

TeleHealth 2007

"Telemedicine and innovative technologies for chronic disease management"

**Conference covering presentations relating to telemedicine (including
telehealth, telemonitoring, and teleradiology)**

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“TeleHealth 2007: Telemedicine and innovative technologies for chronic disease management”

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READING NOTES

In addition to an internal quality review by the Strateqo consortium, this draft has been circulated to Commission service staff for their comments and criticism. The manuscript was also shared with the cited speakers, several of whom have taken the opportunity to review their individual contributions to the conference. A group of experts in telemedicine, which met at the Commission’s request on 4 February 2008, has also had a similar opportunity.

Any errors remaining are the responsibility of the authors.

This document does not necessarily reflect the formal opinion of the European Commission.

http://ec.europa.eu/information_society/events/telehealth_2007/index_en.htm

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Executive summary

As a continent, Europe is facing a convergence of socio-economic and technological factors that may challenge European healthcare systems at the same time as offering it considerable opportunities. The European Union is confronted by an ageing population that is also experiencing increasing numbers and intensity of chronic diseases. These two issues pose dilemmas with regard to the provision of accessible, high-quality, safe, and sustainable healthcare in individual Member States, and in the Union as a whole. Empirical evidence and relevant figures illustrate this.

Shared challenges: a telemedicine solution? These challenges are common to the European continent. It is proposed that telemedicine can play a role in resolving them. Plans are underway on the part of the European Commission to launch a telemedicine-related initiative that aims to contribute towards solving some of these problems.

Here, the scene is set for the need for telemedicine. While a precise definition of telemedicine is not offered at this point, a commonly used understanding of telemedicine implies “care at a distance”. Indeed, the interpretation of “care at a distance” is considered sufficiently flexible to include teleradiology – an application at a distance – which is commonly used in Europe. Among the other telemedicine applications explored here are telehealth and telemonitoring.

Learning from experience: benefits and problems: Multiple concrete experiences of telemedicine deployment and use are laid out: some are national, some regional, while some are city-based or are even more local. A portrayal is presented of exactly what can be learned from these experiences. There are many opportunities offered by telemedicine, but there are also considerable barriers or hindrances to its further use. The specific benefits that telemedicine provides, and the particular problems that it can create, are outlined here.

What next? An exploration is sketched out of those legal and regulatory challenges (including accreditation, labelling, and certification), financial and reimbursement dilemmas, organisational and professional difficulties, and standardisation and occasionally interoperability issues.

A first conference organised by the European Commission, held as a first step in consulting the community on these issues, took place on 11 December 2007.

This report outlines the conferences’ main ideas, presentations, discussions and debates. It provides a first insight into all the possible reasons why the European Commission is exploring the possibilities for a future action plan for Europe on telemedicine. A proposed timetable is introduced that lasts over the course of 2008-2009 which shows the directions towards the publication of a possible Communication.

A challenge: This report encourages the members of the Union, and the wide range of stakeholders concerned, to explore what difficulties may have to be overcome to facilitate wider telemedicine deployment throughout Europe.

Method and structure of the report

This report is an amalgamation of notes taken directly during the day of the conference that was merged with the summaries of the speeches provided in advance of the day by the various speakers. To facilitate a smooth and comprehensive coverage of the notions raised throughout the conference, the report adapts the order of the presentations. It does not reflect fixedly the order of speeches and interventions as they were made on the actual day.

This report is structured broadly using the following format:

- Overview of the conference
- Introduction: challenges to Europe's health situation
- Background to telemedicine (including challenges, problems, and weaknesses)
- Definition(s)
- Telemedicine examples with a particular focus on teleradiology
- The organisational context
- Legal, regulatory, and professional issues
- Issues relating to professional conduct
- Coverage of the discussion and debates throughout the day
- Concluding remarks

1. Overview of the conference

The conference aimed to highlight good practice and use cases in telemedicine in Europe, but also to identify the various, possible barriers to the broad deployment of telemedicine initiatives. It explored concrete actions that the European institutions, Member States, regions, user organisations, and other stakeholders can take with the objective of deploying more broadly telemedicine services in Europe. The main focus of the day was on identifying organisational, legal and regulatory, and professional (or occupational) frameworks of analysis for future actions.

The morning session concentrated particularly on good practice and use cases in telemedicine. It also examined the various obstacles to the provision of healthcare *via* telemedicine, and assessed the benefits of such an approach. The afternoon session provided an open forum for discussion. It was facilitated by a number of targeted presentations, and interspersed with interventions by various discussants.

It should be noted that the role of industry was not covered in detail at this event; it is, however, the European Commission's intention to organise a smaller-scale event which explores issues related to telemedicine that are importance to both large corporations and medium-sized and small-sized enterprises.

In this report, section 3 covers briefly the need to examine different definitions of telemedicine. Sections 2 and 4 provide an outline of those interventions which set the scene in relation to wider telemedicine deployment. The perspectives described are those of the European Commission and a European association that represents doctors. Sections 5 and 6 focus on a range of different practical implementations of telemedicine. The various benefits offered by telemedicine applications are described here. Sections 7, 8, and 9 form a trio of approaches that might enhance the greater deployment of telemedicine in Europe: they highlight the different organisational, and legal and regulatory issues, and matters relating to professional associations or professional conduct. Section 10 provides an overview of the principal debates that were stimulated during the day, with a focus on the new issues, dilemmas, and potential solutions that emerged. The final section summarises the main issues raised at the conference. It identifies the next steps in terms of the European Commission's endeavours to introduce a Communication on telemedicine deployment.

The boxed items at the start of each section provide a synthesis of the discussions raised at that stage of the debate.

Where used, the boxed items at the end of each section illustrate links that can be made to an assessment of the potential impacts that the introduction of wider telemedicine deployment might have (i.e., the problem definition; the objectives; the policy options, if identifiable at this stage; and an analysis of the eventual impacts).

2. Challenges to Europe's health situation

Frans de Bruïne (Former Director, DG INFSO, Directorate H) and Gérard Comyn (Head of Unit, DG INFSO, ICT for Health Unit, and now Acting Director), European Commission

Europe is facing a convergence of socio-economic and technological factors that may both challenge and offer opportunities to Europe's health situation. Telemedicine, as one of the various fields implicit in the wider term of eHealth, may provide a partial solution. This talk by Mr Frans de Bruïne introduced the problem area. It was further commented on and expanded by Mr Gérard Comyn.

Europe as a continent is faced with an ageing population that is also experiencing increasing numbers and intensity of chronic diseases. These two issues challenge the provision of accessible, high-quality, safe, and sustainable and economic healthcare in individual Member States, and in the Union as a whole. Relevant figures and empirical evidence are cited. Plans that are underway for the launch of a telemedicine-related initiative that contributes towards the solution of these problems, and its proposed timetable, were introduced by the European Commission.

"Everyone in Europe is getting older and chronic diseases are on the rise. A telemedicine initiative could offer a constructive way of dealing with these growing challenges," began Mr Frans de Bruïne, Director of DG INFSO's Directorate on ICT for citizens and businesses. Society is ageing, and its members want to age well and get older both well and happily. As Mr de Bruïne (who was due to retire from the European Commission on 31 December, 2007), quipped in relation to this initiative to introduce telemedicine initiatives to facilitate the provision of healthcare, **"I will myself immediately apply the results."**

Chronic diseases affect a large part of the European population, and are on the rise as illustrated by figures that are available from the World Health Organisation, Germany and the United Kingdom (in the latter, the number of people aged over sixty-five years old with chronic conditions is likely to double by 2030)¹. The challenges posed by an ageing population that is experiencing a great number and intensity of chronic diseases is not yet discussed intensively at the policy level either in individual countries or at the European level. Europe should not underestimate the importance of this issue at the level of the Union. Many people might suffer at a later date if the discussion is not started; this could particularly impact today's younger generations as they age.

There are some very real issues and challenges that arise from these societal and demographic changes: they are both economic and related to the lack of availability of human resources. Financially, the stability pact maximum growth in debt is to be held at 3 per cent in terms of individual Member States' gross national product. If these very real healthcare challenges are not addressed, Europe will simply not be able to keep within this limitation in budget growth; the cost (20 per cent of gross national product on healthcare will be spent in 2020); seventy per cent of healthcare expenditure is already spent on coping with chronic diseases, and these diseases will absorb an increasing share of the consumption of the healthcare budget. European society will not have the population

¹ PowerPoint presentation entitled 'EC Strategy – Telemedicine and innovative solutions for Chronic Disease Management' http://ec.europa.eu/information_society/events/telehealth_2007/docs/telehealth2007debruine.pdf

available, willing or able, to look after its older generations. **“As Europeans,”** said Mr de Bruïne, **“we cannot start early enough to make positive change happen.”**

Various forms of experimentation, pilot projects, and concrete applications have already been introduced in different geographical areas, and among interested and motivated policy-makers and clinicians: examples were cited in, for example, the United Kingdom (specifically Scotland) and Italy. However, perhaps not enough effort is being made in this direction, especially in view of the expectations of what telemedicine initiatives can fulfil. Technological development is moving very fast, and it is increasingly possible to make positive advances happen. Broadband telecommunications and personal health systems are especially being introduced at a rapid pace. They can enhance face-to-face communications in remote areas.

Similarly, in the research field, European researchers have been strongly involved in eHealth and telemedicine over the past twenty years. They are now moving in three major directions: personalised health systems; information systems that support patient safety; and, what is called, the “virtual physiological human” (these are modelling and visualisation processes relating to the human body for healthcare purposes).

Telemedicine can thus lead to an enhancement of the quality, access, sustainability, and safety of care provision. Telemedicine is by no means uniquely a method for driving down costs. For example, patients are happier when they leave the hospital early and return to their own homes. In the Lombardy region of Italy, a telemedicine initiative – presented at the Conference – led to a one-third to one-half reduction in the number of patients who needed re-hospitalisation. In geographically remote areas, for example in Denmark, from which young people move away and where the older people stay behind, telemedicine can also play a role in coping with care and health provision, and in providing services when there is a lack of personnel.

A further, brief intervention by Gérard Comyn reinforced the notion of Europe’s common challenges in the healthcare domain and the role that can be played in facing these through telemedicine. Those difficulties that are not limited or specific to particular countries – these are its generally ageing society and the increase in the impact of chronic diseases. Telemedicine can help to respond to these challenges. He then raised a more pragmatic question: if telemedicine is considered important, and it is considered that its use should be promoted, should the potential focus be on telemedicine generally or on a specific field of tele-related activity such as teleradiology? In resolving the particular challenges cited, would it be most effective to focus on a single specific telemedicine domain? And, if so, should that domain be the domain of teleradiology? Or should several telemedicine domains be selected?

Gérard Comyn made a number of specific observations about the proposed telemedicine initiative. He noted that there are a number of super-ordinate challenges which Europe is currently facing. The increase in the experience of chronic diseases is one of these, whether it occurs in parallel with such problems as obesity or increased alcohol consumption, which take place either independent of the ageing problem or are exacerbated by the phenomenon of ageing. These dilemmas are unconstrained by the principle of subsidiarity. They need to be treated at a higher level than the purely national (often referred to as “domestic”), individual Member State level. Certain Member States may be more immediately targeted than others. They may be hit more dramatically by dilemmas related

to ageing and to increases in chronic diseases. Hence, they may need to face the problems more rapidly. It is, however, possible to examine the potential resolution of such issues in terms of building relationships among the healthcare systems of various countries and through the provision of cross-border care.

Of all the myriad fields potentially covered by telemedicine², it was proposed that teleradiology is a field that can be used in two ways. On the one hand, it may illustrate the relative ease of deployment of a form of telemedicine. On the other hand, specific barriers to its use may be identified reasonably easily. Teleradiology use is already occurring on a reasonably large scale. Today, its provision and implementation is at least partially addressed by various legal instruments such as the Electronic Commerce Directive³. However, because teleradiology often involves the processing of data by experts who are located outside the European Union (on a global scale, examples include Australia and India), dilemmas may be raised (for example, in relation to the European Data Protection Directive⁴). Concrete, practical challenges could include several that are related to a view of professional practice. For example, should – and, if so, how are – the relevant contents of a patient’s electronic medical record to be made available to a diagnosing radiologist in order to enable her/him to assess a patient’s full health condition more effectively.

A domain such as teleradiology may provide a solution to the specific challenge of how to limit the parameters of the discussion about the ways in which telemedicine can enhance the diagnosis, treatment, and continuing care of people with chronic diseases, and also the eventual solutions.

PROBLEM DEFINITION AND OBJECTIVES

These two introductory interventions correspond to a preliminary **definition of a perceived problem**: mainly the consequences of an aging population on healthcare systems and the financial constraints with which all Member States are faced.

It is considered that:

- This problem is **not limited to the restrictions of subsidiarity** (i.e., Article 129 of the European Union Treaty), but has aspects that affect every single Member State and therefore the whole of the European Union.
- **Telemedicine**, as a form of support offered to the health system and services of Europe by information and communication technologies, can be beneficial in helping to resolve the challenge of this problem (supporting care for ageing persons, and care for persons with chronic diseases). Through the Research Framework Programme, the European Union has invested significant amounts of money to support research that is aimed at developing information and communication technologies (ICT) solutions to deploy telemedicine services. These solutions include: regional networks, tools for health professionals, and personal healthcare systems for monitoring and prevention.
- The **purpose (or objectives) of a possible telemedicine initiative** would be to build on these past research and development activities and to address issues that still hinder a wider deployment of telemedicine services in Europe.

Implicitly, the **problem resolution** may need to be **incremental** and **staged**. Possibly in the **short term**, therefore, there is a specific field of telemedicine use that can be enhanced, and used to explore some of

² The challenge of providing a particular definition of telemedicine was not taken up in this particular conference. See, however, briefly, Section 3 of this document.

³ The Electronic Commerce Directive (00/31/EC) and the Electronic Commerce (EC Directive) Regulations 2002 (SI 2002 No. 213).

⁴ Directive 95/46/EC http://www.cdt.org/privacy/eudirective/EU_Directive_.html

the broader difficulties that may affect a more widespread acceptance of the eventual use of telemedicine. **Teleradiology** is proposed as the possible specific field.

3. Definition(s)

To facilitate a comprehensive and open discussion, at an early stage of informal consultation with the communities and stakeholders involved in the field of telemedicine, the conference deliberately steered away from a focus on the need for a precise definition of telemedicine. Instead, the conference used largely a “good practice” or case study type approach with a focus on what is already taking place in and between different Member States of Europe, and also with the so-called third countries (i.e., countries outside the European Union and the European Economic Area with which the Union has developed collaborative relationships).

There exist many different fields of telemedicine, several examples of which are explored during the course of the conference. Most of the speakers emphasised the experience of introducing and using telemedicine, the obstacles and the facilitating factors to its use, and the organisational and process-related implications of its use, rather than presenting an academic or policy definition of the form of telemedicine of which they have experience.

Several speakers did, however, premise their speeches on a general notion of telemedicine. These ranged from a broad encompassing term (e.g., the version offered by Petra Wilson) to one based on more precision (e.g., that cited by Stefaan Callens). In Callens’ case, his underpinning principle was that “**telemedicine – which consists of medicine delivered at a distance by electronic means** – also offers the possibility to increase trans-border care.” (Richard Wootton, who was not cited directly during the day, similarly refers to telemedicine as “an umbrella term that encompasses any medical activity involving an element of distance⁵.)

Eventually, definitions of telemedicine and its various applications could be extracted from proposed national legislations such as the proposed 2005 Belgian national project for a law on telemedicine. Here, the definitions are of telemedicine itself, tele-second opinion, tele-consultation, tele-consultation for continuity of care; and tele-monitoring.

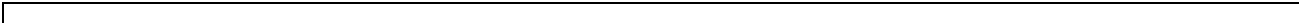
As a next step towards **problem definition**, an analysis needs to be undertaken of the **appropriate definition(s) of telemedicine**.

It should be noted that several frequently used definitions of telemedicine focus on the notion of the use of the applications **at a distance**, meaning geographic distance (which is, indeed, the principle of ‘tele’). However, distance can also be conceived as having a **socio-economic component**. Some longstanding definitions of telemedicine fail to take on board the more contemporary notion of the **a-synchronicity** of processing of the data exchanged (i.e., that the distance at which the data is exchanged provides benefits in terms of different time zones or simply the data processing taking place at another time).

In parallel to an exploration of telemedicine definitions, an understanding is needed of the various **stages of health and care** at which telemedicine support can be most appropriate (such as prevention, diagnosis, treatment, rehabilitation, homecare, maintenance of general health situation). Equally, of the extent to which **telemedicine use occurs between individuals or between organisations/businesses**.

It was also noted that one can distinguish when telemedicine is used between health professionals and/or healthcare providers (i.e. second opinion, or teleradiology) and/or between a health professional (or healthcare institution) and a single patient (i.e. homecare, tele-consultation etc). These two “modalities” seem to pose different types of challenges.

⁵ Wootton R *et al* (2001) Recent advances: Telemedicine. *BMJ*, 323:557-560



4. Telemedicine: a doctor's view

Health professionals, and especially doctors, are among the key players in the provision of health advice and health solutions to patients. Their medical training and inculcation means that they focus on not harming the patient, and assuring her/his quality of care. Some doctors already use telemedicine applications to provide their services. They are aware, however, of technical difficulties with the technologies that pose challenges to the quality of care to the patient. These include: availability of services; network security; the quality of transmission; issues of identification and authentication; encryption; and logging procedures. Other issues related to professional conduct and work organisation (such as professional responsibility, and reimbursement/remuneration) are treated in this section as well as at several other different points during the conference.

Daniel Mart of the Comité Permanent des Médecins Européens/Standing Committee of European Doctors (CPME) insisted that, **“We are now out of the definitions game.”** It was not, he contended, a helpful approach to start a discussion with definitions which specify what telemedicine is *not*. He, however, did stipulate, when making a list of his own “nots” that **“telemedicine is not a replacement for a ‘normal’ doctor-patient relationship, not a cost-cutting exercise, and not a technological gimmick.”**

Rather, for Mart, **“telemedicine constitutes virtual patient teleconsultation at a distance which consists of a medical act performed without physical contact or without the presence of the patient.”** According to such a definition, telemedicine can be composed of a wide form of activities that range from support for treatment, data extraction, ePrescription, teaching, and access to specialised knowledge.

As a doctor, Mart insisted, **“I want things that are easy to use for me, practical, and good for the patient.”** Therefore, in this doctor's view, **“Telemedicine should definitely be used as a tool by health professionals, but it should definitely be at the service of the patients. It should not change the way clinicians practice. It has to fit within the existing framework. There can be an exaggerated belief in technology. It is important for clinicians to be aware of the risk of the dehumanisation of healthcare. Its use should be to support medicine, not the other way around. It is important for a doctor to look in the patient's eye. The screen cuts in between.”**

So, what are doctors currently doing with technology? The challenge is for doctors to interact especially with systems designers and computer scientists. Mart stipulated that he still works for 12 hours a day with patients, even if he is also involved in with three or four technology projects that have formed part of the various European Commission framework programmes. Telemedicine is used in remote areas, in regions that lack facilities, and to provide comfort to patients.

There are several technical problems related to telemedicine, which were described as being “these are mainly the same problems as with eHealth; so, there should be a ‘global’ solution.” The technical challenges include:

- Availability.
- Network security.

- Quality of transmission.
- Identification and authentication. (In Mart's view, "As a doctor, you have to make deadly sure that the person on the other side is the person to whom you need to speak.")
- Encryption.
- Logging procedures.

There are various professional or 'ethical' challenges, which may require a change in various laws, and a determination of whether the changes should be at the European level or at the level of the individual Member States. These relate to:

- Responsibility in relation to a number of different players (e.g., physicians, patients, network providers, and device producers). For example, in relation to semi-automatic devices: what if there is a signal failure or an improper signal?
- Remuneration or reimbursement. Is the clinician paid correctly within the appropriate budget structures? Should there be special nomenclatures/forms of accreditation? Also, for how long or how short a period of registration? What form of contract should there be, and between how many persons?

OVERCOMING BARRIERS TO TELEMEDICINE USE

Since at least a part of the proposed objectives of a telemedicine initiative would be to overcome the issues that inhibit the wider deployment of telemedicine in Europe, there should be a certain amount of concentration on the potential **technical or technological hindrances**, and on those **barriers related to take-up by key players, such as health professionals**.

5. Benefits and problems related to telemedicine: empirical evidence

The challenges that are posed to the healthcare sector in terms of using new strategic tools and methods are massive. They include a growing ageing population, an epidemic evolution in the amount of citizens with one or several chronic conditions, and further development in medical progress which offers new and better treatments. At the same time, there are professional recruitment problems, restricted economic resources, increased expectations on the part of the “engaged consumer”, and the “future patient”, with regard to achieving and regaining optimal health. All these are accompanied by a never-ending demand of development in quality and treatment.

This section focuses on telemedicine and the potential solutions it offers for a concrete response to the current and future challenges that face the healthcare sector. Of crucial concern is the need to assess and measure such interventions, with a view to examining the degree of their effectiveness.

5.1 General introduction

Alain Franco, University Hospital Grenoble, France

A number of benefits to current and future healthcare can be achieved through the implementation of telemedicine. However, some areas of telemedicine pose distinct problems. This general introduction to the field of telemedicine is considerably wider than the official title of this presentation on “Telemedicine for disease or for case management”. This presentation formed an interesting bridge to the following presentation made Simonetta Scalvini of Italy whose team has assessed in some detail the effects of telemedicine introduction particularly in the domain of telecardiology.

Alain Franco highlighted that to date there is relatively little empirical evidence of the relative benefits available. To take a single example, in research terms, in the field of telepsychometry: there is evidence that a 90 per cent certain diagnosis of Alzheimer’s disease can be achieved at a distance. However, telemedicine apparently does not, paradoxically, work well as a first diagnostic tool in the field of dermatology.

Franco illustrated his talk with examples of various telemedicine systems that are in practical use today:

- a telecommunications system (provided by France Telecom) that includes a ‘smart room’ in which telemedicine sensors are used.
- a “digital home” provided by Intel⁶.
- tele assistance provided by the use of ‘smart jackets’.
- therapeutic robots, which are developed mainly in Asia.

A variety of considerations that must be borne in mind when using telemedicine were cited. Several of these constitute the drivers that underpin the underlying health context’s challenges (such as a decline in healthcare provision and available personnel). Others are more specific to the use of telemedicine itself.

⁶ See http://www.intel.com/research/exploratory/digital_home.htm

- **Decline in provision and personnel:** there has been a recent decline (up to 30 per cent) in the number of hospital beds; a decline in hospital stays; a shift towards ambulatory care and care in the home; and a lack of nurses (estimated in 2002 at around 1 million in the United States and other countries)⁷.
- **Issues related to professional conduct, good practice, and ethics:** examples include user acceptance, psychological implications, and the protection of both private space and hospital space. Time to give care is also needed.
- **Socio-professional impact:** changes in doctor-nurse working relations may occur⁸.
- **Issues relating to the end user:** there is a multiplicity of stakeholders involved in the use of telemedicine. The end user is not usually the main user. The actual users are very often neither the designers, the decision-makers, nor the payers. Here the term “end user *quid pro quos*” was used.

“Telemedicine may be perceived as easier to apply as an industrial concept for disease management than for case management.” Such a view, according to Franco, is coherent with the current approach of the pharmaceutical companies, an adult clinical model, the dominant macro-economic model, and a view of adult mono-pathology. It is also linked with a failure to understand the implications of economic lag (i.e., that applications which are introduced today may take time to have an economic impact), and – in parallel – generational change. Both younger health professionals and younger patients may be more willing to use telemedicine applications. Why telemedicine can be used more effectively for case management was an issue taken up in greater detail by fellow speaker, Petra Wilson.

Franco concluded that new cost benefit and cost efficiency studies need to be undertaken that focus on methods of financing telemedicine. Examples of different forms of use of telemedicine that need to be benchmarked include several: when the telemedicine is used in the family or in a substitute family setting, in services, in the health care system, in the social insurance system, or by charity foundations and other institutions. In terms of his own country, Franco commented that **“This can be very difficult to do – for example – in France: this really is my conclusion.”**

To end his presentation, Franco challenged the audience to face the need for multiple assistive technologies; the current lack of caregivers; and the market for healthy ageing. **“Each [of these issues] must be investigated as a differentiated case study; there needs to be a shift from clinical applications to political science.”**

There are several **drivers behind the current problems surrounding the European health context**. With a particular view of potential telemedicine deployment, these include: a decline in resources (whether in physical provision or in personnel in the health system); issues relating to professional conduct, performance, and ethics; the socio-economic impact of changes in the organisational and work system; and the distinction between the end user and the payer/provider.

Telemedicine has much to offer as a **solution** because it enables health provision **at a distance**, asynchronously (i.e., taking advantage of time differences), and uses a **shared model of work distribution**. Hence, it can ease some of the current organisational and personnel pressures on European health systems and services. The **potential benefits** do, however, need **evaluation and measurement**.

⁷ http://findarticles.com/p/articles/mi_m4021/is_2002_Sept_1/ai_90957497

⁸ See Sävenstedt, S. (2002) Nurse-doctor interaction in teleconsultations between a hospital and a geriatric nursing home. *J Telemed and Telecare*. 8 (1), 11-18.

5.2 Benefits of telemedicine, with a focus on telecardiology

Simonetta Scalvini, IRCCS Foundation Salvatore Maugeri, Italy

In the field of telemedicine, although claims about the utility and the efficacy of new telecommunication systems have been widely made, these are not so far founded on strong evidence. The research published in this field has been characterised by a number of deficiencies in design, and the experiments have often not been controlled. Different examples of telemedicine use were cited that have been analysed and assessed by their respective clinical and organisational teams. Telecardiology provides a primary example of benefits for which there is, in the Lombardy region of Italy, clear evidence.

Measuring the benefits of telemedicine has taken place in several fields. In a particular telecardiology initiative, over a 6-month period, only 40 per cent of the patients with chronic diseases were re-hospitalised. The project was based on a disease management model which used a home-based nursing system. It involved telemonitoring, teleassistance, and teleconsultation⁹. Focus was placed on a nurse-led model of care for patients in which the patients were also able to examine their own co-morbidities¹⁰. A follow-up is planned to be held in Brescia, near Milan, in Italy. It is to be compared with a face-to-face programme.

Screening *via* telemedicine should not substitute for the patient's visit to the doctor or the nurse's visit to the patient. It is all about connecting services at a distance with the nearest hospital. 103,000 second opinions that have used telephone contact have taken place from 1998 until today. General practitioners know their patients very well, but – with the patient's consent – they can ask for a further investigation of the problem by a specialist. In the Lombardy initiatives, they seek to connect clinics (doctor's offices) with hospitals so as to provide better care and better quality for patients. See, for example, the Summa and the Telemaco projects¹¹. Other initiatives in telemedicine with which Scalvini has been involved include a service centre; a teleworking centre; a computerised call centre; and services for a hospital service provider.

Using telecardiology as a specific example of experimentation which has taken place in the Lombardy region of Italy, Scalvini highlighted the methodological issues around the monitoring, measurement, assessment, and evaluation of telemedicine. In attempting to resolve how to address these measurements, it is necessary to plan for controlled studies. Recently published results of studies offer some answers to the main open questions that remain in this field¹².

Currently, the Boario Home Care Project¹³ is eight years old. It has demonstrated its value for increasing access to health care services, improving the quality of care, and reducing costs for the National Health Service in Italy. One of the initiative's main characteristics is that it can easily be transferred to another local services context which has different

⁹ This, and three other forms of telemedicine, are referred to in Wootton R (2001) *BMJ* 323 (7312): 557-560.

¹⁰ Useful references include Scalvini S *et al* (2004) *J Telemed and Telecare*; 10(2):113-117; Scalvini S *et al* (2005) *J Telemed and Telecare* 11(suppl 1): 16-18.

¹¹ See <http://www.telemaco.regione.lombardia.it/> and <http://summa.cefriel.it/>

¹² See [Giordano *et al* \(2008\)](#). Multicenter randomised trial on home-based telemanagement to prevent hospital readmission of patients with chronic heart failure. *Int J Cardiol*. 2008 Jan 29 [[http://www.internationaljournalofcardiology.com/article/S0167-5273\(07\)01959-6/abstract](http://www.internationaljournalofcardiology.com/article/S0167-5273(07)01959-6/abstract)]

¹³ Case studies covered by eHealth are cited in S Scalvini *et al* (2006). Telecardiology in Italy: benefits from a telemedicine network connecting *eHealthIMPACT 2006*, pages 2-23.

accessibility and quality requirements. While the Boario Home Care Project has yet to reach maturity and the results can be considered preliminary, evidence indicates that many of the expected results have been achieved.

Similarly, in terms of economic studies: the Lombardy region is currently trying to reorganise its reimbursement model. For these purposes, evidence-based medicine with data collected from articles and papers in journals is becoming very important¹⁴.

Finally, the speaker concluded that **“There are clearly very different models of care provided by clinicians in the different countries around Europe.”** These differences may well alter the relative benefits achieved by various telemedicine initiatives.

The examples referred to above may provide case study material for assessing the possible economic impacts of telemedicine services. The collation of further economic surveys and studies should ideally, however, be undertaken. The diversity of different health systems and models of care throughout Europe should not be underplayed.

5.3 Integrated care services – facing the deployment challenge

Josep Roca: Hospital Clinic, Barcelona University, Spain

Here, the focus was on the provision of integrated care services in a large Spanish city, and the challenge of deploying them effectively. Principally, the issues raised were policy and organisational issues rather than technological challenges. The speaker drew on his 15+ years of experience in the telemedicine field.

Spain is a country that concentrates on regional or inter-regional functionality in the healthcare field. Barcelona is a city – indeed, a region – which consists of 7 million people. Its healthcare functions as a result of public financing (and public coverage health insurance) but also private coverage. The main challenges are the sustainability of the healthcare model; the appropriateness of the business models; and interoperability issues.

From a healthcare perspective, the epidemiological challenges are about needing to change the healthcare model or paradigm. The region is inclined to improve what it does well already e.g., teleradiology. But there is another specific use of telemedicine that involves coordinating the complexity of relationships among the different healthcare actors.

The main difficulties for Barcelona lay in getting the various actors to speak to each other. The players include the Catalonia parliament; the health department; the CatSalut initiative; and the various providers –of which there is a large range.

The main driving forces were a health roadmap and the re-organisation of the principal Barcelona hospital. A roadmap was developed that contained the key organisational and technological issues. A mandate from the regional parliament was received to adapt the Catalonia/Barcelona healthcare system to the needs of the ageing population. A new

¹⁴ Examples include S Scalvini and F Glisenti (2005) *J Telemed and Telecare*; 11:325-330 and S. Scalvini *et al* (2003) *Monaldi Archives for Chest Disease*; 60:254-257.

healthcare plan that covers a ten-year time-period was developed called 'Services for health: looking ahead 2006-2015'. The intention was to establish an integrated form of governance in a given territoriality, thereby integrating providers in particular geographic areas. The aim was to create a link-up between hospital, home, and the primary care institution so as to provide "shared care across the system".

The main hospital was re-organised, particularly in terms of what was to be done in relation to disease management. The aim was to develop a "transversal organisation": which dealt, as a result of technology innovation, with a range of illnesses and care such as cancer, organ transplantation, and integrated care for all its 540,000 potential inhabitants. Information and communication technologies in Barcelona are considered good support tools to achieve integrated care.

The hospital first addressed those issues which were its main problems: shifting a pre-occupation with acute care into early prevention, early discharge from hospital, and "home hospitalisation" and end-of-life support.

Roca concluded that there is no longer a need – at least in Barcelona – for pilot operations. The city/region has shifted, in 2006, from exploring new approaches to actual implementation. In 2007, it concentrated on the challenges of tertiary care. In 2008, it plans to expand the application of the scheme so that it can be applied to a population of 1 million. With similarities to a 2005 World Health Organisation report¹⁵, Barcelona is trying to focus on "patient-centred care which is independent of budget".

In the face of the difficulties posed to patients by co-morbidity (i.e., when people experience a multiplicity of serious health conditions that may threaten their life expectancy), Roca believes that the key to the success for proposed solutions include:

- a shift to patient management and case management.
- an appropriate articulation of healthcare and community service which is modular, scaleable, and interoperable within a given provider and/or among providers.
- identification of business models on the part of all the actors involved so to ensure sustainability, and
- finally, the timing of the implementation process and all its relevant factors so as to facilitate the engagement of all the appropriate actors.

A number of the potential benefits of telemedicine use (distance working, a-synchronicity, and collaborative work practices) need to be set in a background of **appropriate contextual, organisational, and business analysis** of the dilemmas currently facing the healthcare sector. **Innovative and dynamic leadership and management**, political as well as health-based, is needed to **lead the initiative**.

¹⁵ *Preparing a Health Care Workforce for the 21st Century: The Challenge of Chronic Conditions*
<http://www.who.int/>

6. Benefits and problems related to telemedicine: case studies

A number of good practice case studies that range from the national, to the regional, to the city level were presented by a series of different speakers. While they illustrated the opportunities and benefits offered to these different levels of healthcare provision by telemedicine, they also covered the barriers to telemedicine introduction and the ways in which these barriers could be overcome by implementing positive solutions.

The focus of these presentations was largely on the organisational challenges of introducing telemedicine, and the appropriate organisational solutions.

6.1 The Swedish experience

Silas Olsson, VINNOVA, Sweden

Sweden has been performing different forms of telemedicine for more than eighty years. Silas Olsson highlighted the vast range of health technology-related applications that Sweden uses, particularly in the area of telemedicine services. These include: electronic regional networks; online multi-site videoconferences; pre hospital care *via* hook-ups between ambulances and hospitals; on-line consultations during neurosurgery; telepsychiatry and outpatient care; and telemonitoring for diabetes care and for integrated care. Teleradiology, above all, is a standard procedure, and in addition virtually all services in clinical chemistry are supported by telemedicine in Sweden. Lastly, in cross-border and international terms, Sweden exchanges services in a diversity of fields with countries both in Europe e.g. the Baltic countries, Denmark, Finland, Norway, Germany and Spain, and further with Australia, Japan, and the United States of America.

A number of the challenges that Sweden still has to face in the telemedicine field are organisational: such as the integration of electronic health records into the system; resistance to change; perceived threats to the (health) organisation and (health) workplace; finance and reimbursement; issues relating to time, responsibility, sustainability; the fact that clinicians do not promote the advantages of telemedicine sufficiently to e.g. health managers; and that, also, all the players, such as the citizens, patients, and politicians should be more aware of what is happening in telehealth, and what the possibilities and advantages are. Although Sweden has not experienced difficulties in applying the legal and regulatory conditions relating to domestic use of telemedicine, there are still a number of problems that remain. These are: security and privacy particularly in relation to the handling of data by third countries; and the lack of apparent clarity or knowledge about what can be done or not in any given situation. Olsson therefore advocates the writing of a clear set of guidelines on telemedicine, including "best practices", focussing cross-border legal aspects (domestic, EU, third countries) for clinicians and industry representatives.

The Swedish national healthcare IT strategy works together with the ICT health infrastructure "Sjunet" (a single network and a single operator - that interconnect hospitals, primary health centres, municipalities and gives the industry the possibility to e.g. monitor their equipment in hospitals remotely from their home base) to make possible to safely provide different kind of services including a very direct form of information about

healthcare (it involves a national information and interactive call portal and a national call service for medical advices for the citizens). In this endeavour, the national system brings currently together the regional call centres that Sweden has had for some time. Regarding e-prescriptions, on national base during October 2007, 2,2 million of e-prescription were prescribed which was 66% of the total number of prescriptions in Sweden that month. Figures given in this chapter are based on a national survey and interviews undertaken by Olsson in the autumn of 2007.

How did telemedicine begin in Sweden? Telecardiology was first tested in the 1910th and from 1922, the sea-to-shore services "Radio Medical" started to support Swedish ships around the globe, based in Gothenberg, Sweden: today, around 450 sea-to-shore medical consultations a year are treated.

And how does telemedicine work today in Sweden? Olsson described a wide range of applications in current use. "Teleradiology is a standard procedure in Sweden. The university hospitals are connected with regional hospitals, local clinics and doctors' offices through electronic regional health networks. Multidisciplinary, regional, online teleconferences bring different specialist disciplines together, e.g., in the field of gastro-surgery. In neurosurgery cases, there can be hook-ups between the county central hospital in Karlstad with the university hospital in Uppsala: in emergency situations and surgeries, they do online consultations, so that the operation takes place in Karlstad they are supported by colleagues in Uppsala, who stay online during the surgical operation. In pre-hospital care, virtually the total fleet of 500 ambulances in Sweden are equipped with telemedicine facilities and can be in contact with the various hospitals during emergency patient transports. For diabetic retinopathy, telemedicine is used in a broad term in Gothenburg. The service is provided by RetiNet, a local programme which covers screening, diagnostic evaluation and post laser follow up. Written information to patients and health care providers are automatically printed out by each data reading. Both type 1 and type 2 diabetes are included. The area has about 22.000 patients. A service that just introduced and started in Sweden is telemonitoring for chronic or long-term conditions: it uses standard new versions of mobile telephones with special developed software. Here, Novatelligence Medipal helps e.g. heart patients to measure and control e.g. their salt intake: it is all about 'the power of the patient'. There are many projects related to homecare, care of elderly, and telecare: developing integrated care solutions is the challenge and currently most common."

Olsson also introduced the notion of telepsychiatry. In the Stockholm area, an integrated care project called Telecoach™ (which is run by Anne Berman) supports forensic psychiatry outpatients. These are outpatients who can potentially be dangerous for themselves and others (they number around 2,000 in Sweden). Linked with the Karolinska Institute, the automatic call centre offer up to 200 pre-played support messages to the outpatients, especially if call at night-time. This provides a bridge to other forms of personal contacts.

Lastly, in terms of cross-border collaboration between Sweden and other nations, such as the Baltic countries, Olsson drew attention to an initiative related to neurophysiology Sweden and the Baltic countries which started in 1998. On a wider scale, Sweden cooperate with organisations in e.g. Australia and Spain for radiological analyses; Denmark for oncology applications; Norway for obstetrics; and it also exchanges a certain amount of medical bio-related data with the United States of America.

There are a number of practical difficulties in Sweden relating to telemedicine, and they include:

- the integration of electronic health records into the system

- resistance to change
- perceived threats to the (health) organisation and (health) workplace
- finance and reimbursement
- issues relating to time, responsibility, sustainability
- clinicians do not promote the advantages of telemedicine sufficiently
- all the players, such as the citizens, patients, and politicians should be more aware of what is happening in telehealth, and what the advantages are.

With respect to those aspects of the legal and regulatory system in Sweden related to telemedicine:

- there are several legal acts that relate to e.g., patient medical records, medical care registries, and medical privacy, and a new legal act for IT in health services is expected to be approved by the parliament during 2008
- the European Union data protection legislation was easier to implement than perhaps the Swedes had originally thought, however, the knowledge of what the legislation allows and not allows are limited amongst clinicians and industry

However, there are a number of legal and regulatory issues remaining:

- security and privacy in general remains a problem – to find practical workable solutions within the legal framework
- medical consultation with a third country is perceived as difficult (“we do not know how the third country is actually treating that data; so, security and privacy are the major questions”)
- there can remain unclear legal questions about what can be done or what can not be done.

While, in Silas Olsson’s view, there is a lot that can actually be done in a country, and in cross-border services, in relation to telemedicine, but there is often a lack of awareness of these possibilities on the part of clinicians, health professionals and health managers. “Therefore, a kind of handbook or guidelines, and “best practice” on telemedicine and how to do it, that could be read by medical professionals and industry, would be needed.”

This section of the day continued to highlight the **benefits offered** by telemedicine, in this case at a **national level** and throughout a **range** of different telemedicine solutions. It also started to outline a number of **perceived solutions** to some of the challenges facing telemedicine introduction and deployment. In the Swedish context, they seem not to have been insurmountable. They appear to have been dealt with in a **clear and systematic** manner after the phase of R&D and first trials. One option for handling a single, remaining **professional challenge** would be to write a clear set of guidelines, including “best practices”, on telemedicine use for clinicians. This solution was also advocated by other speakers throughout the day.

6.2 A Danish experience in the Funen region

Peder Jest M.D., Funen Hospital, Denmark

The challenges in healthcare for using new strategic tools and methods, according to Peder Jest, are massive: particularly relating to a growing ageing population. There is an “epidemic evolution” in the amount of citizens with one or more chronic conditions. Recent developments enable new and better treatments in medicine. However, there are a number

of problems. At the same time as more health professionals than ever before are working in the health sector, there are considerable recruitment problems. Economic resources are restricted. Meanwhile, “engaged consumers” are expressing increased expectations about achieving and regaining their optimal health whether as a current patient or as a future patient. These challenges are accompanied by a never-ending demand on the need for the development of quality and treatment. Fifteen years of telemedicine experience in the Funen region enables Jest to speak in a useful and down-to-earth way about the kinds of technologies that really can be used to support patients and to manage an overstretched health service.

As Peder Jest said, “There are problems in the rural areas of Denmark. Funen Hospital covers a large area with five hospital locations – one of them on an island, which is only reachable by ferry. Healthcare is under pressure because there is a lack of doctors in rural areas as three out of four vacancies for doctors’ jobs cannot be filled. More than 20 per cent of the population is over sixty years old in the Region of Southern Denmark (one of five regions in Denmark). The average age of citizens is 48 years old. While they do not experience new diseases or have too many accidents, the elderly do experience an increasing number of chronic diseases. What do the people of the rural areas want? A survey showed that healthcare is the issue that is most important to them. (From the Baltic eHealth project – The Rural eHealth Report, March 2007¹⁶)

Working with telemedicine has had a good impact in Denmark – especially in the rural areas. At the Funen Hospital, we work with a multidisciplinary electronic patient record that works well together with the telemedicine solutions as we fulfil the requirements and guidelines from the National Board of Health when implementing these solutions. While we do still use a lot of paper, it is archived once it has been used.

The Funen Hospital has participated in many European funded telemedicine projects (including Baltic eHealth, R-Bay, Better Breathing and HEALTH OPTIMUM). And today the Funen Hospital has more than 15 telemedicine applications¹⁷ implemented.

The telemedicine solutions are based on point-to-point connections and are used in specialities such as cardiology, endocrinology, radiology etc. By the use of the Danish Health Data Network established and run by MedCom, the solutions could easily become the basis for a European-wide solution, Peder Jest suggests.

In a project called HEALTH OPTIMUM¹⁸, partially financed by European funding, telemedicine conferences have been established to optimise the use of resources and give a better patient care. Because of these conferences over a distance between two hospital units, eighty per cent of medical investigations can be done by a nurse instead of by a doctor. This re-organisation enables a more effective use of doctors’ time and of the patient’s time because he/she does not have to travel far to receive treatment. Because of this solution diabetic patients on the remote island of Aeroe are treated better than the average Danish diabetic patient. “In Funen, we have to think in this way because of our lack of doctors. Unfortunately, we have a lack of nurses too!”, Peder Jest remarks.

¹⁶ http://www.baltic-ehealth.org/intern/Finalized_deliverables/D1.7_Rural_eHealth_report+exec.summary_final.pdf

¹⁷ Telemedicine solutions in daily clinical functions have been established in cardiology, endocrinology, chronic obstructive lung diseases (COPD), alcohol abuse, neurology and neonatology. Projects with telemedicine solutions and videoconference systems in discharge situations, in home visiting procedures and in rehabilitation have also been established.

¹⁸ <http://www.healthoptimum.info/>

So, the Funen region has had a particularly positive experience of telemedicine solutions. But the future challenges are still considerable. Denmark is opening its horizons to collaboration with its neighbours.

As an example of this collaboration across borders, the Funen Hospital has established a cross-border telemedicine solution where images are being sent between hospitals in Europe. This solution is part of the R-Bay project (also part-financed by European funding) where a Structured Reporting Tool is being used. "A structured reporting tool, which is currently operational in the Baltic region, offers a structured translation between languages when describing radiological images across borders. The initiative is quality audited and it is a possible way to solve the legal problems. The patients accept this system because they get diagnosis within a few days only – instead of waiting for longer periods of time due to the lack of radiologists. The solution should in the longer run be an offer to the rest of Europe!" Peder Jest says.

The telemedicine solutions are being used in both stable and not-stable situations at the Funen Hospital. The following is a listing of telemedicine solutions, where the patient is not stable:

- Tele-electrocardiology; Electrocardiograms are sent direct from ambulances to the coronary intervention unit at hospitals.
- Tele-care: Instead of admitting patients with chronic obstructive pulmonary disease (smoker's lung disease) for up to 14 days, we admit patients only for one day – and then we send them home, Peder Jest explains. We equip them with a highly advanced telemedicine solution – we call it the patient's briefcase. Over either an Internet connection or a closed satellite system, it is possible to establish a connection between the patient's home and the hospital thus monitoring the patient from a distance. This solution is part of the Better Breathing project, and is part-financed by the European Commission. During the project period a randomised controlled study will be carried out. "So far, we have seen a 50 per cent reduction in re-admittance, even if only 50-60 patients only have passed through the system so far", Peder Jest says.
- Tele-neonatology; Both observations and supervision of premature newborns are available over a distance between the Funen Hospital and the department of neonatology at a University Hospital.

In conclusion, Jest noted that, "Telemedicine is a useful strategic tool in clinical medicine. When creating a health care system, which is secure, effective, patient centred and with high quality, it is a demand each time you invest in technology you must also make sure that the health professionals and the patients are using this technology in new work flows and processes. Therefore, telemedicine must be used as a strategic tool on every level of the organisation as a strong organisation, vision and leadership are fundamental when implementing telemedicine.

Again, the **benefits** generated by telemedicine are particularly evident in this **isolated, rural community**. This Danish telemedicine solution is proposed by its exponents as a possible interesting **good case study** example for further exploration and application throughout Europe. In addition, the Danish region itself is interested in exploring the deployment and application of a further, wider, range of sometimes more experimental technologies in its setting. A clear-cut example of **quality assessment** operates, however. Expansion and application of telemedicine takes place according to certain **criteria for evaluation and assessment**.

6.3 An English experience in telehealth

Adrian Flowerday, Docobo Intellect, United Kingdom

Governments are now warning about the increasing burden that the ageing society and its related increase in chronic disease is having on our economies. Telehealth, according to Adrian Flowerday, has the potential to change the way patients manage their own conditions. A specific EU-based initiative – the Docobo doc@HOME service – has rolled out these kinds of services into the market. This presenter described a series of benefits from this particular telehealth experience: such as personalisation of the care process, increase in patient awareness of own responsibilities and own health status. From an economic perspective, he has also seen a reduction in various costs (e.g., hospitalisation and telephones). However, he also listed a number of ongoing challenges to implementation and barriers to the mainstreaming personal eHealth: these include the relative strength of clinical gatekeepers, and the extent to which their perceived notions of medical “good practice” may need revisiting.

The Docobo doc@HOME initiative was some eight years in technical and clinical development. In the early part of this decade, it received European Commission co-funding. Docobo, the company, was founded to commercialise the output from this successful EU project. It is experiencing successful commercialisation currently in the UK. Flowerday concedes that “the very ‘anti’ British attitude to telemedicine has now been overcome”. Sales of the software – which complies with the standard, CEN 13485 – have really taken off since 2004. Eventually, “the Docobo solution will lead to ‘cradle to grave’ health monitoring”.

Docobo is used in eighteen, separate, patient care trusts. The specific, very personal, example of a specific patient was cited: she calls the equipment ‘Ernest’ after the name of her late husband.

In Barnsley, south Yorkshire (in England), the equipment is now reducing the need for patients to see physicians; it has also led to the early detection of heart problems. In Southampton, Hampshire (again, in England), there has been upto 50 per cent reduction in hospital re-admissions. Community Matrons (who typically Case Manage complex patients)) have noted that there is also a considerable reduction in the use of telephones, even within the last two weeks of use. The scheme has saved £39,000¹⁹ within nine months on one patient alone.

However, telemedicine is not uniquely about budgetary benefits. It can also be seen as a form of patient education, reducing the degree of demands on the healthcare system. Using the Docobo equipment, a community matron ended up by going to see Stan, a particular patient, once a week rather than every single day.

Another example of a patient involved a person who phoned her doctor’s office out of office hours 55 times, and experienced 24 separate hospital admissions. “This poor woman really was in the wars.” However, she now knows what her characteristic blood readings are. Whereas she was previously on palliative care treatment, she is now on a rehabilitation programme. These enhancements have reduced substantially the need for the provision of care, and reduced the burden on the local patient care trust.

¹⁹ Around (cite figure) in euros.

However, there are difficulties surrounding the telemedicine system: it would appear that these relate principally to the clinicians.

Some gatekeepers inhibit the technology being rolled out (for example, even though the patients experience reduced anxiety, and understand what their blood pressure readings and what hypertension means, the clinicians still say “My patients need to see me”)

Telemedicine also challenges the perceived or orthodox notion of so-called ‘best practice’. It highlights the need for a demand for empirical evidence in order to be able to assess whether current medical practice is still considered “good” in the light of recent findings. One cardiologist was cited as having said, “Even measuring my patients BP once a month, I don’t really know what my patient’s blood pressure is, or indeed whether the medication they are taking has had any effect. The doc@HOME system has enabled me to know the answer to both problems”.

This particular illustration shows how telemedicine is used in the **context of care**, and in relation to ageing persons who experience chronic diseases. Both **patients and nurses** appear to appreciate the benefits that result from telemedicine deployment. It is possible that the benefits of telemedicine use need to be introduced more persuasively to **clinicians**.

6.4 A Spanish experience with teleradiology

Hans Billing, Telemedicine Clinic, Spain

Hans Billing describes himself as a “cross border person” who has shifted from the provision of radiology in Sweden to become the co-founder of a Spanish hospital. He bases his learning experience in teleradiology on his five years spent in Barcelona, Spain.

Billing’s presentation focused on three issues:

- communication among radiology departments and clinicians.
- quality assurance, which must be maximised and transparent.
- accreditation of telemedicine providers, which must be pertinent and homogeneous within the European Union.

One vision of teleradiology sees it as a more effective use of ‘global’ resources, that aims to provide efficiency and effectiveness, optimal work conditions, and learning experiences. Billing sees it as offering “support to European public healthcare by providing specialised medical competence and using state-of-the-art telemedicine solutions.”

The centre of which Billing is in charge is the largest teleradiology and magnetic resonance imaging (MRI) reading centre in Europe. It employs 85 radiologists from 14 countries. Since 2002, the centre has conducted more than 90,000 radiological examinations a month. Since summer 2007, it is linked with Australia. He perceives the centre as providing “volume outsourcing and knowledge in-sourcing” (the latter is a new business which is under development).

In Billing’s experience, teleradiology faces certain problems and concerns. These include a large list of general concerns, organisational challenges, and cross-border challenges.

- **General concerns:** quality of services, competencies and/or lack of competencies, lack of clinical awareness, lack of physical training and development, various medico-legal issues, communications among local radiologists and physicians, language challenges (which could be e.g., based on automatic language translation), anonymity of collaborators, and liaison with direct colleagues.
- **Organisation challenges:** need for organisation of services, the variety of clients, the variety of radiologists, the varying volumes of work required, double reading, the short turnaround times required, the need to bypass the usual workflow if there is an exception or an emergency, the close contact with the client need, and the need for quality assurance. In the speaker’s experience, teleradiology requires a mature organisational platform.
- **Quality control:** this includes a tight recruitment filter, double reading with feedback, continuous performance evaluation, and client feedback.
- **Cross-border challenges:** access to patient data, transmission of images and data across borders, malpractice issues, accreditation of radiologists, and accreditation of service providers.

Billing noted that his own centre’s radiologists come from many different countries but they need to be accredited as radiologists “in that country”. They need as a minimum to hold the commonly-demonstrated skills and expertise acknowledged by the relevant, recognised,

organisations. Mammography and its processing, he cited, is a particularly difficult case to deal with in the Europe as the Union is experiencing scarce resources in the field.

It is possible that this form of telemedicine use – **teleradiology** – is faced by fewer hindrances to deployment; indeed, it is already in widespread use. Nevertheless, its further implementation is confronted by some specific challenges, e.g., **general and organisational problems, the challenge of cross-border use, and quality control**. The **accreditation of telemedicine providers** is an important issue.

This raises the possibility that **two sets of intervention** could be advocated with regard to telemedicine in Europe: a) support for those telemedicine services which have not yet experienced wide deployment, and b) the introduction or reinforcement of quality criteria in telemedicine services which are already widely used.

7. Contextual issues: opportunities and barriers

The talk which follows acted as an introduction to the overview of the legal, regulatory, and financial challenges that are related to the trans-national provision of telemedicine. However, its theme provided a wider and more comprehensive view of the contextual and organisational characteristics of the telemedicine scene. It highlighted the potential future directions that may be taken by eHealth to support of health systems and services.

7.1 Telemedicine – the organisational context: opportunities

Petra Wilson: CISCO Systems, Belgium

Petra Wilson's analysis emphasised the specific challenges to Europe's health systems and services. These include the challenges posed by a reduction in healthcare services that is occurring in parallel with an explosion in the availability of health data. Her solutions for dealing with this increase in data include a concept of **"shared data, shared liabilities, and shared funding"**. This places a focus on information systems management and information governance. Three proposed mechanisms that could lead to the improvement of information governance included **new regulatory responses** i.e., specific, targeted, codes of professional conduct; **more patient involvement in healthcare**; and **more effective organisational change management** in the health system.

Telemedicine enables care to be more patient-focused and patient-driven. Yet, it would also allow healthcare service provision to be scaled appropriately to a context of changing world demographics (in which more and more people in chronic ill-health will have to be cared for by fewer professional and voluntary carers).

Telehealth holds many promises. While it has the potential to change the way patients manage their own condition so that they become the "keepers of their own healthcare", it can enable cross-communication between different communities of interest and encourage a cross-pollination of innovative, fertile, new (e.g., scientific) ideas.

Europe is experiencing a reduction in the number of traditional healthcare physical locations. It also has fewer and fewer healthcare personnel, like nurses and doctors, available to be employed. Yet at the same time, we are creating more and more health data all the time: the growth in health data is exponential.

We need to find new ways of organising healthcare and new ways of using these data. What is the way to make best use of the information? We need secure and timely information that is based on shared data, shared liabilities, and shared funding. But – here is a warning – healthcare systems are currently very fragmented. Whether we are healthcare professionals or patient, we are not used to sharing our decision-making or our health data.

We need information systems management and information governance, and a new understanding of data storage and ways of sharing data. We should not, however, be totally hidebound to issues of data protection and privacy. Anxiety with regard to the privacy and security of health data comes up again and again; certainly, clinicians and health professionals receive a form of training that ensures that patient data must be confidential.

They should now learn not to compromise patients' information but to place it in the context of sharing.

High quality, safe, accessible, and sustainable healthcare, and the degree to which it is dependent and relies on information systems and services, is now crucial. Current circumstances permit us to re-open a debate about the ways in which we handle data. There are perhaps three basic responses to these conditions. They are: new regulatory responses; more patient involvement in healthcare; and more effective organisational change management.

- **New regulatory responses, such as targeted codes of conduct.** We could build a **specific code of conduct for sharing health information**. If the appropriate bodies²⁰ were to get together to collaborate on how to share patient data while continuing to respect privacy and confidentiality, maybe the powers-that-be which have the right to express their opinions on data protection²¹ would be able to conclude that that is a good way to share data? On the use of clinical data, for example: some Member States have been very brave with regard to their stance on secondary uses of clinical data (even though the European Commission has queried whether it is an appropriate use of data or whether it is not a potential source of wealth, data, and control).
- **More patient involvement.** Examples include completion of personal health records, appropriate use of “personalised data envelopes”, development of communities of interest in different health conditions; and social networking around health issues. As we experience a growth in more and more use of electronic personal (health) records, there will need to be more “citizens’ opt-in and opt-out systems”. Communities of interest that use Web 2.0, for example, will enable patients to share health information or perhaps to garner useful health information from appropriate social networks: an example could include Facebook. We need “personalised data envelopes” and “sealed envelopes for personal health data”. To cite a specific example of particularly personal health data, in certain circumstances it is also important to say to an individual patient that her/his sexual data should be available to a healthcare clinician other than her/his general practitioner.
- **Organisational change/change management:** With regard to shared data ownership and shared liabilities, there are a number of definite questions that need to be asked. These include: What outcomes do we want from the data? What do we want to achieve with those data? What kind of control of data do we need? How does that control affect liability? Do we have the right processes in place to collaborate safely? Are we putting data to work effectively? Are the data accessible to the right people at the right time? As a result, we can then build the format and content of the data in the most appropriate way. Building the distribution mechanisms from the very beginning with a focus on the following issues: outcomes, content, distribution, control, process, and system.

²⁰ Cited purely as examples were CPME, the European Health Telematics Association (EHTEL), and the World of Health IT (WHIT) support organisation.

²¹ The example cited of such an authority was the Article 29 working party.

POLICY OPTIONS

To make the most of the potential of telemedicine we need to **develop not only new technologies**, but also to **adapt established working practice and legal frameworks**. While a considerable number of legal and regulatory issues will need to be addressed, the primary focus should be on:

- New models of **information governance**.
- New systems of **shared liabilities** across public, private and consumer based care systems.
- New schemas for **public/private financing**.

Introductory comments were offered on:

- Moving from privacy to information governance.
- Addressing the challenge of **multi-sector care provision**.

This presentation provided a useful, more generic and organisationally-related introduction to the specific legal issues outlined below.

8. Legal and regulatory issues

An overview of the legal, regulatory, and financial challenges related to the trans-national provision of telemedicine initiated the afternoon session of the conference. Subjects covered in the discussion included data protection, liability, tax, competition; accreditation, labelling, and certification; reimbursement; and public/private financing. The first of the two presentations that follow covers an extremely wide range of issues that relate to telemedicine in general. to the second presentation traces the more specific legal and regulatory issues associated with teleradiology.

8.1 Legal and regulatory issues relating to telemedicine

Stefaan Callens, Callens Law, Belgium²²

The success of telemedicine still depends on the development of a transparent legal framework and on the compliance of existing rules, such as the European Directive on certain legal aspects of information society services in the Internal Market (the Electronic Commerce Directive)²³. This talk focused on issues related to liability and reimbursement in the telemedicine context.

A number of legal and regulatory problems are associated with telemedicine, such as these three:

- **Liability:** What is the liability status of telemonitoring in general and, specifically, for example, if medical devices are implanted?
- **Physical presence (or not) of the clinician (or other health professional):** Does the need for the physical presence of the health professional, in order to ensure reimbursement of her/his performances, form an obstacle to the free movement of services?
- **Reluctance of use:** Perhaps because liability related to telemedicine use is unclear, do medical doctors fear to use the services?

Before focusing on issues of liability and clarification of legal certainty surrounding telemedicine use, Callens situated his talk in the context of patients' expectations.

There are real advantages offered by telemedicine for patients and health professionals, and challenges for politicians. Everyone needs to have access to medicine and good quality of care, whether they are rich or poor and literate or illiterate, on the basis of non-discrimination. Patients have certain rights. These include: to be informed, to receive quality of care, to have a safe patient file, to be able to consent to medical interventions, and to insist both on the privacy of their own data but also to have access to data. Callens began his talk with a reference to a recommendation published by CPME in 2002. It suggested that, by 2009, a framework for greater liability certainty should be created whereby patients, health professionals, and providers would be aware of the rules that govern telemedicine.

Callens' presentation covered the vast range of legal questions that might be asked about the provision of telemedicine.

What about liability and licensing: Should professional licences be limited to specific jurisdictions? Or should there be international licences? Should there be specific telehealth

²² See <http://www.callens-law.be/>.

²³ The Electronic Commerce Directive (00/31/EC) and the Electronic Commerce (EC Directive) Regulations 2002 (SI 2002 No. 2013).

licences? Should medical staff who use telemedicine be subject to an authorisation to practice? Should there be hospital credentialing? Callens focused on the latter set of issues.

Under the current legislation for hospital care²⁴, it is not so easy. More and more hospitals need to outsource their activities. More and more activities, such as telemedicine can be handled under the framework of contractual law. With regard to the personnel who do their work by using telemedicine, what are persons' rights of representation before a hospital board? Is the hospital also liable for the state of the person who receives telemedicine treatment?

The Electronic Commerce Directive and liability: what are the implications of it for telemedicine? Should personnel have a telemedicine licence?

What about liability in relation to the monitoring of a patient's care? Does this require a reorganisation of healthcare? What if a doctor does not see a message from a patient when s/he is on vacation or at a conference? What is also the competent court of law? How can a doctor start and continue her/his registration in the field? The telemedicine expert needs to be aware whether s/he can be sued in the patient's home country and who has to cover the damages. Is it a barrier to insist on having a physician present? Indeed, is there a good reason always to have a physician present?

Several more general areas of legislation were considered. Should a no-fault liability legislation be considered? If a company produces a faulty medical device, it is liable. The same is true in relation to chemical trials. Twenty-three of the European Member States currently have data protection legislation through which a person is entitled to receive compensation. Should the 1995 Directive go further, and be applied to telemedicine? Callens suggested that perhaps a transparency directive would be too much to expect, but possibly a Commission Communication could be anticipated or, at least, a guidance leaflet on how to reimburse telemedicine?

Other potential legal and regulatory issues relate to: reimbursement and the legal framework; and training for physicians. A Belgian draft proposal on the information processing of health data and telemedicine – an ambitious proposal launched in 2005, but still on hold – was cited as an interesting model for exploration. If society wants to introduce telemedicine more widely, it may need an appropriate legal framework.

This speaker feels pretty sure that currently the European court of justice would say that the use of telemedicine cannot be inhibited.

POLICY OPTIONS

Should legal avenues be used to resolve the challenge of wider telemedicine deployment in Europe? The application of a **range of current Directives** to telemedicine needs to be considered. It is **possible that suitable incentives for wider telemedicine deployment are contained already within the frame of these prior Directives**.

On the other hand, perhaps **further expansion or embellishment of legislation** is needed. The core issues of concern with regard to appropriate legal coverage appears to be in two fields: **liability of health professionals and of health service providers**; and **the need for physical presence (or not) of the health professional or provider**. One possible explanation for reluctance to use telemedicine on the part of health professionals may be the **perceived lack of legal and/or regulatory clarity**.

²⁴ It was not made clear which legislation was referred to here, whether, for example, it is the legislation of a particular jurisdiction or Member State.

8.2 Legal caveats in relation to teleradiology

P. Shouckens, KU Leuven, Belgium

In the field of teleradiology, there are a minimum of five legal and regulatory problems to be faced. These are related to registration and accreditation of the particular health professionals:

- Registration of the health professional with the relevant national health care authorities.
- Accreditation of healthcare practitioners.
- Registration of healthcare practitioners with the competent social security authorities and, more precisely, with the health insurance authorities.
- Identification of the competent legislation when dealing with liability claims.
- Application of the various national privacy protection laws.

P. Shouckens is a legal expert to the EURAD firm. EURAD is a Belgium-based firm that provides teleradiology services. This “first virtual hospital” in Belgium – with a hub in Hungary – exports its services particularly to France, South Africa, and the United Kingdom. This forerunner in the cross-border provision of telemedicine provides an interesting case study in the advantages provided by such a service (that include a response to a lack of personnel, and provision of care in emergency situations), and the problems that can be encountered when using it. EURAD can be seen as a kind of mini-Europe. A future shift is possibly towards a European registration of eHealth providers.

One key issue is to determine what is the competent legislation(s) in Europe in the case of teleservices? That is, the provision of teleservices means that neither the patient nor the doctor moves and both are stable.

Can telemedicine be defined as the provision of a service (according to article 49 of the European Union Treaty) or is it about a location-place-establishment? On the European level (as opposed to a country-specific level) is this still unclear? Is the appropriate legislation, that would cover the various issues, already available? Are the ‘problems’ that are currently seen merely ‘bad’ applications of the current law?

When a radiologist works for a particular hospital s/he may not be able to provide all the relevant services; there may be partial or even full outsourcing. When there are patients in different countries (such as in Belgium, Germany, the Netherlands, or the United Kingdom), where should the doctor be registered?

The services directive establishes the free movement of services; this recognition of professional services took place in 2006. But the services directive does not refer to healthcare. However, if a professional person is temporarily moving back and forth, does the directive says that the form of registration should be lighter or easier? Therefore can a briefer form of registration rather than full registration be requested? Therefore, for the time being, full registration is being embarked on.

Accreditation can be obligatory. But where should it take place? In the United States of America there is a central accreditation process. When EURAD tenders to the United Arab Emirates to provide services, it is always asked whether there is a single accreditation process. The answer is no; there are 27, one in each of the Member States. Doctors must be

insured with the appropriate social insurance institution, but even this is not applicable in certain Member States such as the United Kingdom and the Netherlands.

For the provision of its services, EURAD tries to write as strong a contract as possible. It tries to apply all the relevant national legislations as long as they do not contradict each other. It often accepts implied patient consent rather than informed consent. However, there can be conflicts which occur with both the penal law and the text law of the various countries involved.

In EURAD's own response to the 2007 open consultation regarding community action on health services, it replied that the European Commission needs to address the challenges of accreditation, registration, health coverage does the patient (social security), and privacy protection of data.

POLICY SOLUTIONS

Those elements of the legal context which appear to need greater clarification, at least as far as teleradiology is concerned, appear to be **appropriate registration and accreditation of the health professionals** involved; the selection of the appropriate parts of **national legislation** with regard to **data privacy and professional liability**. Two issues emerge. First, are these matters **relevant to other fields of telemedicine**, and should they therefore be expanded to other telemedicine fields? Second, different Member States have different models of legislation and different models of professional associations and professional conduct. So, is a change in national legislation actually necessary to affect such a transition in professional conduct? Or could, rather, a solution in some contexts be provided simply through the **professional associations** themselves?

9. Solutions to be provided by medical and other professionals

Interventions from the platform and from the audience came from representatives of a small number of medical associations such as the Conseil de l'Ordre des Médecins in France, CPME, the Union Européenne des Médecins Spécialistes, and an insurance company, Achmea Health Innovation. They concentrated on the need for professional conduct in particular fields and the challenges posed to particular occupations, such as radiologists, by the current global outsourcing that is taking place and the ensuing organisational and reimbursement challenges. The solutions cited in this section of the conference tended to be limited to very specific problem areas or fields.

9.1 Professional principles

Jacques Lucas, Conseil de l'Ordre des Médecins, France

Medical associations base their work on professional principles. In the telemedicine case, this implies that: in all circumstances of time and place, the intervention of a doctor is justified by the condition and interests of the patient, either at her/his request or at that of her/his family. Telemedicine can be used when the circumstances make direct physical contact difficult or when specialised advice is required from someone who is not local. This concept is in line with the notion of equality of access to care, and the provision of a “virtual medical watch” in difficult-to-access locations (such as aid at sea or in the mountains).

Lucas described himself as believing that the practice of telemedicine should be considered as a completely separate activity from other medical interventions. He considers telemedicine as formally different from giving advice over the telephone or by letter.

Telemedicine must, however, be carried out in strict accordance with the rules of professional conduct. Even if medical care is provided at a distance, it should use both the appropriate communication methods for such a medical activity and be under the control and responsibility of a doctor. Whether conducted for the purposes of diagnosis or delivery of care, telemedicine implies that a detailed set of approaches are to be taken. The speaker listed seven:

- There is a structured protocol that flows from a cooperative activity which respects the informed consent of the patient on: the extent of the medical intervention, the techniques used and how they are used.
- This protocol is bound by legally formalised contracts between doctors and the other health professionals involved.
- The protocol's terms specify the place of legal jurisdiction in common law, in the event that the legal responsibility of the doctor is called on or legal action is taken for compensation.
- Respect for medical confidentiality; de-identification and encryption of data and documents transmitted between doctors, and secure archiving.
- “The Doctor's Responsibility”: using telemedicine means each doctor should know perfectly well how to use it and what its limits are. A doctor's duty of care should encompass a perfect knowledge of the instruments s/he is using, their read-outs and limits, and should involve her/his legal medical responsibility.
- The legal responsibility of doctors who act under such a telemedicine protocol can be invoked if, in transferring the data, the information involves is or becomes “distorted,

damaged or sent to unauthorised third parties” whether this is due to the data themselves or to a third party.

- The use of an advanced electronic signature (i.e., a signature that ensures the identification of the information author, confirms her/his authenticity, controls data integrity and ensures that the data will not be repudiated later by the producer).

In France, in 2004, two legal advances were made that have relevance to telemedicine; they are subject to the wider “Code of Public Health” and they relate to three specific, ethical principles in the medical field:

- The patient’s right of access to care.
- The patient as the subject of care.
- Appropriate co-operation with other health professionals.

To reiterate in a different format some of his earlier points, Lucas proposed that under these conditions:

- Procedures should be enforced.
- Co-operation of work among health professionals should be subject to contract.
- Penalties or disciplinary procedures could occur subject to penal law.
- The confidentiality of the patient-doctor relationship (“medical secrecy”) needs to be maintained.
- The use of telemedicine needs to be based on training.

Overall, however, Lucas believes that the introduction of more refined and sophisticated byelaws and procedures should not seek to inhibit modern uses of technology in the medical field.

The legal example cited in this case emerge from French law. **A review of the extent to which the 27 Member States possess legislation that is pertinent** either to eHealth in general, but particularly to **telemedicine** in particular could form a useful step in the preparation of an impact assessment in the telemedicine deployment field.

In addition in relation to telemedicine, the extent to which **law** and the underpinning **principles and codes of conduct of those professional associations** (which are involved in the regulation of professional persons who provide healthcare) are complementary and can reinforce each others’ content should be borne in mind.

9.2 Overcoming legal uncertainty in relation to teleradiology

Peter Pattynama, Union Européenne des Médecins Spécialistes (UEMS), Netherlands

Teleradiology is considered to be a useful service for the outsourcing of radiology reporting. Current and past experience has, however, shown that there are several examples of badly regulated teleradiology which has increased radiology consumption and total costs.

Teleradiology is often outsourced to suppliers based outside the European Union. Hospitals in the Netherlands, for example, outsource to China, India, and the United States of America. What are the reasons for this? They relate to a lack of capacity for processing in Europe, the need for cost control, the availability of services offered by “for-profit players with a global reach” and by low-wage countries that lie outside the Union, and the medical professionals’ and patients’ own choice.

Teleradiology is subject to the laws of the country in which the patient is her/himself treated. All teleradiology carries certain legal and medical risks. But it is not clear how – if at all – one can practice “defensive medicine”, and keep medical treatment inside the borders of the European Union. The “information asymmetry” involved in these circumstances needs, however, to be regulated. Pattynama pointed out the urgent need for better European Union regulation to solve the situation of present legal uncertainty.

Three parties, possibly four, need to be considered when planning the regulation of teleradiology: patients, insurance mechanisms (whether the health sector itself, agencies, or companies), and the healthcare provider, as well as the radiological provider whether inside or outside Europe.

A major legal and medical issue is that teleradiology reporting (wherever it is done) is undertaken in relative isolation. In such a circumstance, teleradiologists are more likely to interpret the medical images that they see without full knowledge of the clinical context and without the results of previous laboratory and imaging tests (information to which they have no or only limited access). Such an approach is not optimal in Pattynama’s eyes. Examples of conditions where such a lack of knowledge could be dangerous include lung cancer and Paget’s disease.

These issues can be readily resolved if it were to be stipulated that teleradiology is a service that exists among radiologists, that is, respectively, between those who request and those who provide the teleradiology service. This would not only ensure minimal information loss, but would also provide the most effective safeguard for a proper market mechanism in commercial teleradiology.

Should the processing of telemedicine activities be viewed from **one or more geo-political perspectives**? That is, at the global/international level; at the level of the European Union; or at the level of the specific country where the patient is being treated? What too is the correlation between **a legal solution** to the problem definition and one which involves directly **a particular group or grouping (“professional association”), and its specific code of conduct or practice** in relation to a specific form of medical practice? Here was a specific plea for **radiologists to have access to other areas of a patient’s electronic health data (electronic health record)**, so as to be able to analyse or assess her/his situation in a way that acknowledges the full and background context of her/his health status.

9.3 Opinions from medical professional associations

Daniel Mart, CPME

From the medical perspective, the core issue remains: is just any organisational or technological change in the interests of patients' development (the examples cited included the increasing globalisation of telemedicine use and massive outsourcing of the processing of MRI scans)? Doctors are "not likely to turn into technocrats". Doctors will always have as their core preoccupation care for patients.

9.4 Organisational solutions to overcoming barriers

Erwin van Leussen, Achmea Health Innovation, the Netherlands

Erwin van Leussen's presentation was very positive and constructive: he mentioned a range of organisational mechanisms that can be used to encourage telemedicine use. Some organisational topics addressed in van Leussen's brief intervention are the building of courage, win/win contexts, financing structures, acceptance of customers, resistance to change, privacy, compartmentalisation, and the character of the health market itself.

Why is innovation in healthcare, and in telemedicine specifically, so difficult? It is because:

- The legal and regulatory contexts are unclear.
- Professional codes of conduct are also unclear.
- Reimbursement practices differ from country to country.
- Organisational and work practices are very varied.

Achmea Health Innovation (hereafter referred to as "Achmea") is a Dutch-based insurance company with over 3.6 million customers. Its philosophy is to encourage customers and patients to manage their own healthcare and to place "the patient at the centre". Achmea believes in building a cooperative relationship among government, healthcare providers, insurers, employers, and its customers (citizens/patients). It bases its approach on the power of global suppliers.

When Achmea introduces new technologies into its services, it does so based on the needs of the customer base (that is, the client or the "insuree"/citizen/patient). It acts according to the selection of certain selected diagnostic groups (particular segments) within the healthcare chain of provision, and it selects innovations which are financially proven. Fundamentally, as van Leussen said: "Let people manage their own healthcare, and then let the insurer give added value."

The challenge of **reimbursement of the use of telemedicine services**, and the **role of the insurers of healthcare provision** (whose organisation relative to the state and to public-private healthcare provision differs from country to country throughout Europe) was the focus of this presentation; however, it was little mentioned by other speakers who came from a diversity of other backgrounds.

10. Discussion and debate

Within the day, a limited time for debate and for questions-and-answers was available. A brief, but sometimes lively, set of interventions followed the formal presentations. Listed here, in an order of priority that attempts to replicate the structure of the day, are the main issues of interest and concern to the participants. Many new ideas which had not been tackled previously by the speakers emerged from these interventions.

The matters discussed were largely contextual, and occasionally legal or regulatory, and related to industrial standardisation, business organisation and work organisation/division of labour. They also referred to the kinds of methods that can be used for the evaluation and assessment of telemedicine applications.

Contextual issues

- Using technology should become the way we do good healthcare in the twenty-first century.
- Should the field to be tackled consist of telemedicine as a whole (however it is most appropriately defined) or to different, specific fields of telemedicine e.g., telehealth, telemonitoring, and teleradiology?
- The degree of globalisation occurring in the telemedicine field.
- The possibility for Europe to act as the first region in the world to test out the use of telemedicine in healthcare.
- The distinction should be made between international (whether within the European Union or between the Union and third countries), national level, and cross-border challenges vis-à-vis telemedicine use.
- Certain Member States (because of their multiple borders) in healthcare terms, form mini-European contexts in their own right. Hence, they could act as or become 'case studies' or 'pilots' or 'model regions of Europe' for telemedicine provision.
- To what extent do actions have to be taken within the four-year lifecycle of politicians-in-power?
- In terms of the European Commission, close liaison could take place among the relevant Directorate-Generals within the European Commission so as to act seamlessly in relation to telemedicine application and its background context.

Legal and regulatory issues

- Precisely what form of 'instrument' is the most appropriate for the coverage of telemedicine provision: a Directive, Recommendation, or Communication? National law? Codes of practice or conduct in professional associations? Codes of practice or conduct on the part of industry and/or service providers? And many other options?
- The content of existing European Directives needs to be drawn on in order to understand the legal and regulatory issues relating to telemedicine more clearly.
- The appropriate model required for the treatment of services and service provision.
- The extent to which the currently delayed launch of the proposal for progress towards a specific health services directive, pending on its content, will or will not contribute to resolving a number of the legal and regulatory questions that surround telemedicine.

- Available guidance from the relevant courts.
- The provision of clear guidance in fairly simple language about how telemedicine is conducted and how it is regulated to different constituencies (e.g., medical doctors, other healthcare professionals, patients and citizens).

Standardisation issues

- Information-sharing about practices and performance internationally and throughout Europe. For instance, from the industrial perspective, an industrial pre-standard on telemedicine is currently available in the Dutch language and should be available in English in February 2008; an Institute for Electrical and Electronics Engineers (IEEE) guidelines on personal health devices will go to ballot in February 2008.
- The role that the international and European standardisation organisations may play in transforming the use of telemedicine, particularly with a view to provision and procurement undertaken in an open and transparent way rather than use of proprietary standards. Examples cited of areas on which to concentrate that would bear a relationship with telemedicine include: Internet protocols; telephony; telemedicine use in emergency situations; and common user interfaces.
- Formulation, design, and enforcement of standards, e.g., in European Union co-financed research and development projects.
- The degree of interoperability required.

Organisations and organisation

- The role that industry and industrial organisations or associations can play in transformation of telemedicine provision, e.g., the role of networks such as the Continua Alliance and the Integrating the Healthcare Enterprise²⁵.
- The role that other international organisations (such as the North Atlantic Treaty Organisation (NATO))²⁶, because of its past, current, and future – admittedly, military – uses of telemedicine can play in the expansion of telemedicine use into the civil community.
- The extent to which a same (or similar) organisational model for telemedicine can be applied to different countries because the various health systems and services are so very different from country to country.
- The need for an overview and assessment of the outcomes of the relevant European Union co-financed initiatives and projects in the telemedicine field over the past twenty years that could be made available publicly *via* a web portal.
- The extent to which telemedicine differs (if at all) from assistive technology or technologies (e.g., in terms of the provision of homecare).
- Awareness of a possible “generational lag”: younger medical professionals and younger citizens/patients may be more inclined to use telemedicine applications. This generation of adults may be more oriented to build a form of “safer healthcare” *via* telemedicine.

²⁵ See <http://www.continuaalliance.org/> and <http://www.ihe.net/>.

²⁶ See <http://www.nato.int/>.

Work organisation, analysis, and assessment

- The implications of telemedicine for work organisation, and particularly the redistribution of labour and budgets away from the secondary care sector to primary care.
- Optimising aspects of preventive healthcare (i.e., keeping people out of use of the healthcare system for as long as possible): in what ways can telemedicine be used to enhance preventive medicine?
- The difference between expectations vis-à-vis telemedicine and actual, empirical evidence about the benefits (organisational, clinical, financial) that it can bring, e.g., through measurement in terms of the Quality of Life Years (QALYs), or Disability Adjusted Life Years (DALYs).
- The need for clear quality assessment mechanisms for telemedicine applications.
- The extent to which, in telemedicine, the “interest of the patient” is moderated by the medical doctor as a gatekeeper.
- Finally, since there could appear to be a degree of complicity among politicians and health management in terms of the underpinning rationale for telemedicine use, it is possible that the extent to which reticence to use the services exists is rather more on the side of clinicians and health professionals.

Occasionally, in addition to the examples offered by the speakers, further evidence of telemedicine application and implementation were cited by members of the audience, such as speakers from Luxembourg and Poland.

Constructive, additional solutions to challenges provided by members of the audience included: the provision of guidelines on telemedicine implementation and use directed principally at clinicians and other health professionals; and the allotment of a form of quality mark for the provision of telemedicine services and/or accreditation to telemedicine experts.

These different categories of discussion may help to enhance the **rationale** underpinning the need for telemedicine use, and the possibilities offered in each of this different fields as they relate to telemedicine deployment in Europe. They comprise different **contextual, legal or regulatory, industry and standardisation, organisation and work organisation**; and **evaluation and assessment methods**. This classification of issues is not dissimilar to that used in relation to a proposed 2008 draft Recommendation on eHealth interoperability in Europe which is currently pending publication and is expected to be released in spring/summer 2008.

11. Concluding remarks

This conference provided a first overview and introduction to all the reasons why the European Commission is beginning to explore the possibilities for a future action plan for Europe on telemedicine. It would be published in the context of a Commission Communication.

Whereas it is understood that the organisation of healthcare is solely an issue for each Member State itself, telemedicine services have the potential to be used in cross-border settings. Indeed, as this conference showed, they are already being used in many cross-border contexts. The European Commission has a specific mandate to address those cross-border care issues which cannot be dealt with on a national basis alone.

The overall objective of such a Communication proposal would be to support wider deployment of telemedicine services, with a particular focus on cross-border settings. Thus, the main aim would be to encourage or enable Member States, according to their specific needs, to take advantage of the potential benefits of telemedicine. A second aim of the proposed Communication would be to encourage the Member States to deal with, as a common dilemma, important challenges in cross-border care that are associated with the practice of telemedicine. The Communication would be likely to propose specific actions that meet the overall objective.

A set of next steps will be facilitated by the European Commission. It will include an assessment of the prospective rationale of such a Communication, its main focus, its key messages, the extent to which it is an 'information-related' style of Communication or an 'action-oriented' Communication; and, if the latter, a coverage of its potential action points. These could, for example, be in areas such as infrastructure, interoperability, procurement of innovative services, legal issues particularly relating to liability, market issues particularly relating to certification and labelling and, last but not least, assessment, evaluation, and education challenges.

The immediate steps in the proposed calendar include:

- **May 2008:** Dedicated sessions to be held at the proposed eHealth 2008 high-level conference on eHealth to be held in Slovenia in May 6-8, 2008 and which will focus on discussions with policy-makers. Attendance by invitation only.
- **October 2008:** The actual policy document ("Communication") on the provisionally-entitled "telemedicine and innovative solutions for chronic disease management" to be published under the umbrella of the French Presidency of the European Union.
- **Winter 2008-2009:** The policy document to be discussed at a later stage in the various Councils.

We welcome any comments and contributions in the context of the Telemedicine Communication "telemedicine and innovative solutions for chronic disease management" to be sent to eHealth@ec.europa.eu