organisations can be a formidable partner in opening the market for telemonitoring services, because they have a powerful political agenda and are well recognised in the healthcare systems. However, the problem remains to convince a patient organisation that there are measurable benefits to their members, i.e. to their patients, families and carers. Once that is achieved, the patient organisation can be expected to act in several ways.

Most likely, the patient organisation will contribute to a pilot project with knowledge and evaluation support. They may provide input for patient centric requirements engineering and perform validation and evaluation of the outcome. They can also be extremely supportive post-pilot with dissemination and lobbyism vis-à-vis the strategic healthcare authorities, healthcare commissioners and providers and even the general political establishment.

In some cases, where the national healthcare system is not putting enough priority to their field of interest, it may be possible that the patient organisation decides to bring out an eHealth service by itself. It could, for example, be a telemonitoring service, which promotes self-management among patients with diabetes; or a service providing continuous monitoring for epileptic epochs including crisis management. In such case, the cost of the platform may be born exclusively by the patient organisation from their member revenues, or at a subscription fee from members.

8.4 Deployment process

As previously pointed out, the design and implementation of system architectures (beyond technical) is often given insufficient consideration when establishing a telemonitoring service, which not only leads to poor design and difficulties in deployment, but, more importantly, also results in the development of a service that does not fulfil technical, clinical, organisational or user requirements. When planning the deployment of telemonitoring services, it is thus recommended to follow a strict formal procedure.

The first step is to identify an early adaptor and present a convincing case in order to solicit the support and potential financial commitment once the deployment of the service commences.

When the support has been secured, the precise disease or clinical domain must be very carefully defined including medical significance, user requirements, patient needs, potential clinical outcome, traditional and future organisational workflows, ethical and regulatory constrains, business models, and economic viability.

Thereafter, the actual service must be clearly described and visualised so that all stakeholders have a complete and comprehensive understanding of the planned service. Approval and support should be obtained at an early stage for all the involved actors and stakeholders.

Finally, the geographical area must be decided. A confined geographical area (perhaps also described in terms of ethnicity) may make the service easier to deploy, but in the long term make the economic goals and cost-benefit targets difficult to meet. A phased deployment may be the solution.

Once the three steps above have been carried out and decided, the next step is to decide if the service needs a pilot study. If so, the hosting organisation of the pilot study should be identified and details of the study should be agreed. The host could be a local healthcare provider, i.e. a hospital or home care organisation.

Finally, when all the initial steps have been planned and decided, the work on building and implementing the service can commence.

8.5 Partnerships

It is seen as essential for the successful deployment process that the proposer of the telemonitoring service represents a professional, reputable and convincing partnership, since it is unlikely that a single organisation or enterprise can master all the technologies or services involved.

The partnerships are particularly important in the value configuration. Who is actually creating the value for the various stakeholders? The need for partners become evident during the development of the business models based on value creation. The ability to enter into successful partnerships is one of the core capabilities that must be possessed by the firm or organisation in order to develop sustainable business models for telemonitoring services.

Typically, partnerships are needed for activities that are non-core to the proposing organisation but may be core activities in the value creation process. The business modelling analysis will reveal if these suppliers are secondary stakeholders, which services or products need to be secured by partnership agreements, or tertiary stakeholders, where services and products can be secured using ordinary bidding processes.

Needs for partnerships are depending on the actual service to be deployed, but a few stereotypes can be identified:

Partners for the architecture consist of technology partners that can develop and maintain the technical infrastructure in which the telemonitoring service is based. These are typically software companies or consulting firms with software expertise.

Medical devices are almost always in-sourced to the telemonitoring services. If the devices are essential or if they contain proprietary components, it may be desirable to enter into a genuine partnership agreement with the manufacturer. This may also open up for new components in the business model such as leasing or pay-per-user schemes.

The telemonitoring service almost always involves some kind of data storage. In order to avoid the serious issues of data security and privacy, it may be beneficial (or necessary) to enter into a partnership concerning data storage and data management. This partner could either be a service provider for EPR services or other healthcare related data, or a public or private health portal.

Finally, a partner that can provide operational management and infrastructure may be needed. This partnership covers data centres, communication networks, physical security and service scalability and resilience, etc.

When planning partnerships, it is important that a detailed requirement specification is used as the basis for negotiations. The partners should be selected not only with respect to price, but also with a view to the partner's reputation, technical strengths and localisation.

8.6 Revenue streams

The final step in business modelling involves getting all things to work together for a sustainable business case. This step will in thus involve putting monetary values on the model elements, establish the revenue sources and streams and calculate the resulting financial aspects. The firm can have a wide variety of ways in which revenues can flow in to the firm for its services and products.

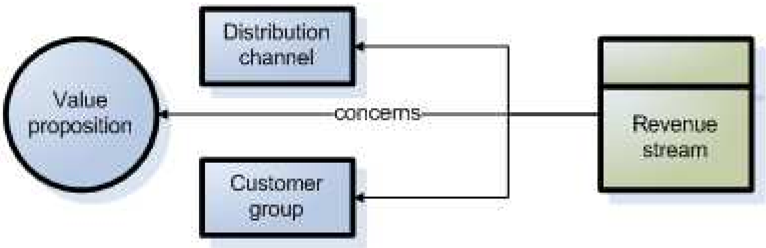

Figure 6 Modelling revenue streams

The different revenues can be analysed assuming certain price structures. Prices may depend on the value that the customer puts on the value proposition, or may be determined according to market expectations for particular customer groups or simply by the competitive structure of the market. In all cases, the choice of price structure will affect the revenue stream.

Revenue streams can also be categorised according to the different price elements. A particular value proposition can be priced as a fixed, one-time purchase price (a mobile phone). It can also be priced on a recurrent basis (the phone is rented and paid for as part of the monthly subscription). A variant of this is to charge based on usage (click fees), in which the product is only paid for in terms of its usage (the phone is free but the cost of using it includes the cost of the phone). Obviously, the revenue stream can include all combinations of the above structures.

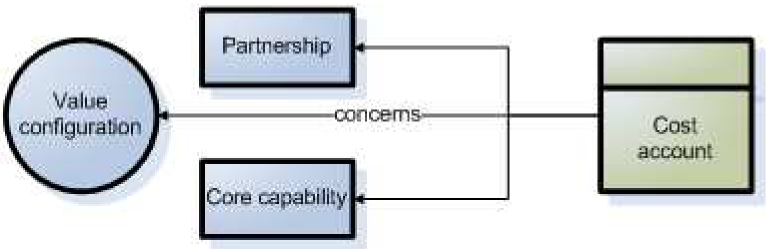

Figure 7 Modelling costs

Once the revenue streams have been determined, the corresponding cost of supporting this revenue stream has to be analysed. The costs obviously depend on which partnership and how many partners are involved in the value net, the exact nature of the value configuration and the core capabilities of the firm itself (cost advantage).

Telemonitoring services have the special characteristic that very little or no revenue streams originate directly from the beneficiaries of the telemonitoring services. The picture differs across Europe, but most often the funding for all actors is predominantly coming from healthcare commissioning bodies and insurance companies with a small fraction coming from patients themselves. If patients, or their supplementary private insurance company, can be persuaded to grab deeper in the pockets and fund more of the telemonitoring services themselves, e.g. buying medical devices or terminals or directly paying for extra, personalised services, remains to be seen. It depends to a large extent on the value proposition offered by the telemonitoring services and what alternative exists.

Contrary to funding bodies, it is easy to identify the cost centres: Primary and secondary healthcare providers and suppliers of devices and services. The challenge of finding the proper business case for Hydra enabled telemonitoring services can be boiled down to the following: Find the proper service that has a sufficient value proposition to attract a sufficient amount of new funding or reduced costs in order to make the service profitable.

9. Business models and cases

The business modelling work aim is to define stakeholder segments that are sufficiently homogenous to render synchronized behaviour in all relevant aspects (usage patterns, buying behaviour, etc.) while at the same time to be sufficiently large to be economically viable for exploitation.

The different stakeholders identified in this way will have different expectations and will see the usefulness of the Hydra middleware from different perspectives. The important first part of any business modelling process is thus about identifying the right value propositions in relation to the relevant stakeholders. For simplicity and overview, we need to define and categorise the different stakeholders and actors that are involved in the business models

The overall analysis is carried out based on the methodology described in deliverable *D10.5 Business modelling concepts* with a three level modelling framework with the following steps:

- Value modelling
- Revenue modelling
- Process modelling

Based on an extensive search for suitable value modelling tools, the e^3value methodology and tool were selected to be used. The e^3value methodology emphasizes the goals to be reached and avoids details, which do not contribute to the goals of the model. A first goal is to create common understanding of the essentials of the e-Business idea. A second goal is to gain confidence in the economic feasibility of the service idea. To this end, the e^3value methodology focuses only on substantial expenses and revenues related to the idea, sufficient to do a sensitivity analysis. Moreover, rather than detailed financial effects, the methodology only performs partial analysis: value propositions and business processes with respect to substantial revenues and expenses.

A complex business modelling reveals a need for a modelling tool to support the development, analysis and communication of model results. Hence for the modelling work, we decided to build value models, analyse business cases and present them using an e^3value software tool developed by the team at VU Amsterdam.

Thus the Business Modelling work will lay the foundations for exploitation by providing illustrations and case studies on which to base business cases. The business case is simple a particular instantiation of the business model. The business case can subsequently be used to derive business plans and to refine the process models prior to implementation.

After the formulation of sustainable value and revenue models, the next step is to define and analyse the proper process models. Process models are an opportunity to understand the cost-benefit potential of the Hydra based telemonitoring services. The idea is to make a simple but effective evaluation on how the healthcare sector is organised before the technology acquisition (As-Is) and how it may change after the introduction of the new services (To-Be). The selected approach is the ROI (Return on investments) model, where the possibility to clearly differentiate the a priori situation from the "after purchase" condition is immediate.

The ROI method is useful to analyse the economic return from investing in the Hydra based telemonitoring service. However, it is not useful to describe the clinical effects on the citizen's health and the potential societal economic gains from a healthier population with better controlled chronic patients. This analysis requires highly skilled medical analysis and is outside the scope of the Hydra project.

The business cases presented in the following chapters touches on three different perceived services that can be developed using the Hydra middleware. The business cases are described as they would appear in a business plan for a commercial company, who wants to enter the market with a Hydra based service platform.

10. Case 1: Diabetes monitoring & self-management

10.1 Business rationale

"X" company's Business Development unit is proposing to install and offer a new diabetes self-management service based on Hydra middleware. The service will initially be offered in Denmark as a service to control hypertension in diabetes management. Each patient enrolling in the system will be provided with a home medical device (initially blood pressure monitors, but other relevant sensors may be added later). The service will allow GP's or hospital clinics to monitor a large number of diabetes patients with high risk of hypertension and a history of non-compliance. The aim of the service is to provide personalised feedback that will help and motivate patients to better control their blood pressure thus reducing the risk of additional conditions.

Denmark has a tax-based healthcare system and the Business Development team has made an initial survey of the market for healthcare services in Denmark.

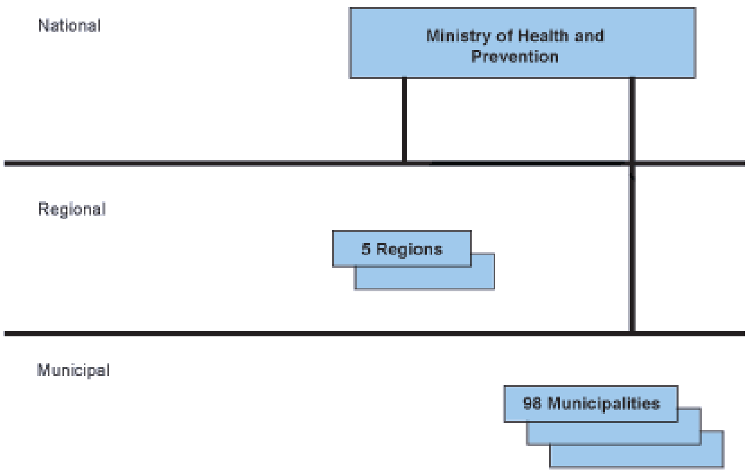

Figure 8 Organisation of the Danish healthcare system (MSF, 2007)

The Ministry of Health and Prevention, in its capacity of principal health authority, is responsible for legislation on healthcare. The Ministry also sets up guidelines for the running of the healthcare service. This is mostly done through the National Board of Health.

A structural reform was completed in 2007, when five health regions were established. The health regions are responsible for commissioning and providing both primary and secondary healthcare services.

The municipalities are responsible for, among other things, home nursing, public healthcare, school health services, prevention and rehabilitation.

In Denmark, healthcare is free of charge at the point of use. The healthcare system is publicly funded through revenue generated from general taxes and paid to the health regions as a block grant, which constitutes 75% of the regions funding with the balance coming from local basic and activity based contributions. The block grant is based on objective criteria for the expenditure needs of each health region. The individual regions can adjust services within the financial and national legal limits according to needs at the different levels, enabling them to ensure the appropriate number of staff and procurement of the appropriate equipment. The local basic contribution is determined by the regions. The limit is fixed by statute (DKK 1,500 per inhabitant in 2003). The activity-related contribution depends on how much the citizens use the regional health services. It primarily reflects the number of hospitalisations and out-patient treatments at hospitals as well as the number of services from general practitioners.

Regions, local authorities and other organisations have secure intranets that are linked by the Healthcare Data Network. The penetration and rates of use are as follows: General practitioners: 97%, full time specialists: 74%, pharmacies and hospitals: 100%, local authorities: 44%. The types of eHealth services delivered through the network include:

- Referrals and discharge summaries
- Prescriptions
- Teleradiology - teledermatology services
- Querying laboratory results through the National Health Portal

In 2005 total healthcare expenditure in Denmark was 9.4 per cent of GDP or app. 2.500 € per capita, which places Denmark well above OECD average. Investments in new equipment and ICT infrastructure amount to app. 70 m€ annually (MSF, 2007).

The company's senior management is going to make a decision on this strategic move and has requested a detailed business plan from the Business Development unit. The business development team follows the prescribed procedure for developing a sustainable business case. The business case forms part of the business plan.

10.2 Early adaptors

The teams' first step is to identify an early adaptor and present a convincing case in order to solicit the support and potential financial commitment once the deployment of the service commences.

Digital healthcare services are widespread and well entrenched in the Danish healthcare system. In 2007, the Ministry of Health and Prevention together with all the healthcare regions established an independent organisation to set the frame for digitalization of the Danish healthcare sector. The organisation is called "Connected Digital Healthcare in Denmark" (Sammenhængende Digital Sundhed i Danmark, SDSD) or "Digital Health". In its first year, Digital Health published "the National Strategy for the Digitalization of the Healthcare Sector 2008-2012" (Digital Health, 2007). It is central for the strategy that the digitalization of the healthcare sector happens as a step-by-step progress and that it is based on needs. This implies that there will be no major "big-bang" solutions where programmes or systems are introduced in one go to the entire sector.

The deployment of a nation-wide service supporting diabetes patients is a typical service that will fit into the National Strategy. In fact, Digital Health already has agreed on an action plan in which telemedicine is used to increase patients' participation in disease management through monitoring at home and self-care. Digital Health also plans to establish a national service platform for data exchange between different healthcare providers and municipalities.

It is evident that the Digital Health would be the most likely early adopter in the Danish healthcare system for a Hydra based telemonitoring service. Firstly, they are the national pinnacle in terms of innovation in digital healthcare and author of the national strategy in eHealth. Secondly, they are the national organisation for implementing nationwide data exchange service platforms. Thirdly, the regions are not meant to install large scale services. All units have experimented with telemonitoring services of varying complexity and scope, but none of them have implemented them in daily clinical use due to the size of the investment and the operating costs.

The present business case will be based on Digital Health establishing the service and putting it in use for the regional health authorities and the municipalities.

10.3 Disease and clinical domain

The next step is to precisely define the disease and the clinical domain in which the service shall be deployed.

Self-management of diabetes is an area that offers exceptionally good prospects, both in clinical terms and in business terms.

Diabetes mellitus is a metabolic disorder characterised by hyperglycaemia (high blood sugar) resulting from defects in the production of or in the body's response to insulin. The disease has two main forms: type 1 and type 2. Type 1 disease is characterised by diminished insulin production resulting from the loss of beta cells in the pancreatic islets of Langerhans, in most cases caused by immune-mediated cell destruction. Disease management entails administration of insulin in combination with careful blood glucose monitoring. Type 2 diabetes sufferers in contrast exhibit both reduced insulin production and resistance or reduced sensitivity to insulin.

Type 2 diabetics are typically over 50 years old with additional health problems, especially cardiovascular disease (CVD). Management principally involves the adjustment of diet and exercise level and the use of oral anti-diabetic drugs (OADs) and insulin to control blood sugar.

Adequate treatment of diabetes type 2, as well as increased emphasis on blood pressure control and lifestyle factors (such as smoking and keeping a healthy body weight), may improve the risk profile of most aforementioned complications and decrease the need for hospitalisation. Self-management of diabetes can include home-testing of blood pressure, blood glucose level, weight and urine (to test for the ketone level).

Patients tend to control their disease less and less over time, especially if they are well controlled and having an active life. People with long-term diabetes 2 problems and poor management are significantly more likely to be admitted to hospital as an inpatient (on average about twice as likely, given a particular problem) and stay in hospital for longer. Enabling patients to become more involved in managing their condition will not only ensure a better and more effective management of their disease, it will also free healthcare resources for other tasks.

Healthcare specialists have in several studies reported that self-management concepts in diabetes management leads to exceptionally good results. Daily monitoring of blood pressure, diet, physical exercise, etc. are excellent parameters for type 2 management, whereas blood glucose monitoring is better done in clinics every two weeks. Studies also points to important case benefits that can be obtained with good compliance with insulin intake.

There are several prerequisites which must be met in order to ensure efficient self-management of chronic conditions. The patient must receive proper education about the condition in order to fully understand the disease itself and its complications. Moreover, the patient must be able continuously carry out various necessary tests and measurements as part of managing the condition, as well as being able to remotely submit these results to the relevant health professional for clinical assessment. Finally, the patient must receive regular feedback which gives concise information on any health risks caused by deviations or changes to their predetermined healthcare plan.

Diabetes management programmes offers highly attractive business opportunities for telemonitoring, because just a slight reduction in admission rates can cause massive economic benefit for the healthcare provider. And well organised management programmes provide marked improvements in the patient's quality of life.

10.4 Description of the planned service

The Business Development team has pinpointed the most promising service proposition in Diabetes telemonitoring of blood-pressure. The service will aim at reducing further complications from hypertension by offering tight blood pressure control combined with self-management support such as compliance with prescribed antihypertensives (drugs for reducing blood pressure), choosing low-fat and low-sodium diets, maintaining regular exercise, and weight control.

Persistent hypertension is one of the risk factors for strokes, heart attacks, heart failure (CHF) and arterial aneurysm, and is a leading cause of chronic renal failure. Even moderate elevation of arterial blood pressure leads to shortened life expectancy.

The process of managing hypertension according the guidelines of the British Hypertension Society suggest that non-pharmacological options should be explored in all patients who are hypertensive or pre-hypertensive. These measures include:

- Weight reduction
- Regular aerobic exercise
- Reducing dietary sugar intake
- Reducing sodium (salt) in the diet
- Additional dietary changes rich in fruits and vegetables
- Discontinuing tobacco use and alcohol consumption
- Reducing stress

The service is planned as a 24/7 multi-parametric monitoring scheme which uses smart home healthcare devices to provide multi-parametric telemonitoring of the patients health parameters such as blood pressure, heart rate, activity frequency, weight and diets. More information about the service can be found in Appendix 4, scenario 1 and 2.

Various devices will be made available for monitoring, including: Blood Pressure Monitors (BPM), pulse meters, electronic scales, activity monitors, etc. Medication compliance will be monitored using an electronic pill dispenser. Information about diets will be communicated between the patient and the backend service using terminals such as smart phones.

Patients will be monitored and reminded to take actions, such as measuring BP or weight, taking medication or doing exercise. Measurements will be collected and transmitted to the backend service, which provides data analysis, complex feature detection. Health status information will be analysed by the service and filtered for abnormalities. The result of the analysis with risk assessment and contextualised with general and specific case specific biomedical and clinical knowledge will be fed back to the patient to promote self-management and life style changes.

In the case of abnormal measurements, the GP or healthcare professional assigned to the patient will be informed. All data will be stored in the patients EPR. The service thus also features as a clinical platform for case management.

10.5 Stakeholders and value objects

The company has identified six major actors and stakeholders in the diabetes self-management business service:

- Diabetic patients
- GPs
- Hospitals
- Health Regions
- The National Board of Health
- The Hydra Service Provider

Diabetic patients

In Denmark, there are a total of 5.5 million residents. In 2007 there were 240,358 persons diagnosed with diabetes, which corresponds to roughly 4% of the population (National Health Agency, 2008). It is estimated that 60% of people with diabetes are not diagnosed (1999) so that the total number of people with diabetes could be as high as 600,000 people. Moreover, it is estimated that 17 % or 850,000 people are in the pre-diabetes stage and is at risk to develop diabetes over a 3-4 year period (Glümer, 2003). The age group 60-69 has the highest prevalence of type 2 diabetes and type 1 diabetes amounts to 5-10 % of the total number.

The target group for the Hydra telemonitoring service is patients with diagnosed type 2 diabetes. From the above figures it is estimated that the target group consist of 216,000 patients with diagnosed type 2. There is a potential for further 250-300,000 patients with undiagnosed diabetes type 2 and further 850,000 patients with pre-diabetes. The annual rate of increase is 6,3 %.

Patients who enrol in the self-management program are expected to obtain substantial benefits due to the improved compliance and better control of their disease.

The obvious benefits, or value objects, for the patient of self-management and telemonitoring are that it can be done at any time and any place. This ensures continuity in the management of the disease and it allows the patient to practically live a normal life without the restraints of having to go to the doctor to have these tests done. The patient is not only mobile but will also save travel time back and forth to the doctor, as well as avoiding being stranded for hours at the health clinic.

Patients will also benefit in terms of receiving more efficient and convenient care and overall better health, thus preventing serious complications.

While other stakeholders have direct financial interests and must obtain financial benefits, patients do not have direct financial interests in the self-management program, beyond the possible extra cost. In the context of the Danish health system, the patient expect most healthcare to be provided by the Regions at no or minimal cost. Thus the value object is compensated by the willingness to pay taxes to the national provisioning of healthcare services.

The relationship between the patient and the telemonitoring service provider is indirect. The service will be offered to the patient as a part of the National Health Agency's healthcare offerings. A possible "co-payment" from the patient for e.g. the blood pressure monitor has been considered and abandoned since there is no tradition in Denmark for individuals paying their own healthcare costs and having to do so will stir considerable political opposition from parties that are traditional hostile to privatisation of healthcare. The patients and other family users are primary stakeholders.

Patients would expect the telemonitoring service and the technology to work effortless. It must work at all times and be very simple for patients to use. If the interaction contained some kind of "gaming" or "entertainment", it would be more interesting to a broad group of patients.

General Practitioners (GPs)

There are about 4,100 general practitioners (GP) in Denmark, who take part in the collective agreement with the public health care scheme. Each general practitioner has about 1,300 patients.

However, in this business case we are only concerned with patients who are diagnosed with diabetes, so we can assume that each GP has 52 patients with diagnosed diabetes, who require 2 yearly check-ups in order to monitor the disease, and potentially more than 200 patients in the pre-diabetes stage.

Diabetes case management is fairly standardised in Denmark. The GP performs initial examination appropriate clinical tests to arrive at a diagnosis. When first diagnosed, a nurse will assist the GP with certain tasks such as testing cholesterol, blood pressure, liver functions and blood sugar. The data from the tests will be presented to the GP who instructs the patient on how to manage and control the disease.

Often, tests have to be taken every six months in order to monitor the development of the disease. In the event of complications, the GP will refer the patient to the hospital for secondary care. If the condition worsens, the patient may not be able to come to the GP's office for tests, in which case, the GP must arrange home visits or having the patient transported into the hospital.

When the self management platform will be introduced, the GP's will mostly benefit from savings in time. Fewer visits by patients in the office would save substantial time for the GP. The opportunity to present fast, targeted education in risk assessment and risk profiling will also save considerable time in the clinic. Finally, communication will be facilitated not only between patient and health professionals, but also between professionals (shared care).

However, there need to be a reimbursement system in place in order for the GPs to fully embrace the system.

General practitioners in Denmark are private entrepreneurs but work under contract with the National Health Insurance body. The pay system includes fee-per-item, fee-per-patient and a fixed amount per doctor. The fees are fixed in the agreement between the GPs' organizations and the National Health Insurance, which specifies the details of the reimbursement system. Fee-per-item comprises about 75 % of the GPs' gross income. Only very few services involve user payment (e.g. medical certificates). The agreement differentiates between base services and supplementary services. Base services are the different types of consultations while the supplementary services are add-ons to the consultations (e.g. laboratory tests and bladder catheterization).

It is noteworthy that, like many other national health systems, Danish fee schedules are build on fees for visits to the doctors office. This means that the GP has a pecuniary interest in having more patients in the clinic. This fee schedule is criticized for encouraging GP to see patients often and having many ill patients in the waiting room.

The present reimbursement scheme (2009) contains the following items (prices in DKK):

0101	Consultation in office (8am – 4pm)	126,86
0105	Electronic communication (including other carers)	49,68
0107	Case management of diabetes patients (annual)	1099,17
2101	Blood sample for laboratory test	43,47
7136	Blood glucose test in office (photometric)	47,44

Table 1 Reimbursement schemes for diabetes patients

Further fees-per-item include home visits or evening consultations, cognitive consultations, preventive consultations, etc., which will not be considered in this first approach to a business case. The fee structure does not yet, for obvious reasons, include special fees for remote monitoring. But it does include fees for email communication.

A new structure has been introduced in 2005, which focus on case management for certain types of chronic diseases, including diabetes. Upon enrolling, the GP receives a one-time fee of 1,000€ and an annual fee of 150€ per diabetes patient. All the GP’s diabetes patients must be under the case management fee structure and the GP is obliged to submit health data for the national diabetes register. The fee covers an annual standard check-up including laboratory tests and related email and telephone consultations plus one interim review consultations. Further visits are reimbursed at the standard rate.

It is believed that this focus in case management has a positive effect on the stabilisation of diabetes patients and avoidance of further complications.

A new fee schedule for telemonitoring, if and when introduced, could well be based on the same principle with a one time subscription element for setting up the service and configuring it to the GP’s needs plus an annual reimbursement per patient enrolled in the telemonitoring scheme.

The relationship between the GP and the telemonitoring service provider is indirect. The service will be offered to the GP as a part of the National Health Agency’s healthcare offerings. GPs would expect the service and the technology to work at all times and be very simple for them and their nurses to use. Further, it must be possible to personalise each monitoring scheme to both the individual patient and to the individual GP. The GP, nurses and other users are primary stakeholders.

Hospitals

The five Danish Health Regions run most hospitals in Denmark and are responsible for specialised patient care and services. The regions must provide free hospital treatment for the residents of the region and emergency treatment for persons in need who are temporarily resident.

The regions operate a total of 69 hospitals, some of which have more than one physical location. In addition, there are 20 private hospitals, primarily providing specialised treatment on contract with the one or more regions. Only one private hospital is relevant for the diabetes case. This is the Steno Diabetes Centre, owned and managed by the Novo Nordisk foundation.

Extended and unnecessary hospitalization is expensive and the government is investigating if for more healthcare services can be provided in the patient’s home or locally. Preventing unnecessary hospitalisation and reducing the length of hospital stays is also a key to reducing waiting lists. The emphasis on improving intermediate care in the community and home care is both in response to general wants and needs of the population, but it is also a huge cost effective strategy, particularly considering the overall demographic and health trends that point towards an aging population and the increase of people with chronic conditions requiring long-term care.

The strategy to move more healthcare services for patients with chronic disease from the secondary to the primary care sector has the potential of reaping enormous benefits. First of all, people having long-term or chronic health problems are twice as likely to be admitted to hospital. Studies have also shown that home monitoring of chronic diseases has the potential to reduce hospital visits by as much as 50% by keeping patients stable through daily monitoring (CTEC, 2009).

In Denmark as a whole in 2007, there were 1,186,412 hospital admissions amounting to 4,907,927 bed days. People with diabetes were admitted 9,138 times and spend 55,384 days in hospital. On the average, diabetes patients spend 6.1 days in hospital whereas the national average is just 4.1 days.

An empirical study by Green et. al. (2006) showed that the cost of diabetes related hospital admission in Denmark amounted to 333 m€ (or 7%) of the total hospitalisation costs of 4,448 m€, whereas the prevalence of diagnosed diabetes is only 4% of population. This over-proportionality is due to costly complications from diabetes, such as renal failure, retinal damage and amputations. If remote monitoring can reduce the risk of hospitalisation and complications, hospitals will be able to reduce cost significantly.

Hospitals are financed by global budgets and since diabetes admissions are more expensive (in resources) to the hospital than other diseases, hospitals can free resources to treat other disease groups and clear backlogs and waiting lists.

The relationship between the hospitals and the telemonitoring service provider is indirect. The service may be offered to the hospitals as a part of the National Health Agency's healthcare offerings, but hospitals will normally not use the services on a daily basis. Hospitals are secondary stakeholders.

Health Regions

The Danish Health Regions have previously been described in details. There are five health regions in Denmark and they are responsible for commissioning and providing both primary and secondary healthcare services.

In 2007, the total expenditures for the regions healthcare services were 10.4 b€ plus capital investments of 0.35 b€. Of this, 350 m€ are estimated to be diabetes related costs, mainly in hospitals.

The Health Regions will be motivated to support telemonitoring services by the outlook of being able to provide better healthcare services and make the healthcare system more efficient by reducing the hospitalisation costs of patients with diabetes.

However, new reimbursement schemes for the primary sector, which will reward more GP's to offer the telemonitoring service, must be introduced, which will be at a cost to the regions, while economic benefits in the secondary sector will not be realised until later.

The relationship between the Health Regions and the telemonitoring service provider in this business case is indirect. However, it is entirely likely that one or more regions would consider installing the Hydra based telemonitoring service for its own purpose. This business case will be dealt with separately. As user and prime beneficiary of the services, the Health Regions will demand a set of performance level requirements. Health Regions are, however, still to be regarded as secondary stakeholders.

Connected Digital Healthcare in Denmark

The Digital Health organisation is described earlier. Established in 2007, the organisation is central in the implementation of the national eHealth strategy and is responsible to the Ministry of Health and Prevention for strategic developments and the National Health Agency for implementation of healthcare and disease management.

The deployment of a telemonitoring service for diabetes patients is a service that will fit into the National Strategy. As mentioned, Digital Health has already agreed on an action plan in which telemedicine is used to increase patients' participation in disease management through monitoring at home and self-care.

Digital Health has thus been chosen as the early adopter in the Danish healthcare system for a Hydra based telemonitoring service. The developed business case will also be used to present the concept and the potential cost-benefits as well as the societal benefits to Danish Health.

The business case will be based on Digital Health establishing the service and putting it in use for the regional health authorities and the municipalities. Danish Health needs to apply for funding for capital expenditures from the Ministry of Finances and The Ministry of Health and Prevention. The business case will identify value creation to the different stakeholders and provide a basis for discussion and negotiations.

The Hydra Service Provider

As can be seen from the above discussion, the Hydra Service Provider will provide primary and secondary healthcare providers in the regions access to the telemonitoring platform with the aim of deploying remote monitoring and personalised feedback to diabetes patients as part for a self-management programme.

In order to offer the services, the Service Provider will have to make investments in server infrastructure, operating systems, hardware, server facilities, perimeter security and access control systems, etc. Moreover, a large number of medical devices are needed for the monitoring.

In addition, the product demands sizable fixed operational costs for support and administrative staff functions, software licences, maintenance and upgrades, etc. Finally the product has a series of variable costs for network communication, power, etc.

However, once the investment is made, the Service Provider is capable of executing several services on the same infrastructure.

10.6 Revenue streams and values

The fundamental question to be answered in the business case is: What do we offer to the customer, who are they and how do we operate to deliver the product or service so that we can create a profitable and sustainable business? In other words, we need to identify and analyse the value proposition in the Hydra based telemonitoring services and analyse the revenue streams and cost models and derive the financial return and thus evaluate the sustainability of the proposed business case.

The analysis is now carried out in the following steps:

- Value modelling
- Revenue modelling
- Process modelling

10.6.1 The value model

In order for the business case to be viable and sustainable, we need to look at the cost-benefit (or profit and loss) implications for all actors. According the discussion in *D10.5 Business modelling concepts*, the proposition needs to provide positive cost-benefit or profitable operations to all actors in order to be sustainable.

The value exchange model used is the following:

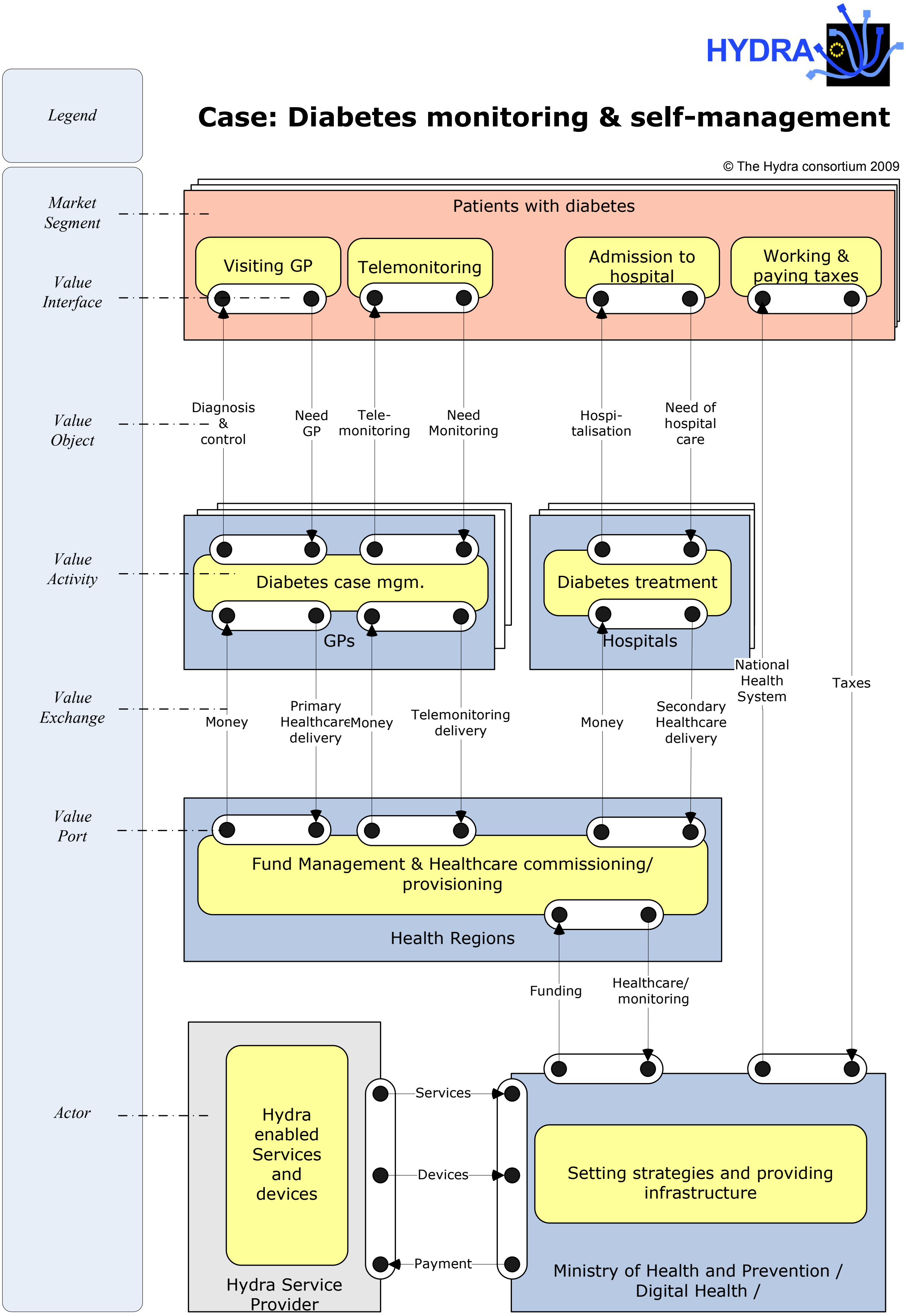

Figure 9 Value model for telemonitoring and self-management of diabetes patients

The financial implications for each actor will be analysed in terms of incremental budgets for two years of operation showing revenues and costs (for the service provider) and costs and benefits (savings) for the healthcare provider(s). Two years are included in the budget to include start-up effects in the calculations.

10.6.2 The revenue model

The company has the intention that the revenue model to be used for the service shall consist of four elements:

1. An initial one-time charge for setting up the specific client domain and customise the services to the needs for diabetes services as specified by each Health Region.
2. Hardware investments per patient for the location gateway and medical devices
3. A fixed monthly usage license to cover availability, upgrades, software licences and technical support
4. Pay-per-use charges to be paid per patient and per transaction

The revenue model must be adjusted to the reimbursement scheme that the Danish Regions will put in place.

The Digital Health organisation is committed to launch new innovative services according to the national eHealth strategy. The organisation applies for project funding from the government appropriation budget for the new services. Once the necessary investments have been made and the service is running, the operational responsibility, including operating costs, is transferred to the regions.

In the following we will look at the revenue elements and reimbursement schemes that have been used as the economic foundation for the modelling work.

The patient

There are 240.000 diabetic patients in Denmark. Diabetes patients need to see their doctors at least 6 times per year. By introducing telemonitoring, the patients are expected to be come better controlled and the number of visits to be reduced to 3 times per year and the number of admissions to hospital by 50%. It is assumed that 20% of the diabetes patients participate in this scheme.

The patient does not pay for the telemonitoring service directly; it is delivered as part of the free health system and is paid for from income taxes.

Event though the patients benefit from the telemonitoring service (in terms of better health and less complications), they are not expected to be willing to pay for the service. The diabetes patients pay taxes as any other citizen and the taxes are perceived to cover any health benefit that is offered.

The taxes attributable to healthcare paid by the 240.000 diabetic patients is estimated to be app. 570 m€ annually. Of this amount, 4% (or 23 m€) is the diabetes patients own contribution to the cost of diabetes treatment; only a small fraction of the app. 350 m€ in total which is the annual cost of diabetes care in Denmark.

The GP

There are 4,100 general practitioners in Denmark. It is assumed that half of the patients are enrolled in the case management scheme whereas the other half are seeing their GP as needed. It is also assumed that each patient needs blood sugar and blood sample test for every visit. The annual cost of one patients visits to the doctors office varies from 214 € to 289 €. The lowest figure corresponds to patients not enrolled in the case management program and not having telemonitoring. The highest figure corresponds to patients enrolled on both schemes.

The GP receives a fee of 145 € annually for the case management program. It is assumed that the reimbursement of the telemonitoring program will carry an additional reimbursement fee of 100 €.

In the business model, the GP's expenses of running their office etc. have not been included in the calculations. This is partly due to the problem of obtaining such data and partly because it is not foreseen that the GP can save any significant amount of costs from introducing telemonitoring services. It is assumed that the number of admissions can be reduced by 50% by those patients participating in the telemonitoring scheme.

The business model shows the increased reimbursements for telemonitoring can be fully offset by savings in consultations in the offices.

The hospital

There are 69 public hospitals in Denmark with a total of 9,100 admissions of diabetes patients per year. The total cost to the hospital of treating diabetes patients is 44.4 m€ annually.

Diabetes patients have a high admission rate and stay longer in hospitals than other patients. By being better controlled, it is assumed that the number of admissions can be reduced by up to 50% for the patients that participate in the telemonitoring program.

This leads to a cost saving in the secondary sector of 4 - 5 m€ per year; money that the regions can either take back (reduce budgets) or leave to the hospital to improve other services. In our business case, the funding to the secondary sector is reduced corresponding to the savings.

The Health Regions

There are 5 Health Regions in Denmark. They fund both the primary and the secondary healthcare sector. The regions are funded partly by the state (Ministry of Health and Prevention) and partly by municipalities.

The activity level must correspond to the funding provided and is established in annual negotiations between the government and the regions. Increased funding can be agreed for initiating new services or undertake investments. Realised savings (from efficiency) can lead to reduced funding, at least in principle.

In our business case we assume that budgets for the regions are reduced with the obtained savings from telemonitoring. This approach is taken in order to isolate all savings in the Ministry of Health.

The Ministry of Health and Prevention

The Ministry of Health and Prevention provides funding for the regions. 80% of the funding is redistributed to the regions via block grants, based on objective criteria (social and demographic indicators), and 20% is redistributed to the municipalities which use these funds to co-finance regional hospital services for the respective population.

As a part of the activity-related contribution to the regions, the regions have to redistribute the contributions to the hospitals. For 2007, in accordance with the agreement between the government and the regions, 50% of the hospital budgets will depend on activity-related contribution. However, for the purpose of simplicity, in our business case all funding to the regions from the ministry is based on block grants. Moreover, it has been assumed that the Ministry of Health and Prevention reduces the funding for the regions with the amount of savings obtained from telemonitoring.

Digital Health

Although Digital Health is the early adaptor organisation identified for this business case, it does not have any operational responsibility. Its sole role is to initiate the formation of the telemonitoring platform the funds for this work will come from the Ministry of Health and Prevention. However, the funding can also be provided from outside the present business case, as we shall discuss later.

The Hydra Service Provider

Finally, we will analyse the Hydra service provider. The Service Provider will operate a "Platform as a Service" concept, in which the platform is created and each Health Region will be offered its own, customised telemonitoring service. The setting up of the platform and customisation of the services will be commissioned and paid for by the Digital Health organisation.

Once the platform and its services are operational, the cost of the service will be paid by the Ministry of Health and Prevention. This model has been used for simplicity in our business case. A different model would have been that each region pays for its own service directly to the Service Provider, with a corresponding increase in funding from the Ministry of Health and Prevention. The financial effect is the same.

The calculations for the business case are based on the following revenue model:

1. An initial one-time charge for setting up the specific client domain
2. Hardware investments per user for the location gateway and additional sensors and actuators
3. A fixed monthly use license to cover availability and support
4. Pay-per-use charges to be paid per patient and per data unit

The base for calculating the prices is shown below.

Cost base of Hydra Service Provider:

Setting up costs:	30.000	€ per site	Access costs:	0,80	€ per user per month
Customisation:	50.000	€ per site	Transaction cost:	0,000	€ per transaction
Software investment:	100.000	€			
Equipment investment:	400.000	€			
Amortisation:	36	months	Devices:	200,00	€ per user
Monthly amortised:	13.889	€			
Monthly operating:	150.000	€			
Fixed yearly cost per contract (@ 5 contracts):			Variable yearly cost per contract (@ 5 contracts):		
Operating costs	30.000	€	Access costs	460.800	€
Amortisations	2.778	€	Transaction costs	0	€
Total fixed costs	32.778	€ / contrac	Total variable costs	460.800	€ per yr per contract

Table 2 Relevant costs for the Hydra Service Provider

Based on the above costs, the revenue model in the business case is established as follows:

1. Initial one-time charge including setting up and customisation of one site, i.e. for a single Health Region: €100,000
2. Devices per patient: €200
3. Annual subscription fee for a single Health Region: €100,000
4. Fixed subscription fee per user (1 patient plus 4 other users): €5 per month
5. Pay-per-use fee €0.01 per transaction.

The Hydra service provider is expected to make a modest profit on the setting-up and customisation costs, but this profit is not included in the business case.

10.7 The business case

The business case can now be build from the business model. The graphical representation of the e^3value business model is shown in Appendix 6: Graphical representation of business cases.

The business model consists of the following value objects:

- Money
- Healthcare
- Opportunity (for getting reimbursed)
- Telemonitoring

The actors exchange these 4 value objects in various constellations. Most value exchanges are evident, but the exchanges between the patients and the healthcare providers require an explanation because there is no monetary exchange involved.

The ingoing value transactions are "Diagnosis & Control", "Monitoring" and "Hospitalisation"; all very beneficial to the patient but they do not have a direct economic counter transaction, because patients do not pay for healthcare services. However, the patient is assumed to work and pay income taxes, which are then used to fund the services.

In order to get the "value exchange" paradigm, which is the basis for the e^3value methodology to work, we introduce the opposite value objects "Needs for…". This value object replaces the direct monetary value object, but represents an opportunity for healthcare provider to collect a fee from the Health Regions. Having thus established the value objects and exchanges, we arrive at the following table of transactions between the actors in the business case:

Actor / Market Segment (€)	Value object in	Value in		Value object out	Value out	
Patients						
GP	Diagnosis & Control			Need for GP		
GP	Monitoring & Feedback			Need for monitoring		
Hospital	Hospitalisation			Need for hospitalisation		
Ministry of health	Having healthcare			Paying taxes	22.691	k€
GP						
Patients	Need for GP			Diagnosis & Control		
Patients	Need for monitoring			Monitoring & Feedback		
Health Region	Payment for primary care	55.344	k€	Providing primary care		
Health Region	Payment for telemonitoring	5.136	k€	Providing telemonitoring		
Hospital						
Patients	Need for hospitalisation			Hospitalisation		
Health Region	Payment for secondary care	42.001	k€	Providing secondary care		
Health Region						
GP	Providing primary care			Payment for primary care	55.344	k€
GP	Providing telemonitoring			Payment for telemonitoring	5.136	k€
Hospital	Proving secondary care			Payment for secondary care	42.001	k€
Ministry of health	Funding diabetes healthcare	102.481	k€	Providing diabetes healthcare		
Ministry of health	Funding telemonitoring	0	k€	Providing telemonitoring		
Ministry of health						
Patients	Taxes paid	22.691	k€	Providing healthcare		
Health Region	Providing diabetes healthcare			Funding diabetes healthcare	102.481	k€
Health Region	Providing telemonitoring			Funding telemonitoring	0	k€
Hydra Service provider	Buying telemonitoring service			Paying telemonitoring service	4.676	k€
Digital Health						
Hydra Service provider	Sourcing platform			Payment for platform	500	k€
Hydra Service provider	Sourcing devices			Payment for devices	9.600	k€
Hydra Service provider						
Ministry of health	Payment for telemonitoring	4.676	k€	Providing telemonitoring serv.		
Digital Health	Payment for platform	500	k€	Delivering platform		
Digital Health	Payment for devices	9.600	k€	Delivering devices		

Table 3 Value transactions between different actors, participating in the scenario

The table shows the value objects exchanged by each actor and the economic value assigned to the value objects. For example, we can see that the GP market segment receives 55.344 k€ for seeing diabetes patients in the office and an additional 5.136 k€ for telemonitoring of their patients. This corresponds to each GP receiving annually 13,592 € in consultation fees and laboratory tests and 1,253 € for performing telemonitoring. The reimbursement fees are paid by the Health Region which again are included in the block grant of 102 m€ that the Ministry of Health provides.

In order to analyse the effect of the business case on the different actors, we have performed two instantiations of the business model: One without the telemonitoring service and one with the service. The results were:

Segment / actor (k€)	Revenues	Payments	Expenses	Cashflow
Patients		22.691		-22.691
GP	60.480			+60.480
Hospital	46.667		46.667	
Health Region	107.147	107.147		
Ministry of health	22.691	107.147		-84.456
Digital Health				
Hydra Service provider				

Table 4 Funding and revenues BEFORE telemonitoring

and:

Segment / actor (k€)	Revenues	Payments	Expenses	Cashflow	Change
Patients		22.691		-22.691	
GP	60.480			+60.480	
Hospital	42.001		42.001		
Health Region	102.481	102.481			
Ministry of health	22.691	102.481	4.676	-84.466	-10
Digital Health					
Hydra Service provider	4.676		4.271	+405	+405

Table 5 Funding and revenues AFTER telemonitoring

It appears that neither patients, healthcare providers nor the Health Regions are economically affected by the introduction of telemonitoring services. The Ministry of Health is almost balanced as well and the new Hydra Service Provider makes a net profit of app. 400 k€ corresponding to 9% EBIT.

The Digital Health organisation has been excluded from the operational business case so far. The organisation is responsible for investing in the telemonitoring services, which poses several problems in traditional financial analysis, which will be discussed in the following section.

10.7.1 The process model

Process models are an opportunity to understand the cost-benefit potential of the Hydra based telemonitoring services. The selected approach is the ROI (Return on Investments) model, which is useful to analyse the economic return from investing in the Hydra based telemonitoring service.

We will look at two actors: The Digital Health organisation and the Hydra Service provider.

The Hydra Service provider:

Using the figures from the business case, a simplified budget for the first two years can be calculated.

Budget for the Hydra service provider (k€)	Year 1		Year 2	
Revenues:				
Start-up charges	500		0	
Subscriptions	500		500	
Monthly license fees	2.880		2.880	
Transaction fees	1.296		1.296	
Total revenues		5.176		4.676
Expenses				
Cost of start up	80			
Variable costs	2.304		2.304	
Operating costs	1.800		1.800	
Total costs		4.184		4.104
EBDIT		992		572
Investments:				
Server infrastructure	400			
Other investments	100			
Software	100			
Total investments		600		0
Cashflow (3 years)	-600	992	572	572
ROI	126%			

Table 6 Simplified budget for Hydra service provider

Digital Health

Digital health is responsible for instigating the service and overseeing the creation of the platform services for the Health Regions.

The cost of setting up the 5 regions nationwide is 500 k€; a relatively small amount compared to the cost of starting other ICT services in the healthcare sector (a recent estimate puts the cost of the unsuccessful implementation if national EPR system in Denmark to more than 300 m€!

However, the business model does not address the substantial costs of providing medical devices to the 48,000 patients. With a conservative estimate of not less than 200€ per device, the total investment in devices runs into 10 m€. It is unlikely that the healthcare system will provide free monitoring devices for this number of patients, so a different implementation model must be worked out together with Digital Health and the other stakeholders. Several options come to mind.

- A certain co-financing from patients, perhaps based on family income, could reduce the investment significantly for the healthcare system.
- The municipalities could be involved and asked to fund the devices as part of their home care programme. The benefit would be in patients being less ill and therefore relieving the already over-stressed corps of home nurses and home carers.
- The diabetes patient organisation could fund some of the devices for low income patients, whereas the rest will buy them at their own cost.
- The manufacturer could establish some kind of leasing scheme to be administrated by pharmacies.
- Municipalities or pharmacies could organise depots of devices that can be used by different patients on a share basis.

The exact process model for providing the necessary devices has not been established because it has to be founded on a realistic setting, to be developed with a real stakeholder.

10.8 Conclusion

A value based business model has been used to identify value objects and value exchanges between stakeholders in the case of a telemonitoring service, to be offered in Denmark, to monitor and control hypertension in diabetes management.

The organisation "Connected Digital Healthcare in Denmark" has been chosen to be the most likely early adopter in the Danish healthcare system for a Hydra based telemonitoring service. Digital Health already has already agreed on an action plan in which telemedicine is used to increase patients' participation in disease management through monitoring at home and self-care.

A Hydra Service Provider will provide primary and secondary healthcare providers in the regions access to the telemonitoring platform. The revenue model will be based on a mix of fixed subscription fees, fees per user and transaction fees. The revenue model is constructed with a relatively small fixed fee and the majority of the revenues for the service provider arriving from activity based fees.

Both primary and secondary healthcare providers benefit form the services, but the business case aggregates all savings in the Ministry of Health. With the set of assumptions, the business case shows that there are additional costs for new reimbursement fees to the GPs for telemonitoring of patients, but that these fees are by and large compensated by savings in the secondary healthcare system stemming from significantly reduced admissions to hospitals.

Setting up the service platform at the Hydra Service Provider is assumed to cost 600 k€ of which 100 k€ is for software including the cost of the Hydra DDK and IDE. The business case shows a rapid return of investment with 8 months payback and ROI of 126%.

The outstanding issue is how the purchase of sufficient numbers of medical devices to be used in the telemonitoring is going to be financed. This issue must await discussions with real stakeholders.

11. Business case 2: Epilepsy seizure monitoring

11.1 Business rationale

"X" company's Business Development unit is proposing to install and offer a new monitoring service for early detection of epilepsy seizures based on the Hydra middleware. The service will initially be offered in Germany in close cooperation with the German Epilepsy Association. Each patient enrolling in the system will be provided with a seizure sensor, which can be mounted on the arm with a plaster. The service will immediately detect a seizure event and the accurate position of the patient. If the patient is in a non-controlled zone, an alarm is send to a crisis management team who can send emergency personnel to assist the patient. The aim of the service is to provide immediate assistance when the patient encounters a seizure, regardless of where and when.

Germany has a social health insurance healthcare system and the Business Development team has made an initial survey of the market for healthcare services in Germany related to epilepsy.

The German healthcare system has a decentralized organization, characterised by federalism and delegation to non-governmental corporatist bodies as the main actors in the social health insurance system: the physicians' and dentists' associations on the providers' side and the sickness funds and their associations on the purchasers' side. Hospitals are not represented by any legal corporatist institution, but by organizations based on private law. The actors are organized on the federal as well as the state (Land) level.

The 292 sickness funds collect contributions and purchase proactively or pay retroactively for health and long-term care services for their members. Since 1996 almost every insured person has had the right to choose a sickness fund freely, while funds are obliged to accept any applicant.

Ambulatory healthcare is mainly delivered by GPs on contract and specialists in private practice. Patients have free choice of physicians, psychotherapists, dentists, pharmacists and emergency care.

Acute inpatient care is delivered by a mix of public and private providers, with the public sector accounting for 53%, non-profit-making organizations for 39% and the private sector for 8% of acute hospital beds in 2001.

In Germany, there are several emergency services which ensure public safety by addressing different emergencies. Some exist solely for addressing certain types of emergencies whilst others deal with ad hoc emergencies as part of their normal responsibilities. Several agencies are connected to religious directions and will engage in community awareness and prevention programs to help the public avoid, detect, and report emergencies effectively.

In 2002, health expenditure in Germany reached 10.9% of GDP, the highest in Europe. Public funds cover 79% of the health expenditure. Of total expenditure, 57% of the funds came from statutory health insurance, 7% from statutory long-term care insurance, 4% from other statutory insurance schemes and 8% from government sources. Private health insurers financed 8%, employers 4% and non-profit-making organizations and households (families) 12%. Most out-of-pocket payments cover purchases of over-the-counter drugs and co-payments for prescribed drugs. On 1 January 2004, co-payments were introduced for outpatient visits and raised for virtually all other benefits.

11.2 Early adopters

The first step is to identify an early adaptor and present a convincing case in order to solicit the support and potential financial commitment once the deployment of the service commences.

The German Epilepsy Association (DE - Deutsche Epilepsievereinigung gem. e. V) undertakes to promote knowledge and understanding of the epilepsy disease and to represent the German epilepsy patients and their interest vis-à-vis the healthcare authorities. Moreover, they publish information material, undertake education, donate funding for epilepsy research, and cooperate with health insurance companies to provide group insurances for epilepsy patients. Patient organisations such as DE can be a great partner in opening the market for telemonitoring services, because they have a powerful political agenda and are well recognised in the care of epilepsy. They are definitely a good proposition for an early adopter of telemonitoring services in Germany. However, it remains to bee seen how much funding they are able and willing to provide.

The largest emergency service organisations in Germany operate partly on a charitable charter and would be able to enter the service at a non-profit basis or even fund part of the service. Event detection and rescue operations are mainstream tasks for the organisation and the services would directly plug into their backend alarm handling centres and other infrastructure. They are also likely candidates as early adopters, but lack the deep medical expertise and narrow clinical focus (in epilepsy), so they would most likely require cooperating with a partner with medical insight.

The business case will be based on a cooperative venture, where DE funds the creation of the monitoring platform and provides its name, expertise and access to the specialist medical network, whereas the Malteser Emergency Service organisation operates the service for epilepsy patients and handles emergency alarms.

11.3 Disease and clinical domain

Epilepsy is a common chronic neurological disorder characterized by recurrent unprovoked seizures (sometimes called fits). A seizure is caused by a transient burst of excess electrical activity in the brain, causing a temporary disruption in the normal message passing between brain cells. This disruption results in the brain’s messages becoming halted or mixed up.

Sometimes the reason epilepsy develops is clear. It could be because of brain damage caused by a difficult birth; a severe blow to the head; a stroke which starves the brain of oxygen; or an infection of the brain such as meningitis. Very occasionally the cause is a brain tumour. Epilepsy with a known cause is called ‘symptomatic’ epilepsy. For most people - six out of ten, in fact - there is no known cause and this is called ‘idiopathic’ epilepsy.

About 50 million people worldwide have epilepsy, with almost 90% of these people being in developing countries. Epilepsy is more likely to occur in young children or people over the age of 65 years. Not all epilepsy syndromes are life-long – some forms are confined to particular stages of childhood.

Epilepsy is the most common serious neurological condition seen in general practice but unfortunately its management is often less than ideal. With effective management of the condition, about 70 per cent of people with active epilepsy could become seizure free. Epilepsy is usually controlled, but not cured, with medication, although surgery may be considered in difficult cases.

Although proper medication can prevent many seizures, seizures do happen and while certain conditions such as tiredness or stress are risk factors that may lead to a person having a seizure, there is no real warning signal. This state of not knowing when a seizure might (suddenly) occur is often a source of worry and anxiety for the epileptic himself as well as for his/her family, friends, and co-workers and employer, and as such may actually lower the quality of life for the individual.

The brain is responsible for the functions of the body, so what is experienced during a seizure will depend on where in the brain the epileptic activity begins and how widely and rapidly it spreads. For this reason, there are many different types of seizure and each person will experience epilepsy in a way that is unique to them. In terms of their origin within the brain, seizures may be described as either partial (focal) or generalized. Partial seizures only involve a localized part of the brain, whereas generalized seizures involve the whole of both hemispheres.

In most cases, the proper emergency response to a generalized tonic-clonic (grand mal) epileptic seizure is simply to prevent the patient from self-injury by moving him or her away from sharp edges, placing something soft beneath the head, and carefully rolling the person into the recovery position to avoid asphyxiation. If a seizure lasts longer than 5 minutes, or if the seizures begin coming in waves - one after the other - then emergency medical services should be contacted immediately.

Prolonged seizures may develop into status epilepticus, a dangerous condition requiring hospitalization and emergency treatment. Status epilepticus is a life-threatening condition in which the brain is in a state of persistent seizure. Traditionally it is defined as one continuous unremitting seizure lasting longer than 30 minutes but there is some evidence that 5 minutes is sufficient to damage neurons and that seizures are unlikely to self-terminate by that time.

11.4 Description of service

Some people with epilepsy manage to "safe-proof" their home environment as a precaution and to prevent serious injuries if a seizure should occur. However, just as there is no way of knowing *when* a seizure might happen, there is also no way of knowing *where*. Thus, precautionary measures are only effective if and when a seizure happens in the "safe" environment. The possibility of monitoring epileptic patients and automatically send out an alarm when a seizure occurs would be a relief to most epileptics and their relatives; knowing that no matter when or where a seizure occurs an alarm will be raised to notify the appropriate – as well as someone in nearest proximity - health professional or crisis management team and/or relative will undoubted ease some of the worries and fears of having another seizure.

Another important factor is that the alarm will be raised to someone, health professional or relative, who knows how to deal with the situation. Some people with epilepsy experience discrimination or exclusion due to ignorance about their condition. This may be in relation to e.g. work or leisure activities, particularly children may suffer from unnecessary exclusion from leisure or sport activities, and it is often based on both a fear and ignorance of epilepsy. If these social and professional circles know that in case of the person suffering from a seizure, the appropriate persons will be notified instantly and the appropriate action will be taken, the discrimination against someone with epilepsy may cease or disappear altogether.

The telemonitoring platform will be based on the Hydra enabled service architecture with event management and wireless mobile connectivity. It will support a collection of loosely coupled monitoring devices and mobile communication terminals with GPS, such as smart phones or PDA's. The mobility features allow the patient to be monitored anywhere, anytime. It also empowers the patient to switch off the monitoring when desired, i.e. in a smart "safe-proof" setting or when together with friends and relatives.

When an epileptic tonic-clonic seizure is detected, an alarm state is triggered. The alarm state is transmitted to the patient's registered emergency service centre together with GPS based location information. The information also includes time of seizure and perhaps relative strength of the seizure. The crisis management centre is now able to dispatch assistance, either from its emergency staff or by calling relatives or non-formal carers known to be in the vicinity of the patient.

Epileptic seizures are detected using Electromyography electrodes attached to the patient's skin surface with plasters. The sensors register the electric activity from muscle fibre contractions. When an epileptic seizure emerges, the electric activity raises. In order to single out tonic-clonic seizures and avoid false readings from normal muscular activity, a special arrangement of electrodes is used. The biceps and triceps muscles of the upper arm are physiologically connected so that during normal muscular activity, the two muscles are never contracting at the same time. But during seizures they are. By time-correlating myographic signals from the two muscles, unambiguous detection of tonic-clonic seizures can be achieved.

The Hydra middleware allows for seamless, plug-and-play integration of wearable, non invasive sensors and mobile devices. The service will use wireless body networks with wearable non-invasive electromyography sensors based on the electronic patch (or ePatch) concept. An electronic patch is a small body sensor, which senses physiological signals and is embedded in a skin-friendly adhesive. An ePatch looks like a normal plaster but contains various kinds of miniaturised body sensors for measuring physiological parameters, microelectronics for data analysis, a wireless radio module for communication and a battery power source. The myographic data are analysed in the sensor and communicated to the mobile device, where the time correlation is performed. The sensors can run for one week on the batteries. Then the plasters must be changed and the batteries re-charged.

When a tonic-clonic seizure is detected, an alarm is sent to the emergency service centre together with GPS information and identification. The alarm will contain an overview of the patient's medical history. The patient's family or other non-professional carers are informed about the alarm and a record is transmitted to the patients EPR where the GP can see it the day after.

After the alarm is sent, an instructive animation with voice-over is automatically downloaded to the mobile devices and launched. The animation video explains in voice and pictures to bystanders what is happening and how they can help the patient. It also announces that help has been called and when it is expected to arrive. If the bystander is able to use the mobile device, he or she is urged to call the emergency service centre and provide additional information about the situation. The animation is downloaded in the native language of the patient plus the preferred language on the location where the seizure took place, as determined by the GPS coordinates.

11.5 Stakeholders and value objects

The company has identified six major actors and stakeholders in the epilepsy seizure monitoring service:

- Epileptic patients
- The Germany Epilepsy Association
- Emergency service organisations
- Private health insurance companies
- Physicians' specialised in epilepsy
- The Hydra Service Provider

Epileptic patients

In Germany, 500.000 people have been diagnosed with epilepsy, of which 270.000 are in the working age group. The potential prevalence of epilepsy for all ages is 3.4 % of population so potentially 2.8 million people could be affected.

A nationwide study (Pfäfflin, 2000) showed that people with epilepsy were affected the most in the areas of education and occupation. Almost half of those affected in the working age had no or very low occupational related impairments. Patients who were free of seizures at a very early age have the same opportunities in the labour market as healthy people. Nevertheless, the employment rate among people with epilepsy is significantly lower (45%) than in the general population (68%). From the age of 40, this difference increases so that people in the employment range of 50 - 54 year with suffering from epilepsy is only half of the general population.

The telemonitoring service would help people to avoid serious effects of traumas caused by falls and prolonged hospitalisations. It will also reduce the mortality rates from status epilepticus. At the personal level, the services will provide a sense of security, increased self esteem and quality of life. For many, it will lead to a better chance of being employed or staying employed.

The relationship between the patient and the telemonitoring service provider is indirect. The service will be offered to the patient as a subscription service, which carries a co-payment from the health insurance company. The patient is also required to invest in a suitable mobile device. Even though the sensors are reusable, the disposable plasters pose a continuous cost to the patient. The patients and family users are primary stakeholders.

The Germany Epilepsy Association

The German Epilepsy Association (DE - Deutsche Epilepsievereinigung gem. e. V) has the expected willingness to initiate a telemonitoring service for their members, i.e. people with epilepsy. The initiative is based partly on the efforts to minimise impact of status epilepticus and improve the quality of life for people with epilepsy, as well as a tool to implement their strategy against discrimination of people with epilepsy.

The DE has about 1,000 personal members, which is a small fraction of the total number of people with epilepsy in Germany. The annual fee is 56 € but the DE receives substantial contributions from charity and sponsors.

Establishing the telemonitoring service will be a major step in recognising the status of the DE in Germany and contribute to a range of the DE's main objectives, including improve the understanding of epilepsy in the population, provide services to it's members, and improve employment rates of people with epilepsy.

The relationship between the German Epilepsy Association and the telemonitoring service provider in this business case is indirect.

Emergency service organisations

The two largest emergency services in Germany are: The Johanniter-Unfall-Hilfe e.V. (JUH) and the Malteser emergency service (MHD).

The Johanniter-Unfall-Hilfe e.V. (JUH), commonly referred to as "Die Johanniter", is a voluntary humanitarian organisation affiliated with the Brandenburg Bailiwick of the Order of St John, the German Protestant descendant of the Knights Hospitaller. The organisation was founded in 1952 in Hanover. One of the main reasons for its creation was the rise in injuries and deaths from road traffic accidents. The JUH performs the following services related to emergency assistance to individual patients and groups of patients:

- JUH operates about 210 rescue guards, which are equipped with patient carriages, rescue cars or emergency surgeon employment vehicles in Germany.
- JUH cares for children, young people, in the school medical service, people with handicaps and seniors. They operate and/or operated social service buildings, kindergartens, house emergency calls and delivery of "meals on wheels.
- JUH is also engaged in the caring for dementia patients

The Malteser emergency service (MHD) is a catholic relief organisation created of the Order of Malta and the Caritas is 1953. The guiding principle of the organization goes back to the knights of the Knights Hospitaller, an organisation founded in Jerusalem in 1050 as an Amalfitan hospital to provide care for poor and sick pilgrims to the Holy Land. It reads: "Tuitio fidei et obsequium pauperum", or "Defence of the faith and assistance to the poor ".

MHD offers emergency service and social services e.g. handicap driving service, house emergency call, "meals on wheels", as well as different medical service and assistance. It also offers individual and group therapy in various areas, including self-management of diseases.

Event detection and rescue operations are mainstream tasks for JUH and MHD and telemonitoring services could directly plug into their backend alarm handling centres and other infrastructure. Moreover, the services could, in the future, be extended to other types of monitoring of people with chronic conditions.

The business case will be based on the Malteser emergency service (MHD) establishing the service and putting it in use for the subscribers, the customers of the health insurance company and the members of DE. The business case will identify value creation to the different stakeholders and provide a basis for discussion and negotiations. MHD will have direct relationship with the telemonitoring service provider.

Private health insurance companies

The private health insurance companies offer voluntary supplementary healthcare coverage to its clients. They purchase proactively or pay retroactively for health and long-term care services for their members. Patients pay a share of the cost depending on the type of service.

The health insurance companies are funding new healthcare services, mainly from their own funds. When new services are added to the list of eligible fees, the cost benefit of the service is analysed and impact on long term disease trends and effectiveness in disease management is taken into consideration.

They expect that people with epilepsy, who are not members of DE, as well as members, who do not have a supplementary voluntary health insurance or who has a different voluntary health insure may take out an insurance policy with them in order to join the monitoring service. Taking out an insurance that fully covers this service is in the end a lot cheaper for the individual than paying for it out-of-pocket.

Physicians' specialised in epilepsy

Clinical examination and treatment of epilepsy is not routine. Important clinical features of a syndrome include the type of seizures, their localization, frequency, sequence of events, circadian distribution, precipitating factors, age at onset, mode of inheritance, physical or mental symptoms and signs, prognosis, and response to treatment. The co-existence of seizures and other disorders presents a complex landscape of medical study and practice.

Although the family physician is often well aware of the possible forms and treatments of epilepsy, patients are often urged to see a physician specialised in epilepsy; especially after a seizure.

The Hydra Service Provider

The Hydra Service Provider will provide Emergency Service organisations access to the telemonitoring platform. In order to offer the services, the Service Provider will have to make investments in server infrastructure, operating systems, hardware, server facilities, perimeter security and access control systems, etc. Moreover, a large number of medical seizure devices and smart phones are needed for the monitoring.

In addition, the product demands sizable fixed operational costs for support and administrative staff functions, software licences, maintenance and upgrades, etc. Finally the product has a series of variable costs for network communication, power, etc.

However, once the investment is made, the Service Provider is capable of executing several services on the same infrastructure.

11.6 Revenue streams and values

The fundamental question to be answered in the business case is: What do we offer to the customer, who are they and how do we operate to deliver the product or service so that we can create a profitable and sustainable business? In other words, we need to identify and analyse the value proposition in the Hydra based telemonitoring services and analyse the revenue streams and cost models and derive the financial return and thus evaluate the sustainability of the proposed business case.

The analysis is now carried out in the following steps:

- Value modelling
- Revenue modelling
- Process modelling

11.6.1 The value model

In order for the business case to be viable and sustainable, we need to look at the cost-benefit (or profit and loss) implications for all actors. According the discussion in *D10.5 Business modelling concepts*, the proposition needs to provide positive cost-benefit or profitable operations to all actors in order to be sustainable.

The value exchange model used is the following:

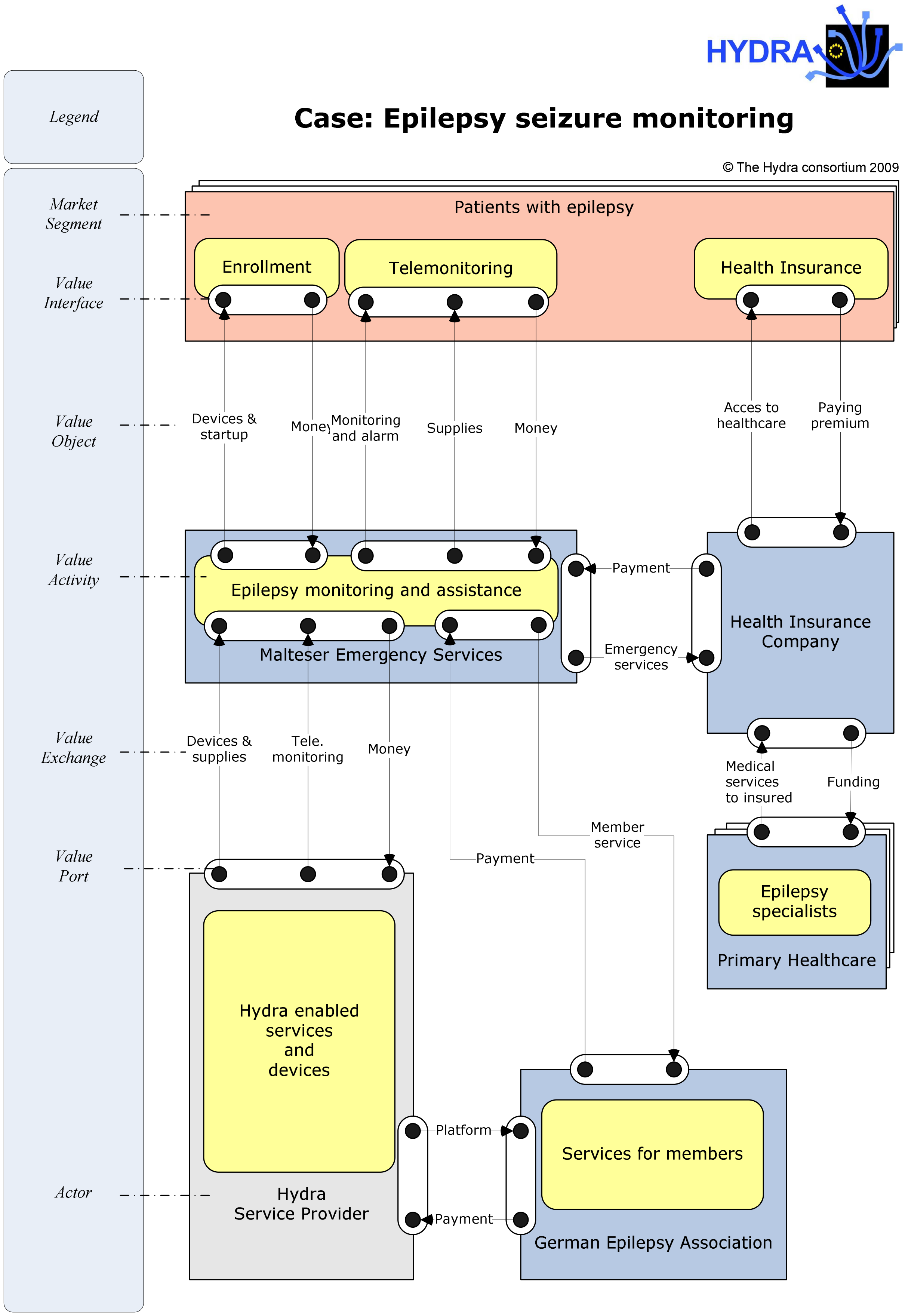

Figure 10 Value model for telemonitoring and seizure detection for epilepsy patients

The financial implications for each actor will be analysed in terms of incremental budgets for two years of operation showing revenues and costs (for the service provider) and costs and benefits (savings) for the healthcare provider(s). Two years are included in the budget to include start-up effects in the calculations.

11.6.2 The revenue model

The company has the intention that the revenue model to be used for the service shall consist of four elements:

1. An initial one-time charge for setting up the specific client domain and customise the services to epilepsy seizure monitoring services as specified by the Emergency Service organisation and the German Epilepsy Association.
2. Hardware investments for the seizure sensor and a smart phone with GPS.
3. A fixed monthly usage license to cover availability, upgrades, software licences and technical support
4. Monthly charges per registered patients and according to transaction volume.

The revenue model must be adjusted to the reimbursement scheme that the Emergency Service organisation will put in place.

The service will initially be launched in cooperation with one Emergency Service organisation only. After 3 years, the service may be extended to other organisations.

The revenue model for the Emergency Service organisation is based on the following components:

1. An initial charge for creating the service.
2. Hardware charges per patient for the seizure sensor and a smart phone with GPS.
3. A fixed annual fee to for the monitoring service
4. A flat fee for each alarm that is registered at the Emergency Service centre.

The German Epilepsy Association (DE) contributes to creating the service by donating the funds for the initial one-time charge for setting up the client domain and customising the services. In addition, DE offers to pay a contribution for each of its members that have enrolled in the service.

In the following we will look at the revenue elements and reimbursements that have been used as the economic foundation for the modelling work.

The patient

There are about 500,000 people in Germany with severe epilepsy. It is estimated that initially, 15,000 of these will be signing up for the new telemonitoring service.

Because of the obvious benefits in security and peace of mind, it is expected that patients are willing to pay for the services. The annual fee is 75€ and there is a one-time registration fee of 10€. However, there is a 100€ cost for each alarm send to the emergency centre. The health insurance companies have included the monitoring in their fee schedules and contribute 25% of these costs. Further, there is a cost of changing the plasters which is estimated to 25€ annually. On the average, the service will cost the patient 267€ annually.

In addition, the patient will have to invest in seizure sensors and a mobile smart phone, which amounts to 460€.

The German Epilepsy Association

The German Epilepsy Association will, as early adopter, donate the platform to persons with epilepsy across Germany. They do so by funding the initial start-up costs of 100,000 € to the Hydra Service Provider. In addition, DE pays a contribution of 2€ for each member enrolled in the service.

Emergency Service organisation

There are several emergency services which ensure public safety by addressing different emergencies. They offer emergency services and social services (e.g. handicap driving service, house emergency call, "meals on wheels", as well as different medical service and assistance. The operate 24/7 emergency service centres where incoming calls are registered and the proper emergency services (ambulance, doctors, nurses, etc.) are dispatched.

As initial Emergency Service organisation in this business case, the Malteser emergency service (MHD) has been selected. The MHD will operate the monitoring service as a commercial subscription service, but an associated healthcare insurance company will co-fund 25% of the fees for monitoring and alarm. The business case as seen from MHD is that the continuous monitoring is practically at no cost to them and should be priced relatively low. But when alarms are registered, the real service of MHD is charged to the customer, because it is really needed.

The prices are 75€ annually for the monitoring and 100€ for each alarm (this price correspond to the cost in Germany of calling the police with a private, commercial alarm system). There is an initial fee of 10€ to start the service plus the cost of the seizure sensors, plasters and the mobile smart phone. The startup costs amounts to 460€ per patient.

Besides from the patients, MHD receives reimbursements directly from the health insurance company. It also receives a small contribution from the German Epilepsy Associations of 2€ for each of its members enrolled in the service.

The monitoring services, devices and supplies are provided by the Hydra Service Provider.

The private health insurance company

The health insurance company reimburses 25% of the cost of monitoring and alarms.

It also funds the regular visits to GP's and 100% of the cost of the physician that is either dispatched to the place of the seizure or, if necessary, where the patient is referred to after the patient has recovered from the seizure.

The epilepsy specialist

In the business case it is assumed that the average person with severe epilepsy needs to see a doctor 6 times per year due to the severe seizures. It is assumed that the number of visits will be reduced due to close monitoring and fast intervention. Consequently, the physician segment will see an overall reduction in reimbursements.

The Hydra Service Provider

Finally, we will analyse the Hydra service provider. The Service Provider will operate a "Platform as a Service" concept, in which the platform is created and the Emergency Service organisation will be offered its own, customised telemonitoring service. The setting up of the platform and customisation of the services will be commissioned and paid for by the German Epilepsy Association.

The calculations for the business case are based on the following revenue model:

1. An initial one-time charge of 100,000€ for setting up the specific client domain and customise the services to epilepsy seizure monitoring services as specified by the Emergency Service organisation and the German Epilepsy Association.
2. Hardware investments for the seizure sensor and a smart phone with GPS.
3. A fixed monthly usage license of 100,000€ to cover availability, upgrades, software licences and technical support
4. A Monthly charge of 5€ per registered patients plus the cost of the transactions.

The base for calculating the prices is shown below.

Cost base of Hydra Service Provider:

Setting up costs:	25.000	€ per site	Access costs:	0,80	€ per user per month
Customisation:	50.000	€ per site	Transaction cost:	0,000	€ per transaction
Software investment:	10.000	€	Devices:	400,00	€ per user
Equipment investment:	100.000	€			
Amortisation:	36	months			
Monthly amortised:	3.056	€			
Monthly operating:	60.000	€			
Fixed yearly cost per contract (@ 1 contracts):			Variable yearly cost per contract (@ 1 contracts):		
Operating costs	60.000	€	Access costs	576.000	€
Amortisations	3.056	€	Transaction costs	0	€
Total fixed costs	63.056	€ / contrac	Total variable costs	576.000	€ per yr per contract

Table 7 Relevant costs for the Hydra Service Provider

Based on the above costs, the revenue model in the business case is established as follows:

The Hydra service provider is expected to make a modest profit on the setting-up and customisation costs, but this profit is not included in the business case.

11.7 The business case

The business case can now be build from the business model. The graphical representation of the e^3value business model is shown in Appendix 6: Graphical representation of business cases.

The business model consists of the following value objects:

- Money
- Telemonitoring
- Devices and supplies
- Healthcare
- Emergency service
- Hydra enabled platform

The actors exchange these 6 value objects in various constellations. Having thus established the value objects and exchanges, we arrive at the following table of transactions between the actors in the business case:

Actor / Market Segment (€)	Value object in	Value in		Value object out	Value out	
Patients						
Emergency Service	Devices and startup			Payment for devices	6.900	k€
Emergency Service	Monitoring & alarm			Payment monitoring & alarm	3.300	k€
Emergency Service	Supplies			Payment for supplies	375	k€
Health Insurance Company	Access to healthcare			Paying premium	330	k€
Emergency Service						
Patients	Payment for devices and st.	6.900	k€	Devices and startup		
Patients	Payment monitoring & alarm	3.300	k€	Monitoring & alarm		
Patients	Payment for supplies	375	k€	Supplies		
Health Insurance Company	Reimbursem. of emergency	825	k€	Providing emergency service		
German Epilepsy Association	Contribution for members	2	k€	Providing monitoring		
Hydra Service provider	Devices and supplies			Payment for devices etc.	6.750	k€
Hydra Service provider	Telemonitoring platform			Payment for monitoring	1.518	k€
Health Insurance Company						
Patients	Payment of premiums	330	k€	Access to healthcare		
Emergency Service	Emergency services			Reimbursement of emergency	825	k€
Epilepsy specialist	Healthcare services			Reimbursement of healthcare	990	k€
Epilepsy specialist						
Health Insurance Company	Reimbursement of healthcare	990	k€	Provide primary healthcare		
German Epilepsy Association						
Hydra Service provider	Monitoring platform			Payment for platform	100	k€
Emergency Service	Monitoring for members			Contribution to services	2	k€
Hydra Service provider						
Emergency Service	Payment for telemonitoring	1.518	k€	Providing telemonitoring serv.		
Emergency Service	Payment for devices/supplies	6.750	k€	Devices and supplies		
German Epilepsy Association	Payment for platform	100	k€	Monitoring platform		

Table 8 Value transactions between different actors, participating in the scenario

The table shows the value objects exchanged by each actor and the economic value assigned to the value objects. For example, we can see that the patient market segment pays a total of 10,575 k€ for the monitoring services and 330 k€ in insurance premiums. The payment for devices and start-up (6,900k€) goes to the Emergency Service organisation, which pays 6,750 k€ to the Hydra Service Provider, and keeps the 150 k€ for the internal work of establishing the services for the 15,000 clients.

In order to analyse the effect of the business case on the different actors, we have performed two instantiations of the business model: One without the telemonitoring service and one with the service. The results were:

Segment / actor (k€)	Revenues	Payments	Expenses	Cashflow
Patients		330		-330
Emergency Service				
Health Insurance Company	330	1.980		-1.650
Epilepsy specialist	1.980			+1.980
German Epilepsy Associatic				
Hydra Service provider				

Table 9 Funding and revenues BEFORE telemonitoring

and:

Segment / actor (k€)	Revenues	Payments	Expenses	Cashflow	Change
Patients		10.905		-10.905	-10.575
Emergency Service	11.402	8.268	2.500	+634	+634
Health Insurance Company	330	1.815		-1.485	+165
Epilepsy specialist	990			+990	-990
German Epilepsy Associatic		102		-102	-102
Hydra Service provider	8.368		8.183	+186	+186

Table 10 Funding and revenues AFTER telemonitoring

It appears from the two tables that the 15,000 patients are funding the new services with a total of 10.6 m€, the health insurance company with 165 k€ and the German Epilepsy Association 102 k€.

The Emergency Service organisation has a net increase in profits of 643 k€ whereas the newly established Hydra Service Provider can book a net profit of 186 k€. The epilepsy specialists are loosing 990 k€ due to a decreasing number of visits.

11.7.1 The process model

Process models are an opportunity to understand the cost-benefit potential of the Hydra based telemonitoring services. The selected approach is the ROI (Return on Investments) model, which is useful to analyse the economic return from investing in the Hydra based telemonitoring service.

We will look at two actors: The Hydra Service provider and the Malteser Emergency Service organisation.

The Hydra Service provider:

Using the figures from the business case, a simplified budget for the first two years can be calculated.

Budget for the Hydra service provider (k€)	Year 1		Year 2	
Revenues:				
Start-up charges	100		0	
Subscriptions	100		100	
Monthly license fees	900		900	
Transaction fees	518		518	
Total revenues		1.618		1.518
Expenses				
Cost of start up	75			
Variable costs	576		576	
Operating costs	720		720	
Total costs		1.371		1.296
EBDIT		247		222
Investments:				
Server infrastructure	100			
Other investments	100			
Software	10			
Total investments		210		0
Cash flow	-210	247	222	222
ROI	104%			

Table 11 Simplified budget for Hydra service provider

The budget shows a nice income and reasonable EBDIT of 247 k€ corresponding to 15% of recurrent earnings. The business case shows a rapid return of investment with 10 months payback and ROI of 104%.

The Malteser Emergency Service organisation:

Using the figures from the business case, a simplified budget for the first two years can be calculated.

Budget for the Emergency Service organisation (k€)	Year 1		Year 2	
Revenues:				
Start-up charges	150		0	
Subscriptions	3.675		3.675	
Monthly license fees	825		825	
Transaction fees	2		2	
Total revenues		4.652		4.502
Expenses				
Cost of start up	150			
Variable costs	1.668		1.668	
Operating costs	2.200		2.200	
Total costs		4.018		3.868
EBDIT		634		634
Total investments				
Cash flow	0	634	634	634

Table 12 Simplified budget for Emergency Service organisation

The budget shows a nice income and reasonable EBDIT of 634€ mainly coming from the alarm emergency services.

11.8 Conclusion

A value based business model has been used to identify value objects and value exchanges between stakeholders in the case of a telemonitoring service, to be offered in Germany, to monitor seizures in people with epilepsy and transmit alarms to emergency services organisations.

The organisation Malteser emergency service (MHD) has been chosen to be the most likely early adopter in German emergency system for a Hydra based telemonitoring service in co-operation with the German Epilepsy Association.

A Hydra Service Provider will provide the telemonitoring platform. The revenue model will be based on a mix of fixed start-up and subscription fees, fees per user and per alarm as well as transaction fees. The revenue model is constructed with a relatively small fixed fee and the majority of the revenues for the service and emergency providers arriving from activity based fees.

Both patients and insurance companies benefit form the services, but in short term monetary terms, the patients and the health insurance company are funding the new services. A small contribution is also coming from the German Epilepsy Association.

Setting up the service platform at the Hydra Service Provider is assumed to cost 100 k€ of including the cost of the Hydra DDK and IDE. The business case shows a rapid return of investment with less than 12 months payback and ROI of 104%.

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13. Figures and Tables

14. Appendix 1: Workshop agenda

Meeting Subject:	Sustainable business models in networked e-health services
Venue:	Siemens AG, Nonnendammallee 101, Berlin, Room number C4085
Date:	8th June 2009

Time	Subject	Topics to be covered	Time (mins)	Lead participant
08:45	**Welcome**	Arrival and coffee Welcome and introductions	15	In-JeT
09:00	**Technologies for innovative healthcare services**	Networking systems and devices – visions and possibilities in the Internet of Things and Services Overview of the Hydra middleware	20	In-JeT
09:20	**HYDRA Vision Scenarios**	Monitoring service scenarios: 1) Multi-parametric monitoring of health parameters in out-patients with chronic diseases 2) Self-management and personalised risk assessment for people at risk 3) Therapy, rehabilitation and exercise monitoring	25	In-JeT
09:45	***Break***			
10:00	**Healthcare provisioning**	Discussion of scenarios for innovative healthcare applications & provisioning of e-health services	60	Moderator Siemens IS
11:00	**Business modelling**	Overview of value based business modelling in dynamic multi-stakeholder domains Discussion of value models in healthcare	60	Moderator Siemens IS
12:00	***Lunch***			
13:00	**HYDRA Business Modelling (1)**	Discussion of business framework, actors and stakeholders, viewports (domain or product view) in healthcare management	90	Moderator In-JeT
14:30	***Break***			
15:00	**HYDRA Business Modelling (2)**	Discussion of value and revenue streams, pricing models and cooperation strategies in healthcare management	90	Moderator Innova
16:30	**Summary**	Summary, conclusions, identified business cases, possible actors and revenues	30	In-JeT
17:00	***Close of day***			

15. Appendix 2: List of participants

Name	Organisation
Experts:	
1. Clemens Busch	Research Assistant Rehabilitation, Schüchtermann Klinik, DE
2. Darko Loncar, Consultant	Consultant, health strategies, DK
3. Dr. Malcolm Clark	Senior Lecturer, University of Brunel, UK
4. Dr. Thomas Meischner	Principal Consultant eHealth, Siemens AG, SIS Healthcare, DE
5. Maher Khoury	Managing Director. HMM Heidelberger-Medical-Marketing. DE
6. Domenico Spinelli	Business consultant, Santer Reply, IT
Hydra consortium:	
7. Andrea Guarise	Innova SpA, Italy
8. Jesper Thestrup	In-JeT ApS, Denmark
9. Gernot Graefe	Siemens IT Solutions and Services, Paderborn, Germany
10. Walter Schneider	University of Paderborn, Germany
11. Florian Roehr	Siemens IT Solutions and Services, Paderborn, Germany

16. Appendix 4: Three healthcare scenarios

SCENARIO 1: Multi-parametric monitoring of vital health parameters in out-patients with co-morbidity
Francois Gontran was diagnosed with diabetes II when he was 58 years old. He has always been overweight, has never exercised and has always smoked and drunk too much alcohol. His job as creative director of an international PR agency is very stressful and demands long working hours. Today, five years after being diagnosed, Francois' lifestyle has changed very little and he is in the high risk group of developing co-morbidities of diabetes II such as hypertension and cardiovascular diseases.

Francois has therefore joined a 24/7 multi-parametric monitoring scheme which uses the latest smart home healthcare devices to provide multi-parametric monitoring of vital health parameters such as blood glucose level, heart rate, blood pressure and cholesterol level. Of the various devices available, Francois has chosen to purchase the smart health watch. The smart watch monitors all his vital health parameters and can possibly save his life, as well prevent hospitalisation through careful monitoring and preventative measures. In addition, the smart watch has a movement sensor that allows for a contextualisation of the data measurements as it makes it possible to correlate blood pressure and heart rate variation with activity patterns or levels. This prevents any unwarranted alarms from going on, plus it secures that the medication notifications that Francois receives are accurate, up to date and context sensitive.

The smart watch's BlueTooth automatically transfers medical data to Francois' Electronic Patient Record. He can also choose to have data sent to his mobile and PDA. His GP, the district nurse, the local diabetes clinic, his cardiologist, the local heart clinic have all been granted full access to his medical data. In addition, Francois' multi-parametric data are constantly sent to a central station capable of monitoring treatment and outcome information based on an intelligent decision support system. The system also generates both flags of management feedback and suggestions to all the healthcare specialists involved in Francois' case, such as. In case of irregularities, his smart watch will sound an alarm according to the level of gravity including instruction of actions to Francois. Alarms are also sent to his mobile and PDA, and of course to the healthcare personnel.

Background information
The International Diabetes Foundation estimates that 48 million people suffer from diabetes in Europe. This makes Europe the region with the highest number of diabetics worldwide and as Europe is ageing, the number is expected to increase.[3]

Diabetes is one of the major causes of morbidity and mortality in Europe and it frequently causes the development of other chronic life-threatening diseases, such as hypertension and cardiovascular diseases. Hypertension and cardiovascular diseases are thus two common co-morbidities of diabetes and WHO estimates that 50% of people with diabetes die of cardiovascular diseases. Other co-morbidities of diabetes include hyperlipidemia, kidney disease, non-alcoholic fatty liver disease and obesity.[4] Another common co-morbidity of diabetes is depression. In fact, depression is estimated to be twice as prevalent among persons with diabetes.[5] A recent study revealed that approximately 44% of patients with diabetes had any additional co-morbidity.[6]

[3] http://www.healthfirsteurope.org/index.php?pid=77http://www.healthfirsteurope.org/index.php?pid=77
[4] http://eurpub.oxfordjournals.org/cgi/content/abstract/13/suppl_1/51; http://diabetes.about.com/od/glossaryofterms/g/comorbid.htm
[5] http://www.chronicdisease.org/i4a/pages/index.cfm?pageid=3519; http://www.biomedcentral.com/1472-6963/6/84
[6] http://www.biomedcentral.com/1472-6963/6/84

Considering the high incidence of different co-morbidities associated with diabetes, it is necessary to design treatment, in particular preventative care and health monitoring, with this in mind. For example, the common coexistence of diabetes and hypertension put diabetic patients at high risk of mortality. The good news is that close control and monitoring of especially blood pressure and blood glucose can reduce complications.

Multi-parametric monitoring of vital health parameters in out-patients with co-morbidity

Monitoring and self-management schemes can greatly reduce the morbidity and mortality of diabetes, especially in cases where patients have developed cases of co-morbidities associated with diabetes such as hypertension. As nearly half of diabetic patients have additional diseases (co-morbidities) and 50% actually die from these co-morbidities, multi-parametric monitoring of this group of patients could potentially save lives. In fact, the control and monitoring of blood pressure is the most important intervention to prevent cardiovascular problems.

Yet it is important to remember that diabetes is not a single disease – it causes congestive heart failure, coronary artery disease, heart attack, kidney failure, stroke, hypertension etc. - and thus calls for constant multi-parametric monitoring of e.g. blood pressure, blood glucose and blood lipids. Recently, there has been increased focus on the need to adopt a multiple treatment method of diabetes, thus incorporating treatment of the co-morbidities of diabetes.[7]

The EU funded project HeartCycle intends to use multi-parametric monitoring and analysis to provide a closed-loop disease management solution to patients with heart failure and chronic heart disease. This group of patients is likely to have co-morbidities such as diabetes, hypertension and arrhythmias.[8]

Some figures:

- Approximate 44% of people with diabetes have co-morbidities
- Approximately 50% of people with diabetes die from these co-morbidities
- People with type 2 diabetes are over twice as likely to have a heart attack or stroke as people who do not have diabetes
- People with type 2 diabetes are as likely to suffer a heart attack as people without diabetes who have already had a heart attack
- Up to 80% of type 2 diabetes is preventable by adopting a healthy diet and increasing physical activity
- Type 2 diabetes has become the most frequent condition in people with kidney failure in countries of the Western world. The reported incidence varies between 30% and 40% in countries such as Germany and the USA[9]
- High blood pressure accounts for approximately 20% of the total mortality burden in Europe
- On a global scale, high blood pressure is the leading cause of morbidity and mortality
- Hypertension among adults aged 35-74 years is estimated to range between 30-60% in Europe
- 80% of 65-74 year olds in Europe show signs of hypertension
- Northern and eastern European countries have higher prevalence of high blood pressure than in southern and western European countries[10]
- Depression is estimated to be twice as prevalent among persons with diabetes.[11]

[7] http://www.ajmc.com/Article.cfm?ID=2510; http://drgreene.mediwire.com/main/Default.aspx?P=Content&ArticleID=129076
[8] http://heartcycle.med.auth.gr/index.php
9 http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A
[10] http://www.euphix.org/object_document/o5134n27415.html
[11] http://www.chronicdisease.org/i4a/pages/index.cfm?pageid=3519

SCENARIO 2: Self-management and personalised risk assessment for people at risk

Monica Schmidt was diagnosed with type-1 diabetes in her late teens. She has just celebrated her 50th birthday and although she's very dedicated to control her diabetes through a healthy lifestyle she has suffered from various complications, particularly over the last 10 years. Some of these complications could have been prevented if her condition had been monitored more efficiently; at times she has simply forgotten to take her medication or she has taken it twice forgetting that she had already taken it

To help her control and properly manage her condition, Monica is now using a wearable continuous glucose monitoring device that monitors her blood glucose levels. If the measured value exceeds a preset level set by her physician, the device sounds an alarm to alert her of the need to take an insulin injection. The dose is automatically derived from the context data and her sensitivity factor. The device keeps a complete record of all her insulin intake which is also automatically uploaded to her mobile phone and her electronic patient record. Her GP and the local diabetes clinic also has full access to the record. Should she ever be unsure of whether she's already taken her insulin a quick glance at the device or her mobile will inform her of when she last had an injection.

Her injections are kept either in her fridge or in the special cooler container for use when she is away from her home. All the injections have a small RFID tag on them. The RFID tag reader in the fridge or inside the lid of the container records when the insulin injection is removed. Provided this is done within 10 minutes of the original alarm, no further action is initiated. However, if it does not happen, a second alarm is triggered on her wearable device and an alarm is sent off to the emergency centre with information of where she is, as identified by the GPS component of the wearable device, and that she has not responded.

Background information
ICT-based tools have massive potential to improve personalised risk assessment and risk management for patients with chronic conditions. ICT can also greatly improve the monitoring of the patient's condition, which is particularly important in relation to chronic conditions such as diabetes and hypertension. Effective and constant monitoring using ICT can prevent serious complications from developing while allowing the patient to stay mobile.

Risk prediction generally means using a systematic and proven method of identifying people who may be likely to deteriorate or suffer an exacerbation of a pre-existing risk. Risk management is essential as it allows practitioners to minimise both the risk itself and the consequences of an adverse event. It can also provide an early-warning system and maximise the probability of a positive outcome.[12]

Personalised risk assessment for patients
Each patient is different, they have different social lives, different needs and face different health risks. Personalised risk assessment for patients leads to more personalised risk management which takes each patient's specific situation under consideration, thus ensuring the best possible personalised treatment plan.

ICT-based personalised risk assessment for patients also ensures that the physician automatically has all the necessary updated facts about the patient. This is particularly important because it improves the doctor-patient relationship; patients want personalised health advice, information and care but recent research has indicated that patients feel that the time pressures on doctors mean they have to rely upon general population stereotypes when providing advice. Patients are therefore increasingly turning to the Internet in the

[12] http://www.nursingtimes.net/developing-a-risk-assessment-tool-to-improve-patient-safety/1833916.article

expectation that it can go beyond these population stereotypes and offer relevant, highly personalised advice concerning health matters.[13]

In the case of hypertension, through risk assessment and stratification, patients at higher risk of complications can be identified, and customized intensive care support can be offered. Other types of intervention for lower risk individuals include brief visits with a cardiovascular educator or care manager, group classes, or self-instructional programs. Automated systems employing clinical decision support at the point of care and internet-based patient support strategies offer the hope that comprehensive, individualized disease management for hypertension can be affordable as well as effective.[14]

[13] http://hii.rsmjournals.com/cgi/reprint/48/1/9.pdf
[14] http://ideas.repec.org/a/wkh/dmhout/v9y2001i11p631-640.html

SCENARIO 3: Therapy, rehabilitation and exercise monitoring

Daniel Ross, 68 years old, suffered a heart attack seven months ago. He is now managing rehabilitation treatment at home which is helping him to slowly returning to his normal daily life, albeit with some serious changes to his lifestyle. He has stopped smoking, and is now trying hard to loose weight by changing his diet and exercising. He is being supported by the national ICT enabled self-management scheme for heart patients which has been fully personalised to his specific needs.

After a brief introduction at the local rehabilitation clinic to the exercise regiment that Daniel needs to follow, Daniel is now confident in carrying out these exercises at home. In order to monitor his progress, he uses ePatches which are connected to the Hydra middleware platform. All data is automatically recorded, monitored and analysed and stored in his electronic patient record (EPR). The system is pre-set to provide Daniel with a weekly update on his mobile which includes feedback on his progress as well as suggestions for improvements. At any time though, he can request a full update and evaluation on his health status. The feedback is very important for Daniel as it makes him feel secure to see a full update on his health status, and it also helps to keep him motivated to stick with the programme. His GP and the rehabilitation team also have full access to this data and if Daniel is not showing sufficient progress the system will automatically notify them to contact him in person to offer support.

Changing his diet and stopping smoking have so far been the biggest challenge for Daniel. He therefore participates in online self-management communities for heart patients. Here he finds support from other heart patients who know what he’s going through and from professional dieticians and counsellors. In addition he has access to the latest medical information, however in lay-man language, about heart problems and rehabilitation strategies. When Daniel registered for this online community, he had to upload his medical data from his EPR to his secure profile for the online community. The purpose of this was to connect him with heart patients with similar health histories but also, more importantly, to allow the system to evaluate his health status with the latest medical information available. In this way, the system is able to provide Daniel with a complete feedback on his health, combining the data from his exercise and diet with latest medical data on heart conditions and thus enable Daniel and his healthcarers to monitor the risk factors efficiently in order to prevent a second heart attack.

Background information

Hypertension is another very common condition in Europe and often occurs as a co-morbidity of diabetes. However, people can have hypertension without having diabetes.[15] The prevalence of hypertension among adults aged 35-74 years is estimated to range from about 30 to 60% in European countries. At age 65-74 years, 50 to 80% of the general population in European and North American countries exhibit hypertension. Generally, there is a north-south and east-west gradient in mean population blood pressure with higher levels in northern and eastern European countries.[16]

Monitoring risk factors, medication therapy and lifestyle interventions are complementary approaches in hypertension treatment. Lifestyle interventions are crucial in primary prevention and may prevent the onset of hypertension. Lifestyle interventions that have proved to effectively lower blood pressure and which may also control diabetes and its other co-morbidities are: weight loss, increased physical exercise, moderation of alcohol consumption, dietary sodium restriction, and other dietary changes such as increased fruit and vegetable intake, less consumption of saturated fat, or increased fish and potassium intake.[17]

[15] http://diabetes.about.com/od/glossaryofterms/g/comorbid.htm
[16] http://www.euphix.org/object_document/o5134n27415.html
[17] http://www.euphix.org/object_document/o5134n27415.html

Therapy, rehabilitation and exercise monitoring
Changing one's lifestyle is no easy task, even if one's health is at risk. For many people with chronic conditions, such as diabetes and hypertension, changing their lifestyle and taking the appropriate medicine at the appropriate time may seem incompatible with their daily life as they know it. ICT can help these people to lead a normal working life, for example distant and automatic monitoring saves time going to the GP, reminders and alarms concerning medicine intake can help the patient to not only remember to take his medicine but also to take the right doses, and online communities for people with chronic conditions can help to motivate patients to comply with the recommended lifestyle changes, such as exercise or dietary guidelines.
"Medicines will not work if you do not take them" — Medicines will not be effective if patients do not follow prescribed treatment, yet in developed countries only 50% of patients who suffer from chronic diseases adhere to treatment recommendations.[18] There are often various reasons as to why patients fail to adhere to the prescribed treatments, whether it involves lifestyle changes, medicines or both. No matter the reason, compliance monitoring supported by ICT can have a very positive effect. Compliance to the prescribed treatment or therapy is crucial because the treatment will simply not work otherwise. In regards to chronic conditions such as diabetes and hypertension, compliance is extremely important because it may effectively prevent any serious consequence of the conditions to develop. It is crucial that the patient is offered appropriate support so that he or she can manage his/her condition the best way possible. For example, studies have shown that the relationship between the patient and the healthcare provider influences the level of adherence and compliance to the treatment prescribed.

Facts & Figures

- Up to 80% of type 2 diabetes is preventable by adopting a healthy diet and increasing physical activity.[19]
- In developed countries only 50% of patients who suffer from chronic diseases adhere to treatment recommendations
- In Europe, only 28% of patients with diabetes achieved good glycaemic control
- The common co-morbidities of diabetes, e.g. hypertension, obesity and depression, are also known to be characterised by poor adherence, thus resulting in further increasing the likelihood of poor treatment outcomes
- Poor adherence has been identifies as the main cause of failure to control hypertension
- Poor adherence to therapy contributes to lack of good blood pressure control in more than two-thirds of people with hypertension
- In many countries less than 25% of patients treated for hypertension achieve optimum blood pressure, for example in the UK only 7% of patients had good control of blood pressure
- One study showed that patients who did not adhere to beta-blocker therapy were 4.5 times more likely to have complications from coronary heart disease[20]
- The prevalence of hypertension among adults aged 35-74 years is estimated to range from about 30 to 60% in European countries
- At age 65-74 years, 50 to 80% of the general population in European and North American countries exhibit hypertension.[21]

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[18] http://www.who.int/chp/knowledge/publications/adherence_report/en/print.html
[19] http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A
[20] http://www.who.int/chp/knowledge/publications/adherence_report/en/print.html
[21] http://www.euphix.org/object_document/o5134n27415.html

17. Appendix 3: Mind maps from the workshop

This appendix provides the mind maps that recorded the discussions during the Hydra workshop with external experts on Sustainable business models in networked e-health services. The workshop was held in Berlin on 8th June 2009.

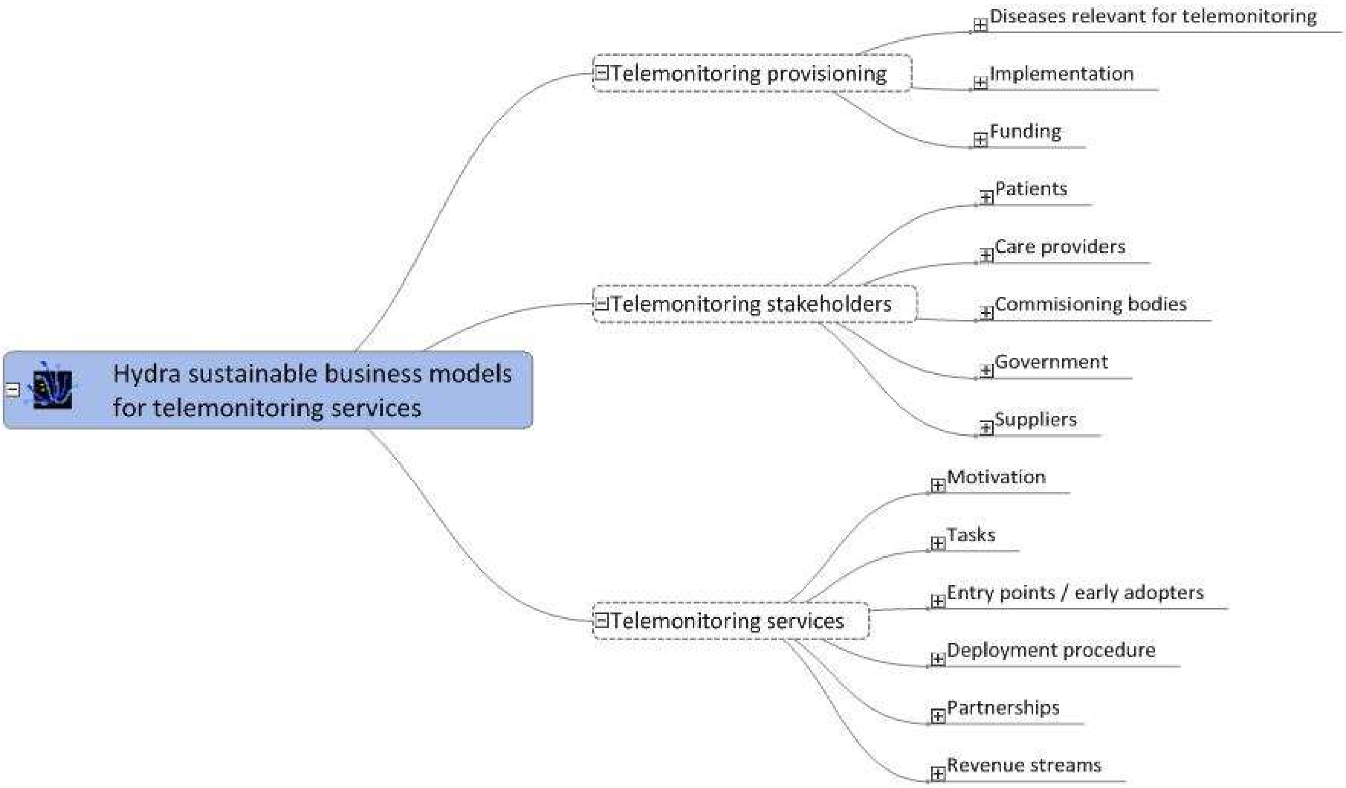


Figure 11 Overview mind map of the workshop discussion

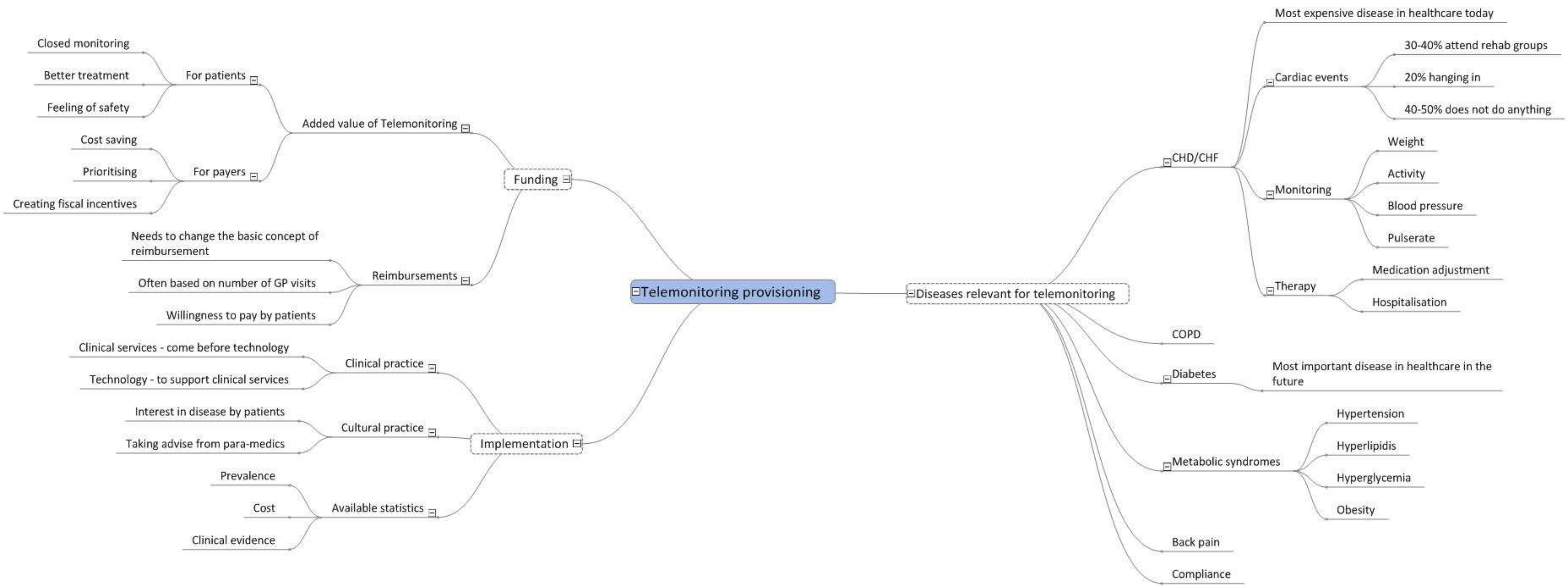


Figure 12 Overview mind map of the provisioning discussion

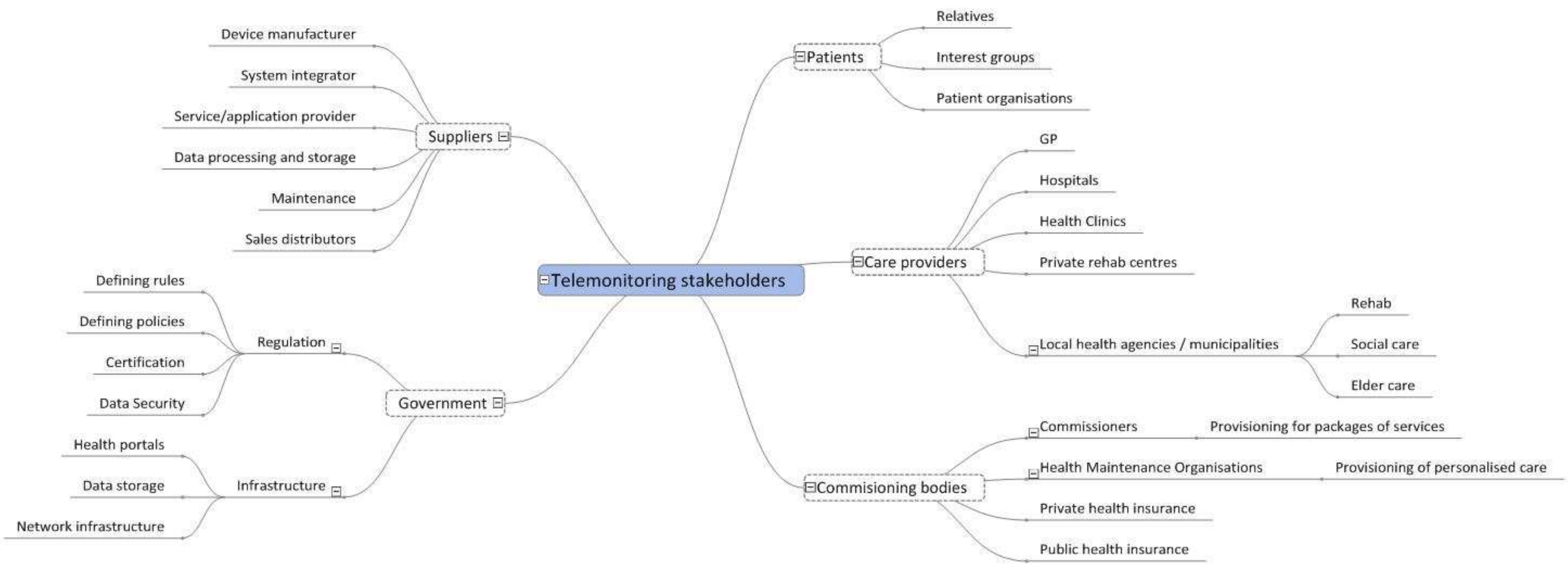


Figure 13 Overview mind map of the stakeholder discussion

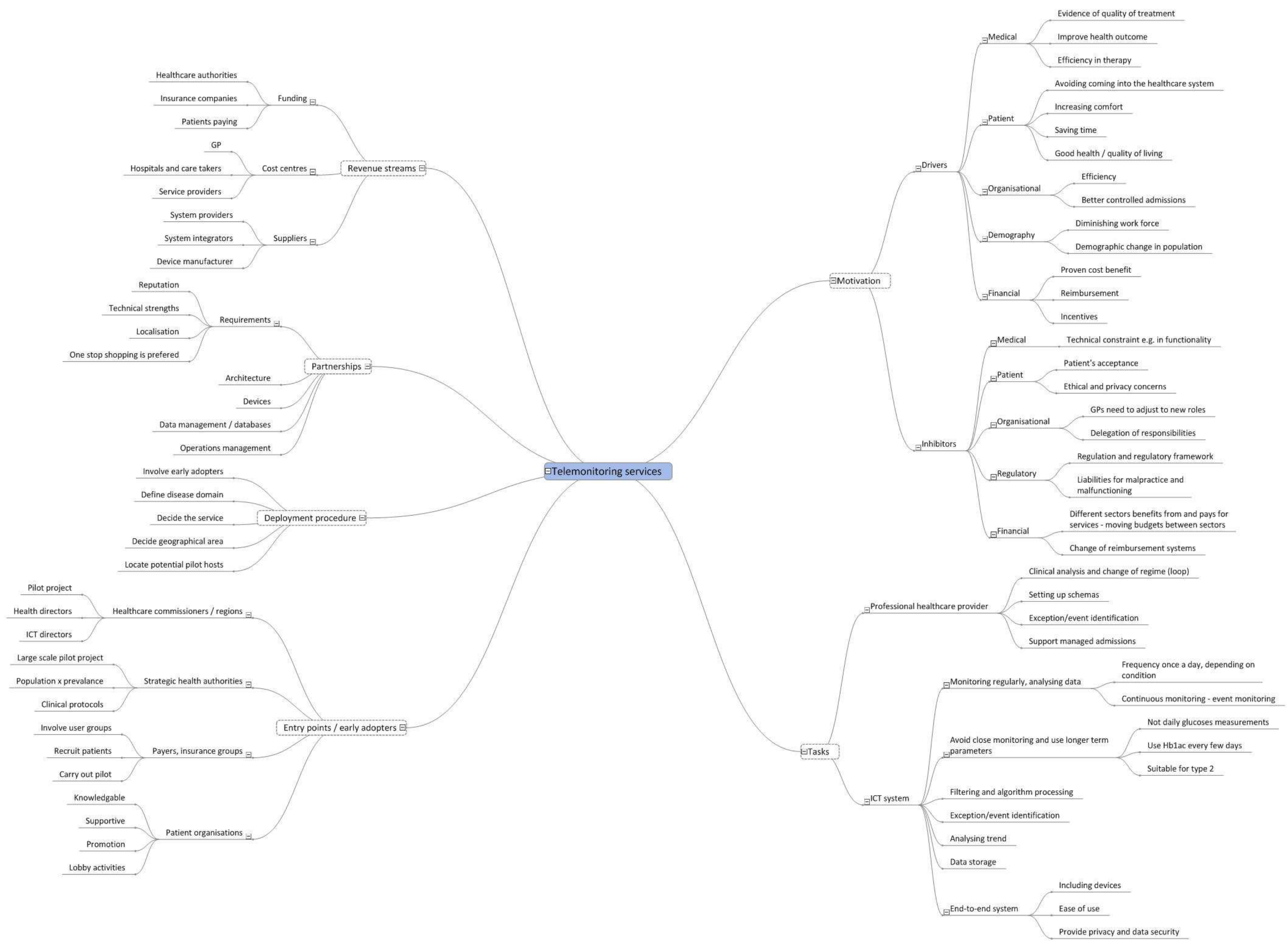


Figure 14 Overview mind map of the service discussion

18. Appendix 5: Relevant eHealth standards

International standards:

Name	Short name	Org.	Description	Category	Comments
Digital Imaging and Communications in Medicine	DICOM	NEMA	DICOM (Digital Imaging and Communications in Medicine) defines the coding of medical images, the protocols of interchange between both sides and a security policy to hide information from third parties.	Imaging	For Computer tomography, image archives, telediagnostic, EEG, ECG. DICOM 3.0 has added waveform support to allow EEG and ECG interchanges. Refer to: www.dclunie.com
MEDICOM	EN 12052	CEN	This standard is the European contribution to the well-known DICOM.	Imaging	For Imaging comms (see DICOM). EN 12052 superseded the former ENV 12052, ENV12623 and ENV12922-1.
Computer-assisted electro-cardiography	ENV 1064	CEN	This standard has been taken up worldwide, not only by European countries	Medical Device Communica tions	SCP-ECG (Standard Communication Protocol Computer Assisted Electro-cardiography)
Interoperability of healthcare multimedia report systems	CR 14300	CEN	Provides interoperability of healthcare multimedia report systems	Knowledge manage-ment	It is not mandatory. It is a recommendation only
HL7 Version 2.5	HL7 v2.XML	ANSI	Old HL7 standards were focused on medical information exchange. With the addition of XML support, multimedia capabilities are now reliable	Messages	Improved support for imaging has been introduced in version 2.5.
Profiles for medical image interchange	CR 12069	CEN	Provides the set of profiles for a given user scenario. Defines greyscale, colour, volumetric and time sequences.	Imaging	CR 12069 is not a mandatory standard, it is a report.
Algorithm for Digital Signature Services in Healthcare	ENV 12388	CEN	Defines the algorithm used for digital signatures in medicine information exchange.	Security	It is required to achieve legal acceptability of the information exchange. SEMRIC: Secure Medical Record Information Communication.
Safety and Security Related Software Quality Standards for Healthcare (SSQS)	UNE-CR 13694	AENOR	Proposes several quality norms related to security and protection in e-Health software.	Security	It associates the system type with the appropriate security measures.

Name	Short name	Org.	Description	Category	Comments
Security for healthcare communication	ENV 13608	CEN	Defines concepts for secure systems, secure data objects and secure data channels.	Security	
Management and security of authentication by passwords	ENV 12251	CEN	It addresses the management and security of authentication by passwords.	Security	Sometimes is mandatory to fulfil legal issues.
Standard Practice for Healthcare Certificate Policy	E2212-02a	ASTM	Addresses the policy for digital certificates that support the authentication, authorization, confidentiality, integrity, and nonrepudiation requirements of persons and organizations that electronically create or transact health information.	Security	There are 3 types of certificate: one for computerized entities, one for individual person and the last one for clinical individuals.
Standard Specification for Healthcare Document Formats	E2184-02	ASTM	Defines requirements for the headings, arrangement, and appearance of sections and subsections when used within healthcare documents.	Standards Method-ology	Use of this specification in conjunction with XML DTDs and the EHR (Electronic Health Records) would further enhance efficiency in time and cost.
Standard Guide for Properties of Electronic Health Records and Record Systems	E1762-95 (2003)	ASTM	The standard defines a document structure for use by electronic signature mechanisms and the characteristics of the electronic signature itself.	Security	
Interoperability of Telehealth Systems and Networks	DTR 16056	ISO	Adresses the interoperability of telehealth systems and networks.	Infra-structure architecture	Part 2 of the standard is related to real-time e-Health systems.
Medical Data Interchange: HIS/RIS-PACS and HIS/RIS	ENV 13939	CEN	Describes the interchange of sanitary data. HIS/RIS-PACS and HIS/RIS.	Medical Device Commun-ications	
Interoperability of patient connected medical devices	ENV 13735	CEN	The standard sets up the basis of interoperability among patient connected devices taking account of VITAL standard to achive device and signal interoperability.	Medical Device Commun-ication	This standard and VITAL standard are designed to work together. Each one specifies a level of interoperability.

Name	Short name	Org.	Description	Category	Comments
Messages for the exchange of information on medicine prescriptions	ENV 13607	CEN	Specifies a message, called prescription dispensing report message, containing information about prescription items that is sent from the dispensing agent to any other party that is legally permitted to receive such message.	Messages	Also available at: http://www.cenorm.be/catweb/35.240.80.htm
Electronic healthcare record communication	ENV 13606	CEN	Proposes a scheme to define a healthcare record in order the information is recognizable and understandable in different applications.	Knowledge manage-ment	It is divided in four parts: Part 1: Extended architecture, Part 2: Domain term list, Part 3: Distribution rules, Part 4: Messages for the exchange of information
Healthcare Information System Architecture (HISA)	ENV 12967	CEN	Describes the Healthcare Information System Architecture (HISA), which is a description of the middleware layer used in healthcare.	Infra-structure architecture	It is described with diagrams.
Messages for the exchange of healthcare administrative information	ENV 12612	CEN	Specifies messages for the exchange of healthcare administrative information to provide safe, efficient and effective healthcare delivery within hospitals and in primary care.	Messages	The messages do not cover the reimbursement nor the admission, discharge and transfer processes themselves, but make such processes much easier because of the overall availability of registration and identification data. More Info at: http://www.ramit.be/
Registration of information objects used for EDI in healthcare	ENV 12537	CEN	Defines the registration of information objects used for EDI in healthcare for the purpose of information interchange related to healthcare.	Termin-ology	It has two parts: Part 1: The Register, Part 2: Procedures for the registration of information objects used for electronic data interchange (EDI) in healthcare
Healthcare Information Framework (HIF)	ENV 12443	CEN	Creates a basic framework to guide healthcare informatics developers. It is a first step in standardising the architectures that will support the latest approaches to the delivery of computer systems such as are required to provide the global information.	Infra-structure architecture	

Name	Short name	Org.	Description	Category	Comments
Identification, administrative, and common clinical data structure for ICDs	ENV 12018	CEN	This standard proposes a standardised framework for data structures used with respect to Intermittently Connected Devices (ICDs).	Infra-structure architecture	An ICD is a device that stores and transmits person related data in such a fashion that the originator of the information may not receive confirmation of receipt by the recipient. Overview info available at: http://www.ramit.be/scripts/imiawg16/1standard
Medical Informatics Vocabulary (MIVoc)	ENV 12017	CEN	Defines the Medical Informatics Vocabulary, which is a foundation for the development of a vocabulary of terms used in Medical Informatics.	Termin-ology	
Messages for exchange of laboratory information	ENV 1613	CEN	Provides a complete implementable specification of the laboratory messages by implementation guidelines to supplement the message definitions. It also provides comprehensive data and structured tables.	Messages	These coding schemes are commonly used to provide precise and unambiguous representation of the data
Point-of-care medical device communication	IEEE 1073.5.x	IEEE	Efforts are underway to add standards for enabling internetworking of medical devices across a LAN/WAN.	Medical Device Commun-ication	It is not a standard, it is a series of standards that will be published soon. More info available at: http://www.ieee1073.org/standards/standards-at-a-glance/standardsataglance.html
Point-of-care medical device communication – Application profile – Optional package, remote control	ISO 11073-20301	ISO	Describes an optional application profile optional packages for remote control.	Medical Device Commun-ication	Some functions are similar or complement the European standard ENV13735.
Point-of-care medical device communication – Application Profiles – MIB Elements	IEEE 1073.2.1.2	IEEE	MIB Element definitions from the revised DIM standard	Medical Device Commun-ication	More information at: http://www.ieee1073.org/standards/standards-at-a-glance/standardsataglance.html

Name	Short name	Org.	Description	Category	Comments
Medical Device Communications – Transport Profile – IrDA Based – Cable Connected	IEEE 1073.3.2	IEEE	Describes the IrDA-based, RS-232, cable connected transport between devices connectivity. It also set up the basis for firmware upgrades for medical devices.	Medical Device Commun-ication	This new transport profile offers a key advantage in fostering implementation and adoption of the IEEE 1073 Medical Information Bus Standards. More info at: http://www.ieee1073.org/standards/11073-30200/11073-30200.html
Categorical structures of systems of concepts - Model for representation of semantics	ENV 12264	CEN	The standard provides the vocabulary and the guide-lines to describe the categorial structure of a concept system: the structure consists in practice of a list of involved categories with reference to the available authoritative sources for detailed values.	Termin-ology	Medical Informatics deals with a great number of large, overlapping coding systems that are facing each other and conflicting in the coming Integrated Healthcare Information Environment. This standard tries to solve these conflicts.
Time Standards for Healthcare Specific Problems	ENV 12381	CEN	Provides a set of basic entities, with precisely defined properties and interrelationships among them, that is sufficient to allow an unambiguous representation of time-related expressions.	Termin-ology	
Messages for Patient Referral and Discharge	ENV 12538	CEN	It refers to referral and discharge but also covers the request for specialist services and the reports by the specialist service provider, including clinic letters and discharge summaries.	Messages	Graphical or image information that forms part of a request for or report of a specialist healthcare service is excluded.
Request and Report Messages for Diagnostic Services Departments	ENV 12539	CEN	It provides the description of the scope of the messages and its functionality and implementation guidelines for different scenarios.	Messages	The scope is limited to character-based messages, but includes: X-rays, CAT, NMR, ultrasound scans, ECGs, lung-function tests, anatomic pathology and nuclear medicine
Standard guide for description of reservation/ registration-admission, discharge, transfer systems for Electronic Health Record (EHR) systems	E1239-00	ASTM	This guide identifies the minimum information capabilities needed by an ambulatory care system or a resident facility R-ADT system.	Electronic Health Record	

Name	Short name	Org.	Description	Category	Comments
Standard guide for content and structure of the Electronic Health Record (EHR)	E1384-02a	ASTM	This guide covers all types of healthcare services, including those given in acute care hospitals, nursing homes, skilled nursing facilities, home healthcare, and specialty care environments as well as ambulatory care.	Electronic Health Record	They apply both to short term contacts (for example, emergency rooms and emergency medical service units) and long term contacts (primary care physicians with long term patients).
Standard guide for view of emergency medical care in the computerized-based patient record	E1744-98	ASTM	It addresses the identification of the information that is necessary to document emergency medical care in a computerized patient record that is part of a paperless patient record system.	Electronic Health Record	
An object-oriented model for registration, admitting, discharge, and transfer functions in computer-based patient record systems	E1715-01	ASTM	Details the objects that make up the reservation, registration, admitting, discharge, and transfer functional domain of the computer-based record of care.	Electronic Health Record	It is intended to amplify guide E1239 with an object-oriented focus.
Specification for management of the confidentiality and security of dictation, transcription, and transcribed health records	E1902-02	ASTM	It describes certain steps that shall be taken by those involved in the processes of dictation and transcription of healthcare documentation.	Security	It also seeks to identify certain dictation and transcription practices that may increase the risks of infringing on privacy and violating security of healthcare documentation.
Standard specification for clinical XML DTDs in healthcare	E2185-02	ASTM	This guide provides a compendium of information for the use of E2183 XML DTDs within healthcare. This guide describes design considerations, the architecture of the DTDs, and implementing systems using the E2183 DTDs.	Standards Method-ology	
Standard guide on security framework for healthcare information	E2085-00a	ASTM	Describes a framework for the protection of healthcare information. It addresses both storage and transmission of information.	Security	It makes use of well-known security algorithms such as SHA-1, triple-DES and others.

Name	Short name	Org.	Description	Category	Comments
Standard guide for information access privileges to health information	E1986-98	ASTM	This guide covers the process of granting and maintaining access privileges to health information. It directly addresses the maintenance of confidentiality of personal, provider, and organizational data in the healthcare domain.	Security	
Standard guide for individual rights regarding health information	E1987-98	ASTM	This guide outlines the rights of individuals, both patients and providers, regarding health information and recommends procedures for the exercise of those rights.	Knowledge manage-ment and Security	This guide is intended to amplify Guide E1869.
Standard Specification for Authentication of Healthcare Information Using Digital Signatures	E2084-00	ASTM	This specification covers the use of digital signatures to provide authentication of healthcare information, as described in Guide E 1762. It describes how the components of a digital signature system meet the requirements specified in Guide E 1762.	Security	This includes specification of allowable signature and hash algorithms, management of public and private keys, and specific formats for keys, certificates, and signed healthcare documents.
Interoperability and compatibility in messaging and communication standards -- Key characteristics	ISO/TR 18307	ISO	Describes a set of key characteristics to achieve interoperability and compatibility in trusted health information interchange between communicant application systems.	Messages	The key characteristics describe inter-application interoperability needs of the healthcare community, in particular the subject of care, the healthcare professional/ caregiver, the healthcare provider organization, its business units and the integrated data
Clinical Context Object Workgroup Version 1.5	CCOW V1.5	HL7	CCOW V1.0 defined the overall technology-neutral context management architecture (CMA), a core set of data definitions, rules for application user interfaces, and the translation of the CMA to Microsoft's COM/ActiveX technology.	User Interfaces/ web services	This version also support technology mapping to SOAP.

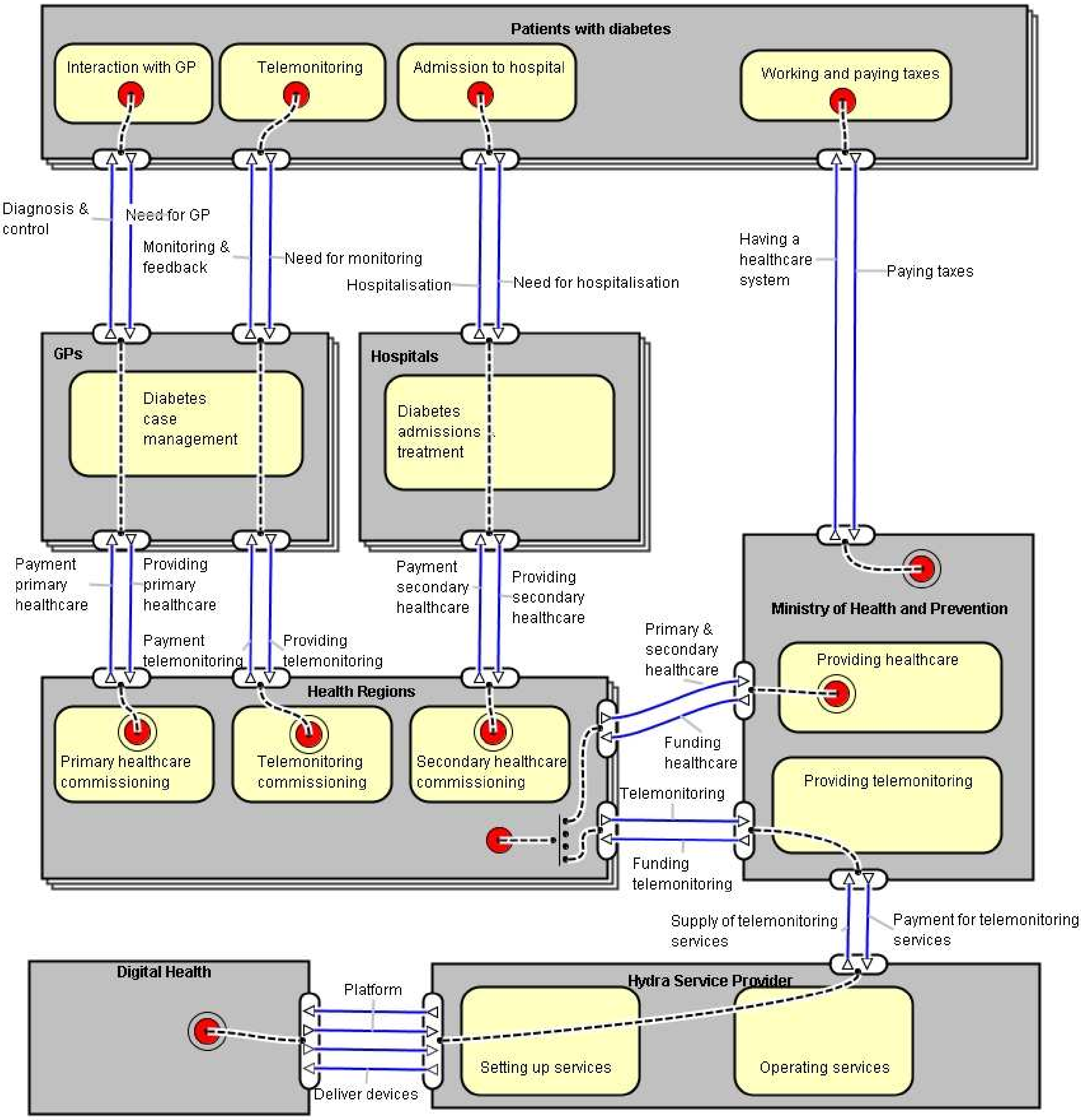
Name	Short name	Org.	Description	Category	Comments
Clinical analyser interfaces to laboratory information systems	ISO 18812	ISO	Specifies general messages for electronic information exchange between analytical instruments and laboratory information systems within a clinical laboratory.	Messages and Medical Device Commun-ication	Covers the specification of messages used by communicating parties and the syntax in which they are communicated. It does not cover the transport mechanisms used for the message interchange.
Standard guide for identification and establish-ment of a quality assurance program for medical transcription	E2117-00	ASTM	It establishes a quality assurance program for dictation, medical transcription, and related processes. Quality assurance is necessary to ensure the accuracy of healthcare documentation.	Standards Method-ology	This guide establishes essential and desirable elements for quality healthcare documentation, but it is not purported to be an exhaustive list.

ISO Projects in Healthcare ICT :

ISO Project reference	Title
ISO/DIS 11073-90101	Health informatics -- Point-of-care medical device communication -- Part 90101: Analytical instruments -- Point of care test
ISO/CD TS 11073-90201	Health informatics -- Medical waveform format -- Part 90201: Encoding rules
ISO/DIS 13606-1	Health informatics -- Electronic health record communication -- Part 1: Reference model
ISO/DIS 17090-1	Health informatics -- Public key infrastructure -- Part 1: Overview of digital certificate services
ISO/DIS 17090-2	Health informatics -- Public key infrastructure -- Part 2: Certificate profile
ISO/DIS 17090-3	Health informatics -- Public key infrastructure -- Part 3: Policy management of certification authority
ISO/DIS 17113.2	Health informatics -- Exchange of information between healthcare information systems -- Method for development of messages
ISO/FDIS 17115	Health informatics -- Vocabulary for terminological systems
ISO/NP TS 17117	Health informatics -- Controlled health terminology -- Structure and high-level indicators
ISO/CD TS 21298	Health informatics -- Functional and structural roles
ISO/DIS 21549-5	Health informatics -- Patient healthcard data -- Part 5: Identification data
ISO/DIS 21549-6	Health informatics -- Patient healthcard data -- Part 6: Administrative data
ISO/FDIS 21549-7	Health informatics -- Patient healthcard data -- Part 7: Medication data
ISO/TR 21730	Health informatics -- Use of mobile wireless communication and computing technology in healthcare facilities
ISO/CD TS 22220	Health Informatics -- Identification of subjects of healthcare
ISO/NP TS 22600-3	Health informatics -- Privilege management and access control -- Part 3: Implementations
ISO/CD TS 22789	Conceptual framework for patient findings and problems in terminologies
ISO/NP TR 22790	Functional characteristics of prescriber support systems
ISO/NP TS 25237	Health informatics -- Pseudonymisation
ISO/PRF TS 25238	Health informatics -- Classification of safety risks from health software
ISO/CD 25720	Genomic sequence variation markup language
ISO/NP TS 27527	Health Informatics -- Provider Identification
ISO/DIS 27799	Health informatics -- Security management in health using ISO/IEC 17799
ISO/HL7 NP 27931	Health Informatics -- HL7 Messaging Standard Version 2.5 -- An application protocol for electronic data exchange in healthcare
ISO/HL7 NP 27932	Health Informatics -- Clinical document architecture, release 2
ISO/HL7 NP 27951	Health informatics -- Common terminology services, release 1

19. Appendix 6: Graphical representation of business cases

19.1 Case 1: Diabetes monitoring & self-management



19.2 Case 2: Epilepsy seizure monitoring