

# Cross-border telemedicine

Opportunities and barriers from an economic  
and legal perspective

Erasmus University  
Institute of Health Policy and Management  
Master Health Economics Policy and Law

Katinka Lops  
Student number: 282858  
November 2008  
Supervisor: mr. dr. H.E.G.M. Hermans  
Co-evaluators: Prof. dr. W.B.F. Brouwer, dr. A.P. Den Exter

## **Preface**

Na een druk jaar waarin ik mijn werk bij de Nederlandse Zorgautoriteit heb gecombineerd met het schrijven van een scriptie, is dit het resultaat geworden. Deze scriptie gaat over een ontwikkeling in de gezondheidszorg, namelijk het toenemende gebruik van ICT bij het leveren van zorg. Ik heb me verdiept in mogelijkheden en barrières voor grensoverschrijdende telemedicine, een interessant onderwerp met beleidsmatige, economische en juridisch aspecten van de gezondheidszorg aspecten.

Ik wil graag van deze gelegenheid gebruik maken om een aantal personen te bedanken. Allereerst wil ik de heer Hermans bedanken voor de adviezen en de prettige begeleiding. Verder wil ik de heer Den Exter en de heer Brouwer bedanken voor hun rol als meelezer.

Mijn speciale dank gaat uit naar Vincent voor zijn steun, geduld en kritische blik. Tot slot wil ik mijn ouders en vrienden bedanken voor de nodige afleiding en steun.

24 October 2008

Katinka Lops

## **Abstract**

Health care systems in the EU are facing different challenges in the coming decades, such as an increasing demand for health care due to an ageing population and an increase in persons with (multiple) chronic diseases. Telemedicine can be a solution for these challenges. The definition of telemedicine is health care delivered to the individual patient and consultations between health care providers for the purpose of the patients' treatment with the use of ICT solutions. A distinction between doctor to doctor (D2D) and doctor to patient (D2P) telemedicine is made.

This thesis analyses barriers and opportunities in cross-border telemedicine from an economic and legal perspective. The right to health care is a central theme in linking these perspectives. The health care system in the Netherlands is the topic in the economic perspective and the cross-border provision of services, data protection and privacy and liability are the topics of the legal perspective.

The health care system provides incentives for financing of telemedicine. The Dutch health care system is based on the regulated competition where access to health care and efficient allocation of resources is balanced. Opportunities within the health care system are competition, available subsidies for innovation and increasing demand for telemedicine services. Barriers are the hybrid financing system and no long term financing solutions.

The legal framework of cross-border telemedicine consists of international law, EU law and national law. Three parts of the legal framework are examined further: the cross-border provision of services, data protection and privacy and liability. The conclusion is that investigated parts of the legal framework do not provide considerable barriers to cross-border telemedicine. However, some legal uncertainty exists on the application of EU legislation in practice, in particular on data protection and liability.

In conclusion, the economic perspective contains more barriers to the development of cross-border telemedicine than the legal perspective. Subsidies and long term financing are solutions to existing barriers to telemedicine. Moreover, evidence on the cost effectiveness is needed in order to make decisions on the wide use of telemedicine services.

## Table of contents

<b>1. Introduction .....</b>	<b>4</b>
1.1 Cross-border telemedicine	4
1.2 Legal and economic issues	5
1.3 Objective and research question	5
1.4 Structure of the thesis	5
<b>2 Telemedicine .....</b>	<b>7</b>
2.1 Definition of telemedicine	7
2.2 Relations between the definitions of eHealth, telemedicine and telecare	8
2.3 D2D and D2P telemedicine	9
2.4 Cross-border telemedicine	10
2.5 Possibilities and risks	11
2.6 Conclusion	11
<b>3. Recent developments and initiatives .....</b>	<b>12</b>
3.1 EU policy on eHealth and telemedicine	12
3.1 Examples of cross-border telemedicine	12
3.2 Telemedicine initiatives in the Netherlands	13
3.4 Conclusion	14
<b>4. Economic possibilities en barriers for telemedicine services .....</b>	<b>15</b>
4.1 The Dutch health care system in general	15
4.2 Incentives within the hospital financing system	16
4.2 Incentives for telemedicine in the health insurance system	17
4.3 Methods of financing and subsidies	17
4.4 Demand for telemedicine	19
4.5 Conclusion	20
<b>5. Legal Framework: barriers .....</b>	<b>21</b>
5.1 Sources of law	21
5.2 The right to health care and community competence	22
5.3 Relevant legal topics	22
5.4 Conclusion	24
<b>6. Cross-border provision of services .....</b>	<b>25</b>
6.1 Legal sources and developments in EU law	25
6.2 Proposed directive on cross-border health care	25
6.3 Right to cross-border health care	26
6.4 Prior authorisation	27
6.5 Barriers for Cross-border telemedicine	28
6.5 Conclusion	28
<b>7. Data protection and privacy .....</b>	<b>29</b>
7.1 Legal sources and developments	29
7.2 Data collection and the electronic medical record	30
7.3 Processing of medical data	30
7.4 Data protection and telemedicine	31
7.5 Conclusion	31
<b>8. Liability .....</b>	<b>32</b>
8.1 Legal sources and developments	32
8.2 Damage caused by the telemedicine product or service	33
8.3 Damage caused by the professional	33
8.4 Conclusion	34
<b>9. Conclusion.....</b>	<b>35</b>
<b>10. Discussion .....</b>	<b>37</b>

**11. Bibliography ..... 39**

**1. Introduction**

Major health system challenges are awaiting Europe in the coming decade. The demand for health care is rising as result of an ageing population and an increase in persons with (multiple) chronic diseases. These developments will also lead to a lack of skilled health care professionals. Furthermore, an increasing mobility of patients and health care providers within a better functioning internal market is another challenge for Europe (EC 2004). As laid down in various legal documents member states have to guarantee minimum standards and provisions of health care to their citizens given the socio-economic conditions of that state (Den Exter 2002). However, the demand for health care almost always exceeds the supply and the challenges generate more demand and less supply. This is why choices in health care have to be made to guarantee the right to health care and more efficient and less expensive ways to deliver health care have to be found.

**1.1 Cross-border telemedicine**

Telemedicine can be a part of the solution for the challenges awaiting health care systems in the near future. It has the potential to make the provision of health care more flexible and efficient while the distance between health care provider and the patient becomes smaller. Telemedicine is a concept with various definitions, generally explained as the delivery of health care at a distance with the use of information and communication technologies (Stanberry 2006). Telemedicine is a different way of delivering health care. Health care is delivered outside the common medical setting, for instance if a patient uses the internet to contact health care providers or during monitoring chronically ill patients at home. This development fits in the ongoing shift of health care delivery from traditional settings to settings closer to the patients' home. Telemedicine is also used by health care professionals to consult colleagues or to outsource diagnostics. Other examples of telemedicine are teleconsultations, teleradiology, telemonitoring and diagnosis, treatment and prescription of pharmaceuticals through the internet (ETHEL 2008).

There are used two terms to define health care with the use of ICT, telemedicine and eHealth. The definitions are different because eHealth refers to all applications of ICT for health. eHealth also contains the supply of medical information through websites and the development of the medical health record. Furthermore, telemedicine has some advantages over the common way of delivering health care. Telemedicine is more efficient as travelling time is reduced and it creates access to high specialized health care (in remote areas). Risks of telemedicine are a compromised relation between the patient and the health care provider and the safety of medical data (Geertsema et al 2007).

Telemedicine makes borders disappear and becomes cross-border if the patient or the health care provider using and the health care provider delivering telemedicine services are residing in different countries. The term 'cross-border' is limited in this thesis to the European Union (EU), because of the developments on the internal market for health care and the EU policy on eHealth and telemedicine services. As a result of the internal market and fundamental freedoms suppliers of telemedicine can offer their services across the European Union (EU).

## **1.2 Legal and economic issues**

In order to let health care providers delivering cross-border telemedicine services, the incentives in the market should stimulate these developments within the health care system and the provision of long term financing solutions. Some issues are related to the financing system as telemedicine services are more expensive to start than regular health care services, but expected to be less expensive on the long run. The legal framework applicable to health care needs to support the delivery of telemedicine services. Most parts of the recent legal framework existed before telemedicine had been developed and is therefore not designed for it. However, the legislation should follow or precede the developments in health care to tackle possible barriers that may arise (Callens 2007). Although cross-border telemedicine shares some of the issues of the common way of delivering health care, the electronic delivery asks for a different approach of the legislator than the common way of delivering care taking into consideration the provisions of the member states to guarantee access to health care services. First of all, the internal market of the European Union should be open to telemedicine providers to deliver their services. Second, privacy related issues are different in the processing of electronic health data. Information and communication technology (ICT) makes it easier for third parties to gain access to personal health data (Sokalska 2004). Identifiable health data needs to be protected against abuse in order to provide unrestricted access to health care (Buijsen 2002). Last, liability for medical errors is also different as more providers are involved. It must be clear for the patient who can be charged in case of medical errors or other unwanted consequences of the treatment or consult with the health care professional.

## **1.3 Objective and research question**

The aim of this thesis is to investigate the barriers and opportunities for cross-border telemedicine from an economic and legal perspective. The European legal framework is examined to assess whether it is adapted to cross-border telemedicine and what the legal and economic barriers of cross-border telemedicine are. The focus is on data protection, the liability of providers of telemedicine services and the cross-border provision of telemedicine in the Netherlands. These subtopics were chosen because they affect access to health services as interpretation of the right to health care (Den Exter 2002) and results of recent research showing problems are arising at those areas (EHMA 2007d, ETHEL 2008). The Netherlands were chosen for the recent health system change from supply regulated system to a system of regulated competition. This should offer more potential for telemedicine. This leads to the following research question:

What are the legal and economic opportunities and barriers of cross-border telemedicine in the Netherlands?

## **1.4 Structure of the thesis**

In the second chapter the definition of telemedicine is explained. The developments in the field of telemedicine with regard policy of the EU and the Netherlands are explained and illustrated with examples of telemedicine in practice in Chapter 3. Before telemedicine services are delivered, the health care system has to support and stimulate this development. In Chapter 4 is examined if the Dutch health care system provides opportunities for telemedicine or that barriers play a more

important role. In Chapter 5 the European legal framework for telemedicine is set out and an overview of legal opportunities and barriers is made. Three of the topics on which barriers exist are explained more extensively: the cross-border provision of services, data protection and privacy, and medical and professional liability.

## **2 Telemedicine**

Telemedicine does not have one clear definition. The terms eHealth and telemedicine are intertwined and no consistent definition is used by institutions and in the literature (EC 1993, Stanberry 2006, WHO in Geertsema et al 2007, ETHEL 2008). This chapter describes the definition of telemedicine used in this thesis and the relation between eHealth and telemedicine.

First different definitions of telemedicine will be compared. The relation between telemedicine, eHealth and telecare is described. Furthermore, a division will be made into two subgroups, the health care provider to health care provider telemedicine ('D2D' Doctor to doctor) and the health care provider to patient telemedicine ('D2P' Doctor to patient). Last, the general possibilities and risks associated with providing telemedicine services are explored.

### **2.1 Definition of telemedicine**

There is no universal definition of telemedicine. Literally telemedicine means 'far medicine', coming from the Greek word 'tele' meaning 'far'. In order to understand the term 'telemedicine' various definitions should be compared.

'Telemedicine is the rapid access to shared and remote medical expertise by means of telecommunications and information technologies, no matter where the patient or the relevant information is located.' (EC 1993)

'Telemedicine is the practice of medical care using interactive audiovisual and data communications. This includes the delivery of medical care, diagnosis, consultation, and treatment, as well as health education and transfer of medical data.' (WHO in Geertsema et al 2007)

'The use of telecommunication technology to assist in the delivery of health care' (Aas 2007)

'Telemedicine services provide means to improve accessibility to high quality health care in case of shortage of appropriate health care providers or the necessary medical expertise or skills at the site of the patient. Telemedicine thus covers a broad spectrum of services such as teleconsultation, second opinion, telehomecare and teletraining and build on technologies such as video-conferencing supported by the exchange of medical images and medical records as well as remote monitoring. Communication infrastructure include ordinary telephone land-lines, internet connections of various speeds and in many instances also satellite links to enable health care in remote and isolated areas.' (ETHEL 2008)

'Telemedicine is the practice of medical care using interactive audio visual and data



communications. This includes the delivery of medical care, diagnosis, consultation and treatment, as well as health education and the transfer of medical data' (Geertsema et al 2007).

When the various definitions of telemedicine are compared, a common theme is distinguished, 'the delivery of health care at a distance'. This thesis uses this definition of telemedicine including consultations between health care professionals for the diagnostics or treatment of the patient. Examples of telemedicine within the used definition are consultations, diagnosis and treatment at a distance.

## **2.2 Relations between the definitions of eHealth, telemedicine and telecare**

The definition of telemedicine in this thesis is limited to health care delivery as shown in the preceding paragraph. The definition of eHealth is broader, of which telemedicine is a part. The European Commissions uses the following definition: 'eHealth refers to the use of modern information and communication technologies to meet the needs of citizens, patients, health care professionals, health care providers as well as policymakers.' (EC 2003) In Aas (2007) the eHealth is defined as 'all applications of ICT in health care'. Another difference is that telemedicine is about the delivery of health care to the individual patient. eHealth can also comprise services which are not related to the individual patient. The consultation between health care professionals for the treatment of a patient is telemedicine, but contact between health care professionals for learning is eHealth. Examples of eHealth products and services, which are not covered in the definition of telemedicine, are professional learning, health related websites for patients and health care professionals (e.g. discussion forums for patients), an electronic health record, etc. Telemedicine services and eHealth products and services cannot be seen apart from each other. eHealth provides conditions for telemedicine services (Malmqvist et al 2004), for instance, without an electronic medical record (EMR) telemedicine cannot function very well, as medical data of the patient is needed and the transfer over distance of electronic information is easier than the transfer of paper reports (hard copies).

The definition of telecare is a part of the definition of telemedicine. Telecare is the monitoring of patients in order to manage risks associated with independent living, such as chronically ill patients with heart failure, elderly patients, etc (Geertsema et al 2007). The figure below is a representation of the relations between the definitions of eHealth, telemedicine and telecare.

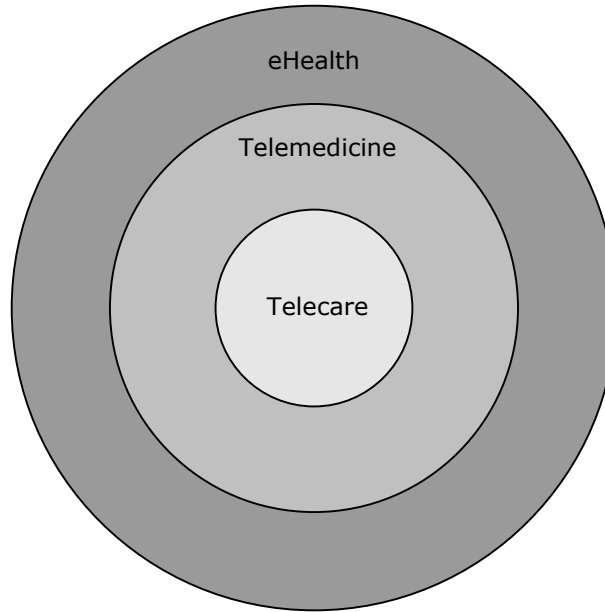


Figure 1: Definitions of eHealth, telemedicine and telecare

### 2.3 D2D and D2P telemedicine

Two types of telemedicine are distinguished, the telemedicine services between health care professionals ('doctor to doctor' D2D) and the telemedicine services between health care professionals and patients ('doctor to patient' D2P) (ETHEL 2008). 'Telemedicine is essentially doctor-to-doctor, with the patient somewhere in the system, and typically involves consultations with specialists at a distance' (Geertsema et al 2007). D2D telemedicine can be useful in creating access in rural areas with small hospitals without all specializations available. Examples of D2D telemedicine are teleconsultations, teleradiology and telepathology. Teleconsultations are mostly used to discuss results of diagnostic tests. Another use of teleconsultations is treatment advice. Specialized fields for teleconsultations are among others dermatology, ophthalmology, surgery and cardiology. Second, teleradiology is the transmission of X-ray images and material generated with other imaging methods and their evaluation (ETHEL 2008). In contrast to teleconsultation the emphasis of teleradiology is the evaluation of (the quality of) the image or diagnosis through images. It has been the most rapidly adopted form of telemedicine services, since use of digital images has increased rapidly. Third, telepathology is the examination of tissues and cells for a rapid historical diagnosis. This can take place during an operation in which a pathologist at a distance is controlling a microscope to examine the tissue or as a second opinion (ETHEL 2008).

D2P telemedicine services are offered directly to patients. This is the second generation of telemedicine services and the development is mostly driven by the scarcity of resources and the patients demand (ETHEL 2008). The main objective of D2P telemedicine is empowering patients, increasing the ability for patients to live independently and disease management and prevention. The following examples of D2P telemedicine are discussed: telemonitoring, emergency care and the care of mobile patients, and patient consultations and internet based online services. Telemonitoring facilitates patients with a deteriorating disease or disability to stay at a familiar

home environment or nursing home. This definition overlaps with the definition of telecare with the difference that telecare is aiming at independent living of elderly and patients and telemonitoring is aiming at the monitoring of the disease or disability. The patients are monitored on a distance by (specialized) health care professionals. Emergency care and the care for mobile patients is the second variant of D2P telemedicine. It is used for health care on distant locations, hospitals with no advanced emergency centre or ill persons on board of ships or airplanes. The physician has contact with the patient directly and a health care professional at the site is assisting the physician. The last type of D2P telemedicine are the patient consultations and the internet based online services. Examples of this type are for instance counselling in mental health care, online prescription of pharmaceuticals, second opinions and online health advice (EHTEL 2008). To make this list complete eHealth services has also a patient to patient (P2P) variant, for example health discussion forums or communities on the internet (NPCF 2008). In figure 2 are the definitions for eHealth, telemedicine and telecare divided into D2D, D2P and P2P. The outer circle of the figure refers other forms of telemedicine which are not D2P or D2D, for example P2P eHealth or the development electronic health record.

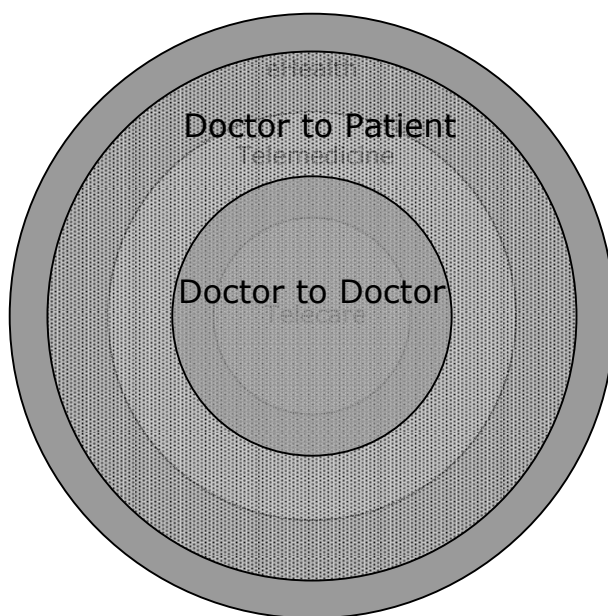


Figure 2: The definitions of doctor to patient and doctor to doctor telemedicine

#### **2.4 Cross-border telemedicine**

Cross-border telemedicine is a telemedicine service with a health care provider or patient involved not residing in the same member state. Reasons for cross-border health care are for instance: the patient falls ill during a stay or visit in another member state; waiting lists in the member state of residence causing medical problems; patients using facilities in border regions; or because of the availability of high specialized health care in another member state of the European Union (Bertinato 2005). Cross-border health care does not account for large expenditures compared to expenditures on health care in the home member state. Only a very small part of the health expenditures in the EU is spent on these services (Bertinato 2005).

Cross-border telemedicine, however, is not common in the EU. Cross-border telemedicine originates from a certain need, such as the distance between cooperating health care providers being too large, shortage of qualified health care professionals or specialized health care needed in remote areas.

Cross-border telemedicine compared to telemedicine within the border of a member state also requires various technical aspects, for instance the interoperability of telemedicine application in the member state concerned. Standardization of telemedicine applications is key in this situation (Geertsema et al 2007).

### **2.5 Possibilities and risks**

Telemedicine has much of potential now and in the future. The most important advantage of telemedicine is bridging distance. Telemedicine services lead to improved access to health services and makes possible the provision of care not deliverable before. Emergency health care or specialized health care can be provided in rural areas and places that are difficult to access. Second, telemedicine reduces travel time for patients as well as health care providers. These advantages enhance the more efficient health care delivery and therefore more delivery of health care.

Risks for telemedicine are the safety of data transfer, interoperability between different telemedicine applications and organization of the delivery of health care. First of all, the use of information and communication technologies contributes to the risks concerning the security of telemedicine services. Errors in data transmission due to signal fading can lead to false diagnosis or inadequate treatment. In cross-border telemedicine language barriers can also lead to problems due to miscommunication. Furthermore, the transfer of medical data through the internet brings along most of the risks. Telemedicine services using internet connections are vulnerable to hackers, however adequate and up to date security of connections can reduce risks. Telemedicine results in a compromised relationship between the health care professional and the patient and among health care professionals (Geertsema et al 2007). Last, Aas (2007) says about the organizational challenges: 'Telemedicine means having a virtual organization'. The health care professionals have to adjust to the new way of working. The implementation of telemedicine in organizations like hospitals and the challenges faces is a different topic not discussed here, but certainly needs attention.

### **2.6 Conclusion**

This chapter describes the definition of telemedicine that is used in this thesis, the health care delivered to the individual patient and consultations between health care provider for the purpose of diagnostics or treatment. This definition can be divided into D2D and D2P telemedicine. The most important advantage of telemedicine is bridging distances and reducing travel time. Most of the risks refer to technology developments and have to be taken into account, when developing a telemedicine service. Other risks concern the organization and its culture, which should not be underestimated.

### **3. Recent developments and initiatives**

eHealth has become the third largest industry in the health sector of the European Union. The growth of the eHealth industry is a result of development in the ICT sector and the increased attention to eHealth and telemedicine by the EU and the individual member states. Challenges in the health care sector and the changes in the population will cause this sector to grow further (EC 2004). This chapter focuses on the development on the field of cross-border telemedicine in the EU.

This chapter provides the context for the coming chapters where the opportunities and barriers for cross-border telemedicine are investigated. First of all, EU policy is examined, as policy can stimulate the development of cross-border telemedicine services. Some examples of cross-border telemedicine initiatives in the EU are described. In addition some initiatives on telemedicine in the Netherlands are discussed.

#### **3.1 EU policy on eHealth and telemedicine**

The European Commission launched an action plan on eHealth called 'Action plan of a European eHealth Area' in 2004. The goal of the European Commission is to create an eHealth area with free patient mobility and empowerment of citizens (and health care professionals) by means of eHealth services. The focus of the action plan is among others on health authorities leadership, interoperability of health information systems (e.g. the electronic medical record), mobility of patients and health professionals, enhancing infrastructure and technology, and legal and regulatory issues. These points of interest of the commission are set out in a roadmap that extends till 2010 (EC 2004). In addition to this roadmap member states have been encouraged to develop a national or regional roadmap for eHealth (EC 2004).

The Northern countries of Europe have already adopted eHealth policies in the second half of the 1990's. Other countries in Europe started with the development of eHealth policy later. The focus of the member states is mainly on electronic health record and a national infrastructure system. Interoperability and standards and the legal framework have also priority, but they are seen as supporting initiatives by the EU member states. Telemedicine services are not yet included in all national roadmaps, although some member states have prioritised ePrescriptions (ERA 2007). Member states have presumably other priorities, other than telemedicine services.

#### **3.1 Examples of cross-border telemedicine**

Some relatively small cross-border telemedicine initiatives were launched within the borders of the European Union. These initiatives often originate from practical needs, for instance maintaining access to health care in case of a shortage of qualified staff or the large distance between hospitals in remote areas and more equipped hospitals in urban areas. The most member states active are the Northern countries (like the United Kingdom, Sweden and Denmark).

The National Health Service (NHS) of United Kingdom uses cross-border teleradiology to preserve the patient's access to radiology. The initiative for teleradiology in the UK comes from a

commercial party anticipating on the shortage of radiologists. The NHS has subcontracted this initiative for CT scans and X-rays as a (temporary) solution for the shortage of radiologists. A truck with equipment for x-rays and CT-scans drives between hospitals and makes scans there. The digital images taken with the diagnostic device in the truck are sent to radiologists in Belgium. The scans or X-rays are judged two times by different radiologists to prevent errors. Both radiologists write a report and when the two judgements correspond, the report is sent to the physician in the United Kingdom who ordered the scan (EURAD 2007).

In Sweden is (cross-border) teleradiology seen as a standard procedure. The initiative in Sweden is almost similar to the UK initiative. The difference is that scans are sent to a clinic in Spain, who sends the data to radiologists in fourteen other countries in and outside the EU (Olsson 2007).

### **3.2 Telemedicine initiatives in the Netherlands**

In the Netherlands a number of local telemedicine initiatives are set up. However, most of these Dutch initiatives are aimed at the national health care market and the cross-border initiatives are not yet developed.

Two best practice D2P initiatives of telemedicine in the Netherlands are Viedome and Diamuraal. These initiatives focus on improving quality of care by promoting self management of patients and patient empowerment. Viedome is a programme for elderly to live at home on their own. This is a programme for not only for health care but it also focuses on the well-being of elderly people. Viedome places a screen with camera in the patient's home, so patients can communicate with health care professionals, family and personnel for household work (Viedome 2008). Diamuraal is telemonitoring for patients with diabetes. Patients can keep a journal in the electronic medical record with information about the fluctuations of their glucose values. They can also communicate with health care professionals (Diamuraal 2008). Furthermore, other local initiatives exist on the monitoring of patients with COPD and chronic heart failure (ETHEL 2008).

Another example of a D2D telemedicine initiative in the Netherlands is teledermatology. A company specialized in teledermatology offers general practitioners the means (e.g. a digital camera and software) to photograph a patients skin problem and send it to a medical specialist. The specialist judges the picture and sends his opinion with a treatment advice to the general practitioner. This service reduces 50-70% of the patient referrals to dermatologists (Ksyos 2008). The company who offers the teledermatology service had problems with financing of the health care in the existing Dutch health care system. A temporarily solution has been found for the financing of teledermatology as this initiative improves the affordability of health care by subsidy of health care from the hospital to the primary care (NZa 2007).

Last, the ICT company Cisco is planning to introduce telemedicine services for diagnostics into the Dutch health care system early 2009. An assistant carries out the diagnostic tests and a physician watches the procedure at a distance and is able to ask questions or give instructions directly to the assistant. This telemedicine service is aimed at hospital services rather and organizes health care processes more efficient which should improve the affordability of health care (AD 2008).

### **3.4 Conclusion**

The EU pays policy attention to eHealth and telemedicine. Some member states have already implemented telemedicine initiatives as result of limited access to health care in thinly populated areas. In particular the Northern member states were early adopters of (cross-border) telemedicine in Europe. The Netherlands have not started cross-border telemedicine services yet. The focus of the ministry of Health Welfare and Sports is on the development of the infrastructure and the electronic health record. Some local and small scaled initiatives in telemedicine exist. These initiatives are the result of cost and quality considerations.

#### **4. Economic possibilities en barriers for telemedicine services**

The EU member states have different health care systems as result of limited community action on the field of health care. The health care systems of the EU can be generally divided into Bismarck-model<sup>1</sup>, National Health Insurance and National Health Services (Beveridge or Somashko-model), but most health care systems are mixes of these models (Folland, Goodman and Stano 2006). Although differences in health care systems exist, every member state faces the same challenges to their system, increasing expenditure on health care as part of the gross domestic product (GDP). Health care systems should balance between equity and efficiency, access health care to everyone and the efficient allocation of health care resources (Enthoven 1988). The design of the health care system provides incentives for patients, insurers and health care providers.

In this thesis the Dutch health care system is chosen as an example to investigate the opportunities and barriers (also called incentives in economics) for telemedicine as recently regulated competition has been introduced which can provide incentives for innovations like telemedicine. The incentives shall be explored on three different topics. First, the Dutch health care system will be described in general. Second, the possibilities within the hospital financing system are discussed. Third, temporary solutions like subsidies for the financing of innovations including telemedicine. The incentives on the health care purchasers market for telemedicine shall be described next. Finally, the demand for telemedicine services from patients or insured persons will be discussed.

##### **4.1 The Dutch health care system in general**

The Dutch health care system has changed to a system of regulated competition with the pillars equity and efficiency in 2006. This system is based on the system of managed competition as described by Enthoven (1988): 'A carefully designed and managed system of universal health insurance based on cost-conscious consumer choice and price competition among alternative health care financing and delivery plans.' Equity is attained by a mandatory health insurance with open enrolment, a basic benefits package and risk-equalization fund while efficiency is attained by competition between health care providers and health insurers and countervailing power of health insurers. Three different markets can be defined in the system for curative health care: the health insurance market, the health care delivery market and the health care purchasers market. Competition should take place on the health insurance market where health insurers compete with each other on the premium and the content of the (supplementary) insurance and on the health care purchasers market, where health care providers should compete on price and quality in order to enter into a contract with a health insurer.

---

<sup>1</sup> Traditional sickness insurance with a private insurance market approach with a state subsidy (Folland, Goodman, Stano 2004)



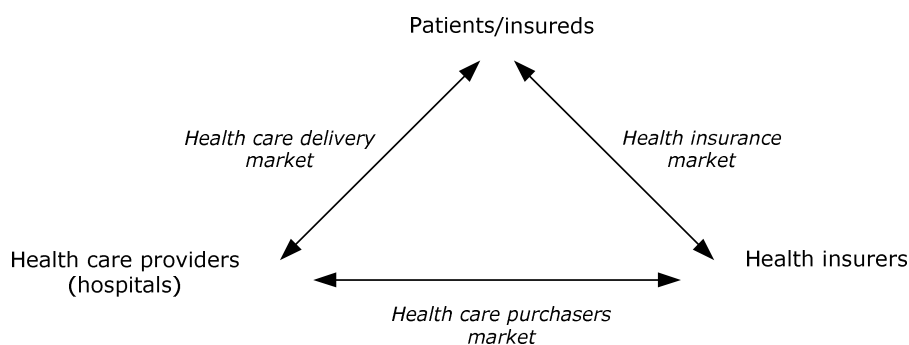


Figure 3: the three markets in the Dutch health care system (Lapr  2001)

A mandatory health insurance executed by private health insurers, basic benefits package, voluntary supplementary insurance and selective contracting are the main features of the insurance system health care based on the Health Insurance Act (*Zorgverzekeringswet*). The health insurance covers primary care, hospital care and since the year 2007 some parts of short term mental health care. There is a separate market for long term health care in which telemedicine applications could be very useful. This market is out of the scope of this thesis, because fewer incentives are present in the market compared to the market for curative health care (Schut 2004). More specific, this thesis focuses on the market for hospital care because the changes in the financing structure make this market more interesting.

#### 4.2 Incentives within the hospital financing system

The introduction of regulated competition involves the introduction product financing as replacement of fee-for-service and budget financing. Product financing increases efficiency in health care as the relation between costs and revenue is restored (Berg 2008). The first use of product financing in health care in the Netherlands are the DBCs (diagnosis treatment combination)<sup>2</sup>. DBCs are an example of product financing in health care, because one price is determined for the diagnosis and the treatment. DBCs are used to finance hospital care. Competition is allowed on 20% of the hospital market (B-segment). In 2009 the B-segment will be extended to 34%. Health insurers can negotiate with hospitals on the volume and the price of DBCs for this part of the health care.

The other part of the hospital care is financed by a budget and has fixed or maximum prices per DBC (A-segment), the health insurers negotiates only on the volume. For the prices of the part of hospital care that is not negotiable (A-segment) the Dutch Health Care Authority (NZA) determines maximum tariffs. These tariffs are equal for every Dutch hospital. When fixed or maximum tariffs are determined, there is less room to provide more expensive forms of health care. Efficient and less expensive delivery of health care services is rewarding in most cases. However, the A-segment is managed by a budget system and more efficient health care delivery leads to fewer budgets in the next year (Lapr  2001).

---

<sup>2</sup> DBCs can be compared with Diagnosis Related Groups (DRGs). The difference is that DBCs are developed from the diagnosis combined with the treatment. At the moment around 30,000 DBCs exist.

Product financing will give more opportunities for new initiatives like telemedicine, as hospitals are free to choose in the way they deliver the health care. However, telemedicine services have often higher equipment costs compared to normal health care services and therefore a higher cost price (EHTEL 2008). In general prospective payment methods of financing like DRGs and DBCs tend to a lower profitability of new technologies and slow down the diffusion of new cost increasing technologies when the prospective payment is low (Folland, Goodman and Stano 2006). The initiator should be able to recoup his investment, which results in higher costs and the price of the DBC has to cover those costs to make it profitable for the initiator to invest in telemedicine. For DBCs with free tariffs, like in the B-segment, health insurers and health care providers can negotiate the price. The question is: are health insurers (and their insured) prepared to pay for it?

#### **4.2 Incentives for telemedicine in the health insurance system**

Health insurers play an important role in the health care system, as they have countervailing power representing their pool of insureds on the health care purchasers market (figure 3). The insurers can affect the price and quality of health care taking in consideration the needs and wishes of their insured. In the first year of regulated competition health insurers mainly negotiated the price of health care as information about quality of care is limited. However, there is more attention for quality of care in negotiations recently. The quality agreements that are made during the negotiations are non-binding (NZa 2008a).

The Dutch health care system has a compulsory health insurance. The content of the basic benefits package is determined by the minister of health and the same for every insured person regardless of his health insurer. A way to get more sustainable financing of telemedicine services is to include it in the basic benefits package. Telemedicine services are not yet included in the basic benefits package, which makes financing and reimbursement of these services difficult. The keeper of the basic benefits package, the Board for Health Insurance (CVZ) advises the minister of health every year on the content of basic benefits package. The advice of the CVZ is based on four principles: necessity, effectiveness, cost-effectiveness and feasibility (CVZ 2007).

In order to advise on the broad application of telemedicine services and whether to support the telemedicine services that turned out to be more expensive than the conventional alternatives CVZ needs cost-effective analyses. Whitten et al (2002) has examined 612 cost effectiveness analyses on quality of the study. The conclusion drawn was that the quality of the available cost-effectiveness analysis studies is insufficient to base reliable decisions on. This is confirmed by Hailey (2005); the way the cost-effectiveness analyses were performed and reported weakens the conclusions. There are no long term macro-economic or health impact studies available on telemedicine services. Based on results of the cost-effective analyses decision makers can make a founded decision whether to stimulate or restrict the application of telemedicine.

#### **4.3 Methods of financing and subsidies**

ICT in health care can contribute at the health care system goals on the macro level as it makes the delivery of health care more efficient by fast data transfer, reduction of administration costs

and the reduction of travelling time (ETHEL 2008). Nevertheless, investments in ICT in the health care sectors in European countries lag behind compared to other sectors (Aho 2006). This slows down the developments of telemedicine services. Subsidies can provide an (temporary) incentive to start telemedicine services. Different subsidies are available for innovation in health care in the Netherlands (CVZ 2007) of which the important subsidies are listed in table 1.

<b>Subsidies and funding</b>
<u>European level</u>
- Seventh framework program
<u>National level</u>
- Health care market regulation act (Wet marktordening gezondheidszorg) <ul style="list-style-type: none"> <li>o Innovation directive (Beleidsregel innovatie ten behoeve van nieuwe zorgprestaties)</li> <li>o Innovation DBC</li> <li>o Local production component</li> </ul>
- Subsidy for health care services that intended to become part of the basic benefits package
- Fund for academic centres (Fonds Academische Component)
- Private funding
- External investments

Table 1: subsidies and funding for innovation in the EU and in the Netherlands

The seventh framework programme of the European Union entails activities to restructure the delivering of health care delivery systems in Europe. There are four specific programmes: cooperation, ideas, people and capacity and a fifth programme on nuclear research. Health is one of the ten themes of the cooperation programme, where emphasis is on eHealth and telemedicine services. The European Commission has provided an amount of 53 billion Euros for the seventh framework programme for the period 2007 to 2013. This programme is intended to stimulate innovation and technology in several fields, among which the health sector (EU 2007).

Second, article 58 of the Health care market regulation Act (Wmg) provides the Dutch health care authority with the means to allow experiments with innovative health care for five years and defines conditions for experiments. This is not a subsidy, but an opportunity for health care providers to declare the costs of innovative health care at the patients' health insurer. The Innovation directive of the Dutch Health Care Authority is based on this article. The directive provides parties with a declaration title for an experiment with an innovative health care product for the maximum of three years. This experiment must be conducted in a health care programme aimed at a specific group of patients. One of the conditions for declaration is an agreement between a health care insurer and a health care provider. The innovation directive has not resulted in cross-border telemedicine projects (NZa 2008), but has resulted in a telemedicine experiment. It is an experiment with a decision making system for G.P.'s to diagnose mental health problems in an early stage so the patient gets the right care more quickly.

Another financing possibility within the Wmg is the innovation DBC and the Local Production Component (LPC). The innovation DBC is intended to stimulate medical technical innovations which are nationally applicable. The procedure for an innovation DBC is extensive and evidence effectiveness of the treatment is required. The innovation DBC is not intended for scientific and experimental medical treatment. As a result of difficult and extensive procedures only one innovation DBC exist at this moment (CVZ 2007). The Local production component (LPC) is a part of the budget of general and academic hospitals and can be used to finance process-innovation, interventions without budget parameter and extramural health care (CVZ 2007).

The other subsidies or funding for innovation within the health care system are temporary access to the basic benefits package and the Fund for academic centres. The minister of health can provide a temporary subsidy to health care services that are intended to become part of the basic benefits package soon. The Fund for academic centres (Fonds Academische Component) has 580 million Euros available for the academic centres for development, innovation and education. A part of the amount is available for 'innovation and development'. Academic centres decide together on the priorities (CVZ 2007).

Last, private funding and external investments can account for the start up costs for innovations. Foundations like the Dutch Cancer Foundation and the Dutch Heart Disease Fund (Nederlandse Hartstichting) have funds available for innovation. However, the priorities are set by these foundations (CVZ 2007). Investments by external parties like manufacturers of telemedicine systems can provide the equipment for telemedicine or can finance the necessary research for access to the basic benefits package. Reasons for the external parties to invest in innovations are for example to increase their market share.

External investments and subsidies can be a solution for the high investments for telemedicine services. However, these solutions have disadvantages, as temporary sources of financing are provided and therefore cannot guarantee continuation of the project afterwards. A lot of projects do not continue after the pilot period, as a result of a lack of permanent financing (Aas 2007). External sources of financing are hard to find, but demonstrating a return on investment will help to find more permanent financing which is essential for the sustainability of telemedicine, such as access to the basic benefits package (Heinzelmann 2005).

#### **4.4 Demand for telemedicine**

Demand for health services comes from the patient and the health insurers representing their insured. As a result of the ageing of the population the number of persons with chronic illnesses or multiple chronic illnesses will rise. The demand for health care will therefore increase.

The Dutch patient organisation (NPCF) supports developments in telemedicine and eHealth, but is concerned about the ethical aspects of eHealth and equal opportunities for patient to use eHealth. The NPCF thinks that eHealth has added value for the patient in terms of quality of care, access to health care and patient empowerment (NPCF 2007, 2008). In a vision about telemedicine the

NPCF wants to strengthen the demand side for telemedicine by showing the possibilities in order to create demand when the services are actually offered.

An example is the demand for an e-consult with a general practitioner. Verheij (2008) studied the demand for e-consults with a GP in the Netherlands. This e-consult is becoming more popular with general practitioners, 9.3% is offering this service. However, 75% of the patients are asking for an electronic consult with his general practitioner. The general practitioners are reserved towards offering e-consults, because the time they are investing in answering questions is the same compared to normal consult, but rewarded with half the tariff of a normal consult. The main reason that they are offering an e-consult is to meet the wishes of the patient (Verheij 2008). Furthermore, only general practitioners and psychologist are able to declare an e-consult within the Wmg, but they have to address some conditions. For example, the e-consult has to be a replacement for the normal consult and the general practitioner has to know the patient. For general practitioners a maximum tariff exists and psychologists have no determined tariff (NZa 2008b).

#### 4.5 Conclusion

Regulated competition and product financing create opportunities for telemedicine services in the Dutch health care system. Hospitals are confronted with a hybrid hospital financing system which generates different and possibly incentives. Economic barriers for the development of telemedicine services exist on different levels in the Dutch health care system. Most of the barriers relate to insufficient sources of financing, especially long term financing is a problem as incentives to regain the investments are not sufficient. The table below provides an overview of the economic barriers and opportunities for telemedicine in the Dutch health care system.

<b>Economic opportunities and barriers</b>
<p><u>Opportunities</u></p> <ul style="list-style-type: none"> <li>- Regulated competition</li> <li>- Increase of the B-segment</li> <li>- Subsidies available for innovation</li> <li>- Health system challenges increase demand for health care</li> <li>- Demand for e-consults by patients</li> </ul> <p><u>Barriers</u></p> <ul style="list-style-type: none"> <li>- Hybrid system of hospital financing (A- and B-segment)</li> <li>- No cost effectiveness analysis studies of good quality on telemedicine</li> <li>- No long term financing solutions</li> </ul>

Table 2: Economic opportunities and barriers for telemedicine services.

## **5. Legal Framework: barriers**

The market for health care is an imperfect market with market failure such as information asymmetry. Health care systems have to manage the trade-off between equity and efficiency (Cutler 2002). A free market will not consider these values as market failure exists, therefore regulation is necessary to protect these values. The legal framework has an important function to achieve a less imperfect market and to protect equity and efficiency in the health care system.

The legal framework can stimulate or restrict the development of telemedicine services. 'Whether telemedicine will be successful in the future will partly depend on the creation of a transparent legal framework' (Callens 2002). Besides 'legal certainty is a pre-requisite for businesses to invest in innovation and for buyers and users to take up new products and services for which they know in advance who has legal responsibility for each aspect of an application.' (EC 2007)

In this chapter the sources of law from general legal framework of the EU are described, with a focus on the right to health care. Furthermore, barriers to telemedicine are identified based on literature and experiences. The relevance for telemedicine is explained per subtopic.

### **5.1 Sources of law**

The general legal framework is composed of different sources of law: international law, European law, national law and jurisprudence. First, international law regulates the relations between states and between states and persons. There are two types of international law: 'hard law' and 'soft law'. Soft law is non-binding, but may provide an interpretative reference point for 'hard law', of which declarations and resolutions are examples (Hervey 2004). Other examples of non-binding law are the laws which have not been ratified yet. International law in particular is used to lay down human rights. The most important sources for human rights are the Universal Declaration of Human Rights, International Covenant on Economic, Social and Cultural Right, the European Convention of Human Rights and Fundamental Freedoms (ECHR) and the Charter of Fundamental Rights and Freedoms. The second source is European law, the law of the European Union. The European Union is a treaty organisation with its pillars established in the Treaty of Rome of 1957 and the Treaty of Maastricht in 1992. The creation of the internal market is one of the goals of the EU with pillars as the promotion of trade and free competition. In order to achieve an internal market the EU has laid down the freedom of persons, goods, services and capital within the EU. These fundamental freedoms are laid down in article 49 of the EC Treaty.

National law is the third part of the legal framework. The Dutch law consists of the constitution, civil code, penal code and various other laws. Article 94 of the Dutch constitution says international law and European law which is incompatible with Dutch law, has priority above Dutch law.

The last source of law is jurisprudence. Rulings of the European Court of Justices, the European Court of Human Rights and national courts in the Netherlands are an interpretation of laws and regulations. These are in some cases, like cross-border health care, an important source of law.

## **5.2 The right to health care and community competence**

An important human right is the right to health care which is established in various international and European sources of law. The Netherlands have established this right in article 22 of the constitution of the Netherlands: 'The government shall take measures to promote public health.' The right to health care is laid down as a social right containing an obligation to governments according to the current socio-economic conditions of the state. Some legal scholars observe that the legal status of the right to health care is changing from a social right to an individual right due to the current socio-economic environment (Den Exter 2002), which entails the right to access health care services. The Netherlands interpret the right to health care as access, quality and affordability of health care. These values are protected by the Dutch government executed by the Dutch Health Care Authority. Member states can have a different interpretation of the right to health care in the context of limited recourses and should find a compromise between the right to health care and cost-containment (Den Exter and Hermans 1999).

In the field of health care the responsibility is based on the competence of the individual member state. Article 152 of the EC Treaty states that member states are responsible for health care provision and protection and promotion of health within their territory. The community action is limited to that which cannot sufficiently be achieved by the member state and therefore can better be achieved by the Community. Article 152 states: 'Community action (...) shall be directed towards improving public health, preventing human illnesses and diseases, and obviating sources of danger to human health.' Telemedicine and eHealth are examples which require coordination between member states, for example on interoperability of the electronic health record or telemedicine services. However, the commission is reserved in taking action as member states should solve the problems first. This principle is known as subsidiarity which is established in article 5 of the EC Treaty (Hervey 2004).

## **5.3 Relevant legal topics**

The most relevant legal topics on telemedicine are listed below. The topics are: data protection and privacy, liability, cross-border provision of services, competition and trade law, professional qualifications, and cooperation between health care providers. These topics will be explained shortly in relation to the basic values access, quality and affordability of health care. At the end of this chapter three topics are chosen that will be discussed more extensively in the next chapters.

### **5.2.1 Data protection and privacy**

D2D telemedicine requires the exchange of the patients' medical data between two health care providers and in case of D2P telemedicine the patient has to confide his medical data with the health care professional. If this data gets in hands of insurers, employers or researchers, it can have undesired consequences for the patient and the patient will be discouraged to seek treatment (Hervey 2004). The protection of health data and privacy therefore is the safeguard of the access to health care services. Health data should be transferred between health care providers and/or

the patient over a secure connection. How is the protection of medical data regulated? The health care professional involved in a treatment can only access the information needed for his treatment and not for example the mental condition of the patient when it is no necessary information for the treatments (Sokalska 2004, Stanberry 2006). This topic is discussed in Chapter 7 of this thesis.

### **5.3.2 Liability**

Two types of liability apply to telemedicine: professional liability and product liability. During the medical treatment or the diagnosis mistakes can occur or the telemedicine application can fail and cause damage to the patient. Legal certainty on liability is important as the access to health care of a minimum quality standard is guaranteed. In case of cross-border telemedicine the patient can have contact with a foreign health care provider directly or the health care professional in the Netherlands can have contact with a foreign health care provider (Callens 2002, Stanberry 2006). Who is liable in case of medical errors or a failing telemedicine application? To which court can the patient appeal to? These questions are addressed in Chapter 8 of this thesis.

### **5.3.3 Cross-border provision of services**

Borders are disappearing for telemedicine. As a result of rulings of the European Court of Justice the right to cross-border health care has been formulated. But does the right to cross-border health care exist? Are these rulings applicable to cross-border telemedicine services? Cross-border health care can have advantages for market like health care systems as competition from foreign health care providers can increase efficiency. Reimbursement of cross-border telemedicine is not obvious. For patients reimbursement of the costs of the treatment is an important issue. Residents of the Netherlands have a compulsory health care insurance. The health insurer has to approve the use of health care services in other countries. Do cross-border telemedicine services require prior authorization? The next chapter discusses this topic in more detail.

### **5.3.4 Professional qualifications**

Professional qualifications are important in D2P telemedicine as they guarantee a minimum quality standard for health care professionals. In the Netherlands professional qualifications are regulated by the Individual health care professions act (Wet Beroepen Individuele Gezondheidszorg, BIG). Foreign health care providers who want to deliver health care services for the Netherlands or within the Netherlands require a registration in the BIG-register (RIBIZ 2008). Another aspect of professional qualifications is the exchange of health care professionals within EU member states. The education differs over EU member states, which complicates the exchange of health care professionals. The recognition of professional qualifications regulated in regulation 2005/36/EC. This is a prerequisite to ensure a minimum quality of health care for health care professionals from other EU member states, which is related to medical liability when the minimum level is not obtained. This issue will be shortly discussed in chapter 8 on liability.

### **5.3.5 Competition and trade law**

A telemedicine company often sells services to the public health services provider. Health care is usually hidden from competition law because of its public nature. To what extent do rules on



competition apply to health services, which are often public funded? Does the concept of services of general interest apply to health care services? Competition law is becoming more important as more technical services are furnished by specialized providers, like telemedicine providers. Rules on competition will create a level playing field for health care providers, as competition should contribute to the affordability of health care services. Competition law applies in some cases. Unclear legislation can be a barrier for both public and private health care providers, which is why guidelines are needed to determine when a health care provider is an undertaking or services of general economic interest (EHMA 2007c).

### **5.3.6 Cooperation**

In order to provide D2D cross-border telemedicine, cooperation contracts are agreed upon between health care providers in different member states. Networks of expertise play an important role, for example in consultations between providers. Rules on cooperation within the EU are laid down by the Council of Europe. What happens if a professional doesn't fulfil his obligations? Do the existing laws on cooperation and agreements suffice?

### **5.4 Conclusion**

In this chapter is the general legal framework for health care in the EU set out. The right to health care and community competence are discussed more detailed. The right to health care is formulated as access to health care services, quality of care and affordability of health care services. Some legal topics on the cross-border provision of services were discussed and three were chosen to be discussed more extensively. These were the provision of cross-border health care, liability and data protection. The themes were chosen as literature (EHMA 2007, Stanberry 2006) regard them as important issues. Furthermore, these themes were directly connected to two of the basic values of the right to health care, access to health care and quality of care.

## **6. Cross-border provision of services**

The number of citizens of the European Union travelling to another Member State to receive health care services has increased over the last years. There are several reasons for this development: the liberalization of the provision of services in the EU; the development of medical technologies and techniques though ICT; and the enlargement of the European Union in 2004 (EC 2008). The overall number of patients using cross-border health care services is still relatively low compared to the overall use of health care services in the European Union. Cross-border health care accounts for 0.1% to 0.2% of overall expenditure in the EU. Most of the cases (53%) concerned migrant workers, 33% temporary stays in other member states and 14% pre-authorized health care. In financial terms preauthorized care accounted for 60% of total cost of cross-border health care in the EU, health care during temporary stay in another member state for 25% and health care for migrant workers for 16% (Bertinato 2005). Nevertheless, cross-border health care can be very important for individuals as they are able to claim their right to health care. As telemedicine makes country borders fade away, it can cause an increase in cross-border health care services.

This chapter describes the legal sources applicable on cross-border health care. Moreover, the directive for cross-border health care proposed by the European Commission is discussed.

### **6.1 Legal sources and developments in EU law**

The right for citizens to receive health care in other member states is laid down in regulation 1408/71/EEC on the application of social security schemes to employed persons and their families moving within the Community and in rulings of the European Court of Justice (ECJ). Regulation 1408/71 provides immigrant workers with their social rights when working in another member state. The right to cross-border health care with remuneration is only regulated by rulings of the European Court of Justice. These rules are clear in the individual cases, but offer insufficient legal certainty in all situations. A general and effective application of these rulings is needed. Clarity on a more general level is necessary in the application of the freedom to receive and also to provide health care services within the EU. At the moment legal certainty does not exist. The European Commission is aware of this issue and is working on regulation. Regulation 883/2004 on the coordination of social security schemes is developed to simplify and replace regulation 1408/71. This regulation is planned to go in force in mid 2009. Also, a new directive for the provision of services within the EU has been introduced, which had to establish the rulings of the ECJ on cross-border health care. It was felt that specificities of health services were not sufficiently taken into account. Therefore health care services are excluded from the services directive and a separate directive is being developed for health care services (EC 2006).

### **6.2 Proposed directive on cross-border health care**

The objective of the directive is to make the entitlements of patients clear, ensure that all patients receive high quality and safe health care and establish a framework for European cooperation. The directive is based on case law and its aim is to ensure a clear and transparent framework for the provision of cross-border health care within the EU. This directive should be seen as

supplementary to the existing legal framework on cross-border health care. It also addresses some rules on the cooperation between member states on the interoperability and standardization of different systems for eHealth and telemedicine

Discussions on the new directive exist within the EU. There are concerns among some member states about the legal certainty. It means the introduction of the rules of the internal market into their health care systems. Therefore, the following questions exist at the member states. Should the ECJ ruling be taken as a starting point for the regulation? What is more important, the protection of individual patient or the protection of the health systems of the EU member states? (Euractive 2008) The cross-border health care directive has consequences on various aspects, but on the other hand it provides more legal certainty and information for the patients of the member states. It is expected that this directive will go into force in the end of 2008 or in the beginning of 2009.

<b>Legal sources</b>
<p><u>European law:</u></p> <ul style="list-style-type: none"> <li>- Regulation 1408/71 on the application of social security schemes to employed persons and their families moving within the Community</li> <li>- Regulation 883/2004 on the coordination of social security schemes (not yet in force)</li> <li>- Directive 2006/123 on services in the internal market</li> <li>- Directive on cross-border health care (proposed)</li> <li>- Directive 2005/36/EC on recognition of professional qualifications</li> </ul> <p><u>Rulings of the ECJ</u></p> <ul style="list-style-type: none"> <li>- Luisi and Carbone (286/82 and 26/83)</li> <li>- Kohll (C-158/96) and Decker (C-120/95)</li> <li>- VanBraeckel (C-368/86)</li> <li>- Geraets-Smits and Peerbooms (C-157/99)</li> <li>- Müller-Fauré and Van Riet (C-385/99)</li> <li>- Watts (C-372/04)</li> </ul>

Table 3: Legal sources on the provision of cross-border health care

### **6.3 Right to cross-border health care**

Regulation 1408/71 applies to immigrant workers and their families residing in another member state of the EU than their home member state and protects them from social security risks including illness. However, this regulation is very general and the rulings of the ECJ give an interpretation of this regulation. When migrant workers are in need of medical care in another member state they should be able to obtain the needed health care in the member state they are staying in. The right to cross-border health care comes forward from the cases Luisi (286/82) and Carbone (26/83). In the cases Luisi and Carbone the court held that health care services are subject to the free movement of services in article 49 and 50 of the EC Treaty. Later, in the rulings on the cases Kohll (C-158/96) and Decker (C-120/95) the ECJ concluded that health care services under the social security scheme are also subject to the free movement principle in article 49 of

the Treaty. However, both treatments took place outside the hospital. In the Vanbraekel case (C-368/86) the ECJ ruled that article 49 also applies to hospital care. In cases where the treatment is more expensive than the coverage according to the scheme of the home member state of the patient, this member state has to grant an additional reimbursement covering the difference. The competent member state can set terms on which reimbursement is available (Hervey 2004).

#### **6.4 Prior authorisation**

Member states can make cross-border hospital services subject to prior authorisation. When a hospital service cannot be provided without undue delay in the member state of residence, a patient can go abroad for medical treatment. This holds only for hospital services covered in the home state. Non-hospital services or outpatient service may not be subject to prior authorization as no substantial increase of cross-border mobility is to be expected (Bertinato 2005). In the cases Müller-Fauré and Van Riet (C-385/99) the court ruled that the member state's health care system planning argument, with waiting lists as part of that system, is not enough justification in outpatient health care settings to set restrictions on the freedom of movement principle. This argument for hospital services on the other hand is accepted as the consequences on stability of the health care scheme can be large. In case Geraets-Smits and Peerbooms (C-157/99) the court ruled that prior authorisation for hospital services, by a non contracted health care provider for health services that are to be reimbursed, is necessary and reasonable. In the Watts case (C-372/04) this argument is confirmed for member states with a national health service with regulation of supply. Waiting lists as a health care planning tool are no argument to refuse treatment abroad in case of undue delay.

Prior authorization can obstruct the delivery of health care across the borders of the EU. In the rulings of the ECJ prior authorization is only allowed for hospital services when the risk exists of a financial imbalanced health system and a need to maintain capacity of hospital services and professional competence (Hervey 2004). Restriction on the freedom to provide services has to be necessary and reasonable. In the proposed directive no general prior authorization requirement is set on hospital services<sup>3</sup>. Non-hospital services are excluded from prior authorization as this does not affect the financial equilibrium of the health system. It allows member states to set prior authorization requirements on hospital services when the financial balance of the social security system and hospital planning and organization to avoid overcapacity is undermined by hospital services open to all patients of member states. The directive also defines hospital services in order to avoid the use of different definitions by member states. Hospital services are defined as 'health care which requires overnight accommodation of the patient for at least one night' and 'health care, included in a specific list, that does not require overnight accommodation of the patient for at least one night'. The list will be set up by the European Commission and will be limited to 'health care that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment'. In conclusion prior authorization can be seen as a barrier to the delivery of cross-border telemedicine.

---

<sup>3</sup> The definition of hospital services brings along other difficulties, for example hospital services are not defined in Dutch health law. Provisions within the health insurance law are determined as functional, for example health care delivered by medical specialists.

### **6.5 Barriers for Cross-border telemedicine**

The rulings of the ECJ state: '(...) apply to recipients of health care seeking to receive health care provided in another member state through other means, for example through eHealth services' (EC 2008). This means that cross-border telemedicine services are covered by the rulings on cross-border health care. Prior authorization, however, can work as an obstacle for cross-border telemedicine services. For non hospital care prior authorization requirements are not allowed. Member states themselves can decide to set prior authorization requirements on cross-border health care. Telemedicine, as described in chapter 1, consists of doctor to doctor (D2D) and doctor to patient (D2P) telemedicine. Different parts of telemedicine are D2D teleconsultations, teleradiology, telemonitoring and D2P teleconsultations. In doctor to doctor telemedicine, the hospital itself could make agreements or even form a network of expertise with health care providers in other member states of the EU. The Dutch health insurer contracts the Dutch hospital. Prior authorization is not needed in this case. For D2P telemedicine services, a Dutch health insurer can compose agreements about health care delivery through telemedicine as part of the basic benefits package. When a patient consulting a health care professional in another member state through telemedicine services seeks remuneration, prior authorization requirements are also not allowed according to the new directive on cross-border health care. Hospital services require an overnight accommodation, which is not the case in teleconsultations.

### **6.5 Conclusion**

As the rulings of the ECJ are applicable to telemedicine services, opportunities are created for health care providers to put up cross-border telemedicine services. Therefore, prior authorization requirements can hinder cross-border telemedicine services as the freedom to provide services is restricted. In addition to this, different health care systems within the EU and their interpretation of the right to health care can hinder cross-border telemedicine.

## **7. Data protection and privacy**

Health data is needed for treatment and preventing medical errors. It is a legal obligation for health care providers to keep a medical record. The health care professional has to be informed about the patient's medical condition and his medical history. This data is usually kept in a medical record. In electronic health care service delivery the availability of an electronic medical record is a necessary condition, health data can be send easily to the professional at a distance. Health data has a special and sensitive nature (Hervey 2004). The relation between the health care professional and the patients is based on trust. The patient entrusts his medical problems to the health care professional. Patient may not seek help when their medical status is not under medical confidentiality, as unrestricted access to health data can have undesired consequences for the patient.

Telemedicine services involve data transfer to health care professionals at a distance. This data has to be processed safely and should be protected from undesirable use. In other words patients using telemedicine services needs to be sure that his personal data is not used for other purposes than the consent he has given. The conditions among which data processing is allowed should conform to the use of telemedicine. Otherwise regulation on data protection could hinder developments in telemedicine. Cross-border telemedicine involves data transfer between different member states in the EU. This requires also free movement of personal data.

### **7.1 Legal sources and developments**

The protection of medical data is regulated on all three levels of the legal sources mentioned earlier. The sensitive character of medical data is recognized and therefore protection of medical data is regulated by international law, for instance in the European Convention on Human Rights and the Convention on Human and Rights and Biomedicine. These international sources of law are soft law and therefore have no binding character and provisions about privacy in general are included in international law. More specific, the protection of privacy is laid down in the European Charter of Fundamental Rights and Freedoms. This Charter will be replaced by the Lisbon Treaty when it is ratified by all member states of the EU. Data protection is a more explicit form of privacy protection and regulated by other sources of law with a more binding character, for example in European law for EU member states. The member states have to incorporate the content of the regulations in their national law. Data protection on European level is regulated by the data protection directive, a supplementary on the data protection and e-commerce directive. The most important legal source on the collection and protection in the EU is the directive on data protection. Together with the e-Commerce directive, it is the basis for data protection for telemedicine. The data protection directive contains rules about how personal data may be processed so that the processing itself does not harm the privacy of an individual. Data protection is laid down in an EU directive to attain harmonization of national law of EU member states as unequal rules on data protection in member states of the EU can harm the internal market (EHMA 2007a). Final, on the national level in the Netherlands is data protection regulated by the personal data protection act.

<b>Legal source</b>
<p><u>International law</u></p> <ul style="list-style-type: none"> <li>- European Convention on Human Rights</li> <li>- Convention on Human Rights and Biomedicine</li> </ul>
<p><u>EU law</u></p> <ul style="list-style-type: none"> <li>- Charter of Fundamental Rights and Freedoms</li> <li>- Directive 95/46/EC on data protection</li> <li>- Directive 2000/31/EC on electronic commerce</li> <li>- Directive 2002/58/EC on privacy and electronic communication</li> </ul>
<p><u>National law</u></p> <ul style="list-style-type: none"> <li>- Personal Data Protection Act (Wet Bescherming Persoonsgegevens)</li> <li>- Medical Contracts Act (Wet op de Geneeskundige Behandelingsovereenkomst)</li> </ul>

Table 4: Legal sources on data protection and privacy

## **7.2 Data collection and the electronic medical record**

The collection of health data in a medical record during medical treatment is a legal obligation which is established in the Treatment Contracts Act (Wgbo). Patients have the right to access their record, may rectify the collected data or give the order to destroy the information. Nowadays health data is collected in an electronic medical record instead of a paper record. This brings along some specific risks, for example: 'information and communication technology has made it easier for third parties to gain access to personal medical information and increased the application possibilities for a number of secondary purposes' (Sokalska 2004). According to the data protection directive personal data can only be collected for a specified, explicit and legitimate purpose. In the Personal Data Protection act the use of personal data concerning a person's health is not only allowed for health care providers but also for public health authorities for health care planning and risk assessment by health insurers (Hooghiemstra 2002). Member states need to allow for a proper balance between data processing and the patients and public health interests. A concern of the use of a medical record for data collection is; if a medical record is the primary way of processing health data it can have consequences for the patients health care when he/she opts out of such a system (Article 29 Data Protection Working Party 2007).

## **7.3 Processing of medical data**

The data must only be processed for the purposes for which the data was collected and cannot further process the data incompatible with the initial purpose. The data must be collected by specified, explicit and legitimated purposes. The final purpose has to be clear before the data collection starts and consent needs to be explicitly given by the patient to the health care provider. The directive on data protection states that consent must be unambiguous, freely given, specific and informed indication of the data subject's wishes by which the data subject signifies his or her agreement to personal data relating to him or her being processed. The level of protection on the

data is related to the purpose pursued by data processing. The rules on data protection are addressed to the data controller. This person decides the final purpose of the data and the means of data processing and the duties for appropriate data handling are established by this person. In the electronic health record the data is processed electronically and security of data processing needs extra attention, because health data can get into the wrong hands, especially when the use of the internet is involved as 'the internet has the potential to allow information about website users to be tracked and aggregate and at the individual user level' (Callens 2002). Directive 2002/58/EC on privacy and electronic communication has been designed complement the directive on data protection on this point. In this directive protects the confidentiality of communications on a public electronic network (the internet). Communication cannot be stored or tapped by users other than the users concerned (EHMA 2007a).

#### **7.4 Data protection and telemedicine**

The regulations on data protection existed in the EU before the telemedicine services did. Health data was already fairly protected by various EU directives and national law. Problems are more likely to arise in D2P telemedicine than in D2D telemedicine, for example for D2P teleconsultations in which health care is delivered over the internet. Websites have to provide for the consent that should be given, so patients know when they have given their consent for collection of personal data or even the treatment. Furthermore, the transmission of data over the internet may lead to interception (Callens 2002). Moreover, telemedicine services often involve the cooperation of different health care providers and intermediaries. If intermediaries involved are no health care providers, risks of disclosure of health data in an unauthorized way increases. Last, the parties concerned with telemedicine observe that technical standards are not sufficiently developed for health care providers to feel secure about sending health data across the EU (EHMA 2007d). They recommend guidelines on the definition of finality of purpose with an adequate balance between the interests of the data subject and public health management and disease prevention.

#### **7.5 Conclusion**

Based on the regulation and the harmonization of data protection within the EU, the existing regulation on data protection does not cause barriers on cross-border telemedicine. Member states are bounded by the same rules. Security of data needs extra attention and electronic data is gathered and processed easily. However, some uncertainty exists about application of rules on data protection in practice at the health care providers. Guidelines can provide more clarity in this case.



## **8. Liability**

Patients using telemedicine services should be protected from harm, both from a failing telemedicine application and malpractice by health care providers. If damage occurs, a patient should be able to hold the health care professional or the telemedicine provider accountable. In telemedicine services a patient does not always have direct contact with all health care providers concerned, which complicates it for the patient to hold the responsible party liable. Furthermore, defective products can also cause damage to the patient.

This leads to two different types of liability: product liability and professional liability. The topic of liability is too extensive to describe in this thesis, the focus is therefore on the main issues arising on product and professional liability concerning cross-border telemedicine. First, the most relevant legal sources and developments on product and professional liability are described. Medical liability is more interesting for discussion as product liability of telemedicine is not really different from the liability of other (medical) products.

### **8.1 Legal sources and developments**

Product liability is mainly regulated by European legislation to achieve harmonization of rules and the protection of the internal market in the EU. Product liability on European level is laid down by regulation 85/374/EEC and in the Netherlands established in the Civil Code. Directive 2001/95/EC on general product safety imposes a general safety requirement on any product on the market for consumers. Producers have to provide consumers with information on the risks inherent in the use of the product and take appropriate measures to avoid those risks. Directive 1999/44/EC on the sale of consumer goods and associated guarantees regulates the contract between the seller and the buyer of the product. Last, rules on the safety of patients and users of medical devices are established in directive 1993/42/EC. As this thesis concerns the provision of telemedicine services in the first place, product liability is not discussed fully.

In contrast to product liability the professional qualifications for health care providers and medical liability are regulated on the national level. To promote functioning of the internal market a special directive has been introduced on the recognition of professional qualifications. In addition the Council of Europe intends to develop standards on medical liability as part of a larger program on patient safety. Last summer the Council of Europe organized a conference on 'The ever-growing challenge of medical liability: national and European responses'. The results of the conference are among others comprehensive assessment of different approaches to medical liability might be valuable and more cooperation by institutions on medical liability should be established (COE 2008).

The table below provides an overview on the most relevant legal sources on product and professional liability.

<b>Legal sources</b>
<p><u>European law</u></p> <ul style="list-style-type: none"> <li>- Council directive 85/374/EEC concerning liability for defective products</li> <li>- Directive 1999/44/EC on the sale of consumer goods and associated guarantees</li> <li>- Directive 2001/95/EC on general product safety</li> <li>- Council directive 1993/42/EC concerning medical devices</li> <li>- Directive 2005/36/EC on the recognition of professional qualifications</li> </ul> <p><u>National law</u></p> <ul style="list-style-type: none"> <li>- Medical contracts act: Wet op de geneeskundige behandelingsovereenkomst (Wgbo)</li> <li>- Health care professions act: Wet op de beroepen in de individuele gezondheidszorg (Wet BIG)</li> <li>- Part 6 of the Civil Code</li> </ul>

Table 5: Legal sources on medical and product liability

### **8.2 Damage caused by the telemedicine product or service**

Product liability is regulated on the European level with directive on liability for defective products, directive on the sale of consumer goods and directive on general product safety. Additional rules concerning medical devices are laid down in the directive concerning medical devices. The directive on defective products aims at ensuring high levels of consumer protection against damage caused to health or property by a defective product. Furthermore it aims at reducing the disparities in national liability laws to protect the internal market. The producer is responsible for damage caused by defective products. The patient/consumer has to prove the damage, the defect in the product and the causal relation between the two. But what if no defect is found in a device? eHealth and telemedicine devices are covered by the existing regulation on product liability. Examples of eHealth products are software, websites, medical devices for telemedicine, etc. The regulations on product liability, however, do not specifically address eHealth and telemedicine.

### **8.3 Damage caused by the professional**

Cross-border telemedicine services involve health care professionals and non health care professionals of different nationalities. No general European rules on professional qualifications are established, so health care professionals have to meet the qualifications set by the member state of employment. To allow freedom of movement and the provision of services for health care professionals within the EU, a directive regulates the recognition of professional qualifications. Liability for services is covered by the rules of contract law in the member states (EHMA 2007d). The BIG-act establishes the professional requirements for health care professionals working in the Netherlands. They have to register themselves in the BIG-register under the BIG-act before they can practice their profession. This law regulates also the liability of professionals in the register. A disciplinary tribunal can impose punishments on professionals who act or refrain from acting in accordance with their professional duty (Dute and Hermans 2000). In the proposed directive on cross-border health care is regulated that the member state where the treatment takes place has to provide mechanisms for compensation if patients suffer harm of

receiving cross-border health care in place (EC 2008). For instance, through a professional liability insurance.

In relation to professional qualifications, Callens (2002) states that no standards for appropriate care for telemedicine are developed yet. This is important as these standards provide an interpretation of good care. The Royal Dutch Medical Association (KNMG) has developed guidelines for contact between physicians and patients over the internet in 2007. This guideline only covers online health advice to the individual patient, prescription of pharmaceuticals or pharmaceutical treatment advice (KNMG 2007).

In situations where professionals commit an error during the treatment of the patient taking place in the hospital, the patient can hold the hospital accountable. This is regulated in the Medical Contracts Act. When the treatment takes place outside the hospital, the patient has to hold the health care professional accountable. However, during telemedicine several health care professionals of different disciplines and non health care professionals can be involved in the treatment.

#### **8.4 Conclusion**

Based on the existing literature and the given overview of the legal sources, legal uncertainty on medical liability could cause a barrier in cross-border telemedicine. Most questions exist on that topic as medical liability is regulated by member states and not on a community level. Problems can arise when different health care professionals from different countries are involved and the patient does not know who is liable for the damage. Furthermore, guidelines for the delivery of telemedicine services should be developed to offer more guidance to health care professionals.

## 9. Conclusion

In this thesis opportunities and barriers to the provision of cross-border telemedicine from the Netherlands to another EU member state are investigated from an economic and legal perspective. Cross-border telemedicine is defined as the delivery of health care with the use of ICT solutions where the participants are not residing in the same country. Cross-border is restricted to the EU in this thesis. Telemedicine services in Europe are mostly initiated to guarantee access to health care or improve the quality of care due to timely delivery or a patient centered approach of health care. Both the economic as well as the legal opportunities and barriers are derived from the right to health care which is (indirectly) laid down in various EU regulations. Every member state has a different notion of the right to health care and the realization of this right which has resulted in different health system in the EU. The Netherlands defined the right to health care with the values access, affordability and quality. These are the values the government protects by regulation.

It is concluded that both opportunities and barriers exist on the development and delivery of cross-border telemedicine on both the economic and the legal perspective. Moreover, the legal key issues are usually addressed by the European legal framework. The economic perspective concerns the incentives within the health care system to the provision of (cross-border) telemedicine services. The opportunities and barriers on the organization of the health system relate to each other. Member states of the EU are allowed to organize their health care system without interference of the community. The existence of different health care systems in the EU can lead to a barrier for cross-border telemedicine, because in order to provide telemedicine services professionals are facing different incentives. The system based on regulated competition can generate opportunities for telemedicine because it offers more room for financing different ways to deliver health care, like telemedicine. However the hybrid system resulting from a gradual reform of the health system is a barrier as it causes different incentives for the market players. At the same time, the cost effectiveness of telemedicine is not proved by cost effectiveness studies which is a barrier for decision making to decide on long term methods of financing of telemedicine services, for example addition to the basic benefits package. It is assumed that telemedicine services meet the basic values access, quality and affordability of health care, however this has not been proven yet. Increasing demand for telemedicine on the other hand provides an opportunity. Special subsidies or financing opportunities for telemedicine provide a temporary solution for telemedicine services in the health care system and can give health care providers the opportunity gather more evidence about the added value of telemedicine. Nevertheless, to provide a permanent solution for telemedicine long term financing solutions are needed.

In the legal perspective three parts of the legal framework are examined: the cross-border provision of services, data protection and liability. The main conclusion is that legal framework addresses most of the barriers in cross-border telemedicine, which means that the investigated parts provide no considerable opportunities and barriers to cross-border telemedicine. The right to health care applies to every citizen of the EU in their member state of residence and since the

introduction of the internal market also in the whole EU. The rulings of the ECJ provide the legal basis for cross-border provision of services and for patients to obtain health care in other EU member states. Prior authorization for hospital services is allowed by the ECJ, but is considered as a barrier to the internal market and to cross-border telemedicine as government can deny authorization. Furthermore, in practice legal uncertainty exists on the application of existing legal framework to telemedicine, especially for the rules on data protection and liability. Guidelines developed on EU level can create more legal certainty to the health care providers.

On both perspectives opportunities and barriers are observed of which the table below provides an overview.

<b>Opportunities</b>	<b>Barriers</b>
<p><u>Economic</u></p> <ul style="list-style-type: none"> <li>- Regulated competition</li> <li>- Increase of the B-segment</li> <li>- Subsidies available for innovation</li> <li>- Health system challenges increase demand for health care</li> <li>- Demand for e-consults by patients</li> </ul> <p><u>Legal</u></p> <ul style="list-style-type: none"> <li>- Right to health care</li> <li>- Basic benefits package</li> <li>- Internal market and the free movement principles</li> </ul>	<p><u>Economic</u></p> <ul style="list-style-type: none"> <li>- Different EU health care systems</li> <li>- Hybrid system of hospital financing (A- and B-segment)</li> <li>- No cost effectiveness analysis studies of good quality on telemedicine</li> <li>- No long term financing solutions</li> </ul> <p><u>Legal</u></p> <ul style="list-style-type: none"> <li>- Different interpretations of the right to health care by EU member states</li> <li>- Prior authorization for hospital services</li> <li>- Legal uncertainty on data protection and liability</li> </ul>

Table 6: Economic barriers and opportunities for cross-border telemedicine services

In conclusion the barriers on the economic perspective have more impact on the provision of cross-border telemedicine as it directly hinders the provision of telemedicine. The economic and legal perspective are tied by the right to health care.

## 10. Discussion

The chapter is used to discuss the results viewed from the limitations of this study. This thesis provides a multidisciplinary view on opportunities and barriers for cross-border telemedicine. However, a wide view gives a comprehensive description on the opportunities and barriers faced, the reverse is that it has consequences for the depth of the analysis. Nevertheless, the multidisciplinary view is chosen as literature on (cross-border) telemedicine in Europe is limited which makes in depth analysis more difficult. Therefore, further research is being recommended. This has implications for the results of the thesis and these have to be interpreted within the limitations of this study.

During the research no case was available of an existing cross-border telemedicine case involving the Netherlands. The cases described in Chapter 3 offer context on the developments of telemedicine in Europe and provide some information about the experienced legal barriers on cross-border health care. Telemedicine services are mostly developed as local initiatives originated from a practical need. However, information about the weighing of the opportunities in relation barriers in practice gives insights in the experienced possibilities and problems when providing cross-border telemedicine. A case study is recommended when specific economic and legal opportunities are subject of interest. Another remark is that the thesis focused on telemedicine as part of hospital services. However, telemedicine can also be useful to assist in primary care, mental health care or long term care settings, because these parts of health care are facing challenges to maintain access, quality and affordability of health care.

Furthermore, the scope of this thesis is limited to the EU as a market for cross-border telemedicine. The market for telemedicine is global as borders of the EU are easily crossed and the global market offers more opportunities for telemedicine. For example, low wage countries like India or South Africa provide opportunities for outsourcing standardized procedures as telemedicine services can be delivered at lower costs. The United States of America (USA) where telemedicine is more developed, networks of expertise can be set up for highly specialized knowledge and procedures to be offered to patients. From the legal perspective the global market has more risks than telemedicine services in Europe as the legal framework of the EU is aimed at the development of the internal market. Outside the EU the application of rules and regulations are for each country. For example the application of EU rules on liability and data protection outside the EU are unclear.

eHealth has been used as a collective term for all use of ICT in health care. This is confusing as the term eHealth is used more often compared to the term telemedicine in literature and policy documents. However, they can not be seen as separate definitions as telemedicine is a part of the eHealth definition. eHealth provides some basic infrastructural conditions for telemedicine, such as a secure network, an electronic health record, standardization and interoperability of ICT health care services. The infrastructure and electronic health record is not nationally implemented in the Netherlands yet (NICTIZ 2008). These are conditions for a good functioning telemedicine service

(Malmqvist et al 2004). To provide cross-border telemedicine services exchange of information needs separate network.

## 11. Bibliography

Aas, M.I. 2007. *The organizational challenge for health care from telemedicine and eHealth*. accessed at <http://www.ehto.org/2007/2007-0412-Telemedicine-MAA%5B1%5D.pdf> on 3 October 2008

Aho, E. 2006. *Creating an inventive Europe*. Accessed at [http://ec.europa.eu/invest-in-research/pdf/download\\_en/aho\\_report.pdf](http://ec.europa.eu/invest-in-research/pdf/download_en/aho_report.pdf) on 3 October 2008

AD (Algemeen Dagblad), 2008, *Teledokter in opkomst*, 5 July 2008

Article 29 Data Protection Working Party. 2007. *Opinion 4/2007 on the concept of personal data*. 01248/07/EN

Berg, M. 2007. De toekomst van productfinanciering: Een slim concept dat efficiënte zorg stimuleert. *ZE Magazine*. (7) p. 14-17

Bertinato, L. et al. 2005. *Policy brief Cross-Border Health Care in Europe*. World Health Organisation Observatory

Buijsen, M. 2002. *The concept of health law*. In Den Exter, A.P., & J. Sandor (eds.), *Frontiers of Health Law Yearbook 2002*. 4-9. Rotterdam: Rotterdam University Press.

Callens, S. 2002. Telemedicine and the e-commerce directive. *European Journal of Health Law* (9) p.93-109

Callens, S. 2007. *Legal Thought on telemedicine, liability and reimbursement*. Presentation. 11 December 2007 on Telehealth 2007 Conference

CEO (Council of Europe). 2008. *The ever-growing challenge of medical liability: national and European Responses*. European Conference Strasbourg 2-3 June 2008

Cutler, D.M. 2002. Equality, efficiency and market fundamentals: The dynamics of international medical-care reform. *Journal of Economic Literature*. (40) p.135-151

CVZ (College voor Zorgverzekeringen). 2007. *Tijdelijke toelating veelbelovende innovaties tot het pakket*. report 6 November 2007. Accessed at [http://www.cvz.nl/resources/rpt0711\\_innovaties\\_tcm28-25014.pdf](http://www.cvz.nl/resources/rpt0711_innovaties_tcm28-25014.pdf) on 4 September 2008

Diamuraal, 2008. Website. Accessed at <http://www.diamuraal.nl> on 4 October 2008



Den Exter, A.P. & H.E.G.M. Hermans (eds.). 1999. *The Right to Health care in Several European Countries*. The Hague: Kluwer International

Den Exter, A.P., 2002, *The right to health care in international law*, In Den Exter, A.P., & J. Sandor (eds.), *Frontiers of Health Law Yearbook 2002*. 12-26. Rotterdam: Rotterdam University Press.

Dute, J.C.J. & H.E.G.M. Hermans (eds.). 2000. *Regulering van de gezondheidszorg*. Maarssen: Elsevier Gezondheidszorg

EC (European Commission). 1993. *Research and Technology Development on Telematics Systems in health care*. Annual technical report on RTC in health care. Brussels: AIM 1993

EC (European Commission). 2003. *Ministerial Declaration Brussels 22 May 2003*. eHealth convention 2003, accessed at [http://ec.europa.eu/information\\_society/eeurope/ehealth/conference/2003/doc/min\\_dec\\_22\\_may\\_03.pdf](http://ec.europa.eu/information_society/eeurope/ehealth/conference/2003/doc/min_dec_22_may_03.pdf) on 4 September 2008

EC (European Commission). 2004. *e-Health – making healthcare better for European citizens: An action plan for a European e-Health Area*. 30 April 2004. COM (2004) 356 final

EC (European Commission). 2006. *Communication from the commission: Consultation regarding Community action on health services*. 26 September 2006

EC (European Commission). 2007. *Accelerating the Development of the eHealth Market in Europe*. eHealth taskforce report 2007

EC (European Commission). 2008. *Proposal for a directive of the European Parliament and of the Council on the application of patients' right in cross-border health care*. 2 July 2008. COM(2008) 414 final

EHMA (European Health Management Association). 2007a. *Legally eHealth: Deliverable 2 – Processing medical data: Data protection, confidentiality and security*. Accessed at <http://www.ehma.org/projects/default.asp?NCID=140> on 15 October 2008

EHMA (European Health Management Association). 2007b. *Legally eHealth: Deliverable 3 - Issues of liability and consumer protection*. Accessed at <http://www.ehma.org/projects/default.asp?NCID=140> on 15 October 2008

EHMA (European Health Management Association). 2007c. *Legally eHealth: Deliverable 4 – Aspects of competition and trade law*. Accessed at <http://www.ehma.org/projects/default.asp?NCID=140> on 4 October 2008

- EHMA (European Health Management Association). 2007d. *Legally eHealth: Deliverable 5 – Final recommendations on legal issues in eHealth*. Accessed at <http://www.ehma.org/projects/default.asp?NCID=140> on 4 October 2008
- EHTEL (European Health Telematics Association). 2008. *Sustainable Telemedicine: paradigms for future-proof health care*. 20 February 2008. Accessed at <http://www.ehtel.org/> on 4 October 2008
- Enthoven. A.C. 1988. *Managed competition of alternative delivery systems*. *Journal of Health Politics and Policy*. 13(2) p 305-321
- ERA. 2007. *eHealth priorities and strategies in European countries*. March 2007
- EU. 2007. *Seventh Framework Programme (2007 to 2013): Building the Europe of Knowledge*. Accessed at <http://europa.eu/scadplus/leg/en/lvb/i23022.htm> on 4 September 2008
- Euractive. 2008. *EU faces 'long row' over cross-border healthcare*. News item. 17 July 2008. Accessed at <http://www.euractiv.com/en/health/eu-faces-long-row-cross-border-healthcare/article-174265> on 4 October 2008
- EURAD. 2007. Website. Accessed at <http://www.euradconsult.net/en/> on 4 September 2008
- Folland, S., A.C. Goodman & M. Stano, 2006. *Economics of health and health care: 5th edition*. New Jersey: Prentice Hall
- Geertsema, R.E., et al. 2007. *New and Emerging Medical Technologies, a horizontal scan of opportunities and risks*. RIVM. 2 February 2007. Accessed at <http://www.rivm.nl/bibliotheek/rapporten/360020002.pdf> on 4 September 2008
- Hailey, D. 2005. The need for cost-effectiveness studies in telemedicine. *Journal of Telemedicine and Telecare*. (11)
- Heinzelmann, P.J., N.E. Lugin & J.C. Kvedar. 2005. Telemedicine in the Future. *Journal of Telemedicine and Telecare*. 2005 (11). p. 384-390
- Hervey. T. & J.V. McHale. 2004. *Health law and the European Union*. Cambridge: Cambridge University Press.
- Hooghiemstra. T.. 2002. The implementation of directive 95/46/EC in the Netherlands. with special regard to medical data. *European Journal of Health law* (9) p.219-227
- KNMG (Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst). 2007. *Richtlijn online arts-patiënt contact*. Accessed at

[http://knmg.artsennet.nl/uri/?uri=AMGATE\\_6059\\_100\\_TICH\\_R155953955076415&xsl=AMGATE\\_6059\\_100\\_TICH\\_R15495243970383](http://knmg.artsennet.nl/uri/?uri=AMGATE_6059_100_TICH_R155953955076415&xsl=AMGATE_6059_100_TICH_R15495243970383) on 4 September 2008

Ksyos. 2008. Website. Accessed at <http://www.ksyos.org> on 4 October 2008

Lapr , R., F. Rutten, E. Schut. 2001. *Algemene Economie van de Gezondheidszorg*. Elsevier Gezondheidszorg. Maarssen (1999)

Malmqvist, G., K.G. Nerander & M. Larson. 2004. *Sjunet – The national IT infrastructure for health care in Sweden*. In I. Iakovidis, P. Wilson & J.C. Healy. *E-Health – Current situation and examples of implemented beneficial eHealth application 2004*.

NICTIZ (Nationaal ICT Instituut in de Zorg). 2008. *Hoe ver staat het met de invoering?* Accessed at <https://www.nictiz.nl/?mid=103&pg=136> on 4 October 2008

NPCF. 2007. *Remote control! Toekomst en betekenis van telemedicine voor de zorggebruiker*. Report September 2007. Accessed at <http://www.npcf.nl/uploads/files////visiedoctelemedicine.pdf> on 4 October 2008

NPCF (Nederlandse Pati nten en Consumenten Federatie). 2008. *Gezondheid 2.0: Toekomst en betekenis van e-Health voor de zorgconsument*. Report May 2008. Accessed at [http://www.npcf.nl/uploads/files////visiedoc\\_e-health\\_npcf.pdf](http://www.npcf.nl/uploads/files////visiedoc_e-health_npcf.pdf) on 4 October 2008

NZa (Nederlandse Zorgautoriteit). 2007. *NZa stelt financiering teledermatologie vast*. News item. 12 December 2007. Accessed at [http://www.nza.nl/nza/Nieuws/vaststelling\\_financiering\\_teled/](http://www.nza.nl/nza/Nieuws/vaststelling_financiering_teled/) on 3 October 2008

NZa (Nederlandse Zorgautoriteit). 2008a. *Ziekenhuiszorg 2008: Een analyse van de marktontwikkelingen in het B-segment 2008*. Accessed at [http://www.nza.nl/7113/10083/monitor\\_ziekenhuiszorg\\_2008.pdf](http://www.nza.nl/7113/10083/monitor_ziekenhuiszorg_2008.pdf) on 4 October 2008

NZa (Nederlandse Zorgautoriteit). 2008b. *Rekening voor e-consult vaak onterecht*. News item. 12 February 2008. Accessed at [http://www.nza.nl/nza/Nieuws/rekening\\_e\\_mailconsult/](http://www.nza.nl/nza/Nieuws/rekening_e_mailconsult/) on 16 October 2008

Olsson, S. 2007. *Telemedicine/Telehealth experiences and challenges in Sweden*. Presentation. 11 December 2007 on Telehealth 2007 Conference

RIBIZ (Registratie en Informatie Beroepsbeoefenaren in de Zorg). 2008. *Buitenlands diploma*. Accessed at <http://www.ribiz.nl/diplomaenwerk/buitenlandsdiploma/> on 16 October 2008

Schut, F.T. 2004. Rivaliserende sturingsconcepten in de gezondheidszorg. *Beleid & Maatschappij*. (31) p.222-231

Sokalska. M.E.. 2004. Medical confidentiality: Qui vadis? *European Journal of Health Law* (11) p. 35-43

Stanberry, B. 2006. Legal and ethical aspects of telemedicine. *Journal of Telemedicine and Telecare* (12) p.166-175

Verheij, T., C. Ton, & K.Tates. 2008. Het eConsult: Hoe vaak en met wie? *Huisarts & Wetenschap* 51(7)

Viedome. 2008. Website. Accessed at <http://www.viedome.nl/> on 4 October 2008

Whitten, P.S. et al. 2002. Systematic Review of Cost Effectiveness Studies of Telemedicine Interventions. *BMJ*. 2002 (324)