Master Thesis

Regional need analysis for using existing eHealth solutions for transnational treatment of chronic heart patients in consideration of legal aspects in the Baltic Sea Regions

A project work

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Abbreviations

ACCA	The **A**ssociation of **C**hartered **C**ertified **A**ccountants
ACC/AHA	American College of Cardiology / American Heart Association
ADMIRAL	**A**bciximab before **D**irect angioplasty and stenting in **M**yocardial **I**nfarction **R**egarding **A**cute and **L**ong term follow up
AMI	Acute Myocardial Infarction
AOK	Allgemeine Orts Krankenkasse (an insurance company in Germany)
ASEM	**AS**ia **E**urope **M**eeting
ATA	American Telemedicine Association
CEN	Comité Européen de Normalisation (European Committee for Standardization)
CENELEC	Comité Européen de Normalisation Electrotechnique (European Committee for Electrotechnical Standardization)
CSIRO	Commonwealth Scientific Industry and Research Organisation
DIMDI	**D**eutsche **I**nstitut für **m**edizinische **D**okumentation und **I**nformatik (German Institution for Medical Documentation and Informatics)
EC	European Commission
ECG	Electro-Cardio-Gram
EHR	Electronic Health Record
EHTEL	„European Health Telematics“ Association
EIPA	European Institute of Public Administration

EPILOG	**E**valuation in **P**TCA to **I**mprove **L**ong term **O**utcome with abciximab **G**P IIb / IIIa blockade
ERDF	European Regional Development Fund
ESDIS	Employment and Social Dimension of the Information Society
ETSI	European Telecommunications Standards Institute
EU	European Union
GPs	General Practitioner
GP IIb / IIIa	Glycoprotein (type IIb / type IIIa)
HIMSS	Health Information and Management Systems Society
HINE	Health Information Network Europe
HON	Health on the Net
ICT	Information and Communication technology
Ipv6	Internet Protocol Version 6 (IPv6 is the "next generation" protocol designed by the „Internet Engineering Task Force“ to replace the current version Internet Protocol, IP Version 4 ("Ipv4").
IST	Information Society Technologys
MI	Myocardial Infarction
NHS	National Health Service
NPfIT	National Programe for Information Technology
OECD	Organisation for Economic Cooperation and Development
PHCT	Primary Health Care Trust
PTCA	Percutaneous Transluminal Coronary Angioplasty

RAND	A nonprifitable research organization providing objective analysis and effective solutions. Initially the name „RAND“ was derived from a contraction of the term „**R**esearch **AN**d **D**evelopment“.
SME	Small and Medium sized Enterprises
TIMI	Thrombolysis In Myocardial Infarction
TSGZ	**T**elemedizinische **S**ervice- und **G**esundheits**Z**entrum (Telemedicine Service- and Healthcare Centre)
UKEHA	UK E-Health Association
VNP	Virtual Private Network
WP	Work Package
WS	Winter Semester
3G	3rd Generation of mobile communications technology (3G is an „International Telecommunication Union’s“ specification for the third generation of mobile communications technology (analog cellular was the first generation, digital Personal Communications Services the second). 3G workes over wireless air interfaces.

Prologue

I am a medical doctor from Pakistan. Access to health care is a public health problem in my country, especially for the rural arear. This problem cultivated in me an interest in the field of public health. During my studies at the “University of Applied Sciences Hamburg”, I realised that “eHealth” can be the solution for those living in ruarl (remote) areas and also for the travellers. My present master thesis, which is actually a project work, covers “eHealth” as an important aspect of public health that needs attention at the local, national and international levels, to build the networks for the better access of health care both in developing and in developed countries.

Summary

This master thesis is a project work, conducted within the framework of a European transnational eHealth project, “eHealth for Regions” in the Baltic Sea region. 17 partners from 7 countries are taking part in this project. There are 4 work-packages, which are the four pillars of the working strategy of the project. I took active part in wok-packages 1 & 2 and was responsible for the milestone “Regional Need Analysis” in all the partner countries. I also took part in work-package 4 for the implementation of USB-Stick pilot project for data storage and transfer for travelling patients.

This project work consists of 4 parts. The first part consists of general background of eHealth with respect to EU/EC initiatives, introduction and importance of eHealth, eHealth activities of EU/EC and place, importance and the goals of “eHealth for Regions” project.

The second part consists of a questionnaire survey to analyse the awareness and acceptance of eHealth in the province of Schleswig Holstein, Germany, under the heading of “Regional Need Analysis”.

The third part consists of evidence based existing solutions of eHealth for transnational treatment of heart patients and the implementation of TSGZ concept of telemonitoring for cardiac patients in the partner countries.

The fourth part describes the legal issues (aspects) of eHealth. In this part the challenges facing the eHealth and their possible solutions are discussed.

1. General Background

Information Society is moving from a "pilot phase" to a "wide deployment" as the ICT world becomes more mature and global. Since 2000, the ICT context has changed substantially, not only from a technological point of view (e.g. 3G, Ipv6, nanotechnologies, convergence, a new generation of computers, ambient intelligent scenarios…) but also for economic players (for instance, with the entrance into a major deployment phase, with the end of the burst of the Internet bubble, better internal market regulation, and the development of public-private partnerships).

The Report from the High Level Group chaired by W. Kok makes a strong recommendation for Europe to reap the full benefits of ICT: "*In order to ensure future economic growth, the EU needs a comprehensive and holistic strategy to spur on the growth of the ICT sector and the diffusion of ICT in all parts of the economy*"***(8).***

The EU's Information Society activities translate ist policies into progress 'on the ground', and so range from stimulating the emergence of cutting-edge technologies to directing the EU's Structural Funds towards Information Society projects in regions across Europe.

One of the many important EU activities is "e-health", which is directly relevant to the eEurope initiative, launched by the EUs' Information Society.

1.1. eEurope Initiative of European Information Society

On 8 December 1999 the European Commission has launched an initiative entitled „e*Europe-An Information Society for All*", which proposes ambitious targets to bring the benefits of the Information Society within reach of all Europeans. The initiative focuses on ten priority areas, from education to transport and from healthcare to the disabled ***(1).***

The key objectives of the *e*Europe Initiative are:

- Bringing every citizen, home and school, every business and administration, online and into the digital age.
- Creating a digitally literate Europe, supported by an entrepreneurial culture ready to finance and develop new ideas.
- Ensuring that the whole process is socially inclusive, builds consumer trust and strengthens social cohesion ***(1).***

To achieve these objectives, the Commission proposes 10 priority areas for action with ambitious targets to be achieved through joint action by the Commission, the Member States, industry and the citizens of Europe. One of these areas of action is:

- *Healthcare online: maximise the use of networking and smart technologies for health monitoring, information access and healthcare* ***(1).***

At the Lisbon summit on 23 -24 March 2000, the EU's heads of state adopted a strategy aiming to make the EU the most dynamic and competitive economy by 2010. At the same time, the summit also approved an initiative brought forward in a communication from the Commission: *"An Information Society For All - eEurope".* The European Council invited the Council and the Commission to draw up "…a comprehensive eEurope Action Plan".

Since 2000, EU ICT policy development has been split into three separate tranches:

- eEurope 2002 action Plan
- eEurope 2005 Action Plan
- eEurope 2010 (i2010) Action Plan

1.1.1. eEurope 2002 Action Plan

The original list of eEurope objectives, proposed in December 1999 at the launch of the Initiative, was further developed on proposals of Member States and the European Parliament, and refined at the March 2000 Lisbon Extraordinary Summit. An Action Plan was approved at the European Council in Feira, Portugal, 19-20 June 2000 ***(2),*** called "eEurope 2002 Action Plan".

eEurope 2002, which sets policy objectives to stimulate the use of a cheaper, faster and more secure internet. Its main focus was on connectivity (i.e. getting people on line) and it ran from 2000 to 2005.

1.1.2. eEurope 2005 Action Plan

The Barcelona European Council called on the Commission to draw up an *e*Europe action plan focussing on "*the widespread availability and use of broadband networks throughout the Union by 2005 and the development of Internet protocol IPv6 …. and the security of networks and information, eGovernment, eLearning, eHealth and eBusiness*" ***(3).***

The eEurope 2005 Action Plan, which was launched at the Seville European Council ***(4)*** in June 2002 and endorsed by the Council of Ministers in the "eEurope Resolution" of January 2003, focused on "stimulating use and creating new services", more precisely it aimed "to stimulate secure services, applications and content based on a widely available broadband infrastructure".

It contains chapters on Broadband, Benchmarking, e-Learning, e-Government, e-Health, e-Business, e-Inclusion, on Digital Rights Management and on Trust. It looked at providing a favourable investment environment, modernising public services and ensuring all have the opportunity to participate in the global information society. It ran until the end of 2005 ***(4).***

Updating the eEurope 2005 action plan

On 17 May 2004, the Commission published a communication on updating the eEurope 2005 action plan, which proposed minor changes to the plan, aiming mainly at speeding up transposition of the declared objectives.

In parallel, the ***e*Europe+ 2003 Action Plan** had been launched in June 2001 on the initiative of the then 13 candidate countries. *e*Europe+, which had the same targets as the *e*Europe 2002 Action Plan, came to a close in February 2004, with the publication of its final progress report at the Budapest Ministerial conference[1]. (see eEurope 2005-update)

1.1.3. eEurope 2010 (rebranded as i2010) Action Plan

i2010 (rebranded as i2010) is the follow-up plan to eEurope 2005, which has run out at the end of 2005. The need for a new information society strategy arises from the Lisbon objectives and from their *„mid-term review"*, which states: "in order to ensure future economic growth, the EU needs a comprehensive and holistic strategy to spur on the growth of the ICT sector and the diffusion of ICT in all parts of the economy" (W.Kok) ***(8).***

The i2010 initiative was launched with an i2010 Communication from the European Commission in early June 2005. It was then discussed and approved by Telecoms Ministers from across the EU at the end of 2005. It sets EU ICT policy until 2010.

The overarching aim of the i2010 initiative is to ensure that Europe's businesses, governments and citizens make the best use of ICTs in order to improve industrial competitiveness, support growth and the creation of jobs, as well as aiming to address key societal challenges ***(5).***

1.2. eHealth in the context of eEurope initiative of Europe's Information Society

eHealth is directly related to the eEurope initiative, launched by the EUs Information Society. Since the early 1990s the European Commission has invested € 500 million in

[1] *e*Europe+ 2003 Action Plan – Final Progress Report

eHealth research and development initiatives. Priority topics for investment have included electronic health records, regional and national networks, home telecare, tools for prevention and systems for health professionals to work more efficiently and safely ***(6).***

1.2.1. eEurope 2002 Action Plan and eHealth

Also in 2000, eHalth ("Health Online") became an eEurope 2002 policy priority, setting targets for both the European Commission and member states to meet in areas such as:

- Building on the European health insurance card to create a European electronic healthcare system, including functionality such as medical emergency data and secure access to personal health information.
- Develop health information networks to speed the flow of information through the healthcare system.
- Putting services online such as healthy living and health promotion information, electronic health records, telecare and consultation and online claims and reimbursement ***(7).***

1.2.2. eEurope 2005 Action Plan and eHealth

This action plan succeeds the *e*Europe 2002 action plan endorsed by the Feira European Council in June 2000. eHealth was also identified again as one of the priorities of the European Commission's eEurope 2005 Action Plan. Objectives of the plan include:

- *By the end of 2005:* Member States must develop national and regional eHealth strategies. They should focus on deploying eHealth systems, setting targets for interoperability and the use of EHRs and address issues such as the reimbursement of e-Health services.
- *By the end of 2006:* EU members states, in collaboration with the European Commission, must identify and outline interoperability standards for health data messages, EHRs, taking into account best practices and relevent standardisation efforts.
- *By the end of 2009:* EU members and EC to set a baseline for standardised European provision for e-Health services in clinical and administrative settings ***(6).***

The eEurope 2005 Action Plan is focused on seven priority areas where government action can make a significant difference (*www.europa.eu.int):*

- Modern online public services: eGovernment, eLearning, *eHealth*

- A dynamic eBusiness environment
- Widespread availability of broadband access at competitive prices
- A secure information infrastructure (eSecurity)
- An information society embracing eInclusion ***(7)***

1.2.3. i2010 Action Plan and eHealth

eHealth strategy of i2010 addresses three “quality of life” ICT flagship initiatives:

- Technologies for an ageing society, intelligent vehicles that are smarter, safer and cleaner.
- Digital libraries making multimedia and multilingual European culture available to all (2007).
- Actions to overcome the geographic and social “digital divide”, culminating in a European Initiative on e-Inclusion (2008)—***(5).***

1.3 The European eHealth Action Plan: A move towards a „European eHealth Area“ (2004).

A European Union Action for a European eHealth Area was published by the Commission in April 2004 and endrosed by the EU health ministers in June 2004. The European eHealth action plan takes a twin track approach: making the most of new information and communication technologies in the health sector and better integrating a range of e-Health policies and activities. It will provide a framework for exchanging best practices and experience and enable common approaches to shared problems to be developed over time. This plan focuses on specific actions, so to create by the end of the decade a borderless European Health information space.

Developing Electronic health Records was one of the key policy priorities, setting targets for both the Europaen Commission and Member States:

- ***Electronic health cards.*** The Commission intends to support a common approach to patient identifiers and electronic health record architecture through stadardisation and will support the exchange of good practices on possible additional functionalities, such as medical emergency data and secure access to personal health information.
- ***Health information network.*** By the end of 2005, member states should develop health information networks between points of care (hospitals, labortries and homes) with broadband connectivity where relevent. In parallel, the Commission intends to set up European-wide information networks of public

health data and coordinate actions for Europe wide rapid reactions to health thraets (like SARS).

- ***Online health service.*** By the end of 2005, member states will ensure that online health services are provided to citizens (e.g. information on healhy living and illnes prevention, electronic health records, teleconsultation, e-reimbursement). The commission will monitor actins taken by Member States to make health information as accessible as possible to citizens as well as initiatives to implement quality criteria for web sites ***(6).***

The action plan is the third element of the *„Commission's activities in the health area".* The two other activities address*"patient mobility"* and the*"benchmarking of national reforms in health care",* long-term care and social protection ***(7).***

Here follow the concrete actions to be taken as part of the new action plan. Target dates for eHealth include:

- Each member state to develop a roadmap for eHealth *by the end of 2005.*
- Setting up a European Union public health portal *by the end of 2005.*
- Identifying a common approach to patient identifying data *by the end of 2006.*
- Identifying interoperability standards for health data *by the end of 2006***.**
- A collaborative approach should be undertaken among Member States to supporting and boosting investment in eHealth *by the end of 2006.*
- To improve information on patient mobility and mobility of health health professionals at European level.
- Looking ahead *during the period 2004-2008*, supporting the deployment of health information networks base on fixed and wireless broadband and mobile infrastructures and Grid technologies.
- Member States should adopt confirmity testing and accreditation schemes following successful best practices *by the end of 2007.*
- The European Commission, in collaboration with Member States, should undertake activities to: Set a baseline for standardised European qualificaton of eHealth servoces, provide framework for legal certainty of eHealth products, impprove information regarding the rules applying to the assumption of the costs of eHealth services, promote eHealth as a tool for health promotion and prevention *by the end of 2009* ***(9).***

Below is given an illustaration (**figure 1**) about the timelines of Action Plan towards European eHealth Area (Communication COM (2004) 356) ***(24).***

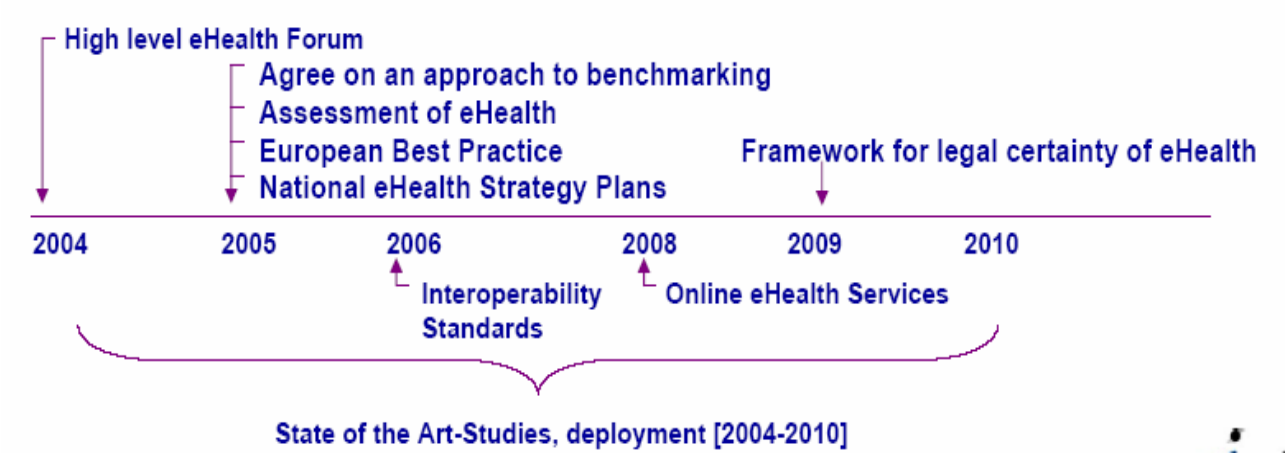


Fig. 1: Timeline for An Action Plan towards European eHealth Area ***(24)***

2. Introduction

eHealth is today's tool for substantial productivity gains, while providing tomorrow's instrument for restructured, *citizen-centred* health systems and, at the same time, respecting the diversity of Europe's multi-cultural, multi-lingual health care traditions. There are many examples of successful eHealth developments including health information networks, electronic health records, telemedicine services, wearable and portable monitoring systems, and health portals. Today, at least four out of five European doctors have an Internet connection, and a quarter of Europeans use the Internet for health information ***(9).***

European Community research programmes have been supporting eHealth for the last fifteen years. Many research results have now been tested and put into practice. This has put Europe in a leading position in the use of electronic health records in primary care and deployment of health (smart) cards.

These developments have contributed to the emergence of a new "*eHealth industry*" that has the potential to be the third largest industry in the health sector with a turnover of €11 billion. By 2010 it could account for 5% of the total health budget. At present, the eHealth industry in Europe – mainly made up of small- and medium-sized enterprises (SMEs) – has a competitive advantage, but it still needs to enjoy a more favourable business environment ***(9).***

Member States have shown that they are keen to take an eHealth agenda forward ***(1),*** drawing on best practices and experience from across the Union. This should enable a move towards a "*European e-Health Area*"; a framework built on a wide range of

European policies and initiatives. In describing this European eHealth Area, an emerging framework for concerted actions and synergies in eHealth is envisaged that provides a favourable environment for the integration of related policies at a Community level. Since the health sector in Europe is a predominantly public sector service, most of the challenges and actions described in the Communication on 'The Role of eGovernment for Europe's future'***(2)*** also apply here.

2.1. What is eHealth?

Several individuals and organisations have attempted to define formally or informally the term "eHealth", in terms of its scope and application; many attempt to use scenarios to illustrate eHealth in action.

2.1.1. Some key definitions

Perhaps the simplest definition of e-health came in 2001 from Thomas Eng, in *The eHealth Landscape*:
"eHealth is the use of emerging information and communication technology, especially the Internet, to improve or enable health and healthcare." (Eng 2001) ***(10).***
Eng also outlined the "5 Cs Model" of functions and capabilities of eHealth (see **Table1**) ***(10):***

Table 1: The 5 Cs Model - Functions and Capabilities of E-Health (Thomas Eng; *The e-health Landscape,2001*)

Content	Connectivity	Community	Commerce	Care
information presence information search assistance health behaviour change informed decision-making distance learning and training	Clinical and public health systems Health services and systems integration administrative transactions clinical and biomedical research	Peer-to-peer and person to person messaging Information exchange Emotional support and community building	eCommerce and Shopping	Self care care coordination and information portability electronic health records shared clinical decision making expert systems disease management telemedicine and telehealth

Table 1 suggests what eHealth may do, and how, but three years on from Eng's publication, no standard definition seems to exist. The Centre for Global eHealth Innovation at the University of Toronto is a leading centre for research in the application of technology to healthcare. In trying to answer the question "What is ehealth?" their web site states:

*"Currently there is no standard definition of eHealth. eHealth can be defined in many different ways. David H. Gustafson…defines eHealth as "something to do with computers, people, and health", which is a very open definition." (Centre for Global e-Health Innovation, 2003)****(10).***

Gunther Eysenbach (2001) suggested the term was first used in industry rather than academia, adding the 'e' prefix to health along with other words such as 'commerce' and 'solutions' to:

"…convey the promises, principles, excitement (and hype)…and to give an account of the new possibilities the Internet is opening up to the area of healthcare." (Eysenbach, 2001) ***(10).***

Eysenbach further outlined conflicting viewpoints on the term, its definition, how it isused and by whom. Another body of thought suggests that the definition of eHealth is contextual and dynamic, and from this Eysenbach bases his definition on the idea that eHealth is more than technology:

"eHealth is an emerging field in the intersection of medical informatics, public health, and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterises not only a technical development, but also a state of mind, a way of thinking, an attitude and a commitment for networked, global thinking, to improve healthcare locally, regionally, and worldwide by using information and communication technology."***(10)***

To support this definition, Eysenbach lists "*10 essential 'e's* in eHealth":

1. Efficiency;
2. Enhancing quality of care;
3. Evidence based;
4. Empowerment of consumers and patients;
5. Encouragement – of a new patient-clinician relationship;
6. Education of physicians and consumers;

7. Enabling standardised information exchange and communication;
8. Extending scope of healthcare beyond conventional boundaries;
9. Ethical;
10. Equity – reducing, not increasing, the divide between those with access to quality healthcare and those who do not ***(10).***

Below are given different views about the definition of eHealth.

2.1.2. European Views

2.1.2a. *The eEurope Initiative*

The European Commission Information Society's eEurope Initiative defines eHealth as:

"The application of information and communication technologies (ICT) across the whole range of functions which, one way or another, affect the health of citizens and patients" (European Commission 2003a).

It further separates eHealth into three key categories:

1. Delivery of Care to patients by healthcare professionals:

- In **hospitals**, systems ranging from administrative to care delivery;
- In **primary care**, computers used by GPs, pharmacists and dentists for patient management, medical records and electronic prescribing;
- For **home care**, care services delivered by home care professionals by telecommunications, including remote vital signs monitoring systems; capitalising on electronic health records.

2. Health-related Information:

- For continuing medical education of healthcare professionals;
- For retrieval of health and medical information by citizens;
- Using the Internet as a commercial publishing medium, and as an additional channel through which to convey public health education campaigns.

3. Trading Health Products

Electronic trading of healthcare goods, including pharmaceuticals, medical devices and information and communication technologies, where in addition to healthcare providers

and citizens, organisations involved may include developers of software and hardware, telecommunications providers, official bodies accrediting applications ***(11).***

2.1.2b. *Definitions presented to the European eHealth Conference*

Denise Silber, presented *"The Case for e-Health"* to the first European eHealth Conference in Brussels in 2003. She defined eHealth thus:

"The term eHealth is much broader than the Internet and dotcom. eHealth describes the application of information and communications technologies (ICT) across the whole range of functions that help health. It is the means to deliver responsive healthcare tailored to the needs of the citizen."(Silber 2003) ***(12).***

This definition is then widened to consider the different settings in which eHealth may functions:

- "The **citizen/patient** uses eHealth when he seeks information on-line, uses self management tools, participates in electronic communities and requests a second opinion."
- **Primary care** includes the use of ICT by the Primary Care Health Team (PHCT) for patient management, medical records and electronic prescribing.Healthcare professionals can also call upon e-health for their Continuing Medical Education.
- **Home Care** includes care services which are delivered by home care professionals via telecommunications to a patient in the home.
- **Hospitals** may call upon ICT for scheduling logistics, patient administration, laboratory information, radiology, pharmacy, nursing, electronic messaging between the hospital and other healthcare actors for communication of clinical and administrative data, and telemedicine and second opinions, in any specialty." (Silber 2003) ***(12).***

2.1.2c. *European Health Telematics Association (EHTEL)*

The European Health Telematics Association have attempted to define the concept of eHealth on a number of occasions. In a High Level Position Paper on eHealth Information Systems, the following definition is offered:

"The emerging world of eHealth can be defined as the application of information, communication and video technologies to the delivery of timely, professional and safe healthcare." (EHTEL 2004) ***(13).***

In a 2002 draft position paper for the European Health Telematics Association (EHTEL) on the development of e-health in Europe, Richardson *et al* (2002) used the following definition of eHealth:

"eHealth means applying new low cost electronic technologies, such as webmenabled transactions, advanced networks and new design approaches, to healthcare delivery. In practice, it implies not only the application of new technologies, but also a fundamental rethinking of healthcare processes based on using electronic communication and computer-based support at all levels and for all functions both within the healthcare service itself and in ist dealings with outside suppliers. eHealth is a term which implies a way of working rather than a specific technology or application."

Richardson *et al* then defined eHealth using a *"Four pillar"* model, illustrated below in figure 2. This model uses as its four core elements a definition of specific technologies and their use (clinical applications), a developmental benefit to the varying healthcare professions (continuing education), a developmental benefit to the public (public health information and education), with the fourth element a series of steps leading to the ultimate goal of improved „**health for all"** ***(10).***

2.1.3. Views from the United States

2.1.3a. *Healthcare Information and Management Systems Society (HIMSS)*

The US-based Healthcare Information and Management Systems Society (HIMSS, http://www.himss.org) is an organisation that focuses on encouraging optimal use of healthcare information technology and management systems towards the advancement of healthcare provision.

In May 2003, the e-health Special Interest Group of HIMSS defined e-health in detail in a white paper (Broderick and Smaltz 2003), and significantly called for the entire healthcare industry to adopt this definition. They identified e-health as:

"The application of the Internet and other related technologies in the healthcare industry to improve the access, efficiency, effectiveness, and quality of clinical and business processes utilized by healthcare organizations, practitioners, patients, and consumers to improve the health status of patients." ***(10)***

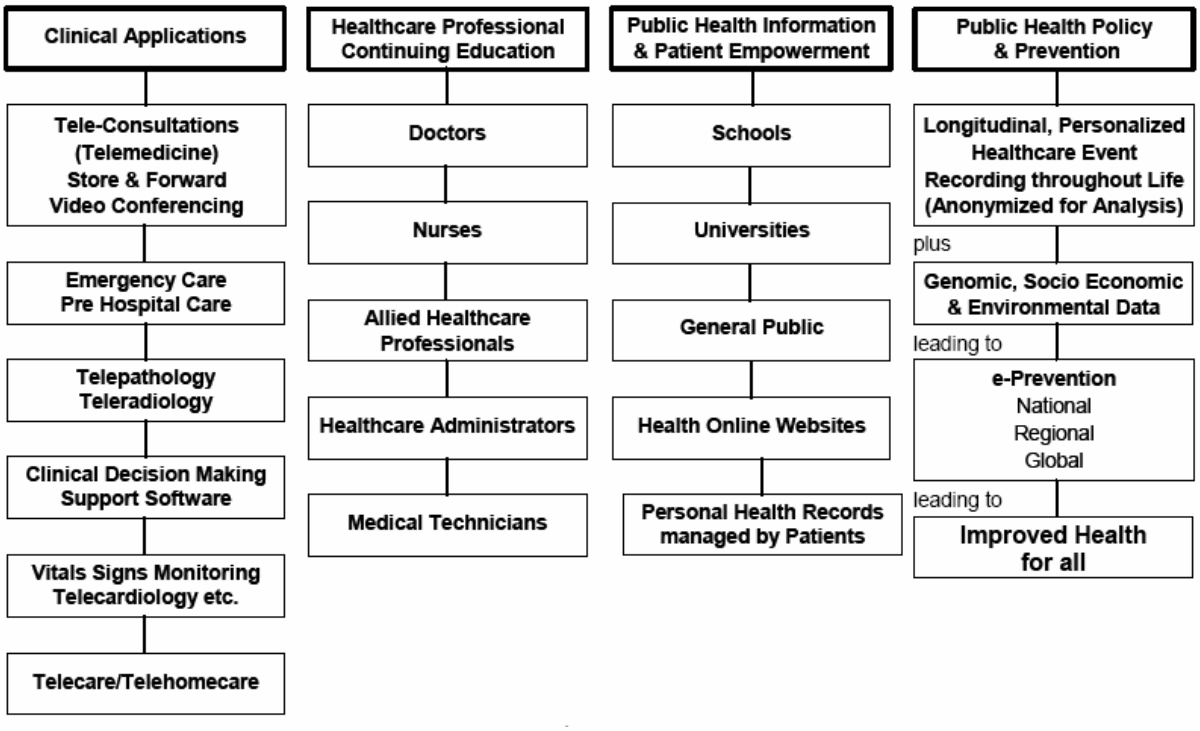


Fig. 2: Four Pillar model of eHealth→ Practical application of eHealth(from Richardson et al 2002; Richardson 2002, adopted from "*eurohealth Vol 8 No 2 Spring 2002*").

2.1.3b. *American College of Physician Executives*

The American College of Physician Executives present a lengthy definition of eHealth (Marcus and Fabius, undated):

"The "e" is for electronic. Placed before the word health, it implies all things transmitted and technological in health care, which help improve the flow of information and the process of health care delivery. "E" networks integrate isolated towers of information and create new knowledge through the creation of relational databases. The spectrum of "E" is broad and goes beyond the use of a computer as a box on the desktop. It includes wireless communication using hand-held devices and the storage and function by the microchip which is revolutionizing health care, as it is inserted into everything we use to diagnose, treat, record, sort, analyze, and conclude. It also incorporates electronic forms of care delivery, such as telemedicine, providing health care over a distance, communicating by sound and image transmission".
*"eHealth is connectivity; it is transactional; it is clinical. It is informational, interactive and interventional."**(10)***

2.1.3c. *The American Telemedicine Association*

The American Telemedicine Association (ATA), in 2001, wrote that:

"eHealth is a very broad term that encompasses many different activities related to the use of the Internet for healthcare. Many of these activities have focused on administrative functions such as claims processing or records storage. However, there is an increasing use of eHealth related to patient and clinical care." (ATA 2001) ***(10)***

2.1.4. Views from the UK

2.1.4a. *The UK E-health Association*

The UK E-health Association (UKEHA) did not appear to provide a definition of eHealth as recognised by the association on its web site, but in its Mission Statement (UK eHealth Association, undated) it outlines the benefits of eHealth for the public, and the ways in which eHealth can support the healthcare professional: eHealth for **professionals** may be either:

- **Real time -** technology facilitating live interaction between participants, for example video-consultation between doctor and patient
- **Store and forward -** involving one participant gathering digital data, and sending it to another participant for analysis, processing and return of results or feedback. ***(10)***

2.1.4b. *An English view of eHealth*

In the 2004 publication *"The NHS Improvement Plan – Putting People at the Heart of Public Services"* (Department of Health 2004a), much discussion is made of the role of ICT in the improvement of healthcare in England. The document outlines the plans of the National Program for Information Technology in the NHS (NPfIT) for new and ongoing technological enhancements to healthcare delivery through:

- electronic health records;
- electronic booking systems;
- electronic prescribing systems;
- the use of the Internet and Digital Television to enhance access to personal health records and public health information and facilitate communication between clinicians and patients.

While other definitions of 'eHealth' may ideally cover those innovations described above, no specific mention is made by the publication of the concept of 'eHealth'.

Even on the NPfIT web site (http://www.npfit.nhs.uk), the term 'eHealth' is conspicuous by its relative absence. Using the site's search facility, a search for 'eHealth' revealed one result, and that was a page referring to the "UK E-health Association".***(10)***

2.1.4c. *eHealth in Scotland*

Malcolm Chisholm MSP, Scotland's Minister for Health and Community Care, has defined eHealth thus:

"It encompasses much more than the deployment of computer technology. It conveys the message of electronics in support of health and stimulates thought and discussion about the broad range of issues and opportunities that technology offers in the health care setting.

eHealth includes the development, application and implementation of technology to improve effectiveness in healthcare. But it also includes getting it out there wherever it's needed in the service and making it happen across the service. It includes the use of telemedicine and clinical systems used for diagnosis and care pathways. We also apply the term to the policies and protocols that assure the confidentiality and security of sensitive data. Most of all it includes those aspects that support major change of working practice - training, support and Organisational Development" (Chisholm 2003) ***(10).***

2.1.4d. *eHealth in Wales*

Breaking with other definitions that promote e-health as an umbrella term, in defining telemedicine, NHS Wales define eHealth as an alternative term for telemedicine and tele-care, and, in fact a sub-set of health informatics:

"More commonly known as "eHealth", the headings of Telemedicine and Telecare are themselves subsumed under the framework category of "health informatics", which basically means the delivery of healthcare and medical knowledge through the application of advanced information and computer technologies." (NHS Wales 2003) ***(10)***

2.1.5. Australia: Commonwealth Scientific Industry and Research Organisation

For the organisation (CSIRO), a publicly funded scientific research organisation, (CSIRO, undated), eHealth means:

"…using Information and Communications Technologies to ensure the right treatment to each patient, specialised to each individual's context and situation, and to deliver healthcare where patients and providers need not be in the same place at the same time" ***(10).***

As a practical expansion of CSIRO's definition, its eHealth research is categorised under four strands:

- Biomedical imaging;
- Collaborative surgical training;
- Telehealth – addressing issues relating to improving quality of healthcare for people who live far from centres of population;
- Personal monitoring – of vital signs and well-being ***(10).***

2.1.6. Other definitions

2.1.6a. *Ontario Hospital ehealth Council (2002)*

"eHealth is a consumer-centred model of health care where stakeholders collaborate utilizing ICTs including Internet technologies to manage health, arrange, deliver, and account for care, and manage the health care system." (Ontario Hospital e-health Council, 2002) ***(10)***

2.1.6b. *World Health Organisation's Eastern Mediterranean Regional Office*

"eHealth is a new term used to describe the combined use of electronic communication and information technology in the health sector OR is the use, in the health sector, of digital data-transmitted, stored and retrieved electronically-for clinical, educational and administrative purposes, both at the local site and at a distance." (World Health Organisation, undated) ***(10)***

2.2. Why eHealth?

The *e*Europe Action Plans and the Research Programmes of the European Union alongside national research and action plans and industry-led initiatives have gone some way to realising the potential of information technology. Thus, these research and practical activities have helped in meeting some of the key challenges in providing European citizens with wide access to health information as well as healthcare and support.

In recent years, the focus of many of these activities has been on „*citizen-centred*" applications which address the fact that we are all becoming more demanding partners in our own healthcare. The shift of focus in the *eEurope Awards for eHealth – 2004* from the general to the citizen-centred is not accidental – citizens and patients are now seen as the prime focus not only of *e*Health tools and applications, but also of health service delivery in general. *We are moving away from a time when patients were the silent and passive partners in medical interaction.* Today patients are encouraged and supported in taking an active role in their own health.

2.2.1. The role of the internet in the change of citizens' attitudes to medical care

The role of the internet in the change of citizens' attitudes to medical care is significant. A recent Eurobarometer study from April 2003 confirms that 40% Europeans use the internet to find health information (EB Flash 135, April 2003). Access to information through internet has radically changed the doctor / patient relationship ***(14).***

In an international study (conducted by Harris Interactive) which interviewed citizens in the United States, France, and Germany, Harris found that about half of all those seeking health information on the net in France (49%) and Germany (50%) believe that the internet has had a major impact in their understanding of their health problems (see figure 3) and on their interaction with their doctor (see figure 4)***(14).***

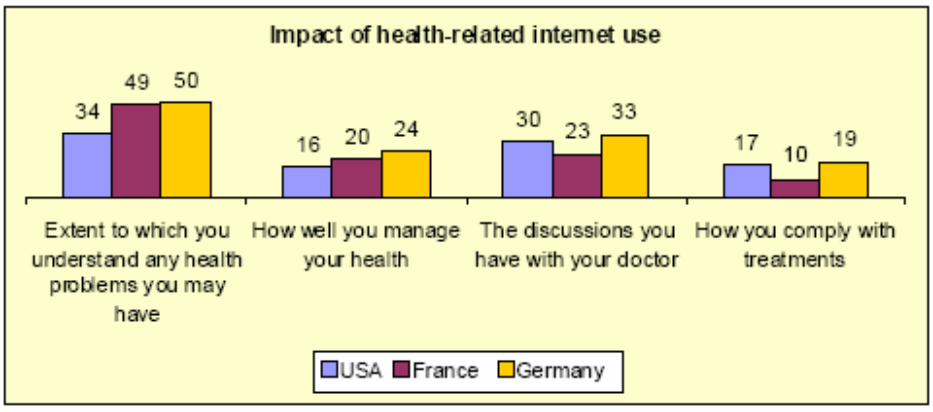


Fig. 3: Source: Harris Interactive (Volume 2, Issue 12—June 11, 2002)

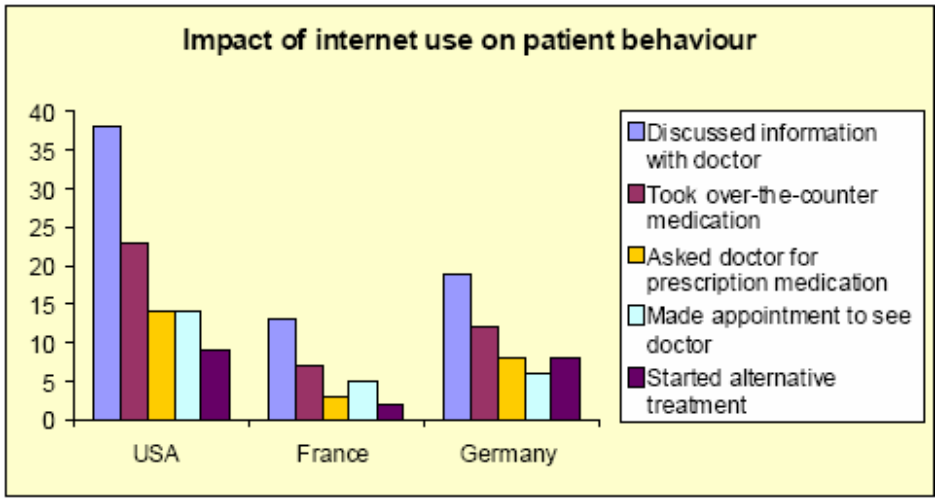


Fig. 4: Source: Harris Interactive (Volume 2, Issue 12—June 11, 2002)

The Health on the Net Foundation found similarly that citizens were significantly influenced by the knowledge and information they gained from internet searches. This research also showed that a significant number (31% of Europeans and 40% of Americans) were using interactive consultation services as well as simply searching for information on health-related websites and reporting on them (see table 2) ***(14).***

Table 2: Citizens' eHealth behaviour. Source: Based on Health on the Net (HON) Survey of 2621 respondents who voluntarily completed a survey questionnaire between May and June 2002. (http://www.hon.ch/Survey/8th_HON_results.html).

Citizens' eHealth behaviour in Europe and in the United States		
Citizens' Behaviour	**Respondents' Origin**	
	U.S.A. (n=676) %	Europe (n=269) %
I have discussed the results of my internet searches for medical/health information with my care provider(s)	69.1%	46.8%
I discuss the drug information I find with my care provider(s)	65.9%	41.3%
I have used online medical consultation services offered by websites	40.8%	31.2%
I buy drugs via online pharmacy services – From prescription – Over-the-counter (OTC)	17.2% 69.7% 30.4%	3.3% 42.9% 57.1%
I engage in email correspondence with my own healthcare provider(s) – Occasionally – Frequently	21.3% (n=115) 88.7% 11.3%	19.3% (n=40) 77.5% 22.5%
I use the web to search for information on drugs	82.5%	69.9%
I use the internet to seek second opinions on medical diagnoses	42.6%	56.1%

2.2.2. Use of EHR is incresing in GPs

The Eurobarometer survey of General Practitioners in 2002 found that on average 48% of European general practitioners use an electronic health record, ranging from 95% in Finland to 17% in France (see figure 5 below) ***(14).*** 66% of general practitioners in Europe obtain laboratory test results electronically (see figure 6 below) ***(14.)***

2.2.3. Healthcare delivery is safety-critical

It is now well established that many illnesses and even deaths arise as a result of medical accidents and errors. In 2000, the Institute of Medicine in the United States published the now famous report entitled *"To Err is Human"* which claimed that, in the United States, 44,000 deaths each year are due to medical errors. According to the Report:

> "More people (44,000) die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516)." (Kohn *et al*, 2000) ***(14).***

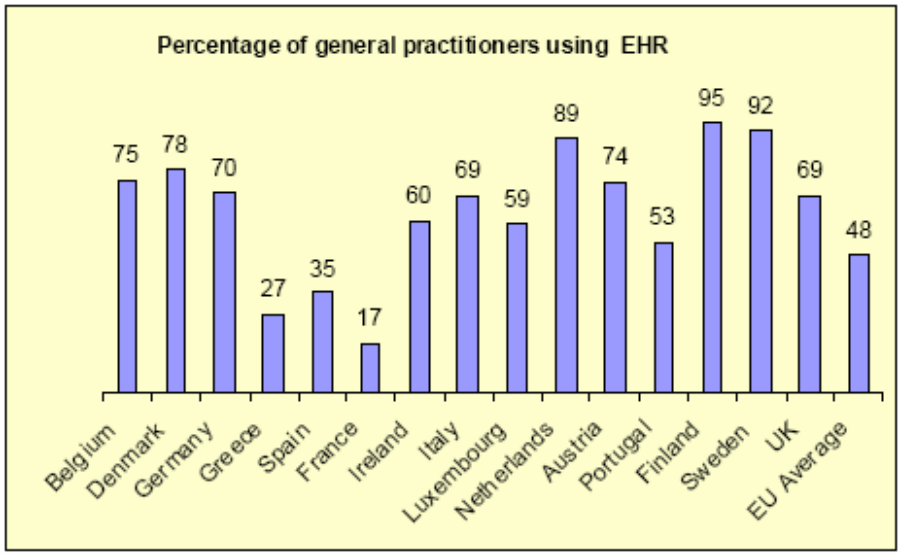


Fig. 5: Source: Eurobarometer EB Flash 126 June 2002

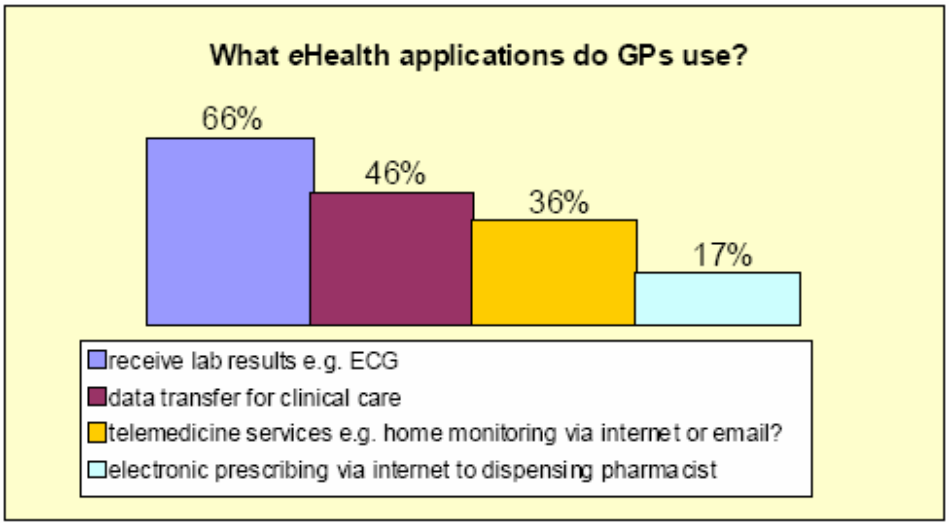


Fig. 6: Source: Flash EB 126 – Fig. 6 June 2002

Can *e*Health tools begin to address these errors? It has been argued that in fact only tools, applications and systems can overcome these human errors:

> "Expecting perfection in human action, or simply telling our doctors and nurses to 'try harder' not to kill their patients by mistake has nothing at all to do with our eventual success…. The remedy is in changing systems of work. The remedy is in design." (Berwick, 2001) ***(14)***

The answer lies in designing better systems in which humans work, and some significant solutions lie in *e*Health. Evidence provided from a controlled trial showed that the implementation of a computerised application for physicians' prescription (which improved communication; made knowledge accessible; included appropriate constraints on choices of drugs, routes, frequencies and doses; helped with calculations; performed real-time checks and assisted with monitoring) resulted in a 55% reduction in serious medication-related error (Bates *et al,* 1998) ***(14).***

2.2.4. Europe is getting greyer

The United Nations has forecast that, over the next 50 years, the number of people above retirement age will grow from 60 million to 100 million in the EU15. During the same period, the proportion of the population over the age of 80 will almost treble to 38 million. By 2051, close to 40% of the EU's population will be older than 65, this will lead to raising demand for health and social services ***(14).*** So, the pressure is on governments and healthcare systems to invest in solutions that improve productivity and

efficiency, and drive down costs while giving better healthcare to an increasing number of people.

A number of clinical conditions such as hypertension, chronic obstructive airways disease, thrombosis risk and many other conditions which are more common in older people have now also become the focus of *e*Health applications which seek to involve patients more actively in their care, reduce the number of in-patient appointments, and support patients better in their own home. Current examples exist in applications to report blood reading from coagulation risk electronically to facilitate accurate and effective use of anti-coagulation medication (see *Terivan*,7 http://www.terivan.com) ***(14).***

2.2.5. Healthcare costs are rising

In 2000 and 2001, health spending in OECD countries increased by 4% per year in real terms on average, while real growth in the gross domestic product averaged just 2.3% per year. Accordingly, a considerable gap exists which gives rise to a further increase in health spending as a share of gross domestic product, reaching 8.4% on average in 2001 (OECD, 2003) ***(14).***

The case study of the Danish hospital referralsystem shows that the technology (eHealth) is mature and that it can deliver cost savings. According to the survey at current levels of use it saves 1 million € each year over paper based systems. If all referrals were sent electronically this could rise to 3.5 million € per year. In short, full electronic referral can cut costs by 25%. (***Ms. Sharon Cannaby et al., "The cost benefit of electronic patient referrals in Denmark", a study performed with the collaboration of EC, Danish Centre for Telematics and ACC***)

Ball and colleagues found that about $500,000 are saved each year by an American health insurer whose clients are enrolled in an *e*Health diabetes programme which kept them out of hospital over the four-year trial programme. Significant savings were also found in the use of home-monitoring applications by patients discharged from hospital after coronary care. The use of a telemonitoring and patient support system reduced the 30-day re-admission rate to zero and the 90-day re-admission rate by 83% (Ball *et al*, 2001) ***(14).***

2.2.6. "Integrated Patient Care"

Healtcare institutions today want to provide patients with a consistent level of care throughout their lives. The target is to achieve what is called "*Integrated Patient Care*", where all levels of patient care are connected – from family doctor to specialist. This means linking up the various departments across different care institutions so that

patient records are accessible at every stage. *eHealth is an important structural component of "Integrated Patient Care"* (see fig. 7 below).

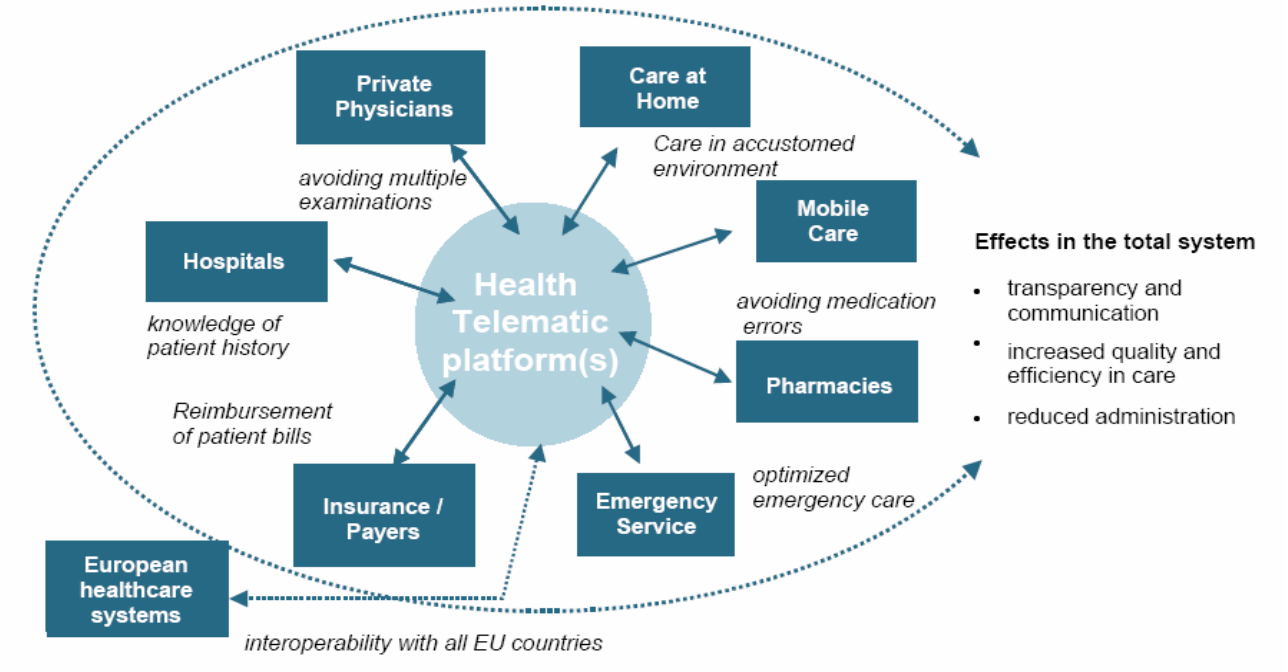


Fig. 7: Interoperability is vital for eHealth (an integrated approach) ***(62).***

2.2.7. Other problems of healthcare sector

In Europe, especially in Germany there is a lack of experts in healthcare system. New and expensive treatments alongwith budget constrains give rise to following uncomfortable scenerio:

- Small rural hospitals are shut down.
- Unequal access to healthcare for urban and rural areas.
- More rural migration.

eHealth networking can provide the solutions for these prpblems too.

2.2.8. A few facts about e-health

According to a recent study ***(15, 24):***

- e-Health is emerging as " 3rd industrial pillar" of health esctor in EU (€11 bn in 2004→ € 50 bn in 2010).
- By 2010, eHealth spending may account for up to 5% of the total health budget of the 25 Member States from just 1% in 2000 (for 15 Member States) ***(16, 24).***
- eHealth networks focus on „citizen-centred health". This requires strong policy and technology base plus regulatory supportive actions.
- Main drivers for eHealth are: *efficiency*, potential *saving* and *improvement* in patient health (e.g. by reducing medical errors)
- eHealth sector in Europe is fragmented, with little competition and many SMEs. There is a need to develop cooperating networks at all levels ***(24***).
- European businesses (including eHealth) have every opportunity to become leading global players in this new industry.

Fifteen years of regional, national, and international research and development in funding for eHealth in Europe have resulted in a wide number of applications that have been implemented in several Member States ***(17).*** There are many good examples of eHealth initiatives at a national and regional level within the European Union ***(18***). Forty out of the over180 real-life e-Health solutions submitted were exhibited at the e-Health Ministerial conference in 2003. Some support the use of smart cards, others are large scale health information networks supporting services such as MEDCOM in Denmark, EVISAND in Spain, SJUNET in Sweden, and HYGEIANET in Greece ***(19).***

There is considerable demand from Member States for further action to promote best practices and share experience in this area. Currently, for example, the Employment and Social Dimension of the Information Society collects best practices on the employment and social inclusion aspects of e-Health and healthcare in the knowledge society***(20).***

2.3. What could eHealth offer?

Not only the patients but all the sectors of healthcare delivery acn benefit throug eHealth. eHealth enables:

- Improvement of healthcare through patient empowerment and involvement ➲ **the better informed patient.**
- Better co-operation of health care providers ➲ **the better informed healthcare partner.**
- Better educated healthcare actors ➲ **the better informed provider.** (see figure 8 below)

2.3.1. Potential of eHealth

eHealth is an example of how technology has the potential to significantly reduce inefficiencies, to cut down on potential error and to reduce costs. The potential of technological advancements in healthcare was explored in some detail by a 2003 eHealth scoping study for the Prisma team by RAND Europe (Ligtvoet 2003).

The potential of e-health was identified as:

- Improving **quality** of healthcare, by tailoring care to individuals, where ICT enables more informed decision-making, based both on existing information and evidence and an individual's circumstances, and a reduction in error
- Improving **access** to healthcare, whereby ICT may alleviate or remove barriers to effective healthcare introduced by physical location or physical and sensory capability of an individual.
- Improving **cost-efficiency** of healthcare by streamlining processes, reducing waiting times and waste and improving accuracy of diagnosis. Reducing costs was though widely acknowledged to be a long-term aim, given often high initial costs of ICT innovations ***(10).***

The benefits of eHealth identified by the Prisma study are outlined in **Table 3** below.

2.3.2. Key applications of eHealth

Key applications of eHealth are:

- Online Electronic Health Information
- Electronic Patient Record
- Clinical and administrative systems
- Decision support tools
- Telemedicine

Table 4 below, provides an overview of five key applications of eHealth, summed up by four key questions:

1. What are they?
2. How are they implemented?
3. Where are they used?
4. Who interacts with them?

Table 3: Benefits of eHealth identified by the Prisma Study (2003).

Quality	**Increasingly patient oriented care**: facilitated by electronic patient records and enhanced communication.
	Individualised medicine : capitalising on developments of the human genome project, more will be known about the human body, and as this knowledge becomes available in digital form, its interrogation will allow for increasingly targeted treatment appropriate to a patient's unique set of circumstances.
	Improved knowledge: The Internet is increasingly providing opportunities for improved knowledge of both patients and clinicians, through enhanced communication and also availability of, for example, clinical guidelines and patient-oriented information on good health practice.
	Evidence-based medicine: Technology can provide a clinician with data sources of evidence matching the specific characteristics of the case currently being dealt with, and diagnosis can be influenced by the evidence presented.
	Co-operation between care providers: Technology can support and enhance clinical and organisational aspects of healthcare delivery.
	Improved safety through error reduction: The use of technology drives improvement in medical diagnosis and treatment strategies, reducing potential for human error.
	Reduction in waiting lists: Technology such as electronic registration may speed up healthcare delivery and reduce waiting lists.
	Healthcare development influenced by technology development: Developments in technology in other fields can stimulate and shape research and development into new and better ways of delivering healthcare, for example, micro- and nano-technology. Remote service delivery, portable insurance and remote clinical care can be the catalyst for changes in healthcare.
Access	Technological developments in healthcare, in particular telemedicine and virtual medicine, enable care to be provided more effectively to **groups who do not at present receive adequate care** , for geographical or economical reasons such as lack of insurance, or due to insufficient information, or because of long waiting lists.
	E-health is widely seen as being particularly important in providing a healthcare system that can best suit the needs of an **ageing society** and the specific demands it will place on care systems.
	Technology is seen as a factor in the **increase in private health services**, easing access and choice for those for whom private care is an option.
Cost Containment	While short term costs related to technological innovation may seem high, for example due to organisational or procedural change, education and re-training of staff, or purchase of hardware, in the longer term, **efficiency improvements** will result in cost benefits.
	Technology can also help **more accurate diagnosis**, reducing the need for patients to seek further opinion, reducing the need for extensive aftercare – electronically available **guidelines** can reduce the likelihood of wasted resources, inappropriate or ineffective action.
	Technology can **reduce fraudulent medical claims**, easing detection by linking services to expenditure.
	Transmural co-ordination can benefit from technology -enabled enhanced efficiency, reducing the need for a patient to physically be present at a number of different care environments.
	Advances in telemedicine can not only reduce costs by cutting down on transportation, but may **create markets that remove monopolistic, high-cost practice**.

Table 4: Key applications of eHealth

Key eHealth Technology	What?	How?	Where?	Who?
Electronic Health Information	Health Information available over a computer network – Information may include static text, images, as documents or in databases. Includes public health information, medical research and evidence, and elearning resources for medical education or continuing professional development. Information may be published content by an authoritative source, individual, or an archived discussion.	Any device capable of accessing digital information – PC, handheld, mobile phone, digital music player. May be networked (i.e. intra/Internet connection).	Potentially anywhere	- Potentially by anyone
Electronic Patient Record	Patient information, provided in a standardised digital form. Ranging from information relating to a specific condition or course of treatment to a lifetime health record including dental and psychiatric information.	Stored in a secure database and/or carried by a patient on a smart card, key-ring, or possibly implantable chip. Updatable by a secure computer interface; for example a web interface.	- Hospitals - Clinics and community health environments - GP practices - In the home	- Clinicians - Administrators - Nurses - Allied Health Professionals - Patients - Citizens - Researchers/ epidemiologists
Clinical and administrative systems	Software to facilitate administration and operation of a care environment. Ranges from use of IT in supporting non-clinical administrative tasks such as logistics, purchasing and human resource management, to clinical administration such as electronic prescribing, electronic booking,	Via PC, handheld/tablet computer, portable digital assistant, mobile phone	- Hospitals - Clinics and community health environments - GP practices	- Clinicians - Nurses - Allied Health Professionals - Administrators
Decision support tools	Technology to allow healthcare professionals and patients to use a computer interface (web or database) to enter specific parameters relating to a case or circumstance, and receive advice on possible options for care decisions, based on analysis of that data. Tools can increasingly take advantage of increasing amounts of clinical data and the knowledge gained.	Access could be by any networked device that has access to a data repository; or potentially stand-alone if the tool comes with a knowledge bas	- Hospitals - Clinics and community health environments - GP practices - In the home or anywhere with Internet access	- Clinicians - Nurses - Allied Health Professionals - Patients - Citizens
Telemedicine	Use of ICT to allow remote care of patients. Communication may be real-time: videoconferencing, telephone, radio, instant messaging. Web chat room, or asynchronous, for example email.	Use of physical or wireless secure or open networks to transmit data/enable communication. Access may be by wire, cable or wireless, via satellite or terrestrial transmitters.	- In hospitals - Clinics and community health environments - GP practices - “In the field” - At home	- Clinicians - Nurses - Allied Health Professionals - Patients

2.4. Public health benefits of eHealth

Due to the citizen-centered health care approach (see figure 9 below), many public health objectives can be achieved through eHealth networking. Some important health promotion approaches are:

- Empowerment (of citizens, health care professionals, health care providers)

- Reaching out to all communities („*Health for All*“ and „*Equity*“)
- The right to privacy, security and safety can be improved—efficiency levels of computors doesn’t change like humans
- Knowledge enhancement and continuing education ***(23)*** (see figures 8,9 &10 below).

2.4.1. Mapping the potential of eHealth – from the citizen to the government and back again

The tools of eHealth may be used **to empower the citizen** to gain information. On the basis of such information, the particular citizen may choose to seek the advice of a health professional, at which point one might become a patient within the health system. Once one is a patient, professionals will enter information into their Electronic Health Record concerning diagnosis, treatments and other relevant factors. The Electronic Health Record will in turn link to local, regional, national and even international systems that will allow the health professionals to better treat the patient. On the basis of secure information, the health professionals involved will be able to adapt their treatments and interaction to the needs of the individual with much greater ease. At the same time, the collected data will allow health managers, planners and regulators to adapt to the needs of the populations they serve more easily and with greater efficiency ***(23).***

HINE’s studies have shown that most health decision makers believe that *e*Health creates new forms of information that change the relationships between institutions, citizens, healthcare professionals and external businesses to create a system in which citizens, patients, healthcare professionals and the central authorities are better empowered (see figure 8 below) ***(23).***

The true potential for *e*Health lies, therefore, not only in its science and technology, but in those who implement it. *e*Health is not only a technological solution but a new approach to citizens-centred healthcare which embodies a commitment to **networked, global thinking, to improve healthcare locally, regionally, and worldwide by using information and communication technology**. *e*Health requires all players in the system, from the citizen to government, to dare to want to the best for their own health and for the health of the nation. It requires all of us to make *e*Health adapt to our own particular needs ***(23).***

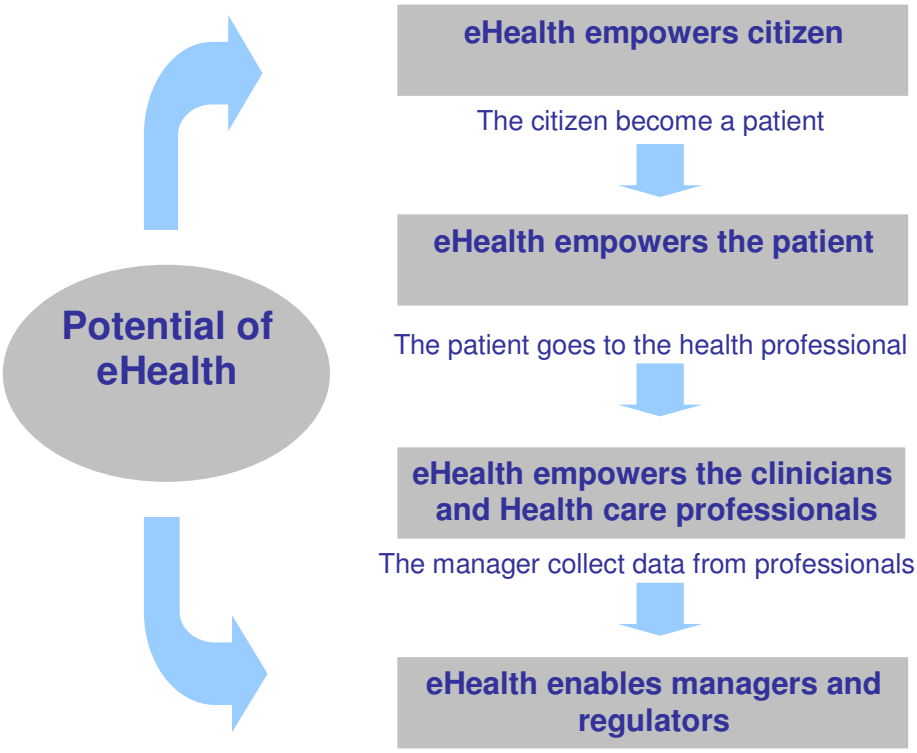


Fig. 8: eHealth a tool for empowerment: (The concept of this illustration is adopted from the benefits map presented in "HINE eHealth 2003 Repor, composed by Fareed A. Rehan).

Figures 9 & 10, below also describes the overall public health benefits of eHealth.

3. "eHealth for Regions" Project

3.1. History

Two running projects (institutions) in Schleswig Holstein province of Germany were behind the planning process for a transnational European eHealth project in the Baltic Sea region. As it is an obligation for applying the budgetory support at the European Union that there must be a running project with some positive results, so the following three projects provided the base for "eHealth for Region" project:

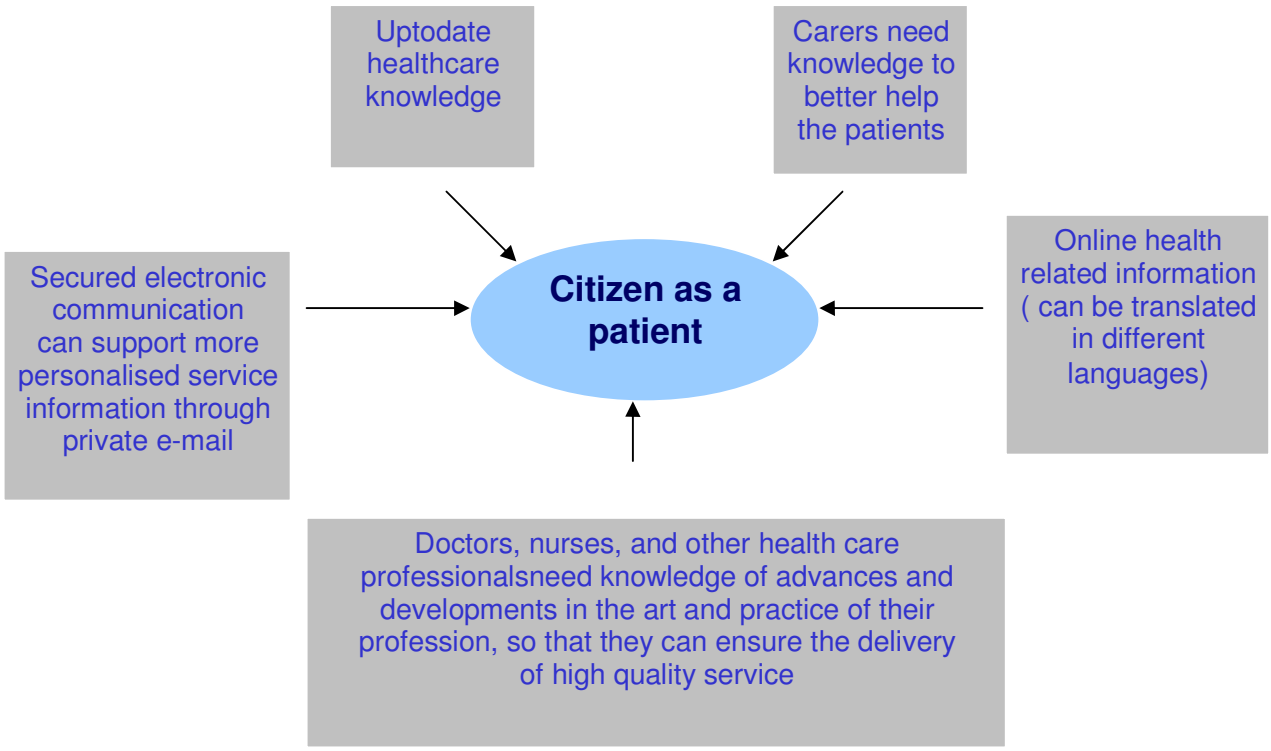


Fig 9: Citizen-centered approach of eHealth networking (composed by Fareed A. Rehan)

- Virtual Private Network (VPN) in the region of Flensburg, Germany
- Telemonitoring (Telecardiology) facility for heart patients at "Telemedicine Service- and Healthcare Centre" (TSGZ) in Bad Segeberg, Germany.
- Teleradiology project between iceland of Sylt and the Diako hospital Flensburg, Germany.

3.1.1. Virtual Private Network (VNP) Flensburg

The project was started in 1999. Out of 140 GPs in the region of Flensburg 40 are taking part in this project. Two big hospitals , DIAKO Hospital Flensburg and MALTESER Hospital are also taking part in this project.These all are connected through internet (VPN Server) to transfer the data and information. There are partners taking part in this

project, including AOK Schleswig Holstein, Siemens, University of Applied Sciences Flensburg and Ministry of Health Schleswig Holstein.

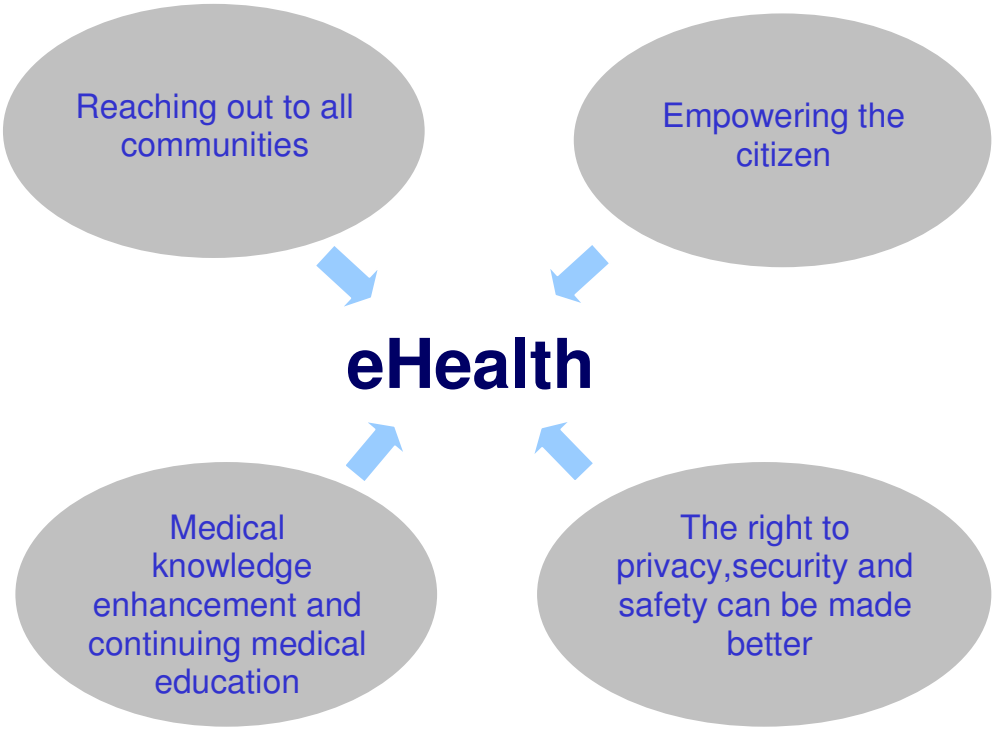


Fig. 10: Public health benefits of eHealth (composed by Fareed A. Rehan).

The main objectives of VNP Flensburg are:

- To ensure the high quality- and cost-effective healthcare through better communication.
- To identify the the possibilities for structural innovation in the healtcare system.
- To provide the opportunity for late consultation (after working hours) for patients.

With the help of VNP patient data can easily be transfered from GPs to specialists and to hospitals (see fig. 11 and 12 below).

This idea of VPN was used for transnational cooperation in BSR.

3.1.2. Telemonitoring (Telecardiology) at TSGZ in Bad Segeberg

Telemedicine is a very important component of integrated healthcare. The concept of telemedicine is based on motto that *"medicine comes to patient, not the patient comes to medicine".*

TSGZ was established as a collaborative initiative taken by AOK Schleswig Holstein (the largest insurance company of Germany) and "Segeber Kliniken GmbH" (Segeberger Group of Hospitals Ltd.). The concept behind the initiative was to address directly the interests of patients, such as:

- Innovative-Telemonitoring with best achievements.
- Application of only evidence based procedures and validated technologies.
- Technologigy based infrastructure with the opportunity for consultation with cardiologysts (doctors) during 365 days of the year, around the clock.

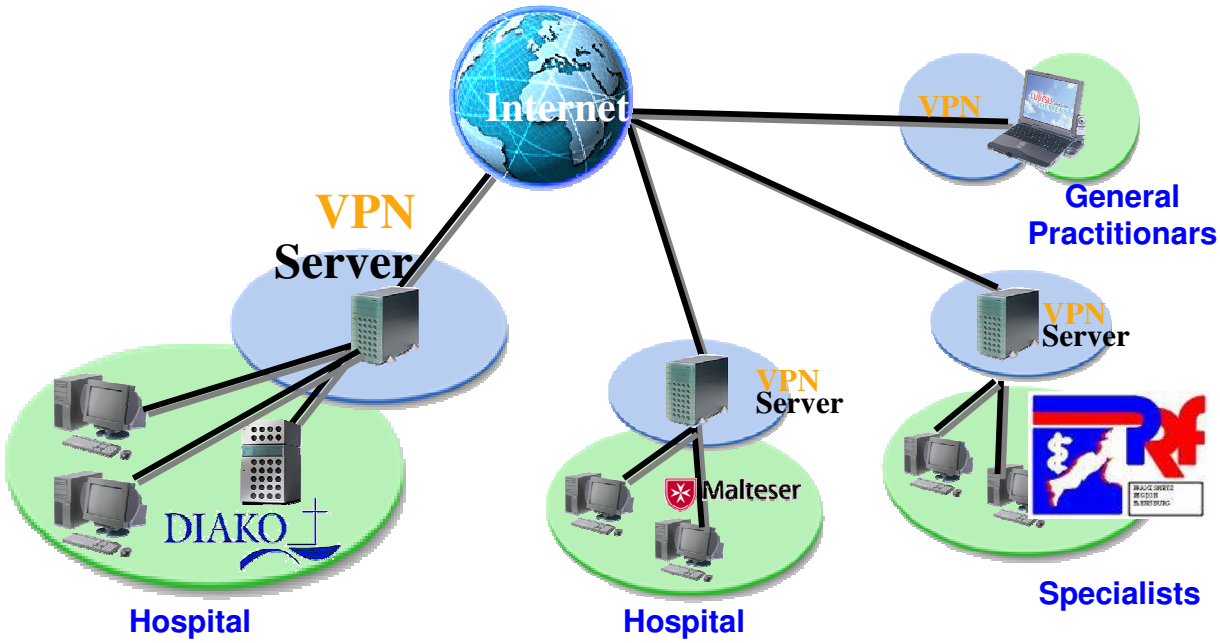


Fig.11: Structure of VPN in the region of Flensburg, Germany.

Telemonitoring of cardiac patients is underway since 2000 at the telemedicine centre (TSGZ) of Segeberger Hospital. It provides the opportunity for both the acute and

choronic heart patients (specially the patients who are at the risk for MI), and heart patients in rehabilitation, to send their ECGs with the help of a *"12 Lead-Mobile ECG-Recorder"* (a poroduct of the "Card Gat" company from Israel) to the telemonitoring centre at Segeberger Hospital, where a cardiologist is available round the clock to give his opinion:

- To provide high quality treatmrnt to heart patients without the restriction of place and time in all over the world.
- To reduce the pre-hospital time delay (critical time) for a heart patient, which results in many deaths.
- To improve the quality of life of heart patients by providing the mobile security.
- To decrease the strain of costs by reducung the hospital admission (e.g. in case of MI and cardiac insufficiency).
- To reduce the mortalit and morbidity.

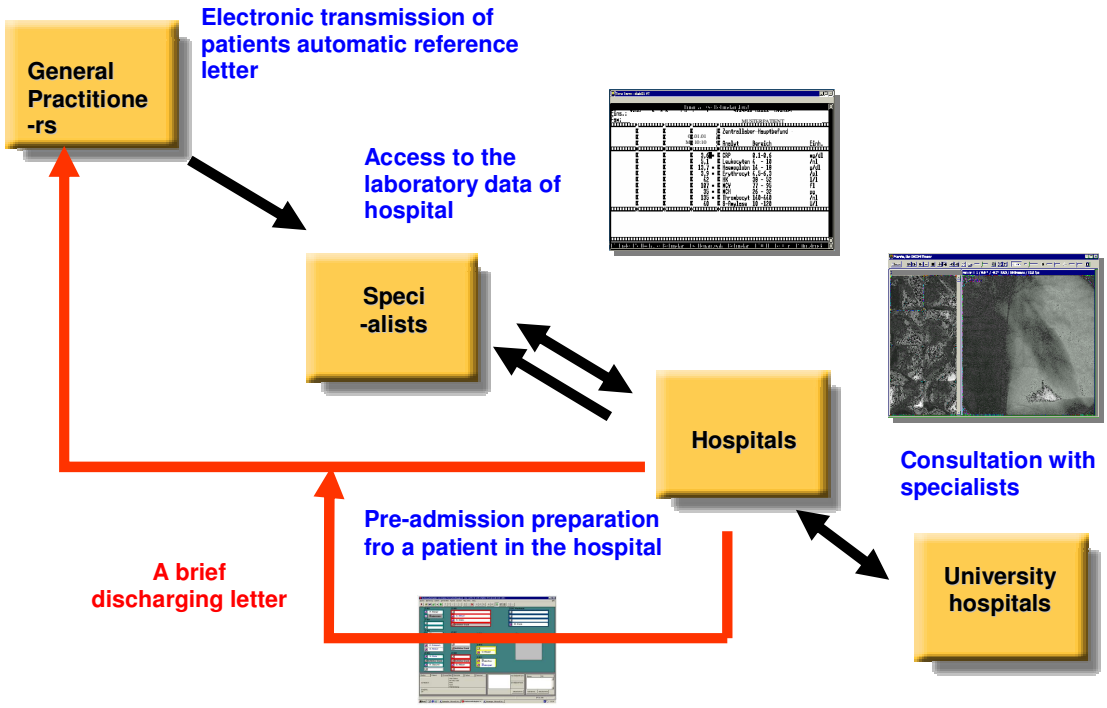


Fig. 12: Schematic diagram of data transfer at VNP in the region of Flensburg, Germany

How TSGZ functions?

Following steps are involved in the function of TSGZ:

- The patient records his ECG himself through a 12 Leads-Telecardio-ECG-Eventrecorder, which is as big as a ciggarate box
- Then, patient dials the number of TSGZ from any country of the world. The patient is then connected automatically to server of his own language, and recieves the directions for further action.
- Then, patient sends his ECG per telephone to the “Telematic Centre” (TSGZ).
- At the “Telematic Centre” (TSGZ) a cardiologyst examines the ECG alongwith the history, and if required a telephone talk with patient. If there is an emergency, the doctor in the centre will immediately arrange an ambulance for the patient, and at the same time the cardiac ward in the hospital is informed to recieve the patient. In this way without losing time and resources , the patient recieves the emergency (acute) treatment as soon as possible (**see figure 13 below**).

TSGZ is an important object between patients and doctors. It does’t take part in the treatment of the patients but transfer the data of acute cardiac patients to doctors and hospitals, so it improves the basis of emergency treatment by reducing the pre-hospital time delay (Entscheidungszeit) (**see Fig. 14 below**).

This concept of treatment is behind the the application of telemedicine for the treatment of heart patients transnationally in “eHealth for Regions” project for the countries of Baltic Sea region.

Spectrum of telematic care (telemonitoring) at TSGZ for cardiac patients

TSGZ offers the telematic care for following heart diseases:

- Coronary heart diseases
- Dysrythmia
- Cardiac syncope
- Cardia failure / cardiac insufficiency
- For follow up, e.g. ambulatory rehabilitation

3.1.3. Teleradiology project between Sylt Island and DIAKO Hospital Flensburg

This project was started in 2001 and is still in function. As there is no radiologyst in the the hospital of the Sylt island, MTR (technician of radiology) takes the images and send them to DIAKO hospital Flensburg, where a qualified radiologyst writes the final report.

3.1.4. Planning process for a transnational European project (vision)

On the basis of the above projects, AOK Scleswig Holstein started to plan a transnational European eHealth project with the vision that: (**see table 5 below**).

- VPN Flensburg , TSGZ Bad Segeberg and Teleradiology Network between Sylt Island and DIAKO hospital Flensburg can be connected with the existing eHealth networks in other countries of BSR (e.g. cardiology, radiology, urology, and chronic patients like diabetes) – information and communication network.

3.1.5. From vision to a project

The decision was taken for a European eHealth project in BSR for:

- The exchange of experiences in the field of eHealth between the countries of BSR—Information and communication network.
- "Best practice" in the field of telecardiology in BSR— Active role of TSGZ in the region.
- Internationalisation of the concept.

3.1.6. EU / EC Policy in eHealth and "eHealth for Regions" project

It remains true, of course, that each Member State organises its own health system, and that the European Union has no role in setting a European agenda on that score. (Article 152 of the EC Treaty provides that the Union's activity in matters of health shall be omplementary to national policy only). Nonetheless, the European Union has a key role o play in mapping a Europewide *e*Health agenda ***(23).***

EU's policy in the field of eHealth has three main objectives (**see figure 15 below**).

- European eHealth area
- Free patient mobility
- Empowerment of Citizen.

There is a long list of policy activities and actions taken at the European level in the field of eHealth. The main policy reflections and activities at the European level are:

- Health Telematics Working Group of the High Level Committee on Health
- Follow-up to the high level reflection process on patient mobility
- *Action Plan for a European eHealth Area*
- Update of the eEurope Action Plan (i2010)
- *Public Health* Action Programme

- High Level group on health services and medical care to facilitate Member States' cooperation between health systems.
- Implementation and deployment plans or roadmaps (including EHR, communication infrastructures, standardisation, security and privacy, research, national and international collaboration) in other Member States ***(24).***

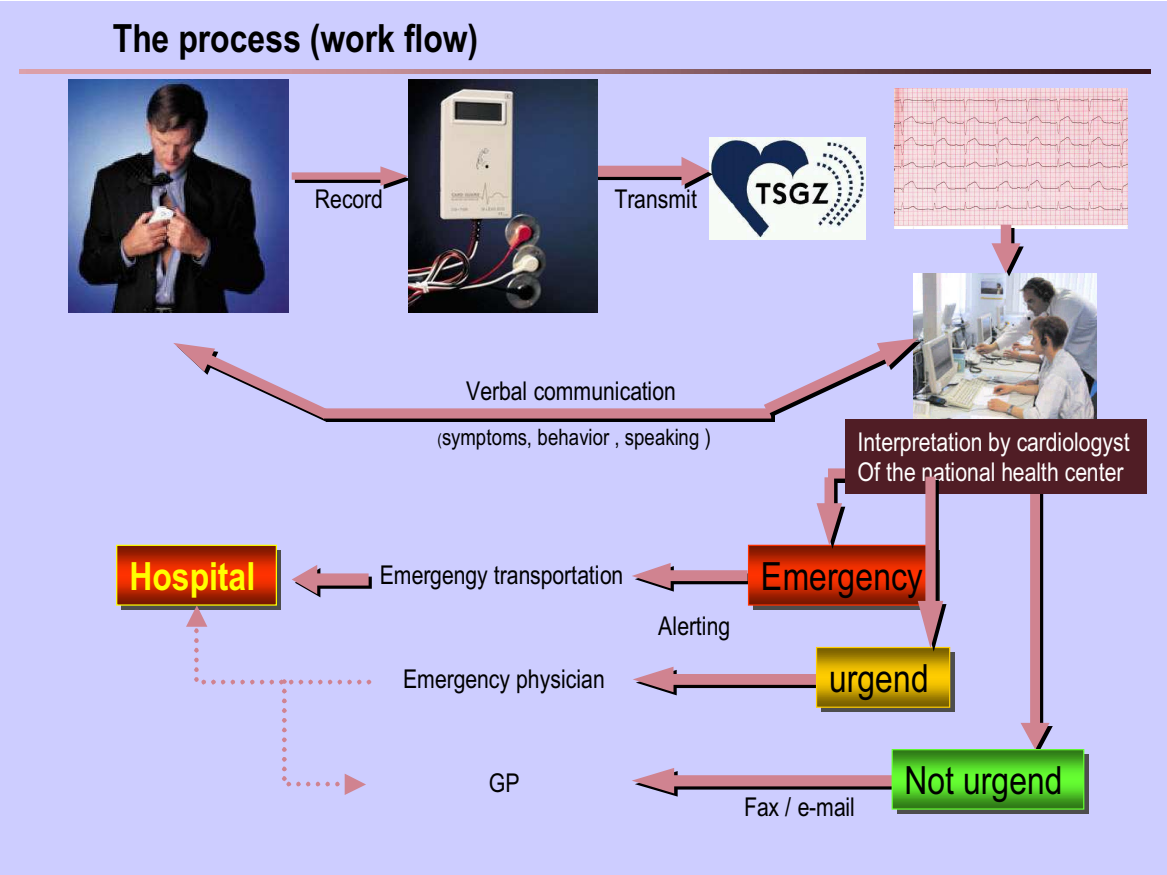


Fig. 13: Concept of working process for telemonoring for cardiac patients at TSGZ in Bad Segeberg, Germany.

The European Commission's policy (IST EC Policy) on *e*Health, which was developed initially within the Information Society Directorate-General, reflects the three focal aspects of ist information society policy: **research, regulation and benchmarking** ***(24).***

3.2. Project details: “eHealth for Regions” Project

eHealth for Regions project is a 3,27 million Euros project, part-financed by the uropean Union (European Regional Development Fund) within the BSR INTERREG III B NP programme. The main highlights of the project are given below.

- 17 project partners from 8 countries in the Baltic Sea Region (see figure 16 below).
- First meeting of the project partners was held in autumn 2003

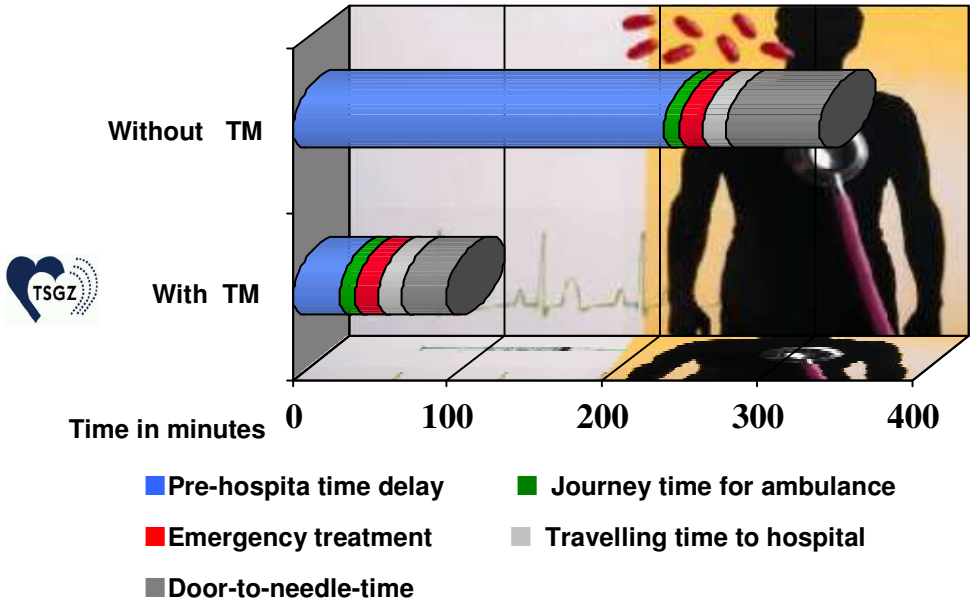


Fig. 14: Heart patient and competition with time *with* and *without* TM (Telemedicine).

- The Baltic Sea Region Interreg III B project commences in June 2004
- 2004 – 2007: three-year project phase
- Project completion in June 2007
- Activities divided into four work-packages
- Financing of 3.27 million Euros
- Financial investment provided by the partners, Norway and the European Union ***(25).***

3.2.1. INTERREG III Programme

INTERREG III is a EC Community Initiative to promote transnational co-operation on spatial planning by encouraging harmonious and balanced development of the European territory. The overall aim is to ensure that national borders are not a barrier to balanced development and the integration of Europe and to strengthen co-operation of areas to their mutual advantage. The Initiative runs from 2000 to the end of 2006.

Table 5: Planning process (vision) for a European eHealth project

Overview of Possible Cooperation Fields in eHealth		
Question	**Area**	**Short Description**
What will we do?	Tourists will get improved cross-border health provision processes with a second opinion of a specialist	**To build up service points within the respective partner countries for cardiology:** - Mobile vacation packages (care abroad with 2nd opinion of the homeland and in urgent cases back carrying into the homeland) - RTW-equipment of ambulances including the networking of clinics
		To establish the opportunity of cross-border second opinions for the examination of cases within: - Urology - Radiology
		To offer the cross-border basic information exchange for chronically sick patients: - Countries across handle the exchange of the digital patient documents - Exchange of available electronic data including the translation of the patient history
How will we do it?	Helping tools	**eHealth Homepage**
		Nationwide Health Care Portal (eg. blood database, asthma club, anorexia)
Which future developments will we have in mind?	Future innovative developments	**Health card with eReceipt** (in Denmark it is already realized; in all other countries it is in preparation)
		Best process of future health care: How could it look like? We don´t use what would be possible today.

INTERREG III has a financial volume of about 4,875 billion Euros and has three strands: INTERREG A, INTERREG B, INTERREG C (**see Fig. 17 below**).

3.2.2. INTERREG III B Programme

The Baltic Sea Region (BSR) INTERREG III B Neighbourhood Programme belongs to one of the three different strands of the European Community Initiative INTERREG III. The programme is part-financed from the European Regional Development Fund (ERDF) covering the period 2000-2006. Strand B of the INTERREG Initiative supports

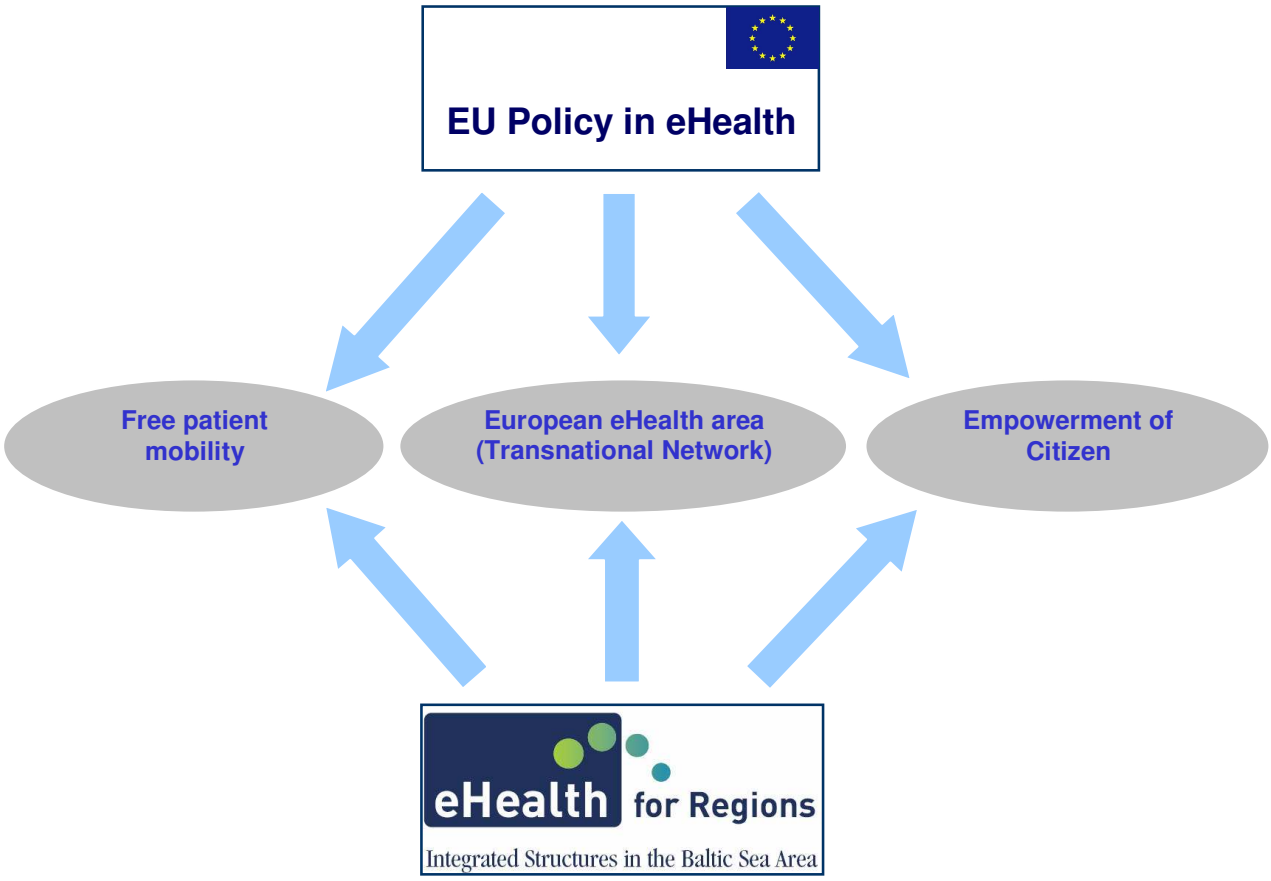


Fig. 15: EU policy in eHealth and “eHealth for Regions” Project (composed by Fareed A. Rehan)

transnational co-operation to enhance balanced and sustainable development of the European territory.

The Baltic Sea Region is one of the 13 European INTERREG III B co-operation areas. Eleven countries, namely the EU Member States Estonia, Denmark, Finland, Germany, Latvia, Lithuania, Poland and Sweden, further on Norway, North-West Russia and Belarus are participating (**see Fig. 18 below**).

Fig. 16: 8 countries of Baltic Sea Region are taking part in "eHealth for Regions" project.

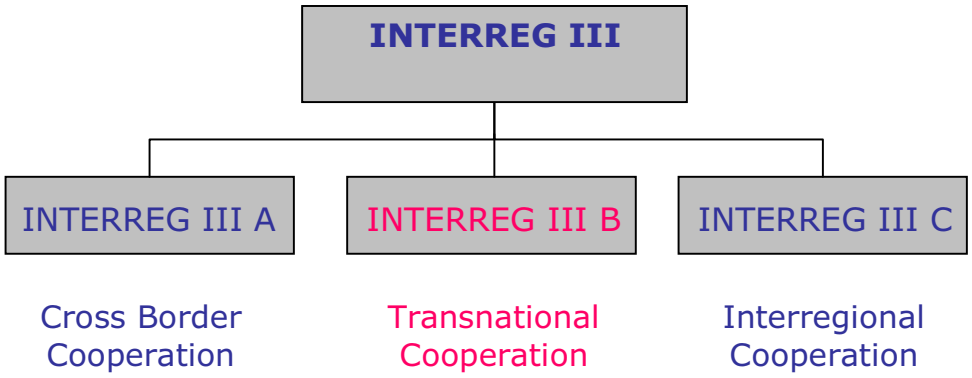


Fig. 17: INTERREG III Programme and its division

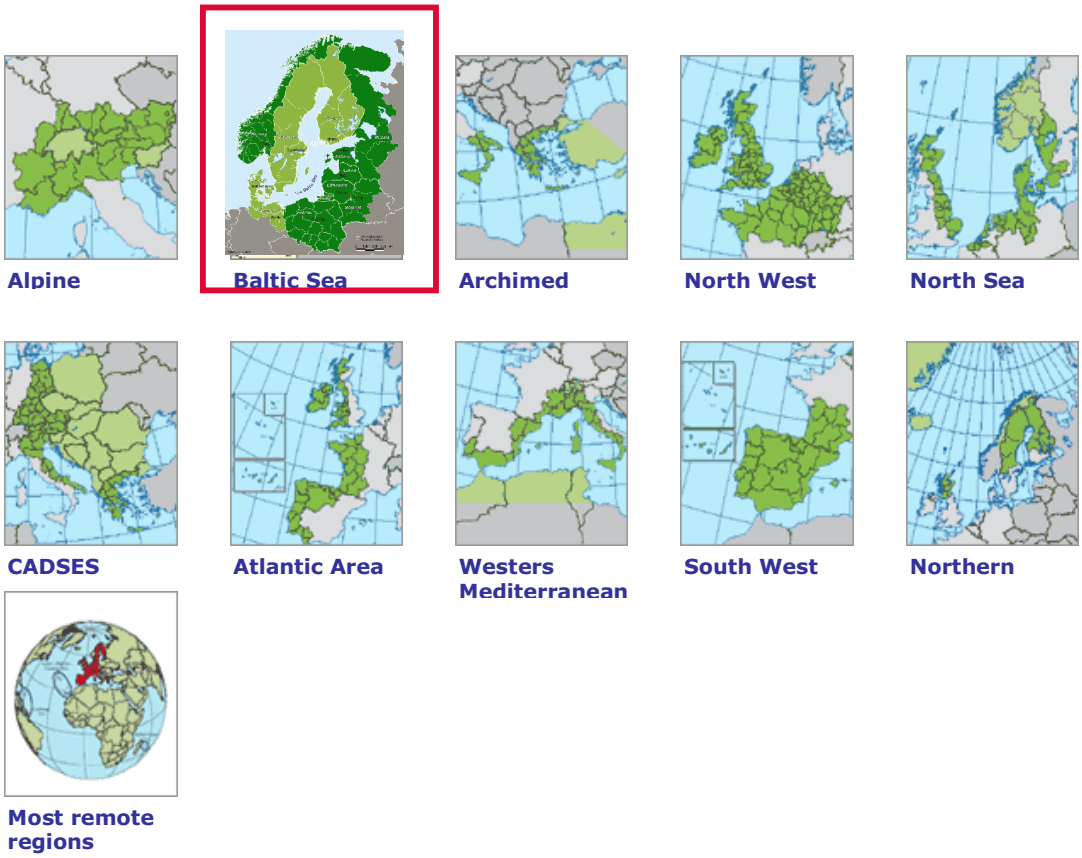


Fig. 18: INTERREG III B Programmes, including BSR INTERREG III B : Transnational Cooperation for spatial planning and regional development ***(25)***

3.2.3. Priorities of INTERREG III B Programme

Priority 1: Promotion of spatial development approaches and actions for specific territories and sectors

Priority 2: Promotion of territorial structures supporting sustainable BSR development

Priority 3: Transnational and bilateral institution and capacity building in the Baltic Sea Region

3.2.4. Strategic objective of INTERREG III B

Strengthening economic, social and spatial cohesion by promoting transnational economic relationships in order to reach an increased level of BSR integration and to form a region with sustainable growth prospects ***(25).***

3.2.5. Why “eHealth for Regions” Project

The main supporting arguments for “eHealth for Regions” project are:

- To deal with rising demand for services (e.g. due to ageing of Europe) in addition to budgetory conditions of Europe.
- To ensure that citizens of Europe in both urban centres and periphral (remote) areas have the same access to health care services— to prevent rural-urban migration.
- To overcome the national and transnational inequalities that are evident in the health care supply in the Baltic Sea region— “Health for All” vision. .
- To develop a model for transnational cooperation in the field of eHealth in the Baltic Sea region— “A model for Europe”.

3.2.6. Objectives and Goals of”eHealth for Regions” Project

“eHealth for Regions” is a move towards “European eHealth Area”, a goal set by the European Commission. The specific objectives of “eHealth for Regions” are:

- To enhance the attractiveness of the regions by using eHealth as an instrument for regional development.
- To improve the accessibility and quality of health care available to citizens in urban and rural areas ("pervasive healthcare on the basis of eHealth").
- To share knowledge and resources through transnational transfer, standardisation and localisation of eHealth solutions.
- To promote the acceptance of patients, doctors and other actors in the health care sector with regard to eHealth services.
- To build a transnational, cross-sectoral network and develop a business model promoting co-operation in the field of eHealth in the Baltic Sea region.

- To experience the transnational network and to co-operate in the field of *telecardiology* and other fields.

3.2.7. The core strategic concept of the project

The project’s proceeding strategy is based upon:

- Dialogue and communication.
- Nettwork building.
- Implementation of solutions.

3.2.8. How works the project? (Working strategy of the project)

The implementation of the project is divided into four work-packages (WP). Work-packages 1 and 2 will create the strategic framework for the transnational network and will specify the structure and organisation of the co-operation. In work-packages 3 and 4, technical solutions and standards for transnational eHealth applications will be developed and implemented in the field of telecardiology.

Structures and processes (WP 1)

Work-package 1 consists of a detailed co-operation concept covering various areas, ranging from strategy development, planning the exact framework of eHealth structures and processes to its implementation among the partners. Strategies are to be developed to gain the acceptance, among others, of patients and physicians as regards eHealth to enable patients to participate in health solutions, to establish eHealth in everyday health care and to intensify co-operation among the partners.

Network and business model (WP 2)

A sustainable transnational and cross-sectoral network will be created within work-package 2. A business model will also be developed to provide a lasting contribution to the stabilisation of the transnational co-operation and will form the basis of future projects and investments. In addition, models for transnational co-operation in the field of eHealth will be created.

Technical aspects (WP 3)

During work-package 3, existing technical solutions will be evaluated, adjusted and regionally adapted for the pilot phase to be implemented in the course of work-package 4, as well as for the different co-operation fields developed during work-package 1 which are to be transferred and localised in the partner regions. The outcome will be the identification of technical solutions that are appropriate for the standard environment and technical infrastructure implemented in the partner regions.

Pilot implementation (WP 4)

A pilot programme in the field of telecardiology will be implemented for experiencing transnational standardisation, transfer and localisation. Structures and processes will be implemented, tested and adjusted in the partner countries. The technical solutions derived from work-package 3 will therefore be used for co-operation in the field of

telecardiology. The experience gained can then be transferred to other areas of co-operation.

3.2.9. Thesis work as a part of project work

I took active part in WP1/WP2 from September 2005 to February 2006, to create strategic framework for the transnational network together with experienced professionals from the 8 countries of Baltic Sea region.

The project duartion is 3 years ( ) with overall 6 milestones, with two milestones each year and one milestone in 6 months (see Table below). Reginal need analysis is a milestone for July-December 2005. The aim of this milestone is to assess / analyse the overall situation about eHealth acceptance and awareness in the region.

Table 6: Overview of milestones in work packages of "eHealth for Regions" project. Main research work of thesis is performed as milestone "Regional need analysis".

	Structure and Processes (WP 1)	**Network and Business Model (WP 2)**
1. June-Dec. 2004	▪ *Data collection:* Analysis of eHealth activities in all partner countries ▪ *Cooperation concept:* 3-5 cooperation fields, strategic goals	▪ *Data collection:* Analysis of existing networks in the field of health and eHealth
2. Jan.-June 2005	▪ *Regional Need Analysis:* Questionnaire ▪ *Cooperation concept:* Matrix of strategic goals and strategy, quality performance measures	▪ *Network building:* Strategic board and peer groups for WP 1-4 set up.
3. July-Dec. 2005	▪ *Regional need analysis:* Survey (e.g. 500 emails in at least 4 countries) ▪ *Strategic realisation:* SWOT; guidelines for transfer, localisation, implementation of eHealth structures and processes; financing options	▪ *Strategic network:* Monitoring and discussions, integration of triple helix actors started ▪ *Business model:* Development started

3.2.10. Who are the partners in the "eHealth for Regions" Project

There are 17 partners from 8 countries (**see fig. 19 below):**

Denmark: Viborg County Council
Finland: Regional Council of South Ostrobothnia, Seinäjoki Polytechnic, South Ostrobothnia Health Care District
Germany: AOK Schleswig-Holstein, District of Segeberg, Ev.-Luth. Diakonissenanstalt Flensburg, Ministry of Public Health Land Schleswig-Holstein
Lithuania: Kaunas Region, Kaunas University of Medicine Heart Center, Vilnius University Hospital Santariskiu Klinikos
Norway: Vestfold Hospital Trust
Poland: City Hospital Lebork, Lebork Town Municipality, Medical University of Gdansk
Sweden: Region Skane, Economic Development / Innovation, Region Skane, Health and Medical Services
Latvia:

4. About the topic of thesis

4.1. Three parts of the thesis

Besides the theoratical part (background, introduction), this thesis consists of three parts :

- **Part I**: "Regional need analysis". It is questionnaire based survey conducted as milestone in WP1/WP2.
- **Part II**: "Use of existing eHealth solutions for transnational (cross-border) treatment of heart patients (both acute and chronic)". This work is mainly performed at the TGSZ Bad Segeberg.
- **Partt III**: "Legal aspects of eHealth" with respect to the project work. This part consists of the legal challenges in the field of eHealth (eHealth for Regions) and their solutions.

4.2. Main objectives of the study (thesis)

- To assess / analyse the acceptance and awareness of eHealth in the region (questionnaire survey in Schleswig Holstein: 250 questionnaire).
- To reduce the pre and in-hospital time delay for a heart patient (MI)
- To check the effectiveness of mobile ECG recorder
- To establish a network of e-health in the Baltic Sea region.

- Challenges to eHealth and their solutions (legal aspects).

5. Regional Need Analysis

It is milestone in WP1 of “eHealth for Regions” project. It was decided that the participats from following 5 countries will perform a questionnaire survey:

- Gerrmany
- Sweden
- Poland
- Finland
- Lithuania.

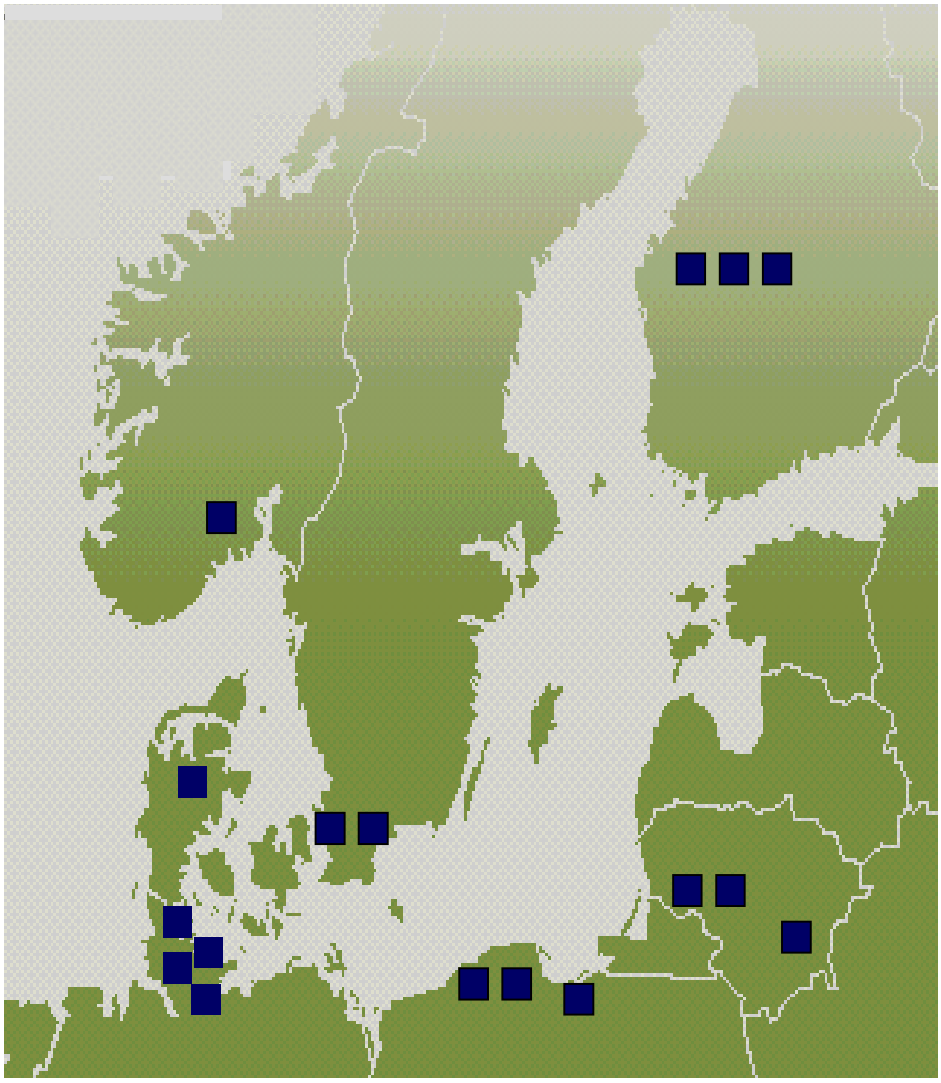


Fig. 19: 17 partners from 8 countries of Baltic Sea region are taking part in “eHealth for Regiona” project.

5.1. Objectives

The aim of this milestone is to assess / analyse the overall situation about eHealth acceptance and awareness in 5 countries of Baltic Sea region (this thesis includes only the survey in SH, Germany).

5.2. Questionnaire development

It was decided in the meeting in Tonsberg, Norway in September 2005 that a questionnaire survey will be done in atleast 5 partner countries of tha project (Germany, Sweden, Poland, Lithuania, later on Finland was also included). In each country about 500 questionnaires will be sent to healthcare professionals (doctors, nurses), decision makers and public and patients. It was my duty within the project to develop the questionnaire for all partner countries and to organise and manage the questionnaire surves in all the partner countries.

Together with Mr. Thorsten Beck and after discussing the issue of questionnaire with the students of"Public Health" during the one day course conducted by Mr. Thorsten Beck and me, we developed 3 different questionnaires for three different target groups. Likewise, we outlined the strategy for questionnaire survey in the province of Schleswig Holstein of Germany. Alongwith the questionnaire, we decided to send a small "Introduction to eHealth". Below you will find the developed questionnaires with the introduction to eHealth, used in 5 partner countries of project (**see tables 7, 8, and 9**). Table 10 below includes the introduction to eHealth, which was sent alongwith questionnaire to all groups.

Group A: Doctors, Nurses, and Others

Group B: Decision makers

Group C: Patients and Public

Plan for Questionnaire survey in 5 countries of BSR

9th December:	Send the questionnaires to all partners
16th December:	Feedback from partners

22nd December: Final version for designing and printing

Till 20th January: Send the questionnaires to the target groups

1st March: Final results

It was decided that a small introdction about eHalth will also be sent alongwith questionnaire to all groups. **(see table 10 below)**

The final version of the questionnaire in german language was designed by the AOK.

Table 7: Questionnaire developed for doctors, nurses (healthcare professionals)

Group A: Doctors, Nurses, and Others

General recommendations:

1. Selection of the target groups:
   - GPs → We can use the electronic record of the association of physicians: „**www.arztfindex.de**"
   - Doctors / Nurses working in the hospitals → We can give it for example to CEO's or Directors of hospitals.

2. Please do not send the questionnairs by e-mail → „data security", availability of internet (especially for Germany)

3. Please send the questionnairs by post.

4. Please send information papers about eHealth to every doctor, nurse and other.

5. Number of questionnaires: 250

Suggested questions:

1. About which of the following key applications of eHealth are you aware (did you came in contact in the past)? (More than one answer can be chosen).

□ electronic health information
□ electronic patient record
□ clinical and administrative systems
□ decision support tools
□ telemedicine
□ none

2. What kind of advantage offers eHealth in your company / institution? (More than one answer can be chosen).

□ better and fast information
□ better quality of care
□ positive cost effects
□ well organised central archive
□ others_____
□ none

3. Which problems do you face through eHealth? low ... 1 2 3 4 5 ... high

1. legal problems 1 2 3 4 5
2. lack of eHealth knowledge 1 2 3 4 5
3. availability 1 2 3 4 5
4. security 1 2 3 4 5
5. lack of standardisation / integration 1 2 3 4 5
6. none 1 2 3 4 5

4. Do you think that cost-investments for eHealth justify with its savings potential?
□ Yes, for a short time
□ Yes, for a long time
□ no saving potential

5. Do you think that the processes of eHealth are a threat for data protection, if we compare these processes with normal traditional paper based data?
□ little acceptable threat
□ big threat
□ no threat

6. What is your vision about the future of eHealth?
□ a well established eHealth networking in the region
□ a well established eHealth networking on the country level
□ a well established cross border eHealth network
□ none

(continue on the next page)

7. How do you rate the acceptance of eHealth: low ... 1 2 3 4 5 ... high

(a) at your working environment? 1 2 3 4 5
(b) on the regional level 1 2 3 4 5
(c) on the country level 1 2 3 4 5
(d) regarding patients care 1 2 3 4 5
(e) none 1 2 3 4 5

8. What do you think about the development of eHealth in your region?
□ almost all health care providers should be connected through eHealth network in the next 3 years.
□ almost all health care providers should be connected through eHealth network in the next 5 years.
□ almost all health care providers should be connected through eHealth network in more than 5 years.

9. How do you rate the exchange and communication of medical information at present?

1 2 3 4 5

10. Exchange of medical information up to now is chracterised by:
□ lack of information 1 2 3 4 5
□ usually unsatisfactory secured archives for the documents (e.g. x-ray films) 1 2 3 4 5
□ repetition of investigations 1 2 3 4 5
□ none

11. Do you think that there will any improvements in the quality of medical care?
low ... 1 2 3 4 5 ... high
Improvement through:
□ optimal flow of information 1 2 3 4 5
□ fast diagnosis & treatment 1 2 3 4 5
□ central archive: reduction of double investigations 1 2 3 4 5
□ securing data from unauthorized persons/institutions 1 2 3 4 5
□ cost-effectiveness 1 2 3 4 5
□ effectiveness in acute cases 1 2 3 4 5

12. Can eHealth increase the access to health care, particularly in the remote (rural) areas of the region?

□ no □ a little bit □ most probably
□ definitely □ I dont know

13. Do you think that by developing a transnational and regional eHealth network, the people of the whole region can profit?

□ yes, especially beneficial for travelling patients
□ no, not beneficial for travelling patients
□ eventually comments …….

14. What is the main reason which makes eHealth significant in the health care system in future?

Table 8: Questionnaire developed for decision makers

Group B: Decision makers

General recommendations:

1. Please send the questionnaires by e-mail.

2. Benchmarking

3. Number of questionnaires: 50

Suggested questions:

1. How is your practical knowledge about eHealth?

□ little □ average □ good □ working with eHealth

2. About which of the following key applications of eHealth are you aware? (More than one answer can be chosen)
□ electronic health information □ electronic patient record
□ clinical and administrative systems □ decision support tools
□ telemedicine □ others_____
□ none

3. What is your source of knowledge about the above mentioned key application?
(More than one answer can be chosen)
□ media (internet) □ conferences / seminars □ further education
□ external education □ experience through working □ projects and research work in eHealth
□ none

4. Would you like to allocate more resources in eHealth at your company / institution?
□ Yes □ No □ eventually comments……

5. Do you think that eHealth is an important factor for your institution?
□ Yes □ No

6. What do you think about the development of eHealth in your region?
□ almost all health care providers should be connected through the eHealth network in the next 3 years.
□ almost all health care providers should be connected through the eHealth network in the next 5 years.
□ almost all health care providers should be connected through the eHealth network in more than 5 years.

7. What do you think about the cross-border (transnational) development of eHealth?

□ good development □ not a good development □ I expect no changes

8. Can eHealth increase the access to health care, particularly in the remote (rural) areas of the region?

□ no □ a little bit □ most probably
□ definitely □ I dont know

9. Do you think that by developing a transnational and regional eHealth network, the people of the whole region can profit?

□ yes, especially beneficial for travelling patients
□ no, not beneficial for travelling patients
□ eventually comments ……

10. How much eHealth networking is important for exchanging experiences transnationally in different fields of medicine?

low….1 2 3 4 5 ….high

11. What is the main reason which makes eHealth significant in the health care system in future?

Table 9: Questionnaire developed for patients and public.

Group C: Patients and Public

General recommendations:

1. Please send the questionnairs by post – remember: old people, people without internet access (to recieve objective results – without bias).
2. Addresses can be achieved from doctors, hospitals, and insurances.
3. Divide the target group according to sex, age, etc.
4. Number of questionnaires: 250

Suggested questions:

1. Personal data (you may leave blank any question you don't want to answer).

Gender: □ Male □ Female
Your age group: □ 20-29 years
□ 30-39 years
□ 40-49 years
□ 50-59 years
□ 60-69 years
□ 70 + years
Higest level of your education: □ no education
□ middle maturity
□ high school
□ university
Use of internet at work and home:
□ less than 5 hrs / week
□ 5-15 hrs / week
□ more than 15 hrs
□ none

2. In which group do you place yourself?

□ doctors, nurses □ decision makers □ patients □ normal public □ none

5. Please rate the level of your acceptance for eHealth:

low... 1 2 3 4 5 ... high

6. What do you think about the cross-border (transnational) development of eHealth?
□ good development □ not a good development □ I expect no changes

7. At which extent eHealth can improve the quality of health care services? Please rate
low … 1 2 3 4 5 …high

8. Which of the following are your positive expectations about eHealth ?
□ I expect rapid supply of health care
□ I expect much better care
□ I expect availability of health services after duty hours
□ I expect reduced contact to family doctors (privacy)

9. Which of the following are your negative expectations about eHealth?
□ little trust in technology and risk for secured data
□ insecure feeling about eHealth
□ eventually comments……..

10. What do you think about the development of eHealth in your region?

□ almost all health care providers should be connected through the eHealth network in the next 3 years
□ almost all health care providers should be connected through the eHealth network in the next 5 years
□ almost all health care providers should be connected through the eHealth network in more than 5 years

11. Do you believe that eHealth can provide equal opportunity for health care service for people of the countries around (equal health care supply for everybody)?
□ Yes □ No

12. Do you think that eHealth networking will improve the availability of medical service?
□ Yes □ No

13. Can eHealth increase the access to health care, particularly in the remote (rural) areas of the region?
□ no □ a little bit □ most probably □ definitely □ I dont know

14. What is the main reason which makes eHealth significant in the health care system in future?

5.3. Methods

The target groups for the questionnauire survey were: doctors and (250), public and patients (250), and the decision makers (50) in each country including Germany. Due to doctors' strike in January 2006 in Germany it was difficult to collect the data from doctors, nurses and decision makers in Germany. So, it was decided to conduct the questionnaire survey only in the "Group C" i.e. public and patients.The results of only one group (250 questionnire) are published at the moment. The remaining results about the questionnair survey in all the 5 countries will be added later to this project work.

5.3.1. Germany

Questionnaire were sent per post to 250 selected insurants (normal public and the patients) in the province of Schleswig Holstein, Germany. The target group of 250 people was selected according to age, sex, qualification.

5.4. Results

5.4.1. Response rate

Overall response rate was 19,6%. Response rate was different in different age groups with maximium response rate of 30,61% in 60-69 years age group followed by 24,48% in over 70 years age group. Response rate was higher in females as compare to males. See the graphs below: Response rate in different age groups and according to sex.

Table 10: "An Introduction to eHealth", sent alongwith questionnaire to the target groups.

An Introduction to eHealth

eHealth is defined as:

„the application of information and communications technologies across the whole range of functions that affect the health sector".

Challenges facing Europe's Health Sector

European regions are facing the similar challenges:

- Problems with "Aging Society"
- Sharing Medical Information and resources
- How to provide best health care regarding growing costs.
- How to provide the best health care to the travelling patients (holiday, business) - „transnational network"
- Problem of equal access to health care facilities both in urban & rural areas

e-Health: systems and services that benefit the health sector

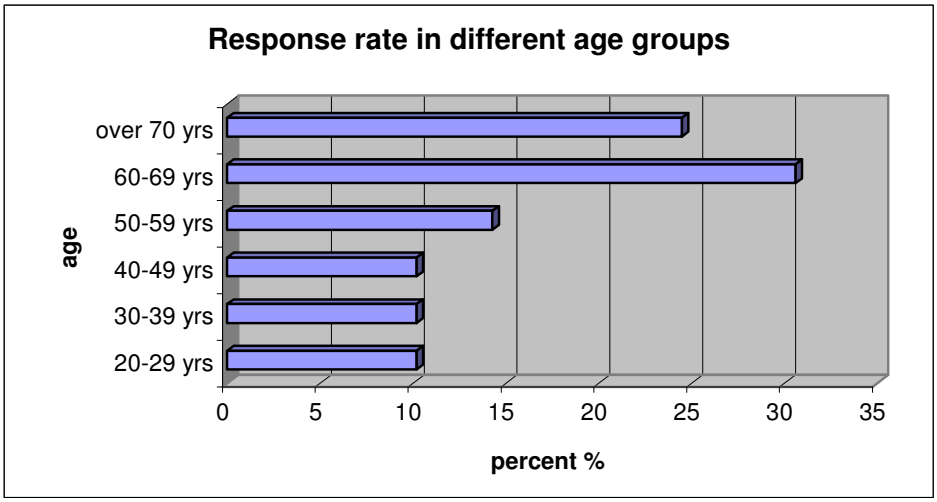
- To improve the quality of healthcare services without increasing costs.
- Specialised online resources are available for health education, safety and security at work, and lifestyle management, both for the patients and the healthy citizens.
- e-Health tools and applications can provide quick and easy access to electronic health records at the point of need.
- Health authorities and managers are responsible for the proper organisation and running of health systems. e-Health systems can empower managers by spreading best practices and helping to limit inefficient and inappropriate treatment. This is the single most important step in releasing resources and ensuring broad access for everyone to quality care.
- e-Health is the third largest industry in the European health sector. By 2010, e-Health spending may account for up to 5% of the total health budget of the 25 Member States from just 1% in 2000 (for 15 Member States).
- To provide equal access to health care facilities, both in urban & rural areas → „Health for All".

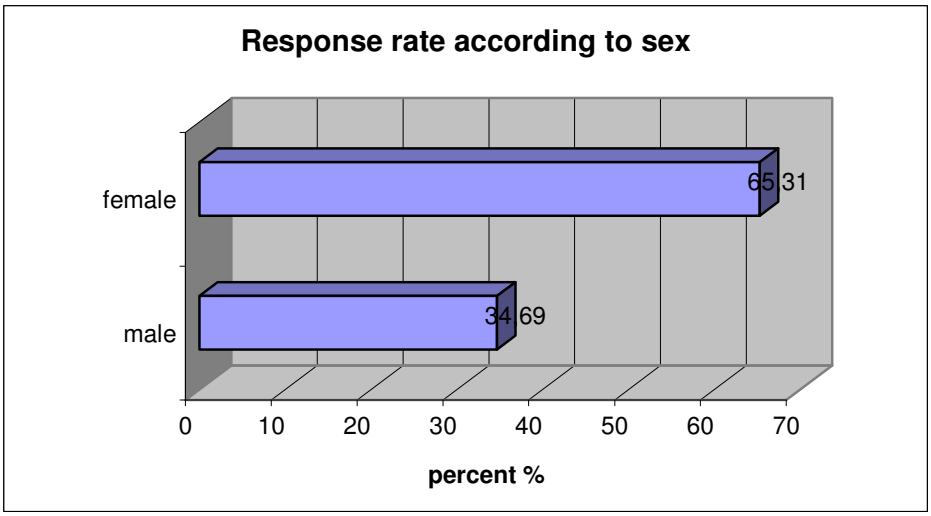
Examples of e-Health and its benefits

1. In Process: Electronic Health Record (EHR) → e.g. Pilot for region Flensburg between GPs, Specialists and Hospitals

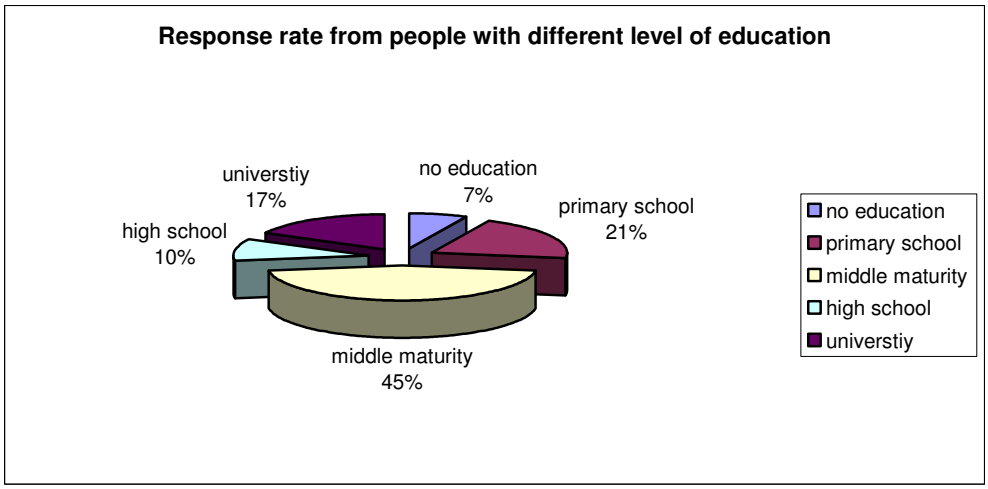
Informations provided by the EHR are:
History / diagnosis; History of allergies; Vaccination; Prescribed medication; and Last visit to doctor etc.

2. Just started: Electronic Health Card & health Professional Card
These are the future projects in Germany.



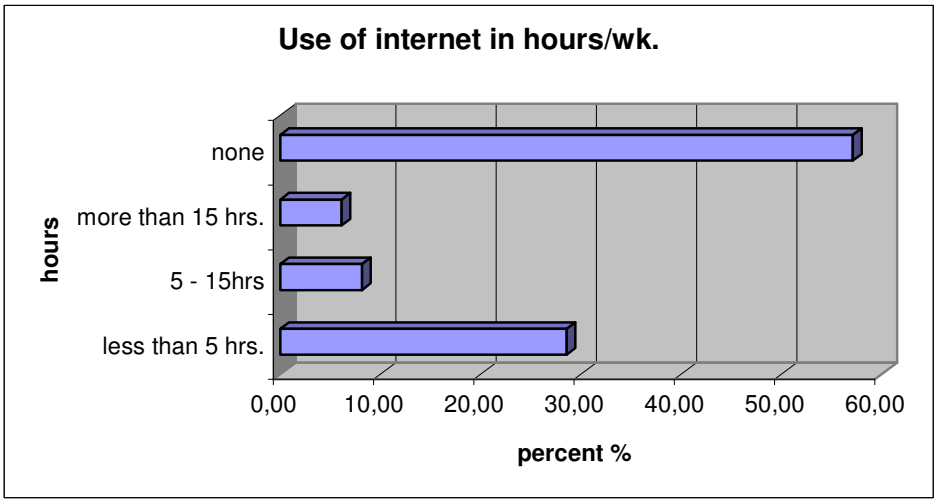


The people with educational level of middle school respoded frequenly (45%) as compared to people with university education (17%). This can be dut to unemployment in the people with middle school level education, as they have enough time. See the diagram below.



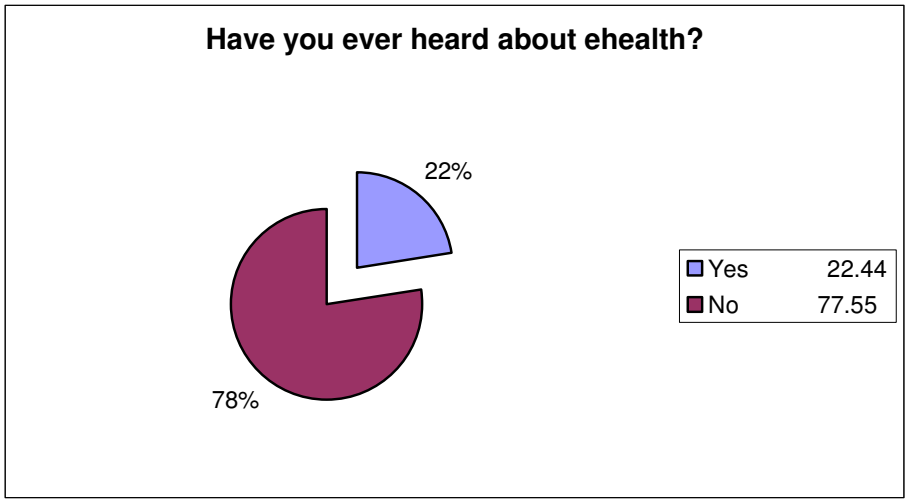
5.4.2. Internet use in hours

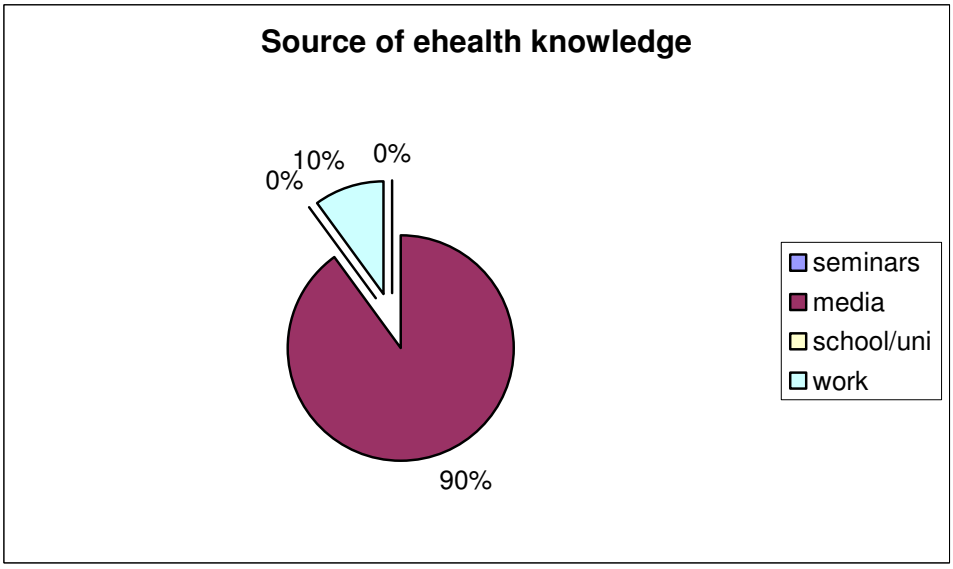
Use of internet is not so common in Germany as compared to Scandinavian Countries. In the age group 60-69 years only 7,69% are using internet.



5.4.3. Have you ever heard about eHealth

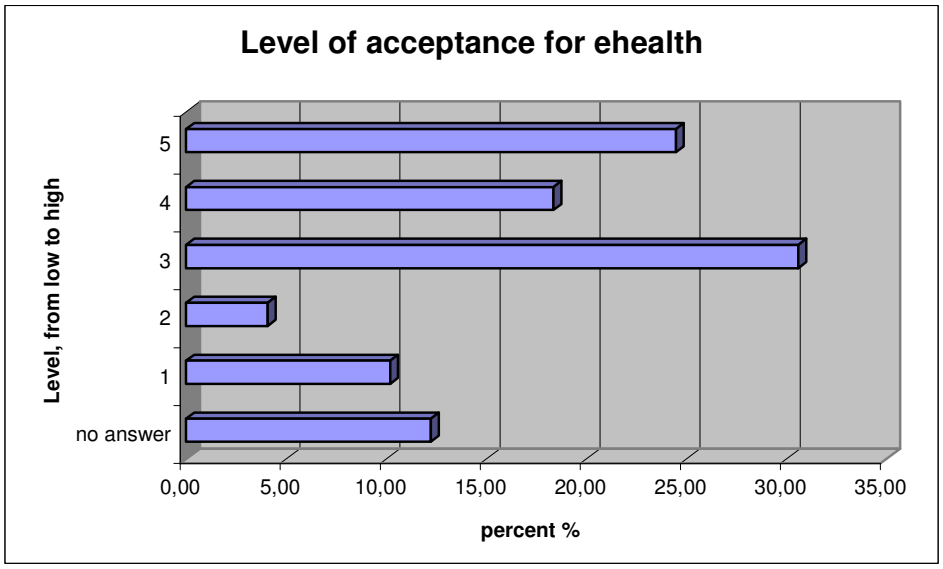
Awareness about ehealth in Germany is not like Denmark, but it is increasing. 22% people have ever heard about eheath, and majority (90%) of them heard about ehealth through media. So, the media can play a vital role for the awareness and acceptance of ehealth in the region.





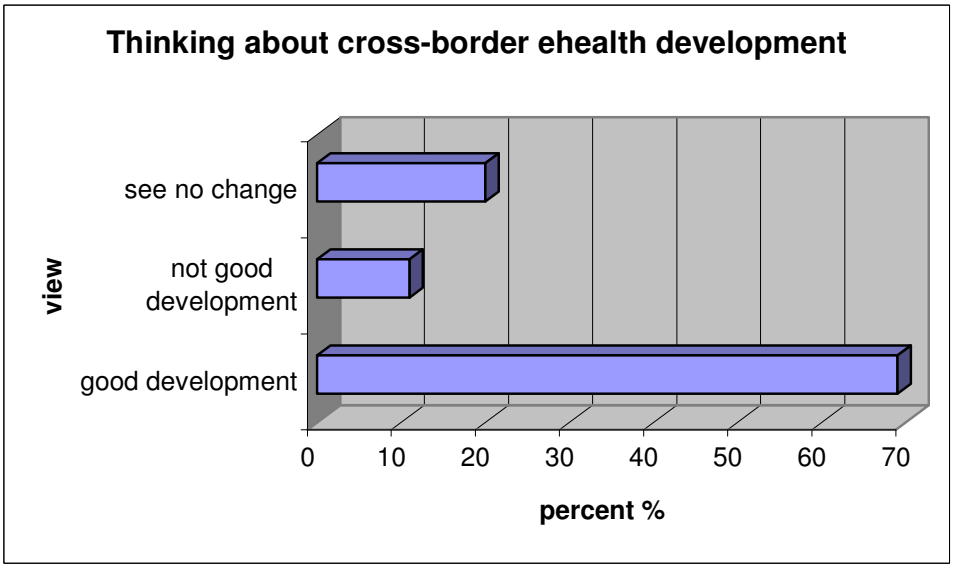
5.4.4. Level of acceptance for eHealth (low....1 2 3 4 5....high)

24,49% people have the highest level of acceptance for ehealth. Overall level of acceptance is good.



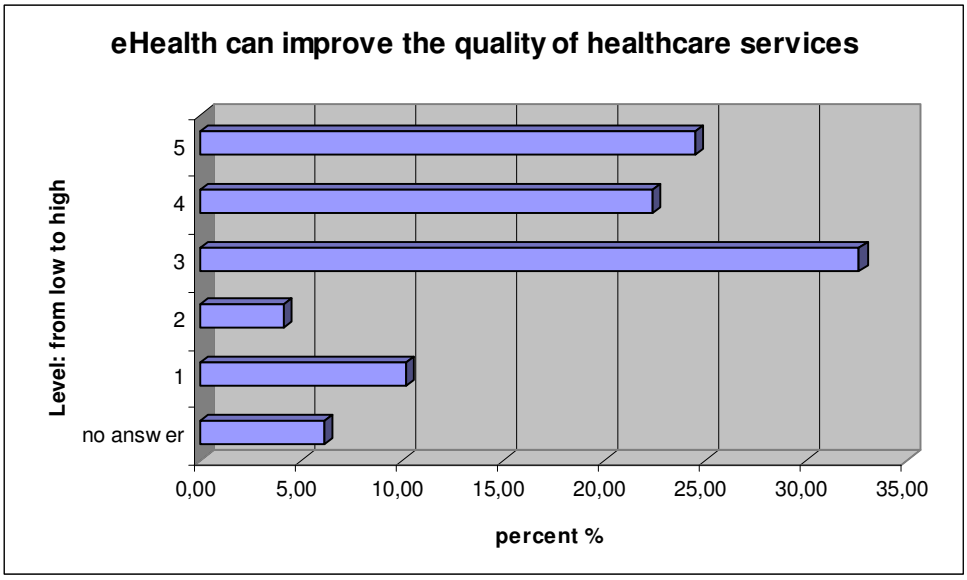
5.4.5. Thinking about the cross-border eHealth development

It is very encouraging for the future of ehealth in Germany that about 69% people see that cross-border ehealth developent is a good development.



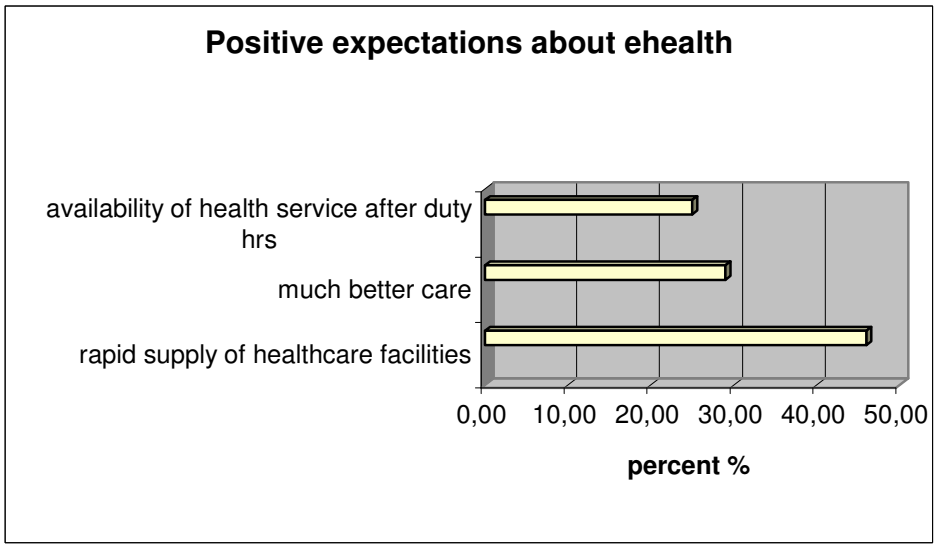
5.4.6. eHealh can improve the quality of healthcare services

Majority of the people accept that ehealth can improve the quality of healthcare services in the region.



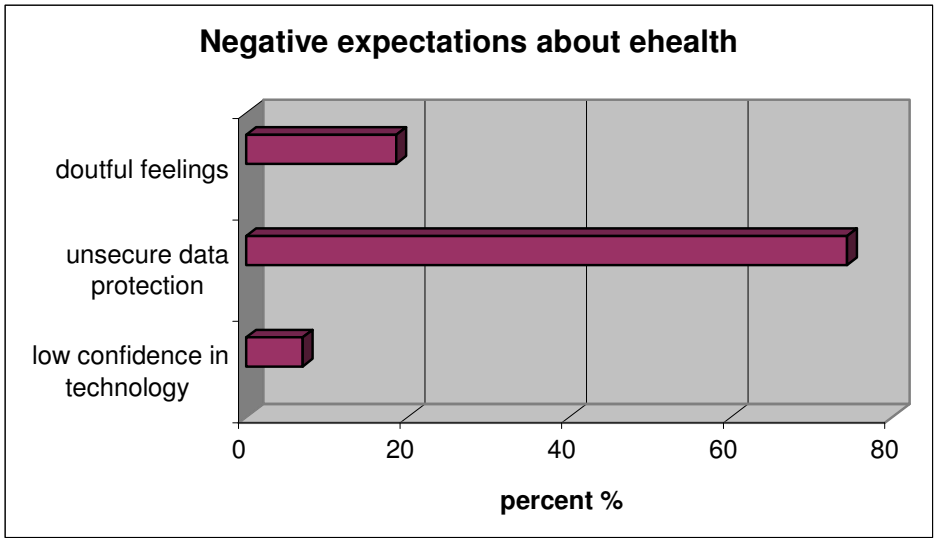
5.4.7. Positive expectations regarding eHealth

About 46% people believe that ehealth can provide rapid healthcare services without any wastage of time and 25% believe that healthcare services can be available after duty hours with the application of ehealth.



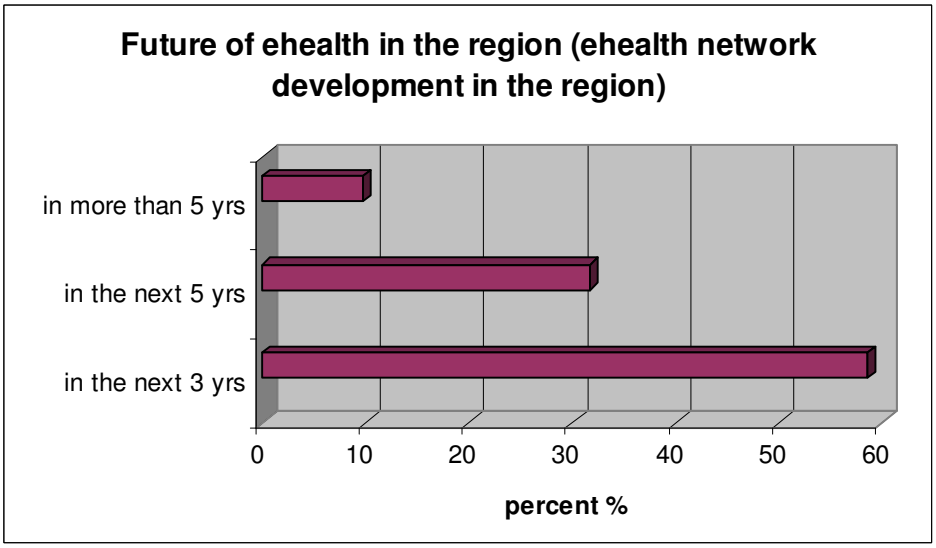
5.4.8. Negative expectations regarding eHealth

People of Germany are very much concerned about the data protection and privacy. Thats why 74,41% express unsecure feelings about the data protection during the application of ehealth solutions in healthcare system.



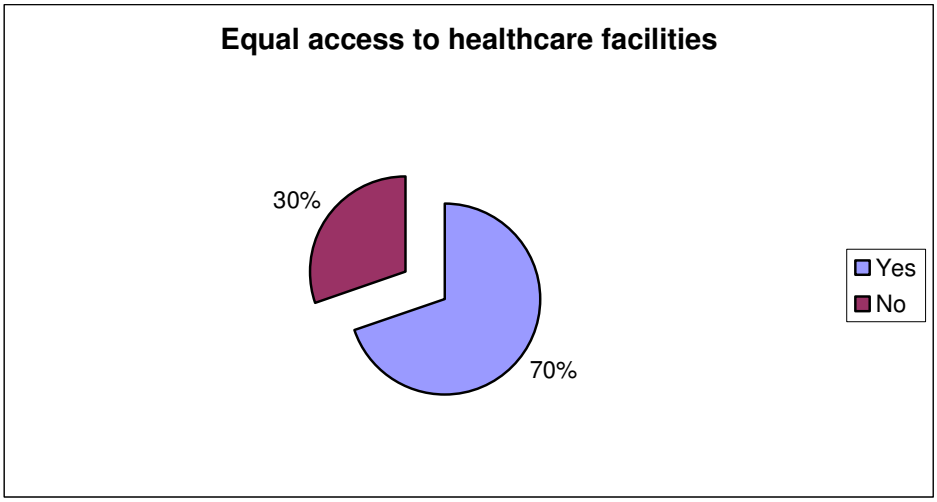
5.4.9. Thinking about the development of eHealth in the region (future of eHealth)

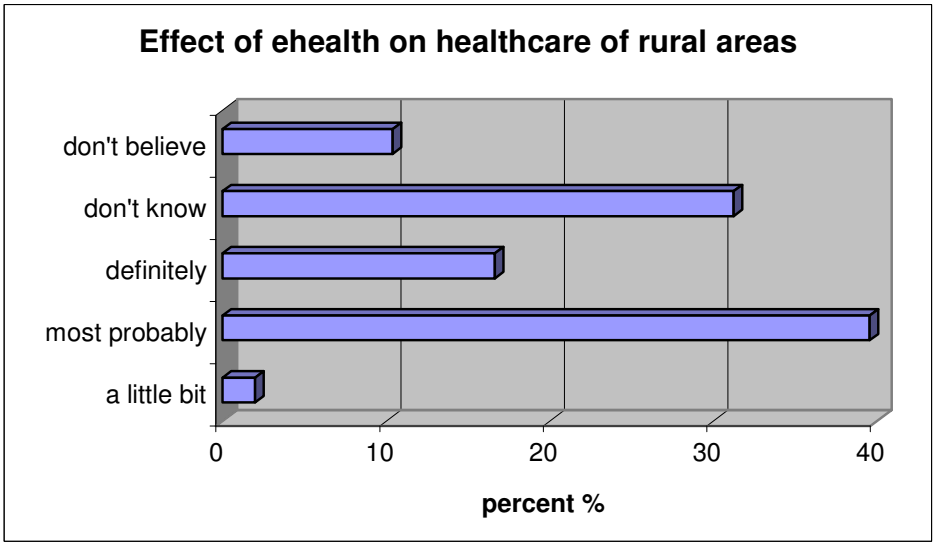
More than 90%people believe that there will be an established ehealth network in the Baltic Sea regions in the next 5 years which is close to the EU goal (i2010).



5.4.10. Equal opportunity for rural and urban areas

Most of the people (70%) believe that ehealth is the best solution to provide equal opportunity for healthcare services both in rural and in urban areas of the region. In addition majority of people believe that there will be positive effect of ehealth on the healthcare delivery services of rural areas. See the diagrams below.





5.5. Discussion

Acceptance and awareness about ehealth is increasing in Germany. Media campaigns and campaigns at workplaces to introduce the ehealth can be helpful. Health insurance companies can sponser such campaigns. Introduction of degree courses, for example “Bachelor” and “Masters” in “eHealth” will increase the interest about ehealth in students at the universities, which is very low at the moment. University of Applied Sciences Flensburg, Germany is introducing a master degree course in “eHealth” from WS 2006.

6. USE OF EXISTING E-HEALTH SOLUTIONS FOR TRANSNATIONAL (CROSS-BORDER) TREATMENT OF HEART PATIENTS (BOTH ACUTE AND CHRONIC)

In this part of the thesis the results of the studies are presented, which provides enough support to implement the existing eHealth solution (state of the art) to develop a transnational (cross border) network for the treatment of heart patients of Baltic Sea Region (“eHealth for Regions”). TSGZ took active part in all thses studies.

6.1. Background

*The medicine comes to the patient, not the patient to medicine.*Telemedicine is a supportive measure, it cannot replace the visit to a doctor but it can be a complement for that.

Most of the epidemiological studies like ADMIRAL showed that within the 6 months after MI, instead of maximum therapy, 28%-33% patients suffer from a new incidence, like reinfarct, reintervention or rehospitalization, even death ***(26).***

MI is a race with time. If the “thrombolytic treatment” or “PTCA” is followed within first 4 hours (Golden 4 hours), the new infarct can be avoided essentially. The average pre-hospital phase lies by 6 hours, which consists mostly of “critical time”***(27).***

The weakest part in the whole treatment chain of heart patient is the patient himself. Most of the patients cannot realize a MI (myocardial Infarction) or arrythmia, which can lead to death. The reason for such death mostly is the loss of valuable time (so called pre-hospital time delay -*"critical time*") for the proper treatment. If a patient comes to the cardiologist in time and doctors know his/her history and ECG findings, they can help the patients effectively ***(28).***

Till now, there was no any optimal solution for this problem, which resulted in:

- High mortality due to late treatment for reinfarct.
- Unnecessary procedures / investigations for diagnosis, wether heart patient is in a critical (emergency) situation or not. This results in loss of time and resources.
- Psychological stress for doctors when a patient comes in emergency and doctor can't do anything, due to late arrival of the patient ***(28).***

So, the reduction of *pre-hospital time delay* of heart patients is a success factor during the fight for life of the patients with reinfarct. This can be achieved through the application of "telemedicine" (eHealth) within the country and transnationally. To support the idea of telemedicine for the

6.2. Objectives (Goals)

The main objectives are:

- To provide the evidence taht pre- and in-hospital time delay for a heart patient can be reduced with the help of telemonitoring concept of TSGZ.
- To provide supporting evidence for the "validity" (safety and efficacy) of ECG recorded by the patiets through 12-Lead-tele-ECG recorder (Mobile Cardio Event Recorder).
- To provide evidence for the best integrated healthcare for heart patients, especially for cardiac insufficient patients.
- To immplement TSGZ strategy for the treatment of cardiac patients transnationally within the "eHealth for Regions" project.

6.3. Methods (Studies reviewed/performed)

The concept behind the TSGZ approach for the transnational treatment of heart patients is completely evidence baesd. There are studies which support the TSGZ concept

(objectives) for treating the cardiac patients with the help of telemedicine, both nationally and transnationally.

6.3.1. ADMIRAL (Abciximab before Direct angioplasty and stenting in Myocardial Infarction regarding Acute and Long term follow up) Study

This study showed that in patients after AMI or coronary syndrome, instead of good treatment (Abciximab) a reinfarct or another cardiac incidence (rehospitalisation) occure within first 6 months in 22,8% of the patients ***(26).*** If the thrombolytic treatment or PTCA is followed within first 4 hours (Golden 4 hours), the new infarct can be avoided essentially ***(26).***

Summary of the study:

Reference:This study was published in European Heart Journal in 1999. ***Title(s):*** (a) Abciximab associated with primary angioplasty and stenting in acute myocardial infarction: the ADMIRAL study, 30-day results (b) Prehospital abciximab administration in the ADMIRAL study. (c) Abciximab associated with primary angioplasty and stenting in acute myocardial infarction: the ADMIRAL study, 30-day final results. ***Purpose:***
To investigate whether early administration of abciximab can improve ***TIMI*** flow and clinical outcomes in patients with AMI referred for urgent primary PTCA. *Design*: Randomised, double blind, placebo-controlled. ***Sample*****:** 300 patients with evolving AMI of < 12 h, reffered for urgent primary PTCA. ***Follow-up:*** 24 h, 30 days, 6 months. ***Treatment regimen*****:** Abciximab, 0.25 mg bolus, followed by 0.125 µg/kg/min for 12 h, or placebo. ***Concomitant therapy*****:** Aspirin (6 months) and ticlopidine (1 month for stent implantation). Unfractionated heparin given according to the EPILOG criteria. ***Results:*** PTCA was performed in 93.1% and stents were implanted in 85.8% of the patients. Patients administered abciximab prehospital had a shorter mean delay to treatment than those administered abciximab in hospital (174 ± 122 min vs 221 ± 150 min; p = 0.15) with better average TIMI (1.4 ± 1.4 vs 0.6 ± 1.1; p = 0.006, and 2.8 ± 1.1 vs 1.7 ± 1.2; p = 0.01) and TIMI 3 (36.0% vs 12.0%; p = 0.004, and 96% vs 78%; p = 0.01) flow rates on immediate and 24-h angiograms, respectively. Coronary stenosis was lower grade (84.6 ± 27.2 vs 94.2 ± 19.0; p = 0.04) in patients treated prehospital. Initial (21.0% vs 10.3%; p < 0.01) and 24-h (85.6% vs 78.4%; p < 0.05) TIMI 3 flow rates were significantly better in the abciximab group. Left ventricular function was significantly improved at 24 h (54.6 ± 12.3% vs 51.4 ± 12.6%; p < 0.05). At 30 days, there was a significant reduction (-46.5%) in the combined primary endpoint of death, recurrent MI

and urgent revascularisation with abciximab compared to placebo (10.7% vs 20.0%; p < 0.03) ***(26).***

6.3.2. Pre-hospital diagnosis of myocardial ischemia by telecardiology: safety and efficacy of a 12-lead electrocardiogram, recorded and transmitted by the patient.

This study was coducted with the affiliation of following institutions.

- Curschmann Klinik, Department of Cardiology and Cardiovascular Rehabilitation, Timmendorfer Strand, Germany.
- Institute of Social Medicine, University of Schleswig Holstein, Campus Lübeck, Germany.
- Segeberger Kliniken, Department of Cardiology, Bad Segeberg, Germany.
- University of Schleswig Holstein, Campus Lübeck, Germany.

Abstract (Summary)

A 12-lead electrocardiogram (ECG) recorded by the patient and transmitted to a cardiology call centre (TSGZ) via telephone (tele-ECG) was compared with a standard (conventional) 12-lead ECG recorded from the same patient at the same time. In 158 patients , tele-ECGs were compared with standard (conventional) ECGs by two cardiologysts and one internist, independently and blindly. In 14 patients periphral electrodes were displaced, and in 12 patients there were baseline artifacts. These technical errors were corrected by telephone communication in all but two individuals. One patient could not use the tele-ECG device because of disability. Hence, in 155 of 158 patients (98%), the quality of tele-ECG was adequate for diagnosis. Reliability coefficient (R) for PQ, QRS and QT intervals between tele- and standard ECG were high, with R values of 0.73, 0.75 and 0.79, depending upon the physician. Negative T-waves could be detected with very good agreement in the tele-ECG as compared with standard ECG (kappa values of 0.97, 0.95 and 0.94). The agreement between tele- and standard ECG concerning alterations of ST segment was very good (kappa=0.99 for all investigators). Residual signs of myocardial infarction could be detected by tele-ECG, with very good agreement for anterior as well as for posterior localisations (kappa=0.99 and 1.00). The tele-ECG technique seems a promising approach to reducing pre- and in-hospital time delays to the initiation of thrombolytic therapy.

Introduction

The efficacy of reperfusion strategies in acute myocardial infarction and acute coronary syndrome could be improved if it was possible to minimize pre- and in-hospital delays ***(29,30,31,32).***

Pre-hospital recording of electrocardiograms (ECGs) has been shown to be useful in this respect ***(33,34,35,36,37).***

In all cases , recording of these ECGs has been performed by paramedics, nurses or physicians who were called to the scene. So far, however, there have been no reports (till Sep. 2004) of ECGs recorded and transmitted via telephone (tele-ECG) by patients themselves ***(38).***

A precondition for the strategy of prehospital diagnosis of myocardial ischemia is the *feasibility* and *reliability* of a complete 12-lead tele-ECG in the hands of the patients. Preliminary results from the work done at TSGZ Bad Segeberg showed that patients in general were capable of handling a telecardiology device ***(39).***

This work was expanded and updated , which was originally performed as a pilot study, to investigate whether tele-ECG in combination with verbal communication with the patient has the potential to reduce pre- and inhospital time delay.

Ojectives

To compare the safety and efficacy of a 12-lead electrocardiogram, recorded and transmitted by the patient via telephone (tele-ECG) with a standard (conventional) 12-lead ECG recorded from the same patient at the same time.

Methods

Sample and ECG recording procedure

In all, 158 patients were randomly chosen from a cardiology ward. Their mean age was 63 years (SD 15) and 24% of them were women. First, a conventional 12-lead ECG (standard ECG) were recorded in the supine position (Cardiovit AT2plus, Schiller, Ottobrunn, Germany; paper speed 50 mm /s, sensitivity 10 mm/1mv).

Immediately afterwards, a 12-lead tele-ECG was recorded by the patient in the same body position using a tele-ECG recorder (CG-7100, Card Guard Scientific Survival LTd, rehovot, Israel;: paper speed 25 mm/s, sensitivity 10 mm/mV).

The limb leads (I, II, III, aVR, aVL, aVF) were recorded by means of three external leads, fixed by self adhesive electrodes on the right and left shoulder, and on the left hip. Using electrodes incorporated into the tele-ECG recorder, the precordial leads were recorded by placing the device on the sternum in the fourth intercostal space (V1, V2), on the left midclavicular line, fifth intercostal space (V3, V4) and on the left midaxillary line (V5, V6). These 12 leads were consecutively recorded for a total of 44s and stored by the tele-ECG recorder (**see table 11**) After acqisition, the data were transmitted by the patient to

the call centre via a normal telephone (transmission is possible via any type of telephone, including mobile phone).

Table 11: Specifications of the tele-ECG recorder (model CG-7100, Card Guard Ltd) for Recording and transmission of a complete 12-lead ECG.

Recording period	44s
Transmitting period	44s
ECG amplitude	10 mm/1mV
A to D sampling rate	500 samples /s
Resolution	10 bits
Bandwidth	0.5 -100 Hz
Carrier frequency	1700 Hz
Deviation	100 Hz /1mV
Weight	127 g
Dimensions	120 x 67 x 22 mm
Storage temperature	- 20 to +65 ℃
Relative humidity	5 % to 95 %

The standard and tele-ECG recording were compared by two cardiologysts and one internist, acting independently. ECGs were distributed in such a way that one physician did not recieve the standard and tele-ECGs of any given patient at the same time. The heart rate and electrical axis of the ECG were determind and an ECG diagnosis was established according to international standards ***(40, 41)*** for every patient. PQ, QRS and QT intervals (ms) were measured manually in the corresponding lead of the standard and tele-ECG.

Statistics

Reliability coefficient (*R*) between standard and tele-ECG were calculated for continuous variables (PQ, QRS, QT intervals) using analysis of variance. An *R* of 1.00 would indicate 100% reproducibility and *R* of 0 no reproducibility (agreement) ***(42).*** The reproducibility (agreement between two ECGs) between categorial variables (e.g. sinus rhythm: *yes or no*) was estimated with kappa coefficient ($\mathcal{K}$). Values of $\mathcal{K} \geq$ indicate very good reproducibility (agreement), values of $0.4<\mathcal{K}<0.75$ good and $\mathcal{K} \leq 0.4$ poor reproducibility (agreement) ***(43).***

Results

Technical errors that occured with self acquisition and self transmission of the tele-ECG consisted of displacemen of the external ECG electrodes (n=14) and baseline artefacts (n=12). These technical errors were corrected by telephone communication in all but two individuals. One patient could not use the tele-ECG device because of disability. Hence,

in 155 out of 158 patients (98%), the quality of the tele-ECG was adequate for correct diagnosis.

Conduction times

Reproducibility (agreement) on conduction times between standard and tele-ECG was satisfactory, as demonstrated by reliability coefficients (Table 2).

Table 12: Comparison of the ECG conduction times (PQ, QRS and QT intervals) in the transmitted 12-lead tele-ECG and the standard ECG (n=155)

	Investigator 1 R 1	**Investigator 2 R 2**	**Investigator 3 R 3**	**Total effect Rtotal**
PQ (ms)	0.55	0.57	0.57	0.79
QRS (ms)	0.43	0.68	0.68	0.75
QT (ms)	0.33	0.62	0.63	0.73

Values are displayed as reliability coefficient (R) for every investigator (1,2 and 3) and for total effect (total).

Negative T-wave

Negative T-waves as a potential marker of myocardial ischemia could be detected with very good reproducibility (agreement) in the tele-ECG as compared with the standard ECG ($\mathcal{K}$ = 0.97, 0.95 and 0.94; Table 3).

ST-segment alterations

The reproducibility (agreement) between tele- and standard ECG concerning alterations of the ST-segment was also very good ($\mathcal{K}$ = 0.99 for all investigators).

Residual signs of MI

Rasidual signs of myocardial infarction could be detected by tele-ECG with very good reproducibility (agreement) for anterior as well as for posterior localizations ($\mathcal{K}$ =0.99 and 1.00)

Subtle changes

Subtle changes in the ECG, such as incomplete right bundle branch block, could be analysed with very good reproducibility (agreement) by tele-ECG ($\mathcal{K}$ = 0.93 and 0.95)

Even the lowest agreement between standard and tele-ECG, found for the detevtion of right heart axes by investigator 3, was adequate, with a $\mathcal{K}$ value of 0.88 (Table 13).

Table 13: Comparison of the ECG diagnosis established in the transmitted 12-lead tele-ECG and that from the standard ECG (n=155)

	Investigator 1 $\mathcal{K}$ 1	Investigator 2 $\mathcal{K}$ 2	Investigator 3 $\mathcal{K}$ 3	Total effect $\mathcal{K}$ total
Sinus rhythm	1.00	1.00	1.00	1.00
Atrial fibrillation	0.99	1.00	0.99	1.00
Atrial flutter	1.00	1.00	1.00	1.00
Pacemaker ECG	0.99	1.00	0.99	1.00
Indifferent axes	0.92	0.96	0.93	0.94
Left axis*	0.99	0.99	0.96	0.98
Right axis	0.91	0.97	0.88	0.92
Other axis	0.96	0.98	0.99	0.97
Posterior myocardial infarction	0.99	1.00	1.00	1.00
Anterior myocardial infarction	0.99	0.99	1.00	0.99
Left ventricular hypertrophy	0.99	0.99	0.99	0.99
Negative T-wave	0.97	0.95	0.94	0.95
ST-segment elevation/depression	0.99	0.99	0.99	0.99
Complete RBBB*	0.96	0.96	0.94	0.95
Incomplete RBBB	0.95	0.93	0.95	0.95
Complete LBBB*	0.96	0.95	0.96	0.96

Axis=electrical heart axis. RBBB=right bundle branch block. LBBB= left bundle branch block.

Discussion

Telmedicine can help to overcome the problem of delayed onset of reperfusion therapy in acute ischaemic heart disease by reducing the pre- and in-hospital time delay ***(33,35,36).*** In addition, telemedicine can facilitate the access to continuous medical support during the chronic phase of coronary heart disease when patients may face new angina or even a re-infarction ***(44)***.

However, in all studies evaluating the effect of prehospital ECGs on the course of acute ischaemic heart disease, ECGs have been recorded by professional staff, mostly paramedics or nurses ***(23-37)***.

After recording the prehospital ECG, further strategies in decision making reveal two different philosophies:

- Transmission of the ECG by mobile phone to a base station cardiologist ***(35,36).***

or

- Interpretation of the ECG on the scene by specially trained paramedics ***(34,37).***

Although there is no direct comparison in the literature, both strategies seem to be equally effective, but to have different advantages and pitfalls ***(33).*** So far, patients themselves have not been included in this particular process of prehospital time gain.

In an observational study, 74% of patients calling for medical advice because of chest pain did not need further medical intervention when the tele-ECG did not exhibit any signes of myocardial ischaemia ***(45).*** Thus, early diagnosis or exclusion of myocardial infarction by means of a 12-lead ECG, recorded and transmitted by the patients themselves, seems a promising method in this scenario. This strategy could avoid many unnecessary calls for an emergancy ambulance. Its clinical efficacy, however, is linked to the feaibility and reliability of the tele-ECG recorder used. In all the studies cited, the tele-ECG recorder used has not been validated before entering the trial ***(33-37).***

In the present study, reproducibility of cardiac conduction times was sufficient to detect even subtle changes in the ECG, such as prolongation of the PQ interval or progression of an inclompete to a complete bundle branch block that might occur during myocardial ischaemia (Table 2). Reproducibility could be even better if the tele-ECG recorder recorded with the same paper speed of 50 mm/s as the standard ECG recorder. Another reason for the accuracy of the device used is the fact that the tele-ECG recorder works with the same sensitivity of 10 mm/1mV as standard ECG recorders. Hence, small changes in ECG morphology such as *RSR´configuration* or *bipolar pacing spikes* were detected with very good agreement in the tele-ECG as compared with the standard ECG (κ between 0.93 and 1.00;**see table 3**).

In contrast to previous studies that used tele-ECG recorders with lower sensitivity ***(46),*** atrial fibrillation an atrial flutter were also detected with very good agreement by the tele-ECG in the present investigation (κ between 0.99 and 1.00).

Using a nine-lead tele-ECG recorder, ST-segment alterations were detected with a sensitivity and a specificity of 89 % and 93%, respectively ***(46).*** The 12-lead tele-ECG recorder used in the present study showed almost 100% agreement between standard and tele-ECG concerning changes of the ST segment (κ = 0.99 for all investigators – **see Table 3**).

There have been two small studies on the use of transtelephonic 12-lead ECG transmission:
1). In 23 patients, Grim et al. reported a similar reproducibility of cardiac conduction times as compared with the resultis of theis study ***(47).*** In addition, there were no differences betweeen standard and tele-ECG concerning ECG complex morpholocical patterns and computer ECG diagnosis.

2). In the study by Roth et al., 20 patients had no difficulties with the recording of the 12-lead tele-ECG by themselves at home, and 82% of the tele-ECGs were interpreted correctly ***(48).*** Furhter details about the ECG morphology and ECG diagnosis were not given in these reports.

In the present expanded and updatet trial, the feasibility of the tele-ECG recorder used was demonstrated by the fact that 98% of patients were able to use the device and to transmitt a high-quality 12-lead ECG. Reliability of the device was demonstrated by independent comparison of the tele-ECG and standard ECG, and a very high agreement was found between both ECG methods.

Wheather the technique of tele-electrocardiography will perform well in the real life conditions onf an acute myocardial infarction of an acute coronary syndrome requires further evaluation.

6.3.3. TeleGuard Study

Started: 07.2004 (recruitment of the patients ended: 09.2006)
Will be published: 08.2006

TeleGuard study is a randomized, controlled, multicentric study, which is planned according to the “ICH Good Clinical Practice”. The main objectives of this project study are:

- To check (estimate) the reduction in the morbidity & mortality by reducing the new incident through pre-hospital use of 12-lead tele-ECG.
- To check (estimate) the reduction in costs by reducing the hospital admissions through prehospital use of 12-lead tele-ECG.
- To check the improvement in the quality of life by the pre-hospital use of 12-lead tele-ECG.

Abut 1700 heart patients are taking part in this study. Heart patients (after cardiac infarct, PTCA etc..) who comes to the different centres are taking part in the study, receive the tele-ECG devices, belong to the intervention group. With heart complaints an electrocardiogram can be recorded by 12-lead tele-ECG device and will be sent to a Telemedizin center (TSGZ) per telephone. If necessary a further treatment or emergency admission is arranged from there. Patients who recieve the noramal routine treatment belong to the control group (without 12-lead tele-ECG device).

After the one year treatment data will be collected from the routine data of the health insurance company involved (AOK Schleswig Holstein: compulsory health insurance

scheme Schleswig-Holstein). The additional data for the patients with 12-lead tele-ECG device will be collected from TSGZ ***(27).***

Within the frame work of “eHealth for Regions” project, the results of this study are expected to be printed in June 2006. These results will be added to this thesis as an appendix later on. As this thesis should be submitted to the university till 28th February, 2006.

The early evaluation after a 12 months test phase at TSGZ showed that 14% cases were diagnised as the suspected cases for new MI attack and were hospitalised for emergency treatment according to the action pathway of TSGZ (**see figure 13 above**)— (high quality of healthcare by reducing the pre-hospital time delay).

The remaining 86% of all the emergency telephone calls with ECG were not diagnosed as the real emergency cases. These cases were not hospitalised (reduction of hospital admissions— cost reduction) ***(27).***

Methodos

Figure 19 below shows the summary of strategic methodology used .
Table 14 & 15 below show some initial results.

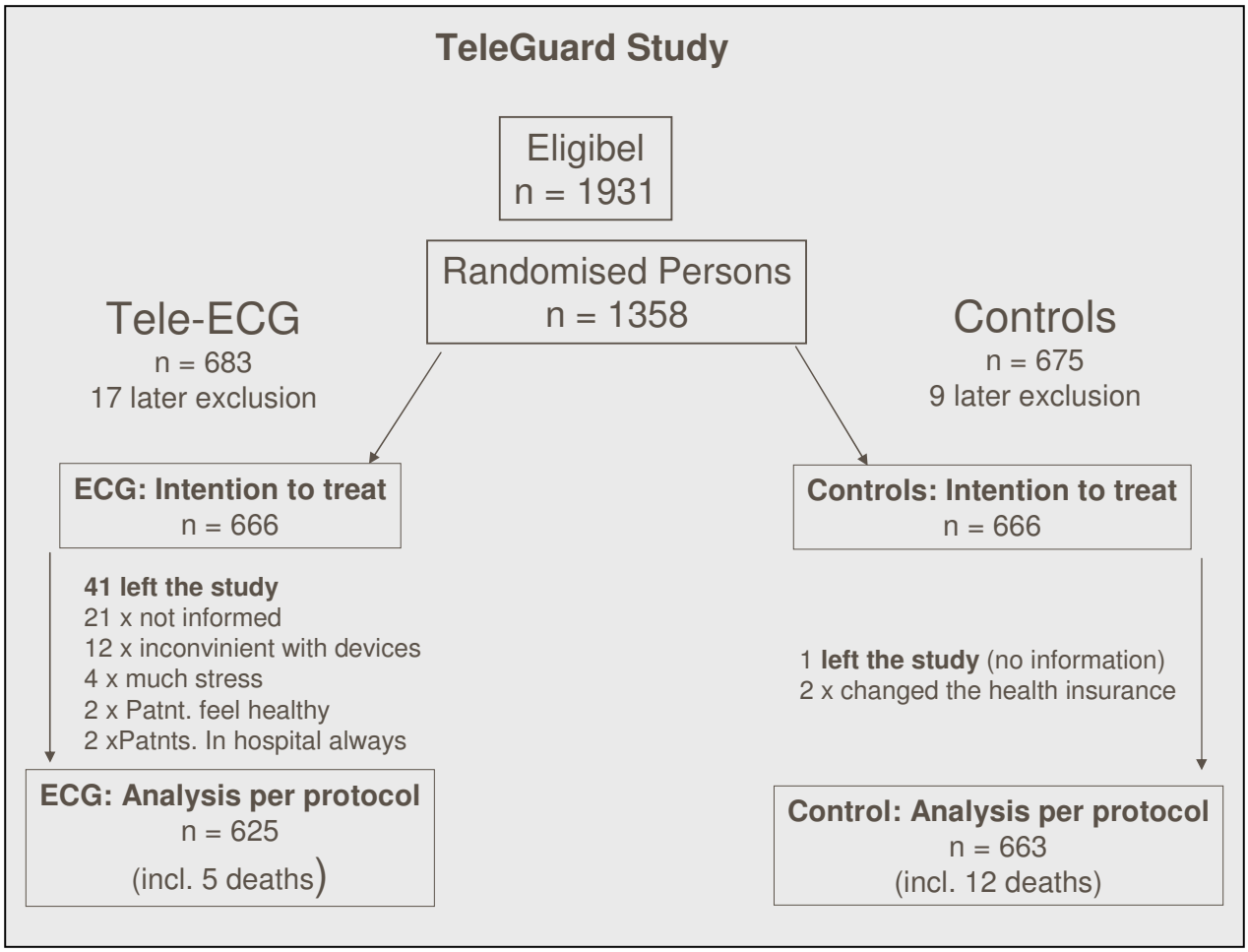


Fig. 19: Schematic diagram of TeleGuard Study (Smidt W, TSGZ Bad Segeberg, Germany).

Table 14: Basic data

	AOK Overall Summary n = 687	ECG-Group n = 326	Control-Gruppe n = 361
Sext (m / w)	75,8 : 24,2	78,8 : 21,2	73,1 : 26,9
Age by randomisation (years)	62,8 +/- 10,3	62,1 +/- 10,7	63,5 +/- 9,84
Number of deaths during intervention	**17** (2,47 %)	**5** (1,53 %)	**12** (3,32 %)

Evaluation of telephone calls:

- 84,2 % not real emergency cases
- 1,8 % Acute Myocardial infarct
- 3 % Inst. Angina pectoris. Non-Q-Myokardinfarkt
- 11 % Acute Coronary Syndrome

Table 15: Patient's opinion

	ECG of the patients	User	Non User
Satisfaction	81,6 %	82,9 %	81,0 %
Was the device helpful	92,2 %	94,3 %	91,1 %
Want to be teated in the future	68,2 %	81,9 %	61,7 %

6.3.4. Telematic care of chronic cardiac insufficient patients within the frame work of integrated healthcare: § 140 ff SGB V, in Germany→ A post TeleGuard Study project.

Background

Telematic care of chronic cardiac insufficient patients within the framework of integrated healthcare delivery was started on 01.02.2005 at TSGZ, Bad Segeberg. Many clinical studies show the bad prognosis of cardiac insufficient patients after the first hospitalization. About 20% patients with cardiac insufficiency die within 30 days after first hospitalization. The reasons can be:

- Decompensation state as the patient reaches the hospital—late start of treatment.

- Late echocardiography

Objectives

- Step by step healthcare concept (GP→ Cardiologyst→ Hospital).
- To increase the compliance of the patient.
- Reduction of hospital admissions.
- Standard medical treatment for the patients.

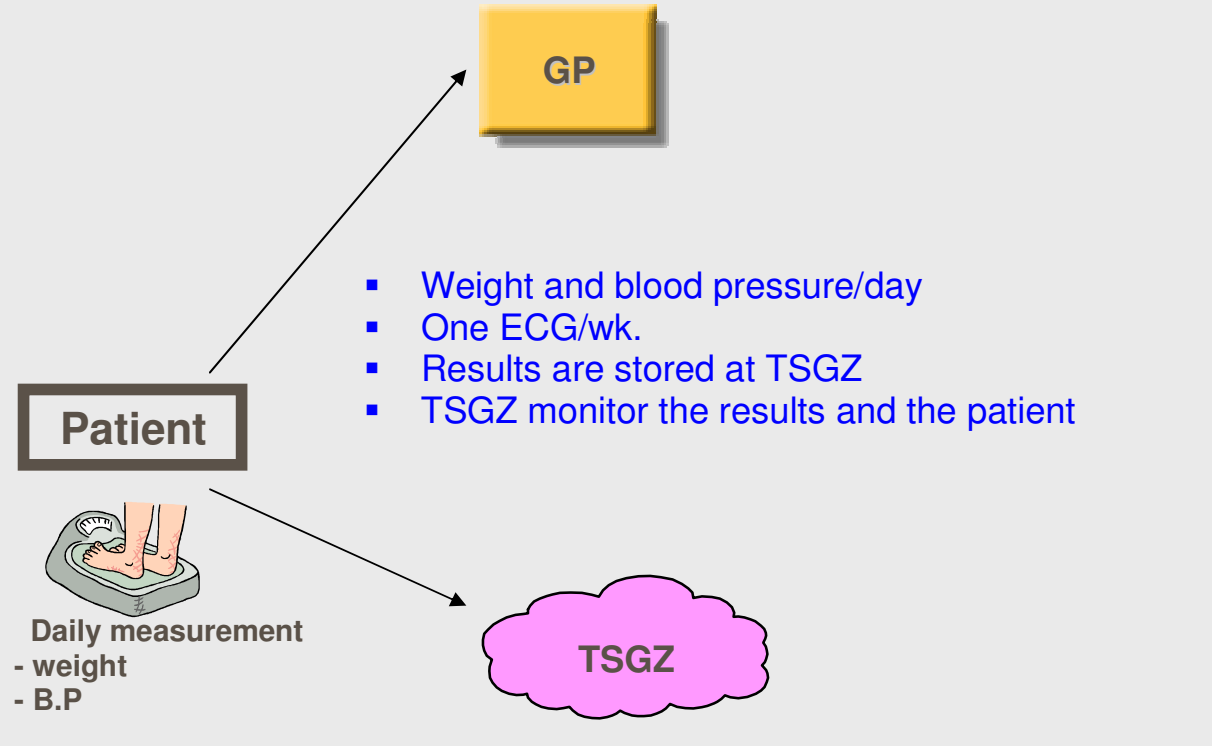


Fig. 20: Patient consultation

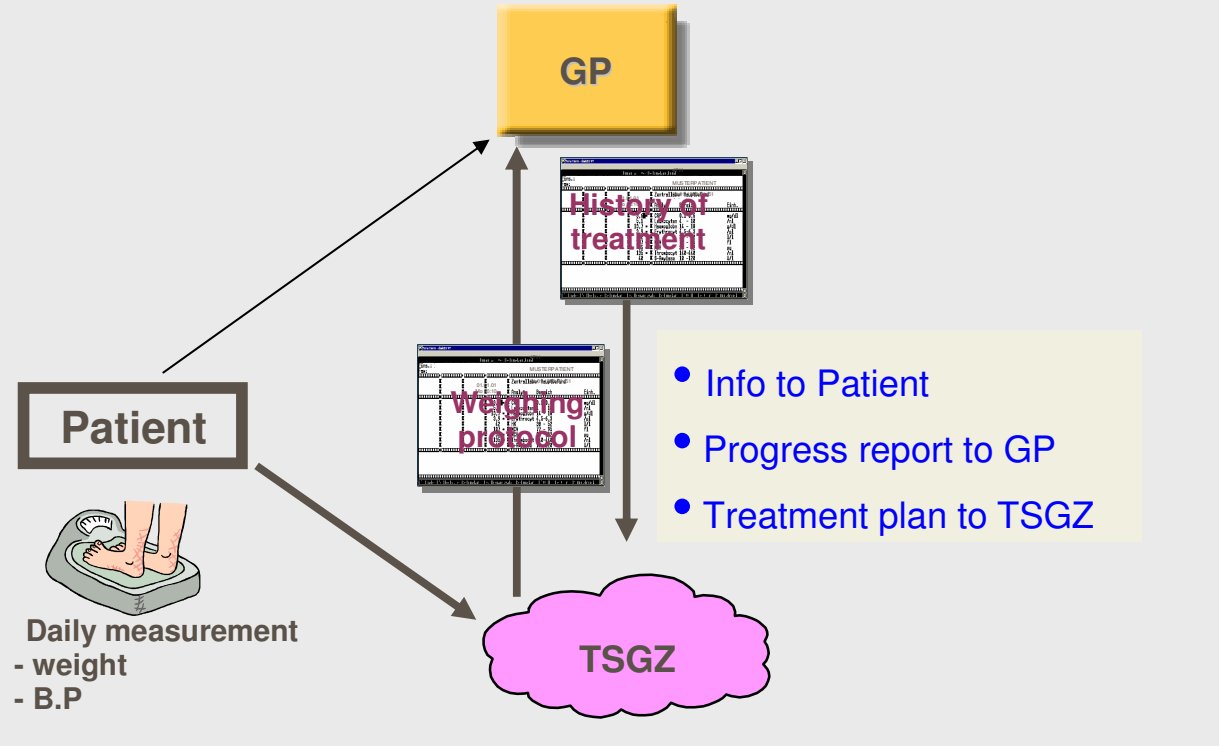


Fig. 21: In case of border-crossing results

Refferal to the cardiologyst

GP performs the general physical examination of the patient and check the results of the laboratory investigations every third month or when needed. GP reffer the patient to cardiologyst through well organized appointment. Verbal communication of doctor (GP) with the patient is very important (**see figure 20 & 21 above**).
The cardiologyst perform the echocardiography once in six months (in routine) or when needed.

To increase the patient's compliance

Patint's compliance is an important factor during the whole process. Regular telephone contact through TSGZ, motivation to send the data and the strong role of the GP are used to increase the compliance of the patient (**see figure 22 below**).

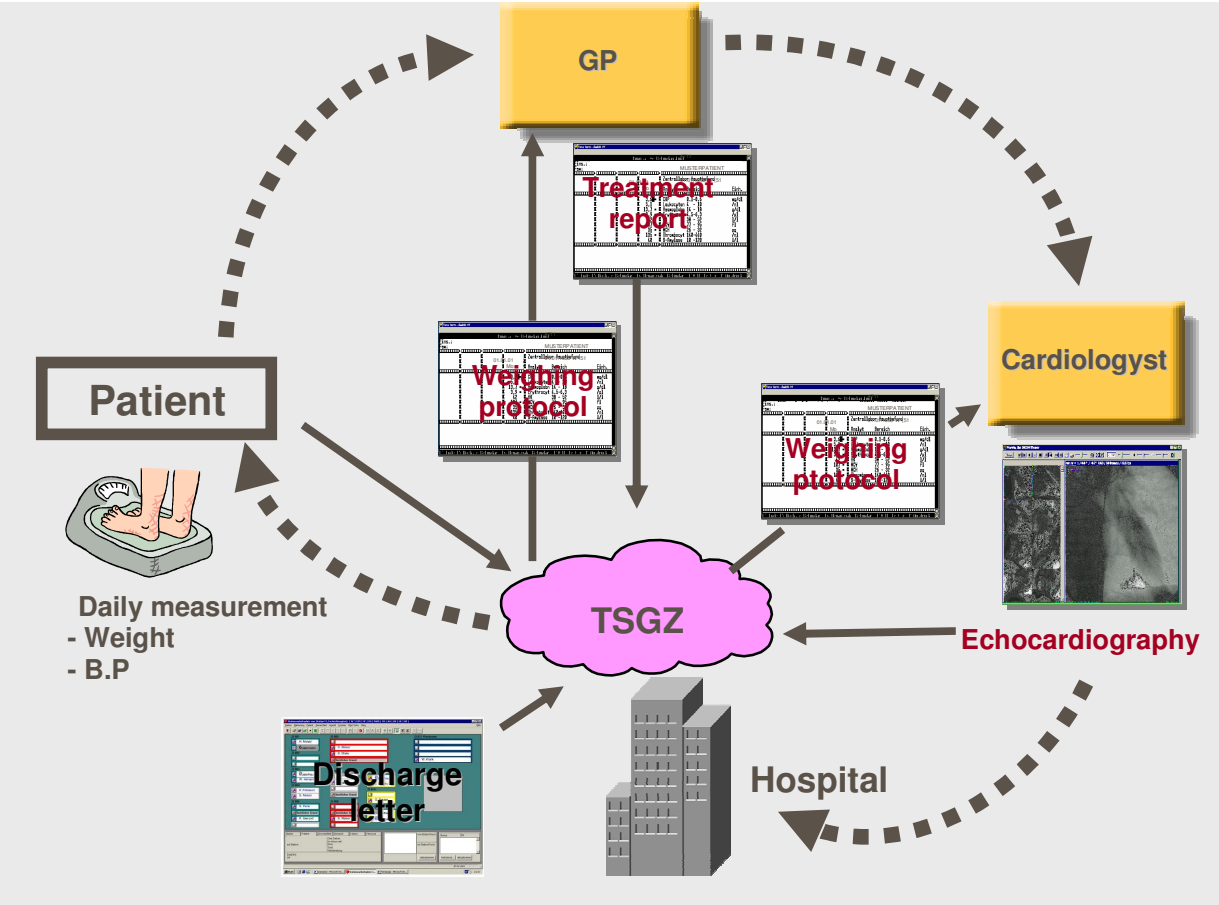


Fig. 22: Hospital admision recommended by heart specialist (cardiologyst)

Conclusion

Telematic care of chronic cardiac insufficient patients within the frame work of integrated healthcare provides the opportunity of early diagnosis in case of deterioration through a fine-meshed infrastructure for monitoring (telemonitoring). This also provides a well structured patient consultation system, leading to better quality of life. Reduction in morbidity through integrated telematic care leads to decrease in hospital dmissions, which in tern reduce the hospital costs. Finally the mortality can also be reduced (**see figure 22**).

6.3.5. Transnationl treatment of heart patients within the framework of "eHealth for Regions" Project – Pilot implementation.

The implementation of eHealth solutions in the partner countries like Poland, Sweden, Lithuania etc are underway, within the framework of "eHealth for Regions" project.

Poland (Pommerania)

University of Gdansk project

The university hospital Gdansk is the only hospital in the region with cardiac facility. Besides the university hospital Gdansk, there are 32 small hospitals in the region without cardiac facilities. The goal is to connect these 32 small hospitals with the university hospital Gdansk through telemedicine facilities. The recorded ECG (with the help of tele-ECG recorder) will be sent to TSGZ Bad Segeberg, Germany and at the same time to the university hospital Gdansk. TSGZ will forward the ECG to the university hospital Gdansk, alonwith the second opinion (see fig. below)

The main advantages which a heart patient will get through eHealth solutions implementation are: .

- Reduction of 4h prehospital phase from symptom to invasive diagnostic.
- Implement the national & international guidelines.

Lebork County

In this region of Pommernia in Poland the patients have to wait for a long time (for 6 months) for the invasive cardiac investigations. The distribution of tele-ECG devices is planned in this region.

Sweden (Region of Skane)

Home care for elderly people (tele homecare)

The activities in the region of Skane are focused on preparation for the pilot implementation of HemEKG in Hässleholm. Following steps have been taken for the pilot implementation (almost fully implemented):

- Nurses from the municipal care have been informed about the project and educated in practical handling of the device and transfer of the ECG files.
- Routines for the reception and storage of ECG have been discussed.
- Documents describing expected effects of the pilot implementation and evaluation forms have been elaborated.
- An information brochure for HemEKG is ready.

- Technical tests have been performed.

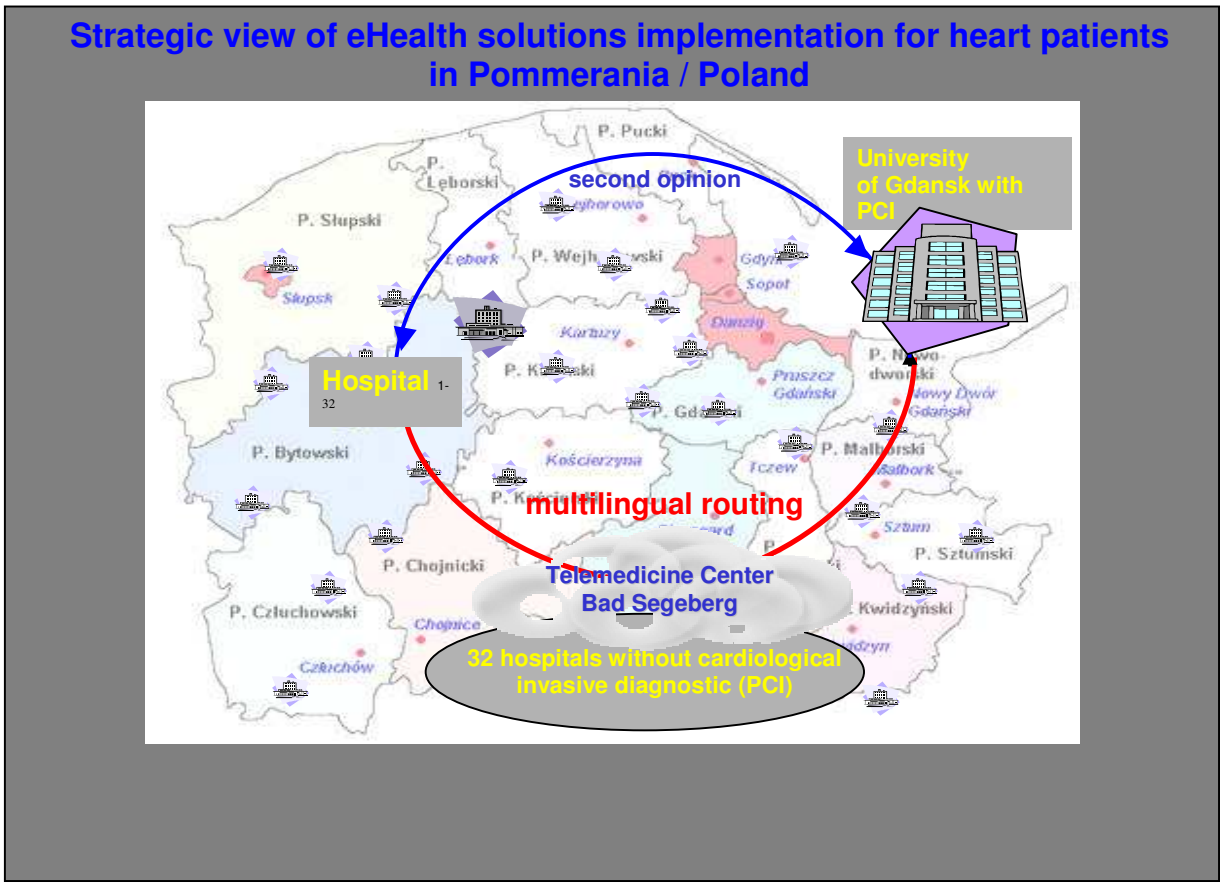


Fig. 23: Strategic planning for eHealth solution implementation for heart patients in Pommerania / Poland.

ECG in school children

A project is also planned in the school children about the ECG recording related to sports activities.

Lithuania (University of Kaunas)

A study project is planned in the region. ECG devices will be distributed in the region. Approval from the ethical committee has been recieved.

6.4. Discussion

To provide transnational treatment for heart patients TSGZ developed a therapy concept on the basis of a cardiac hospital. The main requirements for the better performance are:

- Training of cardiologysts.
- Clearly defind decision process.
- Communication between patients and doctors.
- Leagl and ethical framework.

The studies showed that “practibility”, “reproducibility”, and the “reliability” og the 12-lead tele-ECG recorder was identical to the normal standard (conventional ECG). Most of the patints used the technology correctly (98.4% practibility value). The average reproducibility of 12-lead tele-ECG recorder fro the measured RQ interval , QRS interval, and QT interval in milliseconds, was 76%, as compared with standard ECG, which is satisfactory. The measured reliability from every individual patient, resulted in very high “kappa” values.

Is a reliable ECG is enough for the diagnosis of a heart patient? How can a doctor from afar decide, wether the patient should be treated as an emergency or as a normal patient?

A reliable ECG is the basis for the assessment (provisional diagnosis) of a heart patient. Alongwith 12-lead tele-ECG, the doctor patient talk per telephone, and the available data of the patient at TSGZ, help to assess the patient’s exact situation, wether this is an emergency or not. The doctor at TSGZ then try to answer the following questions:

- Wether the patient needs a cardiologyst and needs more investigations at the hospital?
- Is it a non emergency case and does’nt require a cardiologyst?

This helps to transfer the patient directly to the hospital and save time in case of emergency, in other words, save the lives.

7. Legal aspects (issues) of eHealth

7.1. Introduction

Someone once compraed the legal issues in telemedicine with peeling an onion; there is always another layer. So, only those issues will be discussed which are most important and mainly concerned with Baltic sea region.

The legislation and regulations should not be considered as barriers, at least not at the outset, thats why the term “legal issues” will be used. National and international legislation on health care and data processing is the framework we have to work within if we shall have any hope in keeping up legitimacy and acceptance for the work we do. It is true that developing and expanding technological innovations challenge existing frameworks – legal and other, but we believe that the most fruitful approach in conjunction with this project is to work towards finding solutions that can exist within existing laws and regulations. One should not loose sight of the fact that existing legislation is based on principles and considerations that are important and essential for the whole aspect of health care provision.

7.2. Objectives

- To identify the legal issues and challenges during the implementation of eHealth (telemedicine) solutions for the transnational treatment of patients (e.g. heart patients) in the Baltic Sea region.
- To find a common solution (legal solution) within existing legislations, for the whole BRS despite the differences between the idividual European countriesthese.
- To develop a best business eHealth model in the region, within existing legislations of the countries of the region.

7.3. Challenges identified during the project work

The main praticipants of eHealth are doctor and patient. The whole

The usage of a trans national eHealth network like the “eHealth for Regions” Project brings about a number of critical questions. The most frequent are:

- Is it legal to send patient information between countries (data transfer-security, privacy, confidentiality, security and safety)?
- How does a hospital get reimbursed if it delivers a second opinion to another hospital (reimbursement)?
- How do we deal with cultural differences?
- What if the two collaborating health professionals do not speak the same language (interoperability)?

These questions should be considered carefully before launching a trans national collaboration. However, the problem is that the answers to the questions are still very unclear and this is a barrier to the full scale usage of the transnational networking. Few decision makers will initiate such projects, if for instance the legal basis is unclear. The "eHealth for Regions" project will only be successful in persuading decision makers to use the network for transnational communication, if the project can give clear and unambiguous answers to the above questions.

7.3.1. USB-Sticks-Pilot for data tranfer of mobile patients between partner countries

Following decisions were taken in a meeting held on 14.01.2006 in Kopenhagen (see Appendix 1: Summary from the meeting of the 14.01.2006-Hilton Conference Room "Hermod", Denmark):

Strategy:

A pilot will be started within the "eHalth for Regions" project, to design a business model fro the transnational networking in eHealth, so that the whole region in general and the travelling patients especially can benefit from eHealth.

Two doctors/GPs and 5-10 patients from each country will take part in this pilot, which will be selected till 15.03.2006 by each partner country.

Mobile patients with chronic diseases (heart patients, diabetics, asthma, organ transplantation, pace maker etc.) can be chosen from different areas of life, like students, truck drivers etc.

Use of an USB-Stick

The USB-Sticks will be used to store and transfer the data of the mobile patients in the pilot. This data can be used by the physicians of other countries at the time of visit and

the new data will be stored on the stick by the same physician. The data or information which will be stored on the stick is as under (as decided in the meeting).

- Administrative information about the patient.
- Medical information about the patient.

Legal and technical aspects for using USB-Stick—Strategy

It was decided that two forms will be developed for data storage, one is the "administartive form", which includes the data of the patient for administrative purposes, and the other is "medical form", which includes the medical data of the patient. The summary of the strategy to deal with the technical and legal aspects is given below, **see table 16**).

Table 16: Summary of the strategy of the USB-Sticks pilot project for data storage and transfer transnationally.

1A)	Design medical form and Design administrative form
1B)	Make a technical solution / program for filling in the forms (and describe further development of the forms, verifications etc.)
2A)	Forms into USB - secure version handling - secure no change is possible - secure access to the information
2B)	Forms into database - designing database - administrative "owner" of the database will secure access for the database
3)	Pilot test - choose patient - choose doctors
4)	Evaluation of the concept - doctors - patients - technical
5)	Scaling up - technical - organization - legal issues - economy

Time frame of pilot

Model for data storage and transfer (USB-Sticks) will be ready till 15.02.2006. Selection of 2 GPs and 5-10 patients from each partner country: till 15.03.2006. Project running and evaluation: from 15.03.2006 till ..... (see figure 24 below).

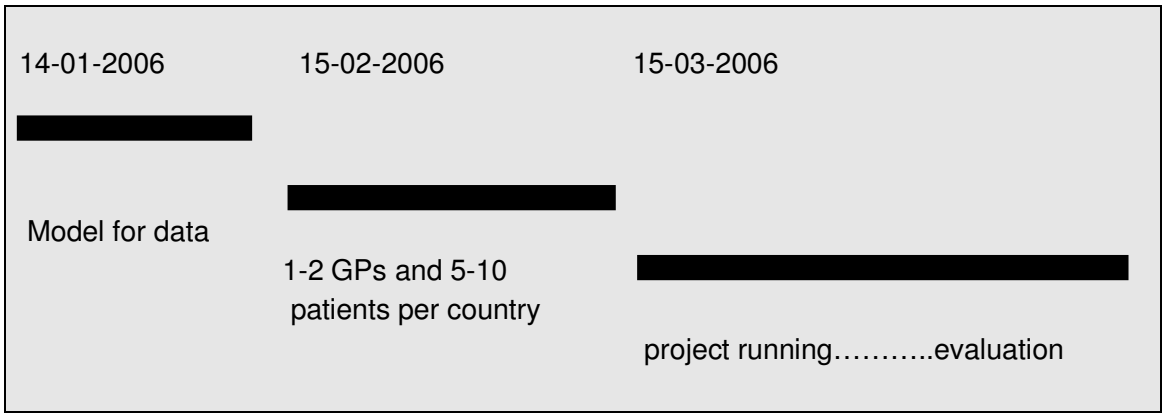


Fig. 24: Time frame of USB-Sticks pilot

This pilot will develop concrete guidelines on how to overcome legal, financial, cultural and linguistic barriers.

7.3.2. eHealth network— German perspective

Regarding Germany, following aspects should be considerd, when talking about an eHealth network.

- Rigt of self determination about the information (das informationelle Selbstbestimmungsrecht; *BVerfGE 65.1*).
- The right to choose the doctor freely (das Recht auf freie Arztwahl; *§ 76 SGB V*).
- Agreement for the treatment between patient and doctor (Bestimmungen zum Behandlungsvertrag zwischen Patient und Arzt; *§ 73 SGB V).*
- Professional obligation for secrecy (die berufs- und strafrechtliche Verpflichtung zur Geheimhaltung; *§ 203 StGB).*
- Legislative trademark (Signaturgesetzgebung; *SigG*).

There are some prerequisits for a telematic healtcare networl in Germany. These prerequisits must be performed by the BMGS (Federal Ministry of Health and Social Security Germany) for the introduction of:

- Telematik settlements (telematischer Abrechnungsziffern);
- Public-Key-Infrastructure (PKI);
- Health Professional Card (HPC);
- The definition and development of basic telematic component and its interfaces (Schnittstellen),
- Infrastructure for security; and
- Semantic interoperability for local and heterogenous EDV-Infrastructure in the clinics and hospitals ***(49).***

7.3.3. Legal aspects of an eHealth project in general

An eHealth / telemedicine plateform can be devided into three categories according to the participants, contents and the type of media used ***(50).***

Category I: Participants

The main participants are doctor and patients. They participate at eHealth plateform in different ways:

- Patient - Information system (doc-search).
- Patient - Patient (Chat-box).
- Doctor - Patient (distant treatment).
- Doctor - Specialist (expert opinion).
- Doctor - Data bank (further training).
- Doctor - Archives (external documentation.

Catagory II: Contents

The main cpntents of eHealth are:

- Record of the findings
- Interpretation of the findings
- Accounts data (Billing record)
- Administrative data
- Clinical examinations
- Epidemiology

Catagory III: Media used

Mostly used media are:

- Telephone
- Telefax
- Internet
- Radio
- Satellite
- Chip cards

A treatment process without the restriction of spac and time in eHealth has an effect On:

- Quality of care
- Rights of personal liability
- Occupational right / justification
- Data processing and data security
- Social rights etc.

7.3.4. Identified legal issues of the Project in the Baltic Sea region

There is an other eHealth project “Baltic eHealth” project, running parallel to “eHealth for Regions” project. Both projects have cooperation in different areas e.g. legal issues, which are almost identical in both progects regarding their location in Baltic Sea Region. The report on “eHealth legal issues”, issued by the “Baltic eHealth” project described many issues faced during the project work. The most important issues are:

- Confidentiality, Privacy and Data Security
- Responsibilita
- Licensure
- Patients Rights
- Reimbursement
- Informed concent

7.3.4a. Confidentiality, Privacy and Data Security

The issue:

These issues are some of the most important issues in the whole area of telemedicine and eHealth. A doctor – patient, patient – nurse or client-provider relationship is based on trust and at the core of this base is confidentiality. The provider is dependent on the

information given by the patient or client and the patient/client rely on that the provider will consider the information given as confidential. Confidentiality is a core "virtue" of any provider of care and/or help to patients or clients.

The professional duty of confidentiality is regulated under national health acts and/or health personnel acts. As an example, the Norwegian Health Personnel Act (*Helsepersonelloven*) states in its article 21 that:

> *"Health personnel shall prevent others from gaining access to or knowledge of information relating to people's health or medical condition or other personal information that they get to know in their capacity as health personnel."*
> (Official translation) ***(51).***

This article impose both an active and a passive duty on health care personnel; both a duty to actively protect such information and a duty not to give out such information, being it orally or otherwise. And the Norwegian Patients Rights Act establishes confidentiality as a right for the patient. Similar legal provisions can be found in most countries. In a way it can be said that this is the legal standard or requirement that organisations, routines and technology must meet.

eHealth solutions must provide levels of security and safety that meets these legal requirements and enables personnel to use the solutions without the risk of breaching an important professional duty.

The right to privacy is considered a Human Right. The right to privacy is derived from the notion of individual autonomy and integrity. Respecting and enhancing (in our case) patients' and clients' rights to privacy is showing respect for personal integrity and autonomy.

Introducing "e-solutions" to health care should not jeopardize any of these important principles. Hardware, software and communication need to be built and used in a way that secures information, meet confidentiality requirements and uphold the right to privacy of those whose information is stored and processed. This is not a small task for any information-system, being it paper-based or electronic ***(51).***

Problems and challenges

Several laws regulate information processing under national legislations. Privacy and security is protected under Data protection acts in all Nordic countries, In addition EU regulations ***(52)*** apply both to the EU- and the EEA countries. In terms of health care provision, specific legislation is in force, regulating the duty of confidentiality for health

care personnel with additional penal provisions. Acting with respect for the patient's privacy and right to confidentiality is a fundamental part of what constitutes responsible and good conduct by the health care provider.

As there may be state-to-state differences between legislations, they all have patient confidentiality in common. The main goal is to establish the basis for trust and confidence in the doctor – patient setting. And it is first and foremost health laws that sets the standards that modern technology must meet.

The challenge is to create, establish and implement solutions that meet strict confidentiality requirements. And the term "solutions" in this respect not only refers to hard- or software but also to organisational changes (change management), new practices and, not to forget, ethics.

The use of modern information- and communication technologies leads to new and exiting possibilities in health care. The challenge is to a large extent to find acceptable technological solutions that meet the legal requirements.

Health care have been considered a static activity, not process oriented as it is today, often with several health care providers sharing their part (and obviously needing to share the same medical information) in the treatment of the patient. Furthermore, current legislation often does not take in to account the increased mobility of both patients and health care personnel. Legislation is based on paper medical records. It is not fit for electronic information processing and the great amount of information that needs to be stored, received, handled and communicated without being at the same time an obstacle for the health care.

These legislative challenges are a concern for health- and juridical authorities in many countries. One need to establish technical, organisational and legal measures that both ensure confidentiality and privacy and at the same time make sharing and distribution of information possible. One can say that there is a need to "synchronise" legislation with information technology.

In assessing the usability and safety/security of given systems, a key process is to perform thorough risk-assessment analyses.
What is utterly important, however, is to have a clear and precise understanding of what the legal requirements are and how these are interpreted under different legislations with regards to the use of IC technologies. Both health authorities and public bodies that supervise data processing legislation ***(53)*** play important roles in the process of finding solutions all parties – patients, professionals, authorities – can live with.

In our work both within the Baltic eHealth project in general and the legal group in particular, we should also advocate – strongly – the fact that the use of electronic means and solutions in fact can enhance security, privacy and confidentiality. As an example, the use of electronic health records gives new possibilities when it comes to secure storing, better access when needed, possibilities to change/correct/erase and logging. Furthermore, the use of electronic patient records can contribute to the reduction of medical errors***(54).***

Taking health services to a cross border level adds another challenge when it comes to security and confidentiality issues. Within the EU and EEA, legislation on data processing has been harmonized in accordance with the mentioned EU Directive on such processing. This does not by any means exclude institutions and/or personnel from establishing a high level of security and safety, especially when it comes to sensitive information. The directive and national legislation furthermore simplify transmission of information in the sense that these regulations establish a principle of acknowledging each country's security regimes. But still one need to have established an acceptable level of security within each institution and the transmission itself must be sufficiently safe and secure.

On Health Networks

The establishment and increasing use of national health networks have proven to be a way to boost use of many telemedicine and eHealth services. Although there are some differences in terms of technological and organisational regimes, a common denominator is that these networks are closed (more or less) and aim at facilitate communication between many (all) parties of the health care system. Most health networks are in one way or another internet-based ***(55).***

But in terms of security and safety it is important to be aware of the limitations of the networks duties and responsibilities. These networks does not by any means remove or take over these responsibilities from personnel or institutions. The end-users are still fully responsible for establishing security and safety regimes. It is the end users that must answer to the national supervising authorities, regardless of the use of health networks. Connecting to and using a health network is something that must be considered together with other aspects of the whole security regime of the end-user. The potential risk of this connection must be made part of the risk assessment study that all users must carry out.
This applies to a national level, and connecting national networks to create regional networks obviously does not change this.

Project pecific issues

As mentioned, the adaptation of the EU Directive on processing of personal data (see above) has lead to a harmonised and quite uniform legislation within the EU and EEA states. This does not, however, limit the national authorities' powers and responsibilities and the end-users must relate to and act according to the provisions of these authorities. Among other things, this usually means that proper risk assessments study must be carried out, taking into account the cross national/cross border aspects of these services.

When used as a routine service, eRadiology can make the establishment of a so-called virtual radiology department possible. This can be graphically described as this:

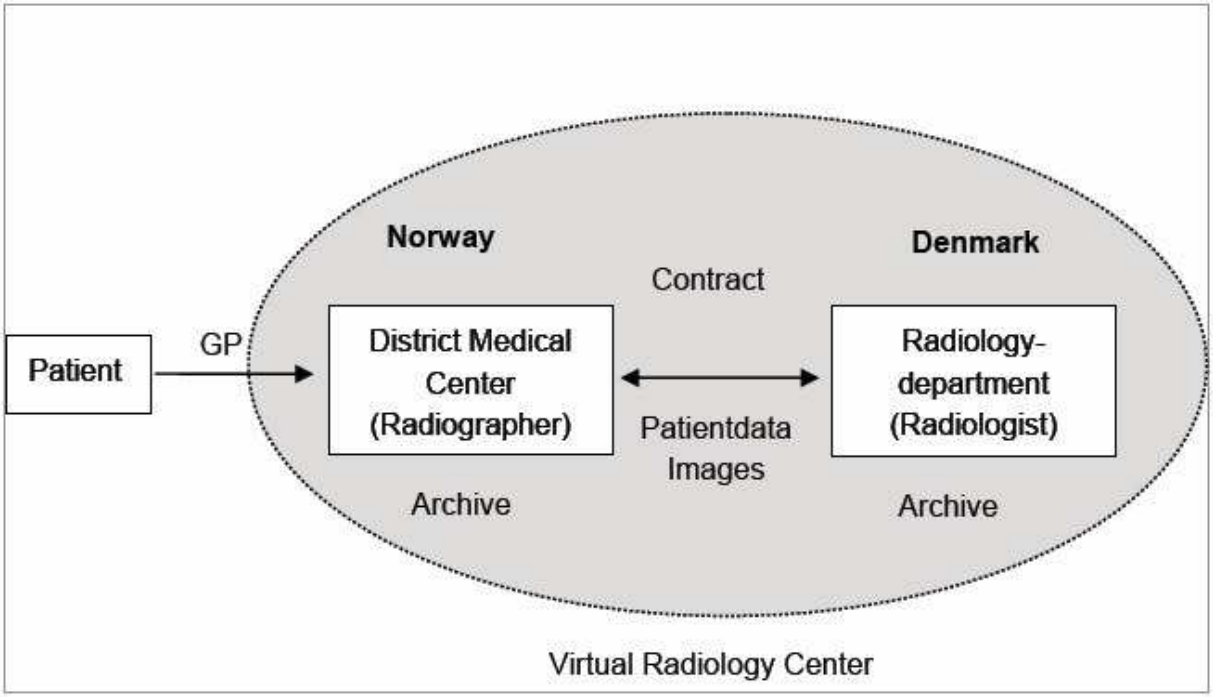


Fig. 25 ***(56):*** The figure is taken from the minutes of the publication "Legal aspects of eHealth" of Baltic eHealth Project. Used by permission).

Having such a centre or department working in according to national legislation is a multifaceted challenge, but obviously security and safety is utterly important.

Further actions

The more detailed and concrete requirements that have to be met in order to act within the national legislations must be clarified in due cause and in cooperation with the project partners from the participating countries, the national health- and data processing authorities.
In a more long-term perspective, it would be very useful to be able to do a more comprehensive study on differences, similarities and barriers between the legislation of the participating countries, but this will probably be to big a task to perform within the limits of this project.

7.3.4b. Responsibility

The issue

The term *"responsibility"* is multi-facetted. There is at least three aspects of it:

- ***Being responsible:***
  For instance when we are dealing with issues like assigning a doctor who is responsible for the treatment of the patient when she/he is at the hospital. In our setting: Who is responsible for the patient in a telemedicine setting?

- ***Acting responsibly:***
  This refers to the ethical-legal norm put on all health care personnel to conduct their practice in accordance with the best standards, and to be "measured" against these standards. This is the aspect of responsibility as a so-called legal standard.

- ***Being held responsible***:
  Refers to the fact that a doctor (or any/many other health care personnel) can be met with sanctions if the legal requirements (or ethical requirements) are not met or not satisfactory fulfilled.

Responsibility is a "legal standard". In terms of law-making, this means that the legislator in the relevant act and article refers to the standard as a legal requirement. These are different *aspects* of the issue and not different issues. The aspects are intertwined in each other. If not anything else, this shows that responsibility is a difficult issue. It is difficult to define and limit, and difficult to discuss. Distance is the core of the issue. And in relation to the three aspects of responsibility mentioned above, the following questions can be asked:

- Can a doctor be the responsible (treating) doctor for a patient that she or he does not see face to face?
- Can a doctor treat a patient that is not physically present and still meet requirements of responsible conduct? Can only some kinds of tele-treatment be considered responsible?
- Can a doctor be held responsible for misconduct or malpractice when treating a patient via a telemedicine/eHealth service?

Official legal interpretation

This principle implies that from the view of Norwegian Health authorities the use of telemedicine (or eHealth) is not considered irresponsible at the outset. This is different than what we have seen elsewhere. There are examples that under some legislations***(57),*** the health authorities and/or the legislators have found it "necessary" to state, more or less explicitly, that no treatment can be based on information received by any other means than traditional face-to-face contact.

In a telemedicine setting, it is important to clarify the situation. What kind of consultation is it? Who is doing what? Is everyone at the same "level" in terms of who is doing what, etc. Some examples of routine questions are given:

- What is the situation at hand; a *referral* from a GP to a specialist, or advise from specialist to GP?
- Is the received information sufficient for a responsible medical judgement?
- Who will keep and be responsible for health records?

Naturally, there is no definitive answer to the question "who is responsible". The answer might not be that one person and/or body is responsible. Different parties can be responsible for different situations, at different stages and based on differences in competence. From a telemedicine/eHealth viewpoint, the important issue is to make sure that the use of these services is not excluded as irresponsible from the start. A way of preventing this from happening is to establish good routines and guidelines on practice as well as making sure that this practice is in accordance with national regulations and governmental interpretations.

Norwegian Ministry of Health, The Swedish Board of Health (Socialstyrelsen) and the Danish health authorities have a common decline towards the interpretation of the term "responsibility", based on the definition described by the Norwegian Ministry of Health in a "Circular letter":

"breach of legislative duties that can have compensation, punishment or administrative reactions as a consequence." (Our translation).

Project specific issues

For transnational (cross border) treatment of heart patients the doctor at the telemedicine centre (which is connected to the TSGZ Bad Segeberg) in the respective country is responsible.

Further actions

It will therefore be an important task for this project to make sure that national legislations do not prohibit our services due to a strict interpretation of responsibility issues. It will probably be necessary at some stage to contact the health authorities in at least some of the participating countries to clarify this issue.

Specific guidelines can be produced on responsibility based on the principles of the Norwegian, Swedish and Danish recommendations.

7.3.4c. Licensure

The issue

Doctors and other health care personnel need to be licensed to practice. National licensure bodies issues general licenses as well as specialist accreditations to doctors and other health care personnel ***(58).***

Since all participants in this project is either EU members or part of the EEA, the EU Directive of 5 April 1993 on mutual recognition of diplomas is relevant and important ***(59).***

The purpose of this Directive and subsequent adaptation of member state laws is to facilitate free movement of doctors (and other health care personnel), by establish a regime where diplomas from medical schools in the area are recognized mutually between the states. This harmonisation makes it much easier to obtain a license in another EU/EEA country, and to some extent it is a *right* for the professional to get such a license.

Questions

Is there a need for a special license in telemedicine/eHealth?

In the early days of telemedicine (some ten years ago) this was a more important and more discussed issue than it is today. At the time many believed that telemedicine should be looked upon as another speciality of medicine, and as such it should at least be subject to specialist accreditation. Malaysia was one of the first countries (if not *the* first) to pass a Telemedicine Bill, as early as 1997 ***(60).*** In this bill, the Malaysian health authorities establish a regime where professionals that want to practice in Malaysia can apply for and get a certificate to practice telemedicine from another state. The impact and use of this bill is not known to us, but might be something to look into as part of our project.

In what country must a doctor be licensed?

Obviously, this question is relevant for services where telemedicine is provided across borders – where the professional and the patient reside in different countries and under different legislations.
The question can be divided into at least three sub-questions:

a) Who is "travelling" – the patient or the doctor?

b) Must an out of state doctor have an in-state license to practice?

If a doctor is offering treatment from another country, the question is whether she or he needs a license to practice medicine in the country where the patients reside. The principal or traditional answer is yes. In order to practice, a doctor must be licensed in the country where she or he is practicing. It does not matter if the doctor is fully licensed in another country. This is the case where the doctor physically moves from the country where she/he is licensed, to another country. Within the EU/EEA region, obtaining license in another member country is, as mentioned, almost a formality. Nonetheless, a license must be obtained.

If this is a requirement also when the doctor continues to practice from the licensing state, solely providing services through telemedicine to another, is still unclear. (see below under "c"). An alternative solution could be to establish a solution like the one proposed in the mentioned Malaysian Telemedicine Bill where a out-of-state license is combined with a in-state telemedicine certificate. Or may be this problem could be solved through contracts or treaties between

countries and/or individual doctors.

c) Can a licensed doctor practice from another country?

This question refers to a situation where a doctor is licensed in one country and offers services via/by telemedicine to patients in this country, but the doctor resides in another country.
Under German, Norwegian and Swedish law, this still is an unclear situation. We have put the question before Norwegian health authorities, but have not yet received a definitive answer.

Questions concerning this have been asked to the Swedish Board of Health and their preliminary point of view is that the out of state doctor must hold a license in her home-country only, and that Swedish patients seeking this doctors treatment, by telemedicine or by travelling, must raise maltreatment complaints under the licensing state's legislation. A Spanish doctor treating Swedish patients through telemedicine can never be held responsible under Swedish legislation.

7.3.4d. Patient's rights

The issue

Legal rights have become part of health care legislation as well. One is talking about the individual citizen's right to health care and rights towards the health care system. It is worth mentioning that Finland passed the first patients' rights act in the world. And even without a specific act or regulation on patients' rights, it is widely recognised that patients have some rights with regards to health care that are secured by law.

Patients' rights can be divided into three aspects:

- The right to *become* a patient (entry rights).
- Rights *as* a patient (e.g. right to information, consent and access to medical records.
- Formal/procedural rights (e.g. right of appeal).

How and to what extent these rights are granted varies under different legislations. The most controversial of these, is probably the right to become a patient. This implies a right to treatment, often specified in terms of level of treatment and a timeframe within which

treatment must be granted. This is a right that must be met with clear obligations from the authorities and it has obvious economic consequences.

To create awareness of patients' rights and ensure such rights in this project, we will produce a set of guidelines on this issue. These guidelines will especially focus on information and consent issues as these have been pointed out as especially important by many of the participants in the project.

7.3.4e. Reimbursement

The issue

Reimbursement/payment is perhaps the most important issue when we are talking about barriers for implementation of telemedicine/eHealth – both on a national and an international level. It is probably a more political than legal issue, but has some legal implications and basis.

The questions to be answered: How telemedicine /eHealth services are considered in each state? Is telemedicine/eHealth recognised as full medical services, or "merely" as support-solutions? Can patients be treated via telemedicine, or can telemedicine be used only for second-opinion? (cf. the discussion on responsibility above). Can out-of-state doctors be paid or patients seek reimbursement for treatment received from out-of-state telemedicine doctors?

To further complicate the situation, payment-/reimbursement-/insurance systems are different in different countries. In the Nordic (and probably the Baltic) countries, however, the systems are mainly public with a limited element of private participation.

Further actions

At the same time as we try to find solutions to this issue on a more superior and "legal" level, we should try to solve this issue within this project through contracts between the parties. This work obviously will have to be done in close cooperation with the work on economics. We believe that contracts can be both a powerful and dynamic tool to solve this issue in this project, but we fully recognise that contracts only to limited extent solve the reimbursement/payment issue.

7.3.4f. Contract issues

We believe that contracts are versatile, dynamic and give the necessary precision. Through contracts we also identify the relevant parties and commit them to their duties in the project. One limitation of using contracts is of course that they are specific to the situation and parties involved in it. In principle they have no power or relevance outside this framework.

There are some issues that need to be clarified before negotiating and working out the contracts:

- ***Contracting parties***

  One needs to point out the person/persons that have in fact the power to commit the institution. In most cases the situation will be that the contract is entered between two or more institutions. If the case is that the contract is entered between individuals, this should be clarified by the management of the institution (usually a hospital).

- ***What can be subject to contracts?***

  Even if national legislation in principle upholds a large extent of contractual freedom, health care is an area where there probably are some limitations. For instance, the mentioned rights of patients can not be violated by contract. It will probably be necessary to quality assess our contracts with both hospital owners/managers and health authorities.

7.3.4g. Informed consent

The issue

Consent can be defined as an unrestricted, unilateral statement, action or disposition based on sufficient information, given by a competent person. It is a specific legal term relevant in many situations where a person commits her-/himself to something.

Requirements for valid consent

- ***Personal competence***

Consent is an individual commitment, and the consenting party must be competent to consent. In general competence to consent coincides with a person being of age, in the Nordic countries this happens at the age of 18.

But even if a person is of age, she or he can be considered incompetent to consent. This is especially relevant for elderly people and people with reduced mental capabilities. This can be a permanent or a temporary condition. It is the duty of the receiver of consent – the health care personnel in our case – to make sure that the consenting party is competent.

- ***Unrestrained***

It is an absolute requirement that the consent is given without any kind of pressure or restrain. A forced consent will not under any circumstance be valid.
This may sound like an obvious and unproblematic issue, but in practice on can easily find situations where the line between persuasion and pressure gets blurred. This can for instance be the case where the patient is in doubt about whether or not to enter into a suggested treatment and the doctor strongly recommends that she or he does.

- ***Information***

Some have pointed out that it is not the consent that should be informed, but the patient ***(61).*** The patient shall be given enough information to be able to judge the situation and to make a reflected decision. In English case law this has been stated as follows:

> *"The health care provider must provide the patient with sufficient information about the proposed treatment and its attendant risks to conform to customary practice of members of the same profession with similar training and experience situated in the same or similar communities. In addition, the health care provider must impart enough information to permit a reasonable person to gain a "general understanding" of both the treatment or procedure and the "usual and most frequent risks and hazards" associated with the treatment"* ***(58).***

This quotation points out a very important aspect of information: As well as information about the treatment in question, the patient must be informed of potential risks. There have been some discussions, both in literature and court cases if the health care provider must inform the patient about *all* risks, however distant. This is probably not necessary.

7.4. Challenges and recommendations

In our project this has raised the question whether we should establish a routine for asking consent from the patient – a routine that is not used in traditional services. If a patient has her pictures taken in Odense (Denmark) and the pictures are transmitted to Estonia and interpreted by a doctor there, should this be based on her consent?

We do not have a definitive answer to this question. It is a point, and a good point, that patients as mentioned usually do not get information on who is interpreting the pictures, and they are not being asked to consent.

However, to be on the safe side, we suggest that we establish a routine where consent from the patients is obtained.

As a general rule, more emphasis should be given to information and clear consent when dealing with untraditional and new procedures. The patient should be informed that the pictures might be transmitted to radiologist/radiology department in another country for interpretation. She or he should be informed about the means of transmission, including safety and security measures. Following the nature of consent, this means that the patient can protest and deny the doctor or radiographer to send the image. This must be respected, and the images must then be dealt with in a traditional matter.

8. Discussion

It is clear that eHealth is an imporatnt component of high quality healtcare delivery system. The implementation of ehealth in healthcare systems is increasing rapidly, resulting in a paradigm change.

The nine main drivers forcing the change in healtcare delivery system (also include eHealth), describrd on 4th Conference on eCommerce 2005 in London are ***(22):***

- Obligatory research for cost containment
- Changing demographics
- Peripheralisation of health care delivery
- Changing disease patterns
- Impact of information technology including IT support for clinical decisions-Telemedicine and eHealth
- More informed and expectant patient's c-Health
- The well-being factor—responsibility shift into patients hands—*The Wellness Paradigm.*

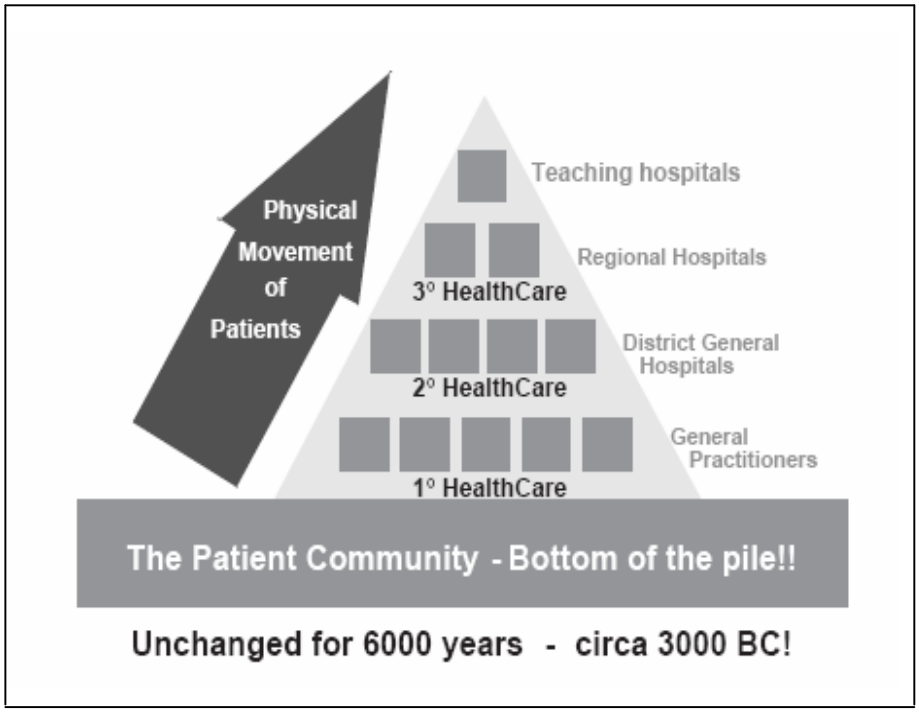


Fig. 26: Traditional healthcare delivery model (adopted from"*eurohealth Vol 8 No 2 Spring 2002"*).

- Moving information and knowledge—No People
- *eHealth creation of Managed clinical Networks.*

8.1. Change management

Perhaps the biggest challenge facing the healthcare sector is how to manage the change in practices and roles that will be, brought about by the widespread introduction of IT. Medicine is an essentially traditional milieu and the healthcare professional body is deeply conservative and suspicious of change. The traditional model for healthcare delivery (**Figure 26 above**) has changed little for six thousand years***!(21)***

This model is already changing. Healthcare services that have traditionally only been available within physical institutions such as hospitals and clinics, are moving into the retail environment and improvements in clinical technology are increasing the range of the services that can be offered in non traditional premises. This trend will increase and will further accelerate with the deployment of homecare services, including the installation of monitoring devices and video systems. However, new models for healthcare delivery made possible by an eHealth environment look very different (see **Figure 27 above**).

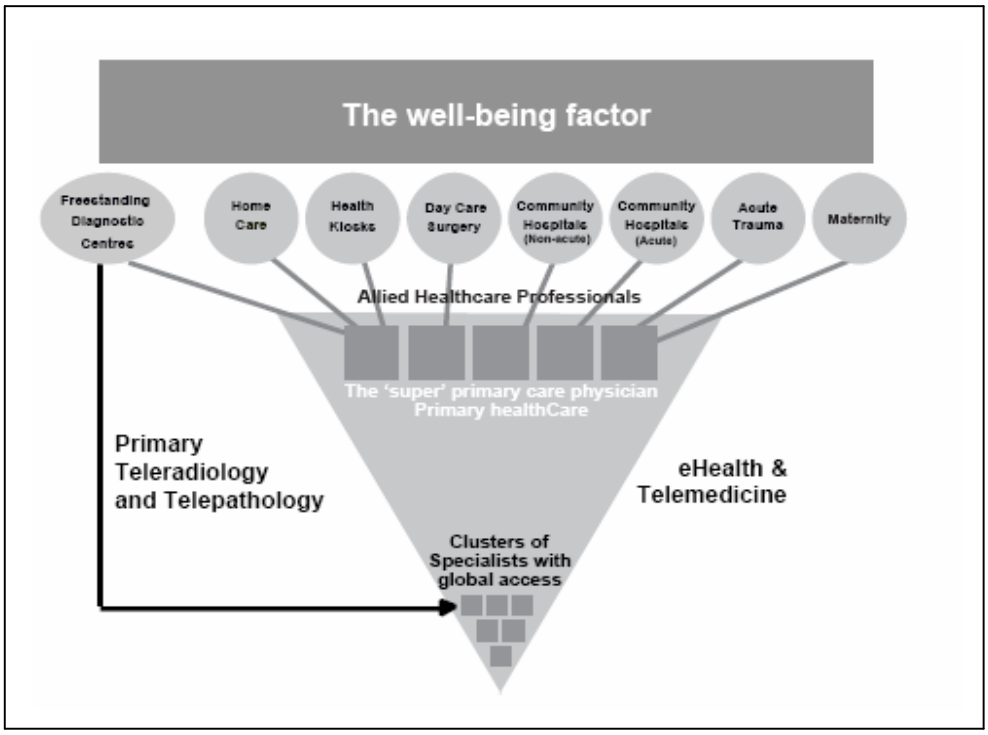


Fig 27: Healthcare delivery model supported by eHealth (changing paradigm).

This will create safe environments for the more vulnerable members of the community such as the elderly, and allow them to live independently, but with instant access to appropriate healthcare services ***(21).***

8.2. Interoperability Focus (for cross boder eHealth networking)

A very important factors for a well established cross border communication network of eHealth in the region are a generic eHealth interoperability framework and common approaches to:

- Patient / professional identifiers
- ePrescribing and health data messages

CEN / ISS eHealth Stand Focus Group recommended in its report:

*"The Member States, with the Commission, should establish a permanent platform with a mandate, and the necessary resources to promote eHealth interoperability based on standards and to facilitate co-operation between Member States."****(62)***

The main areas to be focussed are:

- ***Organisational Interoperability***

This involves the mainly the recognition of physicians authorisations (legal), reimbursement claims, etc.

- **Semantic Interoperability**

This includes issues like pharmaceutical nomenclature & classification:drug composition; branding etc; instructions/quantity (10-10-10 vs. qid; tid).

- **Technical Interoperability**

The main focus should be on: access to digital information and access to authorisation information; etc.

"The challenge is the technology adoption and diffusion in the current system".

9. REFERENCES

1. eEurope Initiative: An Information Society for All; Communication on a Commission Initiative for the Special European Council of Lisbon, 23 and 24 March 2000

2. CEN Management Centre, CENELEC Secretariat and ETSI Secretariat: The contribution of European standardization to the eEurope Initiative; A rolling Action Plan, Final Version 5.3.0 (July 2002).

3. Barcelona European Council, Presidency Conclusions, paragraph 40. (www.ue.eu.int/en/info/eurocouncil/index.htm)

4. Commission of the European Communities: Brussels, 28.05.2002. eEurope 2005: An information society for all. An Action Plan to be presented in view of the Sevilla European Council, 21/22 June 2002.

5. Europe's Information Society: i2010 initiative, Brussels, 1 June 2005. (www.europa.eu.int /i2010)

6. Jon Hoeksma, eHealth Insider; Veronique Lessens, HINE: *Perspectives on eHealth in Europe,* August 2005

7. Europe's Information Society, European Commission (www.europa.eu.int).

8. "Facing the Challenge - The Lisbon strategy for growth and employment" Report from the High Level Group chaired by Wim Kok, November 2004, p. 22.

9. Commission of the European Communities, Brussels, 30.4.2004, COM (2004) 356 final: e-Health – making healthcare better for European citizens: An action plan for a European e-Health Area, {SEC(2004)539}.

10. Pagliari et al. EH1 Scoping Study. Non-Traditional Review. EH1 E-Health Scoping Exercise Review of Wider Web-Based Information Sources

11. Europe's Information Society, European Commission, 2003a (www.europa.eu.int)

12. Denise Silber, „The Case for eHealth"; first European eHealth Conference, Brussels, May 22/23 2003

13. European Health Telematics Association (www.ehtel.org).

14. Petra Wilson, Christine Leitner and Antoinette Moussalli: Mapping the Potential of eHealth: Empowering the Citizen through eHealth Tools and Services; EIPA, 2004.

15. Deloitte and Touche (2003) eHealth. Health Information Network Europe. Final report.

16. *The European e-Business Report - 2002/2003 edition. A portrait of e-business in 15 sectors of the EU economy* - 1st Synthesis Report of the e-Business W@tch. Luxemburg: Office for Official Publications of the European Communities, 2003. ISBN 92-894-5118-1; Empirica, SIBIS, Benchmarking Highlights 2002: Towards the Information Society in Europe and the US, May 2003. See http://www.sibis.org/.

17. A*pplications relating to health. Fifth research and development framework programme 1998-2002*. Final report. April 2003 edition. Information Society General-Directorate: European Commission, 2003.

18. The proven benefits of regional (community, district, county) health information systems are discussed in the guide to the exhibition of the Ministerial e-Health 2003 conference.

19. Silber, D (2003) *The Case for eHealth*. Presented at the European Commission's first high-level conference on eHealth, May 22/23, 2003. EIPA, Netherlands.

20. To date, the High Level Group on the Employment and Social Dimension of the Information Society (ESDIS) has focused on the safe and healthy usage of information and communication technologies at work (SEC(2002) 372 and (SEC(2003) 652), as well as on the the potential opportunities of online health services for disadvantaged groups (SEC(2001) 412), that is also referred to in a Council Resolution on e-Inclusion adopted in October 2001.

21. Eurohealth Vol 8 No 2 Spring 2002. Promoting E-health in Europe: Challenges and opportunities.

22. ASEM, eHealth, mainstreaming of eHealth, 4th Conference on eCommerce 2005 in London

23. Petra Wilson, Maping the potential of eHealth: Empowering the citizen through eHealth tools and systems Presented at the *e*Health Conference, Cork, Ireland, 5-6 May 2004

24. M. Cabrera, *The future of eHealh research.* IPTS, DG Joint Research Centre, European Commission, Krynica-September 2005.

25. INTERREG website (www.

26. Montalescot G et al., ADMIRAL Study. European Heart Journal 1999; 20:170.

27. Sheikhzadeh A., Head of the Telecardiology Department, Segeberger Kliniken (TSGZ), Bad Segeberg."Hospital and ambulatory care can be improved through eHealth"

28. TSGZ website (www.tsgz.de). „The problem of pre hospital time delay in the treatment of cardiac patients: A concept of decreasing thr mortality through MI – 8 deciding questions".

24. Scheikzadeh A.H. , Research Director at TSGZ. (www.tsgz.de).

29. Atmann EM, Tanasijevic M, Thompson B, *et al.* Cardiac specific troponin 1 levels to predict the risk of mortality in patients with acute coronary syndromes. *N Engl J Med* 1996;335:1342-9.

30. Braunwald E, Antmann E, Beasley J, *et al.* ACC/AHA 2002 guideline update fort he management of patients with unstable angina nad non-ST-segment elevation myocardial infarction – summary article: a report of the American College of Cardiology / American Heart Association task force on practice guidelines. *J AM College Cardiol* 2002;40:1366-74.

31. Antmann E, Braunwald E. Acute myocardial infarction. In: Braunwald E, Zipes D, Libby P, eds. *Heart Disease*. 6th edn. Philadelphia, PA: WB Saunders, 2001:1114-230.

32. Bahr RD. Good, better, best "infarctus interuptus" view from a public health cardiologyst's perspective. *Maryland Med* 2001 (suppl.):80-2.

33. Ferguson JD, Brady JD, Perron AD, *et al.* The prehospital 12-lead electrocardiogramm: impact on management of the acute coronary syndrome patient. *Am J Emergency Med* 2003;21:136-42.

34. Pedley DK, Bisset K, connolly EM, *et al.* Prospective observational cohort study of time savede by prehospital thrombolysis for ST elevation myocardial infarction delivered by paramedics. *Br Med J* 2003327:22-6.

35. Terkelsen CJ, Norgaard BL, Lassen JF, *et al.* Telemedicine used for remote prehospital diagnosing in patients suspected of acute myocardial infarction. *J Intern Med* 2002;252:412-20.

36. Weaver WD, Eisenberg MS, Martin JS, *et al.* Myocardial Infarction Triage and Intervention Project – phase I: patient characteristics and feasibility therapy. *J Am College Cardiol* 1990;15:925-31.

37. Keeling P, Hughes D, Price L, Shaw S, Barton A. Safety and feasibility of prehospital thrombolysis carried out by paramedics. *Br Med J* 2003;327:27-8.

38. Schwab B, Sheikhzadeh A, Riedel J, *et al.* Prehospital diagnosis of myocardial ischemia by telecardiology. *Journal of Telemedicine and Telecare* 2005;11:41-44.

39. Schwab B, Katalinic A, Riedel J, Kiepe W, Huhmann W, Shekhzadeh A. Feasibility and reliability of a transtelephonic 12 leads ECG. *Zeitschrift Kardiol* 2003 ;92 :31-8.

40. Ashely EA, Raxwal V, Froelicher V. An evidence based review of the resting electrocardiogram as a screening technique for heart diseas. *Progr Cardiovasc Dis* 2001; 44: 55-67.

41. Silvermann M, Silvermann B. The diagnostic capabilities and limitations of the electrocardiogram : update. In: Hurst J, ed. *The Heart.* New york, NY: McGraw-Hill, 19979:13-45.

42. Fleiss JL. *The Design and Analysis of Clinical Experiments*. 2nd edn. New York: John Wiley and Sons, 1986:1-32.

43. Woodwark M. Epidemiology: *Study Design and Data Analysis*. 1st edn. Boca Raton, FL: Champan & Hall, 1999:88-92.

44. Balas EA, Jaffery F, Kupermann GJ, *et al*. Electronic communication with patients. Evaluation of distance medicine technology. *JAMA* 1997;278:152-9.

45. Scalvini S, Zanelli E, Domenighini D, et al. Telecardiology community: a new approach to take care of cardiac patients. “Boario Home-Care” Investigators. Cardiologia 1999;44:921-4.

46. Dirschedl P, Lenz S, Lollgen H, Fahrenkrog U. Validity of telephone ECG multichannel transmission. *Zeitschrift Kardiol* 1996;85:677-83.

47. Grim P, Feldmann T, Martin M, Donovan R, Nevins V, Childers RW. Cellular telephone transmission of 12-lead electrocardiograms from ambulance to hospital. *Am J Cardiol* 1987;60:715-20.

48. Roth A, Bloch Y, Villa Y, Schlesinger Z, Laniado S, Kaplinsky E. The CB-12L: a new device for transtelephonic transmission of a 12-lead electrocardiogram. *Pacing Clin* Electrophysiol 1997;20:2243-7.

49. Warda F., Noelle G. “ Telemedizin und eHealth in Deutschlend: Materialen und Empfehlungen für eine nationale Telematikplattform“ (Telemedicine and eHealth in Germany: materials and recommendations for a national telematic plateform). DIMDI, 2002.

50. Dierk C. *Social and professional classification of telemedicine application*, powerpoint presentation. Dierks and Bohle, Berlin, 2005.

51. Leif Erik nohr, on behalf of the Baltic eHealth Legal Group. *Report on identified legal issues of Baltic eHealth Project.* Tromso, Norway, June 22nd 2005.. www.baltic-ehealth.org.

52. Proposal for a directive of the European Parliment and of the Council on the retention of data processed in connection with the provision of public electronic communication services and amending Directive 2002/58/EC. Commission of the European communities, Brussels, 2005, Com (2005)438.

53. See www.dp.gov.ee, http://www.datatilsynet.dk, www.datatisynet.no, www.datainspektionen.se, www.ada.lt

54. See the report *” CPR Generation Effectiveness in Reducing Medical Errors”*, issued by the Gartner Group at www.gartner.com.

55. For more information, see for example www.carelink.se (Swedish health network), www.medcom.dk (Danish health network), www.nhn.no (Norwegian health Network).

56. The figure is taken from the minutes of the eRadiology workshop held in Trondheim on March 10 2005. Minutes taken by Morten Jakobsen and Henning Voss. Used by permission.

57. A German guide for medial conduct from 1997 stated that *"The medical practitioner may supply individual medical treatment, especially advice, neither exclusively by letter nor in newspapers or magazines nor exclusively by means of communication media or computer communication networks."* This quotation is taken from "Green Paper. Legal aspects of health telematics" issued by the European Health Telematics Association (EHTEL), www.ehtel.org

58. See for example http://www.safh.no/ which is the website for "Statens autorisasjonskontor for helsepersonell" or "The Norwegian Registration Authority for Health Personnel". (web site partially in English).

59. Full title: *"Council Directive of 93/16/EEC of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications."*

60. See: http://mcsl.mampu.gov.my/english/telemedicBI.html (last accessed 14.12.2004)

61. Rynning E, Samtycke till medicinsk vård och behandling, Iustus Förlag, Upppsala, 1994.

62. Schlug A. S. Cross border communication of health-related data – Interoperability for ePrescribing and other healthcare messages: Interoperability Initiative for an European eHealth area. eTEN, Information Society and Media, 29.08.2005.

10. APPENDICES

During this project work I took active part in the meetings and the conferences held in the partner countries (Germany, Denamrk and Sweden). I got the opportunity to present my work during the project meetings topics like:

- Regional Need Analysis – questionnaire development (developed questionnaire was discussed).
- Legal aspects of eHealth (challenges and solutions).
- Results of questionnaire survey from Schleswig Holstein, Germany .
- Acceptance model for patients.

It was an excellent opportunity to get practical experience by working with the top class experts of Europe in the field of eHealth/Telemedicine.

Below you will find the official minutes of different meetings, in which I took part.

Appendix 1: Work-package 1+2 meeting on 01-02. 12.2005.
Participants: All Partners of the EU project “eHealth for Regions“
Venue: Hotel Pinenhus, Pinen 3, Glyngøre DK-7870 Roslev.

Appendix 2: Summary from the meeting The 14. January 2006 – Hilton Conference room Hermod, Denmark.

Appendix 3: Work-Package Meetings on 01-02.03.2006 in Lund, Sweden
“eHealth for Regions“ Agenda Work group 1 + 2 meeting

Appendix 1

Work-package Meetings
"eHealth for Regions"
- Minutes -

Participants: **All Partners of the EU project "eHealth for Regions"**

Start: 1st of December 2005, 14:30h

End: 2nd of December 2005, 12:00h

Venue: **Hotel Pinenhus, Pinen 3, Glyngøre DK-7870 Roslev**

Agenda Work group 1 + 2 meeting

Chairs: Henning-Bruun-Schmidt, Thorsten Beck

Dec. 1st		
14.30	**Common session**: Short summary of WP1/2/3/4 and PSC	Ralf, work package coordinators
14.45	**Analysis of regional need:** – Prepared questionaire for Germany – Suggestions: Questionaire for Sweden, Poland and Lithuania.	Rehan, Fareed Ahmed
15.45	Break	
16.00 – 18.00	**Report from peer groups:** – Cardiology – Radiology – Exchange of patient information	
Dec 2nd		
8.30	**Guidelines for transfer:** – Technical – Economy – Linguistic	Diako / Viborg Lund Viborg

9.30	Break	
9.45 – 11.00	**Parallell sessions:** **Guidline for transfer** (continued) – Legal – Partners **Survey report:** Outline of the report	 AOK Schleswig-Holstein (Rehan, Fareed Ahmed), Viborg (Henning Schmidt) Lars and Owe
11.00 – 12.00	**Common session** Reporting and next step	Workgroup coordinators

List of Participants

Beck, Thorsten	AOK Schleswig-Holstein, Kiel, Germany
Bender, Janine	AOK Schleswig-Holstein, Kiel, Germany
Bruun-Schmidt, Henning	Viborg County, Viborg, Denmark
Chlebus, Krysztof	Gdansk University Hospital, Gdansk, Poland
Duckert, Ralf	dsn Projekte, Kiel, Germany
Feszak, Jaroslaw	Lebork Hospital, Lebork, Poland
Godderis, Elzbieta	Lebork Town Municipality, Lebork, Poland
Hansen, Ole Filip	Viborg County, Viborg, Denmark
Iwicki, Kamil	Region Skane, Malmö, Sweden
Kitinoja, Helli	Seinäjoki Polytechnic, Seinajöki, Finland
Petersson, Tomas	Region Skane, Malmö, Sweden
Potyra, Pawel	Region Skane, Malmö, Sweden
Rehan, Fareed Ahmed	AOK Schleswig-Holstein, Kiel, Germany
Rising, Sturla	Klinikk Medisinsk Diagnostikk, Tonsberg, Norway
Schröder, Ulrich	Diako Flensburg, Flensburg, Germany
Sjöberg, Lars	Region Skåne, Malmö, Sweden
Stundys , Domantas	VUH Santariskiu Klinikos, Vilnius, Lithuania

Results:

The participants of the AOK Schleswig-Holstein presented the german questionnaires for the individual goal-groups. Changes have been made. Finland agreed additionally to participate in the inquiry.

The following timetable has been agreed for the procedure:

9th December: Send the questionnaires to all partners

16th December: Feedback from partners to Thorsten Beck

22nd December: Final version for designing and printing

Till 20th January: 5 regions send the questionnaires to the target groups

1st March: Final results

The final results of the inquiry of all 5 countries should be represented in the next meeting in March 2006 in Lund.

The peer groups of the 3 areas have continued their work. They are going to concretise their individual project measures in their next meeting on 14th of January 2006.

The points to the subject „legal aspects“, worked out by the AOK Schleswig-Holstein, have been introduced to the participants and will be loged in our homepage „eHealth for Regions“.

Appendix 2

Summary from the meeting The 14. January 2006 – Hilton Conference room Hermod, Denmark.

Participares in the meeting:
Lars Sjoberg (chairman)
Helli Kitinoja, Finland
Sturla Rising, Norway
Thorsten Beck, Germany
Fareed Rehan, Germany
Stundys Domantas, Lithuania
Ulrich Schröder, Germany
Henning Bruun-Schmidt, Denmark
Ole Filip Hansen, Denmark.

Strategy for a USB-Stick pilot project

1. Data – simple way.

Kind of patients	**Adm. Information**	**Med. Information**
Hearth		
Diabetic		
Hearth / diabetic		
Students		
Truck drivers		Vaccination
40-80 years		
Astma		
Organ transplantation		
Pace maker		

2. Med. information

Chronical

1. Diagnoses
    a. Latin name
       ICD no.

    b. Medical History

2. Medication
    a. Generic Name | Name | Atc-code

3. Allergies
    a. Text (English) | Atc-code
       Medical
       Others

4. Implants
    a. Text | Type | Code

5. Vaccination

6. Results of treatment – and New Information

NB: Newest information first in all points.

3. ID – (4 digital code to open stick)

Last Name | First Name

Family GP / Nurse

Relatives / contact
- Name - Address Telephone no.

4. Schedule and concretisation of the forms:

1A) Design medical form Design adm. form

1B) Make a technical solution / program for filling in the forms
(and describe further development of the forms. Verifications etc.)

2A) Forms into USB
- secure version handling
- secure no change is possible
- secure access to the info

2B) Forms into database
- designing database
- adm. “owner” of the database secure access for the database

3) Pilottest
- choose patient
- choose doctors

4) Evaluation of the concept
- doctors
- patients
- technical

5) Scaling up
- technical
- organization
- legal
- economy

5. Schedule program of the points:

14-01-2006 15-02-2006 15-03-2006

[redacted]

[redacted]

[redacted]

Model for data

1-2 GPs and 5-10
patients per county

project running……..evaluation

1) Short description of project (to patients and GPs) – (Rehan)
2) Data model: How to put the info on USB/web – (Lars and Thorsten and review Ole/Jens + Helli)
3) Acceptance model for patients – (Rehan).

Summary of the meeting:
Ole Filip Hansen
Denmark

Appendix 3

Work-Package Meetings on 01.03.2006 in Lund, sweden

"eHealth for Regions"

Agenda Work group 1 + 2 meeting

Chairs: Henning-Bruun-Schmidt, Thorsten Beck

March. 1st		
13.30 – 14.00	**Common session**: *Short summary of PSC meeting* **Results of VPN peer group, Copenhagen 14.01** *Introduction to the eHealth report*	Ralf Thorsten Owe
14.00 – 15.00 14.00 -16.30	**WP 1 and 2 session** **Group A: Analysis of regional need:** – Presentation of national Surveys: Poland, Germany, Finland, Lithuania, Sweden **Group B: external Experts of radiology:** – Can we use the existing Flensborg Modell ??	Jarek, Fareed Rehan, Helli, Domantas Experts of radiology from every country
15.00	Break	
15.15 – 16.30	**WP 1 and 2 session** **Project Progress report and Status:** – Technical – Legal aspects – Linguistic – Economy – Partners Draft Discuss: 1 or 2 documents for every point	(Flensburg, Uli Schröder) (Kiel, Dr. Rehan) (Viborg, Bruun-Schmidt) Lars prepared 1 page Lars prepared1 page (Lars will not participate)
16.30-18.00	*WP 1 and 2 session (strategic process)* Results of radiology expert group	Experts of radiology from every country
19.00	Bus transport to dinner	

March 2nd		
09.00-09.30	*VPN peer group* - Personal Medical information stick in 7 countries - medical history in ehealthforregions homepage	Thorsten Beck
09.30-11.00	*WP 1 and 2 session* Business model 2 - ongoing development**;** Looking into business possibilities: – VPN – Cardiology - Radiology	Ralf, work package coordinators, all members
11.00 – 12.00	**Common session** – Report from the radiology group – Report from the VPN group – Preparations for next meeting in Lebork	Workgroup coordinators