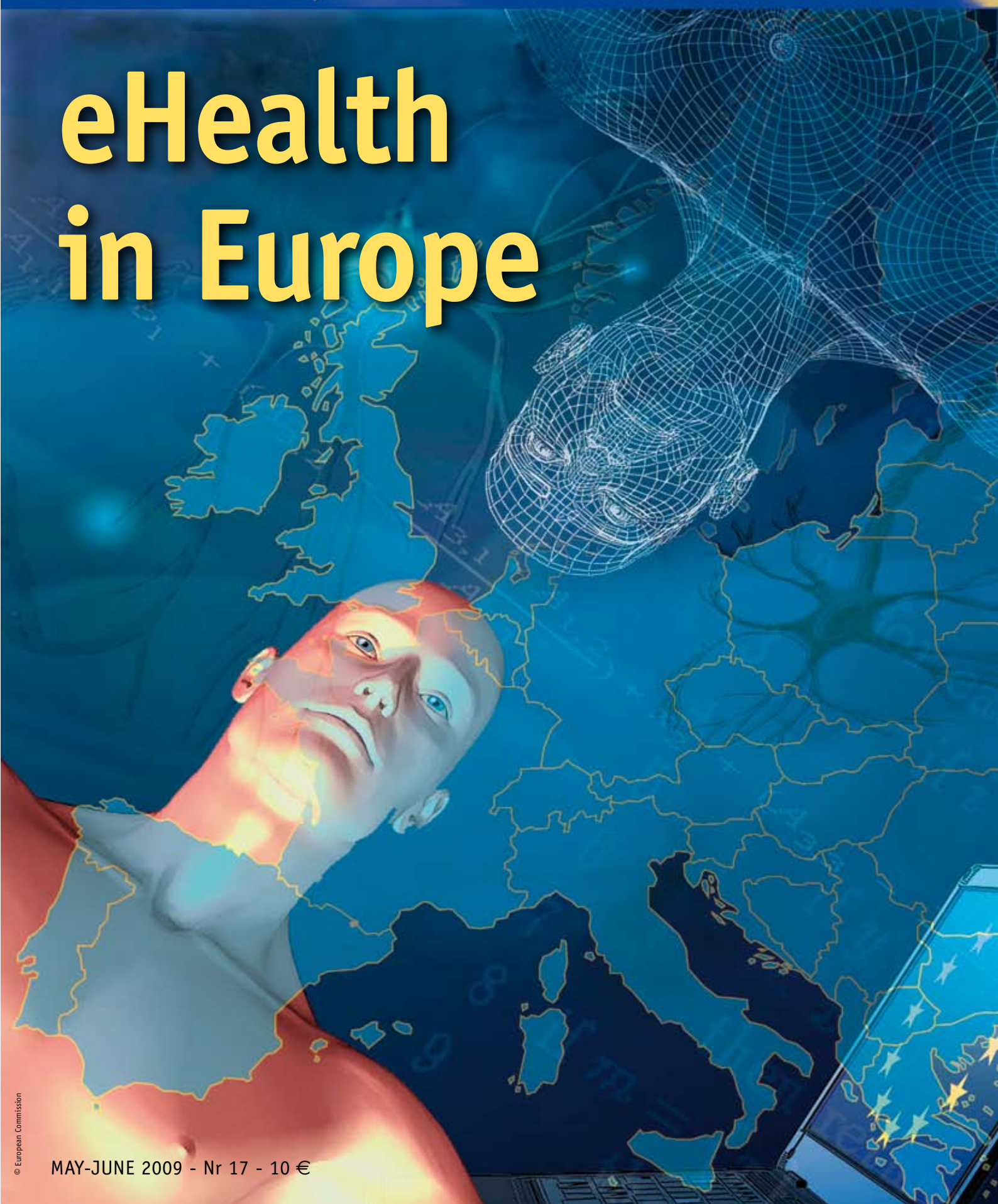


THE  
**EUROPEAN** FILES

# eHealth in Europe



## eHealth: a solution for European healthcare systems?

The term 'eHealth' includes all medical healthcare services and technologies relying on modern information and communication technologies (ICT). These include:

- National and regional healthcare information networks and electronic record systems, including information systems for healthcare professionals and hospitals, online services such as electronic prescriptions, databases used for patient care, research and public health, health related portals and online health promotion services.
- Telemedicine systems and related services (teleconsultation, teleradiology, telemonitoring...).
- Specialized devices for healthcare professionals and researchers (robotics and advanced systems for diagnosis and surgery; simulation and modeling devices; healthcare grids, tools for training).

Therefore, eHealth consists of a large group of technologies and services with a wide scope addressing many stakeholders and many areas of healthcare. eHealth market, currently worth about 20 billion euros, has a strong growth potential surpassing the growth of the traditional health industries, namely pharmaceuticals and medical devices markets.

The introduction of ICTs in the medical field is giving rise to many expectations and questions which will be discussed in this issue.

- Expectations are various: facing the demographic challenge, the possibility to ensure better follow-up for elderly people, generally suffering from chronic diseases, and reducing costs (costs for chronic diseases represent some 60% of total healthcare expenses); to reinforce patient safety, to guarantee healthcare professionals access to patient information, anywhere in Europe; to offer preventive and proactive medical devices; to facilitate personalized treatment and therefore improve its impact; to give patients an active part in managing their healthcare.
- Questions are just as numerous: Will ICTs help protect medical data or on the contrary, by increasing information and service mobility, make it more vulnerable? Do any eHealth evaluation methods exist so we can first focus on the eHealth services with biggest added value? What legislations are further needed for developing eHealth? What new responsibilities are healthcare professionals faced with? Can eHealth be one of the 'locomotives' taking us out of the financial crises?

This special issue reflects the diversity of people involved in developing eHealth and integrating it to healthcare policies. Mobilizing all these people and coordinating their actions, at a regional, national and European level, is essential in order for eHealth to realize its potential.

**Gérard Comyn,**  
Head of Unit 'ICT for Health',  
European Commission



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Gérard COMYN, Head of Unit 'ICT for Health', European Commission



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# eHealth, for a better quality of healthcare



**Androulla VASSILIOU**

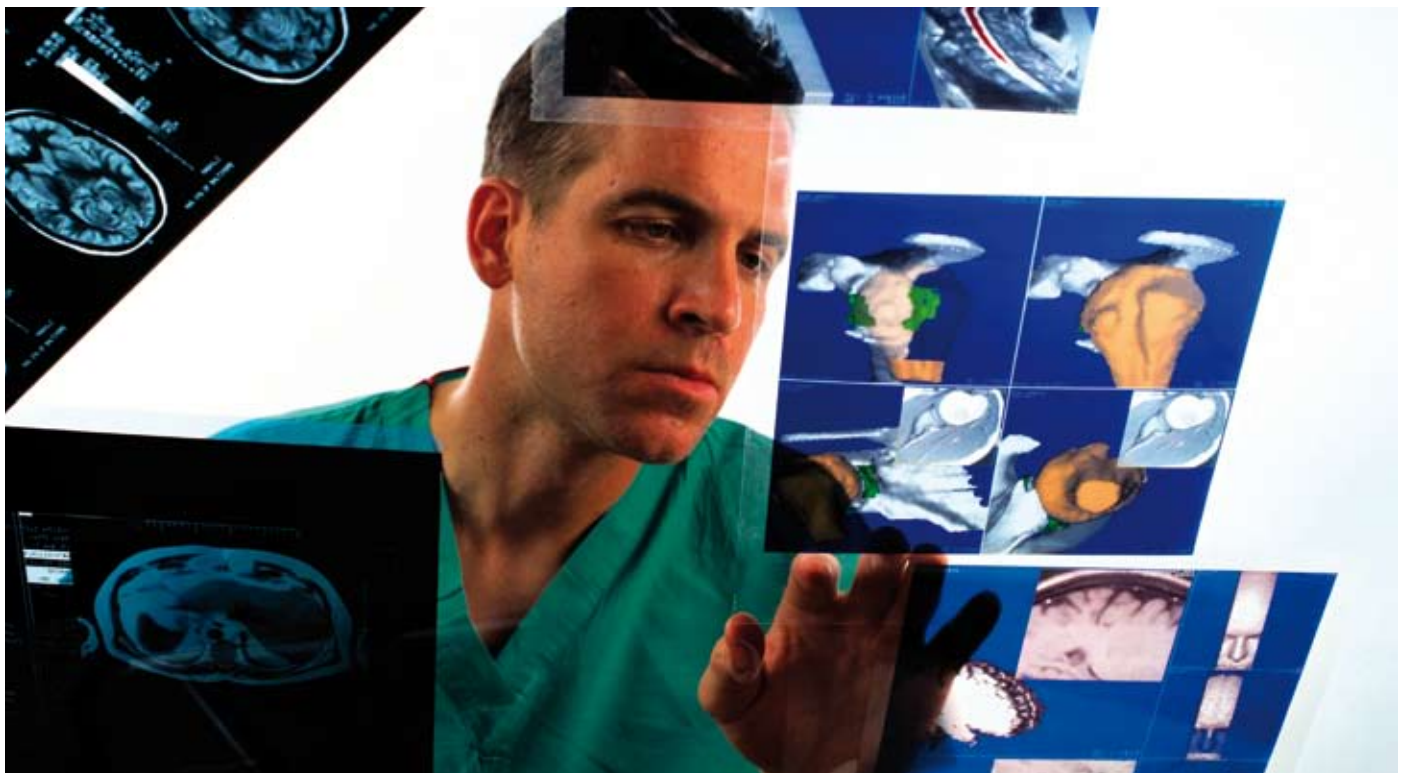
EU Commissioner, Health

**E**-health can be defined as the different applications of information and communication technologies to healthcare. It may well be one of the areas where the added value brought by the action of the EU is the most evident. E-health is situated at the junction of several social and economic objectives set by the EU. It is also an area which particularly benefits from the implementation of scale economies, the exchange of best practices, the esta-

blishment of a solidarity and, last but not least, from technical harmonisation.

In the framework of both the Lisbon Strategy and the i2010 initiative, e-health is a way of accelerating the achievement of a knowledge-based economy. At the same time, e-health is also part of the Renewed Social Agenda and of the Programme of Community Action in the field of Health. Ageing and the recrudescence of chronic diseases question health systems' sustainability. Information and Communication Technologies represent an answer in order to guarantee quality standards in health care for all. Furthermore, the financial crisis accentuates the need to rationalise the health sector and to search for scale economies.

E-health is European because it is naturally suited for cooperation and networking. The purpose is not to question the Member States' competence in determining how e-health should be applied at their level. However, their efforts should be coordinated. For example, the proposal for a Directive on patients' rights in cross-border healthcare creates a health technology assessment network. The proposal does not force Member States to introduce on-line health system or services. Nonetheless, when these applications do exist at national level, the Commission could work on measures to ensure their inter-operability. Finally, the text proposes the creation of European Reference Networks, designed more particularly for patients suffering from rare diseases, which will



maximise the health technologies' speed and scale of diffusion.

E-health clearly has a European dimension. However, its benefits on patients and health professionals are more evident at the level of the Member States. This is the reason why, with its Recommendations and Communications, the EU complements the initiatives adopted at national level.

E-health enhances in several ways the quality of healthcare provided by the health professionals. Electronic medical files give information which can be used to determine with precision the adequate treatment for each patient, including those who come from other Member States when the files are interoperable. E-health is useful to make diagnostics since it can connect different health professionals, regardless of their place of residence. Finally, as the Communication published in November 2008 on telemedicine underlines it, telemonitoring and teleradiology extend the notion of «work place» for health professionals. However, it should be noted that it is only by adequate training that we can ensure that health professionals benefit from these different applications.

Patients should also be made aware of the potential benefits of e-health. In general, e-health makes the health system more patient-oriented. Telemedicine is particularly relevant for those who suffer from chronic diseases and those who live in areas where the offer of healthcare is limited. Interoperable electronic health files ensure a continuity of care for those who travel to another Member State. The future electronic version of the European health card will make it easier for patients to be reimbursed



when they are treated in another Member State. Finally, e-health also refers to all the Internet sites which contain information about health and answer to patients' questions. The Commission has established quality criteria for these sites and is also providing information to patients through the European health portal.

To conclude, e-health is a key part of the «Europe for patients» that I promote. E-health is European because it has a cross-border dimension and

constitutes an answer to the different socio-economic objectives set out by the EU. It is about patients because it contributes to the quality of healthcare provided to all of them, regardless of their place of residence or their age. For all these reasons, we should continue to act together and promote the expansion of e-health, within a framework respecting health data confidentiality.

# Creating a European Health Market based on ICT



**Viviane  
REDING**

EU Commissioner,  
Information Society  
and Media

The synergy of the Health and ICT sectors brings great value to individual patients, health delivery systems and the economy. Traditional European health markets include pharmaceutical products (valued at €205 billion based on retail prices<sup>1</sup>) and medical devices (for which annual European sales are estimated at €64 billion<sup>2</sup>). The emerging third «industrial pillar» is ICT for Health, or eHealth, currently estimated to be worth €60 billion, of which the European Union's (EU) market represents approximately one third<sup>3</sup>. eHealth is the fastest growing of these three main health care sectors, with acknowledged market potential resulting from growing demand due to changing demographics, disease patterns and the need to improve the sustainability of health delivery systems. This article highlights the potential of the eHealth market per se as well as the potential of ICT to revitalise and foster innovation in the other two traditional health sectors.

## Challenges

The sustainability of Europe's health delivery models, based mostly on public finances, is under severe pressure. The number of people over 50 in the EU is projected to rise by 35% between 2005 and 2050. The number of people over 85 will triple by 2050<sup>4</sup>. In response to these developments, health expenditure is expected to increase

from 9% of GDP at present to around 16% by 2020<sup>5</sup>.

Access to quality services anytime and anywhere in the EU, including remote and rural areas, is a top priority of health delivery systems. Unequal distribution of health professionals and high cost of quality health services make it a major challenge. Patients in the EU expect the best treatment, personalised services and a better understanding of how to cope with their condition, especially chronically ill patients.

The eHealth businesses must overcome many barriers preventing them from selling products developed for one healthcare institution, to another. This is mainly due to the lack of the famous interoperability – the ability of one system to work with or 'talk to' another. We are still far from the ideal situation where patients can travel from one EU country to another knowing that, if needed, their medical records will be accessible by their treating physician wherever that may be; that they can receive the required medication; or that their doctor can be «tele-consulted» without them having to move from home

Finally, medical knowledge is exponentially exploding and the optimal management and use of the latest findings at the bedside of the patient to improve early diagnosis, prevention or even prediction of disease can and should be improved.

## eHealth response: Commission initiatives and market potential

eHealth solutions must respond to the evolving needs of patients, consumers, and health professionals, and have a direct impact on access, quality, cost, and safety of healthcare.

The first challenge is to ensure that

**eHealth benefits all Europeans.** In doing so, we are contributing to the goals set by the renewed social agenda presented by the European Commission in July last year. This comprehensive package of social initiatives was set up to create jobs and improve education and skills development, to fight discrimination and support mobility. It also aims to help Europeans live longer and healthier lives.

It is necessary to provide an incentive to all actors involved, to facilitate patient access – even in remote areas – to safe and high quality healthcare via the use of telemedicine services. Innovative technologies for distance healthcare patient centred solutions have given rise to a new segment of the market: the personal health systems, on the basis of which a new generation of telemedicine services will be developed. The growth of telemedicine services is projected at 19%<sup>6</sup> a year provided that legal, organisational and skills issues are addressed properly at regional and national level. The European Commission's Communication on 'Telemedicine for the benefit of patients healthcare systems and society'<sup>7</sup>, adopted in November 2008, highlights the major steps that need to be taken to harness the potential of telemedicine including distance diagnosis.

The Health sector is highly information intensive. Automation and effective use of ICT tools and services is therefore not only logical but necessary to

<sup>1</sup> EFPIA, The Pharmaceutical Industry in Figures, 2008

<sup>2</sup> Eucomed Medical Technology Brief, 2008

<sup>3</sup> eHealth Industry Stakeholders Group, reporting to i2010 sub-group on eHealth, 2008

<sup>4</sup> OECD Forecast – Coping with an ageing population, 2007

<sup>5</sup> Healthcast 2020, PWC, 2007

<sup>6</sup> Telemedicine; Opportunities For Medical and Electronic Providers. BCC Research, 2007

<sup>7</sup> COM (2008)689 final

improve effectiveness and productivity. Assuming that a small percentage, e.g. 3%, of health expenditure will be devoted to digitisation, it already represents significant commitment. The Commission has invested in the development of regional and national health information networks and interoperable electronic health records over the last 20 years. Europe can proudly claim that fully functional regional health information networks bring value to all stakeholders and save a significant amount of money<sup>8</sup>.

The second challenge is the **huge market potential for eHealth tools** that can support continuity of care and patient empowerment especially for our growing 'silver' population. There is a strong will among national health authorities and stakeholders to overcome the obstacles that eHealth instruments and systems have to face because of the lack of interoperability of systems but we are not there yet so, last year, the European Commission issued a «Recommendation on interoperability of Electronic Health Record systems». This European Recommendation provides Member States with basic principles and guidelines on how to bring about interoperability in electronic health record systems, especially in a cross-border context. I would like to urge all Member States and industry to continue their efforts in order to achieve this objective.

Awareness of the need to support the acceleration of the development of the market has caused eHealth to be chosen as one of six market sectors to be addressed by the European Commission's 'Lead Market Initiative' (LMI)<sup>9</sup>. Urgent action is called for to address barriers to deployment, with a 3-year eHealth action plan currently underway aiming

to: Reduce market fragmentation and lack of interoperability; Improve legal certainty and consumer acceptance; Facilitate access to funding; and support procurement of innovative solutions.

The European Commission is also playing its role on the international scene in close cooperation with countries outside Europe, in particular the USA. We are committed to working together with our transatlantic counterparts on common approaches towards interoperability and standardisation.

The challenge of **research in the field of eHealth** is also tackled at European level. The eHealth market has benefitted from pioneering research and development, including over a billion euros of EU funding, which have supported the evolution of ever-more patient-centred applications. More recent research has focused on 'virtual physiological human' (VPH) applications, with ICT providing the possibility to create models of human organs and systems with a view to better prediction and prevention of diseases. VPH allows for innovation in the pharmaceutical sector in the field of 'in silico' design and it also offers new tools for improved design and effectiveness of medical devices.

### eHealth for all

The recent financial crisis has not made the challenge of sustainable healthcare any less significant. On the contrary, the long-term economic benefits that eHealth can provide have been brought into sharper focus, with, for example, considerable investment being outlined in the recent USA administration's recovery plan. With similar commitment in Europe and ongoing support from stakeholders, eHealth can deliver growth and

jobs in a European Health Market based on ICT and bring the quality and safety of healthcare that patients and medical practitioners want to experience.

I am confident that all these initiatives together with the concerted efforts of Member States, the key stakeholders and the European Commission, will contribute to making eHealth a reality for all Europeans and, thus, will improve their general wellbeing by helping them lead longer and healthier lives.

<sup>8</sup> See for example EC funded publication 'eHealth is Worth it' - see [www.ehealth-impact.org](http://www.ehealth-impact.org).

<sup>9</sup> COM(2007)860 (21.12.2007). The specific eHealth Task Force report related to the LMI Communication can be accessed at: [http://ec.europa.eu/information\\_society/activities/health/docs/publications/lmi-report-final-2007dec.pdf](http://ec.europa.eu/information_society/activities/health/docs/publications/lmi-report-final-2007dec.pdf)



## The French eHealth policy



**Roselyne  
BACHELOT-  
NARQUIN**

French Minister  
of Healthcare and  
Sports

The future of our healthcare is moving towards the proper use of healthcare information technology, known as "e-health." This is why France has been initiating numerous experiments in the sector for some years now. I think it is time for a wider and more generalised use.

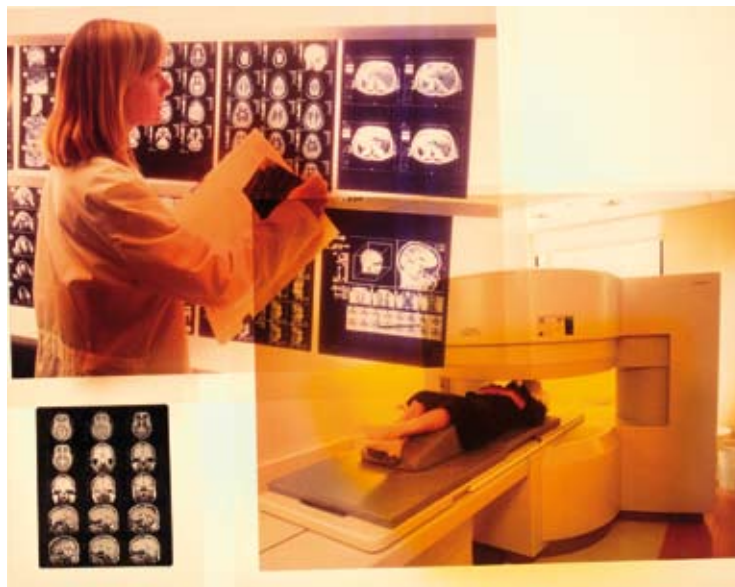
The use of e-health relies on several principles which constitute the basis of my policy. Human interaction is, and will remain, at the heart of our healthcare system. The goal of information and communication technology is primarily to serve medical practice in reinforcing our capacity to prevent and treat. E-health must deliver the same confidence in the reliability and security of the system as patients have in health professionals. Again, I would remind you that I will not be moved with regard to security and confidentiality rules, particularly those relating to personal information.

**E-health must be ambitious. Its contribution is essential to all fields of healthcare.**

E-health will help poorly equipped medical zones open up to the world. It will also be a wonderful opportunity to modernize healthcare. For pathologies dependent on emergency treatment, it will shorten intervention time, improve

chances of survival and reduce the risk of after-effects. For chronic diseases, citizens will have access to better medical follow-up, therefore limiting the number of hospitalizations while maintaining as normal a professional and social life as possible.

In Europe, with projects such as NetC@rds, Calliope or epSOS, E-health is able to provide leverage for effective cooperation between Member States. As an example, epSOS is a major and ambitious project which is supported by over 53 participants, including 12 Member States. Launched last July, it is designed to promote and implement a wide-scale pilot for two e-health services - accessing a patient's record in another Member State and using cross-border electronic prescriptions.



**My proposed strategy relies on four lines of progress.**

- The first consists of modernizing hospital information technology systems. The Hospital 2012 plan, with 1.5 billion euros

earmarked for healthcare information technology, will support systems which optimize hospitalization processes and are likely to be extended to the city.

- The second line regards the personal healthcare record (PHR). The patient will be able to control the data while allowing information sharing and facilitating coordination among healthcare professionals. The PHR, now considered as a group of services, will satisfy specific needs. A basic PHR offering a simple view of healthcare information will progressively be made available across the country.
- The third development is electronic-health, i.e. all the technologies which facilitate surveillance, diagnosis, expertise and long-distance healthcare. The needs are real and numerous, technologies are emerging and systems are being

set up. My ambition is to implement wide-scale operation of these new services. It will be defined and implemented in collaboration with all the stakeholders.

- Finally, at the governance level, the creation of two bodies dedicated to these technologies, plus reinforced strategic management of national healthcare information systems, will enable these objectives to be implemented and monitored.

Development of e-health is a symbol of progress and hope for both patients and healthcare professionals. To succeed, we must not only act decisively, but will full cooperation too.



**Klaus  
SCHRÖDER**  
German Secretary  
of State for Health

## The Health Card in Germany, observations and evolution

### Information technology for public health systems

**P**oday, there is a wealth of information - but paper-based documents and archives fail to bring it all together or structure it effectively - so it's often not available when it's needed. The solution to this problem lies in the use of modern information and communication technology within the public health care system. These technologies enable data to be systematically archived, filed, managed, transported, processed and interpreted, and therefore make a major contribution to improving patient care.

Information and communication technologies have their own tradition in Germany. The first computer was built here, for example. This acts as an incentive for all those involved to approach the deployment of these technologies in all areas of business in a systematic way. And this applies equally to the public health system. For the quality of health care is today no longer simply a question of technical opportunities and doctors' skills. It is also dependent on how quickly, reliably and securely important information can be exchanged between those involved.

### Electronic health card networking project

One important step towards networking the German public health system is the introduction of the electronic health

card. As an integral part of the electronic data transmission infrastructure, it will act as the link which brings together all those involved at the information technology level. It will result in better pharmacotherapy safety, improved quality of treatment, and greater control on the part of patients.

The legal basis for the electronic health card was established by the Modernisation of Statutory Health Insurance Act which came into effect on 01 January 2004. It was legally established that the responsibility for introducing the electronic health card rests with the self-governing organisations, i.e. associations of health insurance companies, doctors, dentists, hospitals and pharmacies. In order to tackle this task, all the self-governing statutory health insurance companies in January 2005 founded a company for health card electronic data transmission applications (gematik GmbH). Its task is to develop the electronic data transmission infras-

tructure and to introduce the electronic health card.

A project of this scale, involving doctors, dentists, hospitals, pharmacies and more than 80 million insured individuals, can be implemented only in phases. This means that the feasibility of each application in practice is tested individually before it is introduced. At the forefront is always the need to guarantee that sensitive patient data will be protected.

Following the successful offline testing of insurance master data, work began on issuing electronic health cards nationally - initially in the North Rhine region. In the first phase, card reading devices were distributed to doctors. Neighbouring regions were then gradually equipped.

A deciding factor in the process was that migration-enabled technology be available from the start of the project. This



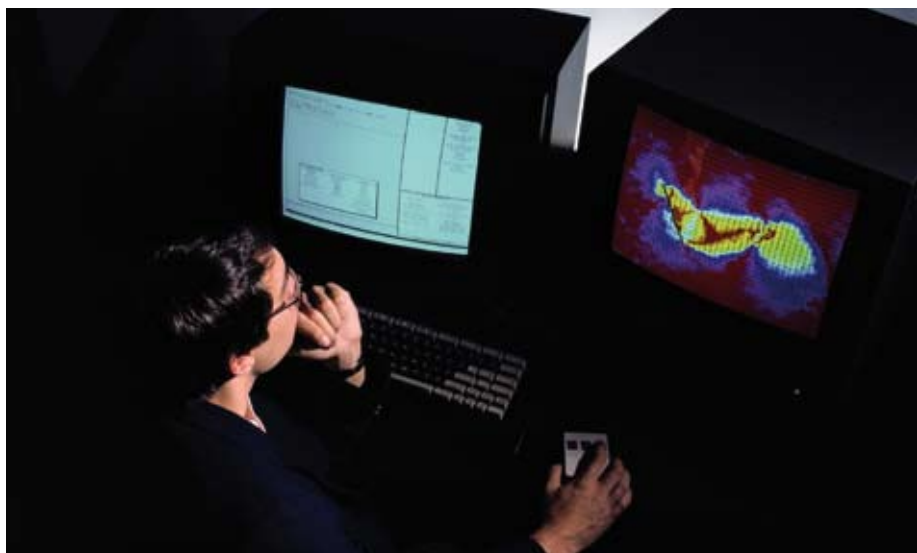
means that the technology now available is already capable of connecting to further applications, e.g. emergency care data, or documentation regarding medications - without exchanging cards. The applications themselves must already be proven in the parallel test process.

The electronic health card will soon be playing a major part in integrating disparate patient data. The use of basic medical data, perhaps to test interactions between medications, or in emergency situations, should be seen as a starting point in building up a commonly useable electronic patient file. The use of electronic patient records is concerned primarily with rapid access to information needed for treatment. This will help to optimise the quality of medical treatment, reduce repeat and multiple investigations and, with an improved basis of information, support reduced treatment times.

## Data protection

If the deployment of information technology in public health care is to meet with acceptance, there must be an approach to data protection which ensures that data is handled securely at all times. Protecting insured parties' sensitive health data from unauthorised access is of challenging significance within the electronic health card project. There is detailed legislation in place for this in Germany, according to which access is permitted and possible only for persons who belong to the professions defined by the legislation, and who have been expressly authorised, including by electronic means, by the patient.

The high level of protection of data against misuse includes technical measures. In real terms, this means that information saved by the health card can be read only if the patient and the doc-



tor agree, and activate their electronic health cards or healthcare profession identification (two keys principle). The data, as soon as it leaves the medical practice or the hospital with the doctor's and the patient's approval, is individually encrypted. Each person insured has their own key via their health card. Since there is no «general key», no one is able to read data without the insured party's cooperation.

Experts all agree that the introduction of electronic health cards, and the associated security structure, will of itself ensure health data is more secure than before.

## Europe

In a Europe without barriers, people are keen to access the benefits of modern information and communications technologies in public health in other Member States, too, e.g. being able to collect prescriptions when they are on holiday or away on business. And the fight against rare diseases, plus resolving care issues in certain regions, can succeed only if tackled together and across borders.

These challenges can be overcome with the support of electronic data transfer. At the eHealth Conference in Berlin in 2007, organised by the German Federal Ministry for Health together with the Federal States, the German insurance association (Gesellschaft für Versicherungswissenschaft und -gestaltung e.V.) and the European Commission, structured collaboration between the Member States was agreed. On this basis of this, a pilot project was instigated, involving 12 Member States, to introduce electronic health cards throughout the EU in order to support continuity of care with an abridged patient file and an electronic decree issued by the commission. Germany, given its own experience, can and will work actively on this project, giving it major impetus.

This has set the course for the structured deployment of information and communication technology within Germany and across Europe, ensuring improved patient care with the highest possible level of data protection.

# It's time to put eHealth on the political agenda!



**Göran  
HÄGGLUND**  
Swedish Minister  
for Health and Social  
Affairs

**T**he time has come to move from words to action, and take our National eHealth Strategies from vision to reality. In Sweden, many of the national eHealth solutions which we have been preparing for many years are now in the final stages of development. They have been procured and are ready to be rolled out on a broad scale. The long awaited National Patient Summary is now being implemented in region by region, and a modern legal framework has been established since July 2008 by the new Patient Data Act.

We thus leave behind us a period of technological development and enter the next phase, which will be focused on organisational change. The work of improving information flows and continuity of care with the help of new ICT support systems, will not be able to reach its full potential until working methods, processes and the culture in healthcare are adapted to this new environment – and adapted to meet the individual needs of the patients.

The involvement of health professionals in all stages of this change process is essential, in order to make the technology reflect the actual needs of doctors and nurses,

and include ICT as a natural part of the basic medical education and training at our teaching University Hospitals.

eHealth is a catalyst for reform and improvement of the healthcare sector, and we as politicians and decision makers must be better to visualize and understand how to use this tool to its full potential. A new generation of patients and health professionals have different expectations for a modern and accessible healthcare system well adapted to their individual needs. If we as decision makers in healthcare cannot meet these expectations, the trust for our healthcare systems will be seriously damaged.

We therefore have to put eHealth firmly on the healthcare agenda as a key enabler for healthcare reform! Looking back, perhaps too much of the work carried out in this field has been delegated to technical experts and has as a consequence not always reflected the political goals for healthcare or the actual needs of patients and health professionals. Often the lack of concrete deliverables and visible benefits for citizens have damaged the credibility. Therefore, a stronger political governance and involvement in this field is imperative.

The EU and international dimension in healthcare and eHealth is increasingly important for all of us. Patient mobility both between and within Member States underscores the importance of strong collaboration at EU level. The majority of Member States are today in the process of rolling out large-scale

eHealth investment and implementation programs. Some Member States have been granted financial support from European Structural Funds in order to reform national healthcare systems by investments in eHealth solutions.

Thereby, we have a unique window of opportunity to build these national solutions on common European standards that enables continuity of care across administrative and national borders. If we fail, there is a clear risk that national investments will be less efficient, more expensive and not providing the potential benefits for the patient that would be possible. Furthermore, the Member States face the risk of finding themselves trapped in national solutions for several years without the financial capability to adapt them to future common standards.

During Sweden's Presidency of the EU in the second half of 2009 we aim to make substantial progress in this area. The main strategic goal is to create political awareness and commitment at the highest level. Furthermore, we aim to change the way eHealth is described, so that the added value for healthcare when implementing eHealth solutions is understandable and self-explaining for everyone outside the eHealth Community.

The Swedish Government has a strong commitment to follow-up and further develop recent initiatives on this area, and create a strong political mandate for a closer and more concrete European co-operation on eHealth, as





well as a structure for this governance process. We also hope to provide new knowledge, evidence and arguments for why eHealth should be addressed in a new way at European and national level by issuing a formal Presidency Report on eHealth. This report will try to visualize the value based costs for healthcare of you don't make the necessary investments in eHealth. The cost of doing nothing can be staggering.

In times of financial difficulties, these aspects are becoming increasingly important. But we must remember that in many cases, the main problem is not the lack of resources, it's the lack of coordina-

tion of how existing resources are actually used that is the main problem. Huge amounts are invested in eHealth solutions annually, and we have an obligation to use these resources wisely. By increasing our exchange of knowledge and experiences across Europe and globally, increased cost-effectiveness for our national investments are self-evident.

When large-scale implementation, deployment and usage of eHealth solutions are on the agenda in the Member States, the European cooperation must be aligned to this development, and provide concrete, hands-on support in areas that cannot be handled only at national

level. By joint efforts from Member States and the European Commission, several projects on this area has also been launched during 2008, namely the epSOS Large Scale Pilot and the CALLIOPE Thematic Network. By these projects, the ambition to move from strategies to services are finally being fulfilled. Sweden is a proud and engaged partner in these projects.

We are starting to see the emergence of a modern, accessible, needs-based healthcare sector, and can now – at last – begin to meet our citizens' long held expectations of an efficient, integrated healthcare system that is available when and where its needed.

# The Slovenian eHealth experience, strategy and objectives



**Borut MIKLAVČIČ**  
Slovenian Minister for Health

## Stratégie et objectifs

**A**fter completion of the feasibility study into an eHealth project, it is assessed that in Slovenia we have reached a breaking point when we are faced with an opportunity to accelerate the development of health information technology based on the eHealth 2010 strategy. The eHealth project was launched by our Ministry in the last quarter of 2008, and is based on the conceptual model of national health information system (eHIS). The basic position and objective of eHIS solution planning is to renew and integrate professional and business processes in the healthcare sector by means of ICT, in order to:

- increase the quality and efficiency of the healthcare system,
- mobilise adequate resources for the areas of information technology and integrated quality in healthcare,
- improve the accessibility to healthcare services for all citizens and prioritise their role in treatment processes,
- Introduce e-administration as a standard method of work in the Slovenian healthcare.

In the future, the core of the healthcare information system will consist of three strategic pillars:

- The central zVEM portal, serving for communication between back-

office systems and healthcare operators, will offer citizens and expert members of the public a range of e-services in the area of healthcare such as, for example, e-appointments.

- The zNET network, which provides a secure and reliable environment with suitable capacity and throughput for data exchange,
- Unification of electronic health records (EHR) pertaining to individuals. It is anticipated that individual EHRs will be collected at the healthcare service providers treating the patient. The basic EHR administrator for a citizen's EHR is his/her selected physician. Possible centralisation and accessibility of these very important but also very sensitive personal data calls for further agreements and a legal framework.

A critical factor in eHealth development is the establishment of the Healthcare IT Centre, which should focus on strategic tasks in the area of healthcare IT and support the development of new solutions, while also developing architecture, standards and "best practice" solutions.

The planned system will facilitate a compatible and rational linkage of the Slovenian healthcare IT system with similar systems in the European Union, thus promoting the mobility of citizens.

## Current activities and implementation plans

The feasibility study into the investment programme for the implementation of the national eHealth

development project with the basic objective of establishing eHIS as planned is in its final phase. The project value amounts to EUR 31 million and 85% of the funding are provided by the European Funds. The first results will be available in 2009.

A few sample solutions aimed at proving the feasibility and rationality of different models and the possibilities of the entire eHealth project implementation were launched in 2008 and work on these continues in 2009. The sample solutions will be designed in a similar way as the global system, though their scope and functionality will be limited.

The main activities in 2009 are however dedicated to the implementation of all the components of the eHealth project. Thus in 2009, activities are envisaged in the following areas:

1. zNET healthcare network establishment

The zNET network should be regarded as the entire platform for ensuring network connectivity (hardware, systems software, rules and standards packages, etc.). The priorities for 2009 include the purchase of central equipment, its set-up and configuration.

2. Establishment of the national zVEM portal

zVEM will include IT solutions for priority eServices of national importance. The activities in the zVEM area envisaged in 2009 are:

- establishment of the zVEM portal framework, including basic services

- development of a system for national waiting lists and e-appointments, intended to solve the problem of long waiting periods
- Exchange of eDocuments envisages the elaboration and implementation of IT solutions for safe exchange of different e-lists and other standardised messages. It is planned that an eDischarge letter, sent by secondary-level healthcare providers to selected physicians, will be established as the first e-document.

3. The development of a uniform healthcare IT model, which will provide a foundation for the establishment of uniform elements of electronic medical records and their summaries.

4. Activities in the area of promotion, training and education

This cluster of activities will be intended for the improvement of healthcare processes and accessibility of healthcare services by organising education and training programmes and raising the awareness of different target groups.

## Conclusion

The baseline plan of eHealth project implementation envisages an undelayed launch of project activities or sub-projects. It is anticipated that approximately 10 sub-projects will be launched in 2009. Sub-projects are planned in such a way as to yield tangible results by October 2009, and thus justify the planned absorption of the EU resources. Continuation of work on these sub-projects and the launch of the remaining sub-projects are envisaged for 2010 as planned.



# Andalusian eHealth Strategy



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**A**ndalusia is one of the largest regions in Europe, with more than 8 million inhabitants. As one of the seventeen Spanish autonomous regions, it assumes full responsibilities on regional health policy and guarantees citizens' rights to health, as well as health care delivery and resources allocation.

The Andalusian Public Health System (APHS) is tax-funded, has universal coverage and public provision. It provides a wide range of health care services, free of charge at the point of care. The citizen is the center of the healthcare system. The APHS has adopted corporate information systems as a strategy, to support citizens' needs, participation and rights in the field of health, and to build a better system with the participation of health professionals.

## I. Tools for health professionals and the health system:

### Diraya

Diraya integrates all the information of each user into a Single Health Record. It is available where and when it is needed for his/her care. It also facilitates access to all the services and provisions of the health system, and ensures that all the relevant information is structu-

red. Diraya, which means "knowledge" in Arabic, is the outcome of the Organization's shared knowledge. More than 400 health professionals participated in its design.

Diraya is based on a set of related modules that share information

- Basic components:
  - User Data Base (UDB) supplies every citizen with a Single Andalusian Health Record Number (NUHSA) to which all his/her information is linked. There are 8 millions registered users (98.8% of the population).
  - Centralized Operator Access Module (COAM).
  - Structure Module, (departments and functional units as well as physical locations).
- Single Health Record in 684 primary health care centers and in all hospitals (emergency departments and outpatient clinics), with over 10.000 working stations (93.76% of the population with clinical data).
- Prescription XXI: electronic prescription in 680 primary health care centers, covering 7,412,378 inhabitants (93.56% total population) and 3,500 pharmacies (97.8%). More than 100 million prescriptions have been issued since 2003.
- Central appointment service: manages primary care, outpatient specialized consultations and diagnostic procedures agendas. More than 150 million appointments since it started.
- Datawarehouse and information system on health activity and performance.
- InterS@S: The Public Health System Virtual Office allows users to change doctors, to see and update their personal data, or to request a second medical opinion.

### Virtual Library

It is available for use in clinical practice, training and research to all the professionals in the Andalusian Health System. It started in 2006, allowing free access to 2500 scientific journals and periodicals, from hospitals and primary health care centers and professionals' homes.

### Innovative Practice Bank

A strategy for identifying, sharing and acknowledging innovative professional practices. It includes a network of agents among health professionals of the organization, and promotes the development of innovation forums, ideas, contests and best practices identification and diffusion.

### Observatory of Innovative Practices in Chronic Disease Management

Created as a network focused on identifying, processing, synthesizing and disseminating innovative practices in Spain and the world, it is accessible at a web page. It supports knowledge management, as well as collaboration between excellence focuses.

## II. Citizen – Health System relationship framework:

### Health Responds (Salud Responde)

Information and Service Center available 24/7. With multi-channel access to the Public Health System of Andalusia, this system has been designed to satisfy needs of information that both citizens and health professionals may have. It improves the capacity of response of the health system and makes it faster. The system offers medical appointments for primary care, general





information of the Public Health System of Andalusia or specific information on topics like the health smart card, the dental health programme, the right to choose hospital or to ask for a second medical opinion, as well as details on community link nursing, living will statement, health campaigns, follow-up on fragile patients after hospital discharge or heat waves, and medical advice. Each citizen can also be subscribed to the text messages information services where they can learn about health campaigns, obtain appointments reminder, or become familiar with health prevention measures, information on tobacco (quit-line), or the citizens' service line for health technology and devices. Recently this year, it has added to its services tele-translation in 46 languages.

#### **Informarse.es Salud**

This health information service uses multichannel platforms such as internet, mobile phones, TV and other mass media. It is meant to be a new model of communication in health, based on innovation. It offers accurate and quality information which can be reached through several channels and platforms.

#### **Opinar.es Saludable**

A tool to learn about the citizens' expectations and requests. People can express their opinions, their suggestions and their needs. This tool helps the Health System seek what the citizenship expects from the services it provides and their opinions on the initiatives that are launched.

IT systems may help as a meeting point for public sector, academia and enterprises. In this field, "Living Lab Salud Andalucía" (Andalusian Health Living Lab) works as an open community for the development of innovative technologies, products and services, and is open to the participation of citizens.

# European eHealth - NPFIT



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CONNELY**

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**L**he National Programme for IT (NPFIT) is introducing electronic records for NHS patients right across the country, thereby completely transforming healthcare as we know it.

The National Programme for IT faces a huge array of challenges, including patient expectations, demographic changes that are seeing more people live longer, and the constant march of technological and medical advances.

This change programme is being implemented across England; both Scotland and Wales have their own programme for digitising their health services. Across England, implementation is proceeding well in a number of important areas.

Whilst electronic patient records in the acute sector are seeing some delay in implementation, the infrastructure to deliver the function is largely in place. More than 54 per cent of patient referrals are now made via our Choose and Book system, which allows patients to electronically book appointments at a time and place convenient to them, and around two-thirds of GP practices are using the GP2GP system to transfer records securely between sites. England was the first G8 country to introduce digitalised imaging (PACS) to every acute trust, improving patients' experience and avoiding repeat X-rays.

As the programme continues, we are committed to continuing to listen to and work closely with health practitioners, to ensure the system is of maximum benefit to those who will most use it.

The contracts which founded this ambitious programme of transformation were purposely constructed with in-built flexibility, so that teething problems could be overcome without any extra cost to the taxpayer. No supplier is paid until we are satisfied that the systems have been delivered and are up and running. By procuring centrally we have also ensured savings of around £3.7 billion (4.13 billion Euros). This has freed up extra budget for personalising systems at a local level, ensuring that both patients and healthcare practitioners are getting a service which is of real benefit to them.

Indeed, local, professional ownership is crucial, which is why the NHS' Chief Executive David Nicholson commissioned the NPFIT Local Ownership Plan (NLOP). This means that Strategic Health Authorities (SHAs) define their own priorities and the IT support they require, helping them to deliver improved services to patients.

NPFIT involved clinicians throughout the country from the early stages of the programme, with a range of practitioners advising on all of our systems, from GPs and nurses to midwives and allied healthcare professionals. These representatives, known as National Clinical Leads, help to coordinate local input, ensuring that the views of those working most closely with the programme are properly represented.

Electronic patient records and PACS have created a workable, efficient system which is shared and understood by all of its users. Doctors, nurses and other healthcare professionals can access vital information when we need it which, ultimately, leads to smoother inter-professional working and better patient care. Substantial achievements have already been made as part of the programme, with the NHS now an international leader in delivering universal coverage of digital X-rays, and it is vital that we build on these successes to deliver systems which further support an already thriving health service and give our patients the care they deserve.

# Encouraging and promoting health online with the 2010 eHealth programme



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CHATZIMARKAKIS**

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**European Commissions e-Health action plan will surely improve quality, access and efficacy of European health care. Nevertheless special attention should be paid to data security.**

**S**tating that the Internet is more and more influencing our life is rather a common thing to say. But it is true. And we haven't so far tapped its full potential. But one area where the internet can be indeed beneficial is the inadequate and bureaucratic health systems in the EU. Putting health care work flow online will improve the quality of care and is going to boost innovation as well as the effectiveness of the services offered.

Just a case in point: according to the German Ministry of Health, inadequate work flow is causing supplementary daily costs of around 14 million Euro. Even worse is that 6.000 patients die each year because of failures due to prescription and administration of drugs. Pursuant to EU-statistics between 8% and 12% of patients admitted to EU hospitals to encounter adverse effects. This amounts 6.7 to 15 million hospital inpatients. In addition, some 37 million primary care patients a year suffer adverse effects linked

directly to the treatment they have received. With e-Health such flaws could be drastically avoided because all medical staff involved in a case can directly access online in order to get vital information. E-Health also includes e.g. devices like cups that tell elderly patients suffering of dehydration that they have not taken the necessary amount of water. Very simple but very beneficial.

Improving health of consumers and patients is already high on the EU agenda. Currently, the European Parliament discusses the pharmaceutical package and patient's rights in relation to cross boarder health care. The latter could pass through Parliament by end of April. And now we have to turn to e-Health.

In my view the e-Health programme is not only good for cutting costs but also important for patients. With e-Health, patients could be involved actively in the health care work flow, could access decisions related to their own health rather than simply accepting doctor's judgment. The considerable discrepancy or non-compliance in knowledge between themselves and health professionals could be reduced.

E-Health services can also provide timely information tailored to persons in need. It also opens new possibilities for people who live in remote areas. By means of teleconsultations and telemonitoring they could get better care. On the European level health systems could compete with each other, costs will become transparent. Last but not least e-Health will also boost inno-

vation and create new jobs – especially regarding small business that are already substantial in this area.

One major problem, though, remains regarding data protection. If all sensible data about patients is stored centrally or on a single chip card and administrated and accessed via Internet, there is a danger of data leakage. European e-Health systems should be able to interconnect to each other. It is clear that a very broad array of persons will have access to confidential data. The bigger the circle of persons having this access, the bigger the danger of leakage.

This leakage might be caused by medical staff's negligence. More and more doctors just store data on portable devices. In July 2007 at the Nottingham University Hospital (UK) an USB stick containing unprotected confidential patient details was stolen. In June 2008, six laptop computers, containing the data of around 20,000 patients were also stolen from a London hospital.

It is evident that there is a huge danger of misuse with medical data. One problem is that stolen information could be traded on the black market. Employers that would like to spy on their staff can easily get those data if willing to. There is also a criminal dimension. People could be blackmailed if discovered of having a certain disease.

The European Union already has a very comprehensive legislation concerning data security. But we should do more to really establish a very tight

framework of data protection with e-Health. This would be a vital point making EU citizens to accept such a system. People want to know that their right to privacy is protected. And of course they want to be sure that their records are safely guarded. Ever since the European Commission put forward its action plan in 2004, stakeholders involved have been working to establish the basis for a European e-Health system. But the question of how to secure patients data has, in my view, not been sufficiently dealt with.

The EU could not only establish a legal or administrative framework but also help developing technically e-Health. The European Institute of Technology could indeed engage in e-Health research. Some 2.4 billion Euro will be spent between 2008 and 2013 for the establishment of six Knowledge and Innovation Communities (KICs). One KIC is supposed to deal with research in information technology. It most probably will deal with IT and energy efficiency. In my opinion, it would be better if the EIT was engaged in aspects of e-Health. This area is certainly a “sleeping giant” in terms of the boost of economic growth. And on top of that: people will become healthier. Isn't this worth discussing?



# eHealth in Europe the contribution of ICT to the modernization of European health systems



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**I**n the definition and implementation of all its policies, the European Commission (EC) is committed to ensuring a high level of protection of public health. These policies support the Member States' pledge for a common set of values for European health systems: universality, access to good quality care, equity and solidarity. These pillars of action are all the more important to keep in mind in these challenging times of economic crisis.

Within this framework, the EC has a long tradition of contributing to the use of eHealth technologies (from Electronic Health Records to remote monitoring and telemedicine), recognizing their potential to bring health benefits to citizens and modernization to health systems.

In fact, we see these technologies as the backbone of the seamless information flow within Member States and across borders that is essential to save lives, increase patient safety and enable better healthcare provision.

There are many strong reasons that support this idea:

- medical science and technology for diagnosis, treatment and disease management are constantly evolving at an ever faster pace;
- both medical and social care are becoming more and more multidisciplinary team activities; at the same time, there is a world-wide shortage of health professionals;
- health and social systems provide a continuum of services, a true challenge for coordination and continuity of care, and, as we move towards more patient-

centric healthcare systems, individuals are themselves also called on to take more active roles in healthcare;

- health information can be very complex, both in nature and in form, and the citizen is often asked to navigate it, and the complexity of the health system, while sick, vulnerable or facing some age-related disability;
- citizens have growing expectations for access to and quality of healthcare, including across borders and about ICT support (in the EU, the generation born around 1975 is the last one to know what life was without a personal computer, without a mobile phone, without the internet); in parallel, substantial inequalities subsist between countries, regions and citizens;
- given the slow demographic growth and the ageing of European societies (a part of larger societal changes that also includes more people living alone for longer periods and looser, more complex family and social support networks), the importance of higher availability of a healthy work force grows;
- there is increasing concern regarding the long-term financial sustainability of the social security and health systems demanding innovative financing but also quality and performance monitoring.

This mounting potential and pressure for increased efficiency in the health sector is underlined by information, for which better support and communication tools are needed, both between the agents of care and with the patient.

As it stands, economies of scale exist for design and implementation of eHealth strategies and projects; they should be

promoted to develop better solutions, avoid market fragmentation, and fully profit from successful experiences, thus saving resources at European level.

Of course, with varying sophistication, eHealth tools are already being used in a variety of medical fields. However, to realise the potential of wider deployment, bold action is needed by Member States, who are responsible for the organisation and delivery of health services.

These obstacles include (i) creating the legal conditions for eHealth to be accepted and for the services rendered with such tools to be reimbursable, at national and cross-border level; (ii) thoroughly validating its use, like any other technology used in the health sector; and, (iii) crucially, recognizing that these services will only be widely used if they are trusted by both patients and healthcare professionals.

The tools must be designed for the real-world use, needs, and problems of citizens and health professionals otherwise, they will not deliver their full value. Doctors, nurses and patients should be called upon to give input to the design and implementation of new processes and equipment, for improvement (instead of resistance) to occur. Regardless of the apparent technological soundness of proposed solutions, early user involvement in project definition, professional training, and management of change are key factors for effective buy-in and for real progress to be made. Ultimately, this will be the way to make the best possible use of the time of skilled health professionals, for the purpose of increasing the quality and time of life of the patients.

The realization of the potential of eHealth for the benefit of citizens and of the healthcare sector calls for the participation and empowerment of both patients and health professionals.

# Introducing Information and Communication technologies into medicine: New challenges for research and development



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The marriage of Information and Communication Technologies (ICT) with an information intensive sector like healthcare has a clear potential for huge societal and economic benefits. The tough demands of medicine and healthcare professionals for reliability, security, correctness and relevance of easily accessible information make this marriage very challenging for the ICT community.

ICT has been dealing with this challenge for several decades with mixed success. On one hand, imaging and other minimally invasive diagnostic tools together with the use of ICT in primary care have progressed very well. On the other hand, a comprehensive use of electronic health records and telemedicine services for improved disease management, continuity of care, safety and ultimately patient centred healthcare as oppose to disease (organ) and hospital centred healthcare has still some way to go.

The prospects for new innovative systems and services in healthcare based on new technologies are very promising. Before we describe the research frontiers of ICT for Health and the EU Agenda in this domain, let us mention that the political, industrial and legal dimensions are very important for the «offsprings» of this marriage to reach adulthood. In other words, large scale eHealth deployment cannot be covered by the R&D programs and needs

additional commitment of the relevant stakeholders and another type of instruments than research projects and pilot funds.

Concrete steps for such commitments are highlighted in recent European Commission policy documents such as eHealth Action plan<sup>1</sup>, Recommendation for cross-border interoperability of electronic health records<sup>2</sup> and Communication on telemedicine<sup>3</sup>.

**Some examples of interesting scenarios** The digitisation of healthcare and simple ICT connectivity is a necessary step that Member States and their regions need to invest in, even if this step is currently neither sufficient nor exciting to be part of the concrete benefits to patients.

The new and exciting things will unfold once people have become interactive parts of such health information networks.

Healthcare today is like travelling in the 10th century in Europe. Back then, travellers relied on experts to guide them through difficult stages (such as mountain ranges and river crossings). Today, an infrastructure (roads, vehicles) and infostructure (signs, maps and GPS) as well as many other services are available to assist both professional and leisure drivers. Translating the analogy to healthcare, we could also invest in an EU-wide (global) intelligent infrastructure and infostructure to help both health professionals and patients navigate easily through the «health space».

For example, we can do much more to provide physicians with timely access to relevant information and assist them in training and management of latest research findings through interoperable and secure electronic health records. This goal has been recently put on the highest agenda in the US by the Obama administration.

Provision of personalised guidance to patients when needed could fundamentally improve illness prevention and chronic disease management and help patients deal better with their condition and any associated risks. Personal health wearable or portable systems based on new generation sensors, including contactless sensors, can measure vital signs and health status non-invasively, and such systems could thus be used to intervene at an early stage to avoid disabling diseases symptoms.

Another emerging technology which is of great interest is that of nanotechnology particles that are able to transmit information and report on the health status from within the body. Such particles can also be designed to either repair damaged tissues or attack emerging tumours, and combined with the new imaging techniques this will enable us in the future to see and treat and/or cure diseases before they can be detected using current diagnostic tests.

Patient specific models of organs and simulators of disease that integrate knowledge from different biological levels (molecule, cell, tissue, organ, organism) will guide us in developing

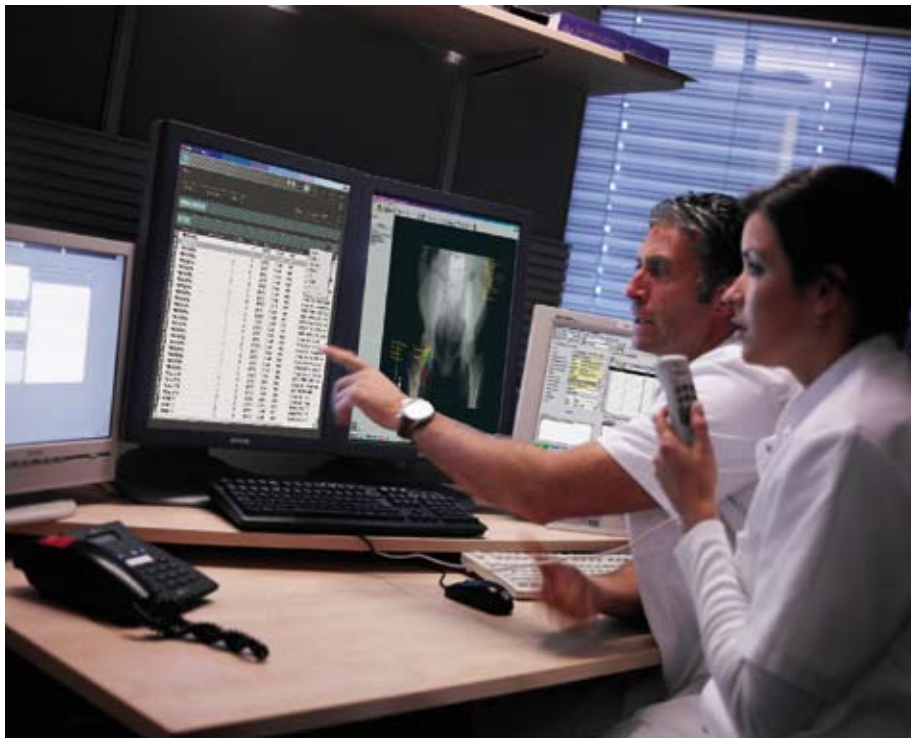
<sup>1</sup> COM(2004) 356 final, 30.4.2004

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52004DC0356:EN:NOT>

<sup>2</sup> COM(2008) 412 final, 2.7.2008 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008H0594:EN:NOT>

<sup>3</sup> COM(2008)689 final 4.11.2008

[http://ec.europa.eu/information\\_society/activities/health/policy/telemedicine/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/policy/telemedicine/index_en.htm)



more effective and safer treatments and therapies by testing the effects «in silico».

## EU Agenda in ICT for Health R&D

European Commission (EC) Research and Development (R&D) programmes have been supporting ICT for Health for the last 20 years, resulting in over 500 projects worth more than € 1 billion. Currently, projects worth over € 200 Mil are supported by EC<sup>4</sup>. The R&D activities of EC can be summarized in 3 Phases:

*Phase 1: Tools for health professionals, connectivity of health delivery system ('90-'99).*

Projects during the 90s focused mainly on the development of specific tools for health professionals such as decision support systems and electronic health records. It centered mainly on digitization and connectivity of all the points of care of a health delivery system at regional and national levels (hospitals,

primary care centers, labs, pharmacies, payers, authorities). The overall aim was to enable fast access to vital information and sharing of information among health professionals to improve access, quality, and efficiency of care. Examples of such health information networks exist<sup>5</sup> and have been shown to deliver concrete benefits to quality of care and even cost benefits for the strained health delivery systems. Europe is a leader in deployment of such health information networks and usage of ICT in primary care. Large scale pilot such as epSOS<sup>6</sup> which is trying to link the national and regional information networks across Europe are also supported by the Commission.

<sup>4</sup> [http://ec.europa.eu/information\\_society/activities/health/research/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/research/index_en.htm)

<sup>5</sup> [www.epractice.eu](http://www.epractice.eu), [www.good-ehealth.org](http://www.good-ehealth.org), [www.ehealth-impact.org](http://www.ehealth-impact.org)

<sup>6</sup> [www.epsos.org](http://www.epsos.org)

<sup>7</sup> [http://ec.europa.eu/information\\_society/activities/health/research/fp7phs/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/research/fp7phs/index_en.htm)

<sup>8</sup> [http://ec.europa.eu/information\\_society/activities/health/cip\\_ict\\_psp/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/cip_ict_psp/index_en.htm)

<sup>9</sup> <http://bioinfomed.isciii.es>, [www.symbiomatics.org](http://www.symbiomatics.org),

<sup>10</sup> [http://ec.europa.eu/information\\_society/activities/health/research/fp7vph/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/research/fp7vph/index_en.htm)

*Phase 2: Tools for patients: Improving Prevention and Personalization ('99 – today).*

The activities of the last 10 years have focused on an intelligent patient-centered environment supporting personalised healthcare. Wearable and portable personal health systems<sup>7</sup> have been developed in order to provide information to patients on health promotion and disease prevention, for (home) health monitoring and for chronic disease management. Smaller scale studies have shown clear benefits in areas such as teleradiology and for chronic disease management. For the latter, European Commission is currently planning to support large scale deployment pilots through its Competitive and Innovation Programme<sup>8</sup>.

*Phase 3: ICT for predictive medicine - Towards Virtual Physiological Human ('01- today)*

The synergy between medical informatics, bioinformatics and neuroinformatics (Biomedical Informatics) and its potential impact on medicine has been recognised and promoted by EC since 2001<sup>9</sup>. The International Physiome project provided the basis for launching a new initiative – **Virtual Physiological Human**<sup>10</sup> which was initiated in the EU in 2005. Within the initiative, patient specific models are developed in order to achieve safer medical operations, development of personalised treatments and safer drugs. First demonstrators are already available and VPH is gathering interest from the global research community for joint projects. Ultimately, VPH is intended to constitute a global «scaffold» of medical knowledge and a «toolbox» for researchers in the field.

## Conclusions

New developments in ICT will greatly impact on how medicine is delivered, how new knowledge discovered and disseminated and how people will manage their conditions. In return, medical and life science challenges will drive advances in ICT. For example, the new petascale supercomputer built in Japan is inspired by the problems of simulating virtual human heart.

In order for the many current and future research results to result in concrete innovations and benefits, Europe and its Member states need to think in terms of new mechanisms and instruments to foster innovation and deployment than relying on focused research projects and pilots. Political commitments, user driven deployments and a clearer legal framework are necessary and urgent steps before benefits can be seen on a large scale. The prevailing «pilot mentality» in eHealth has resulted in thousands of small scale pilots with uncertain future. Current policy developments driven by EC in cooperation with Member States provide a good momentum to progress faster towards the commonly shared goals. It is my personal bet that all patients in EU will enjoy clear and measurable benefits of eHealth, and that ICT will be an integral part of patient centered health delivery systems before we step on Mars (currently planned for 2030+).

We must never forget that **People Save People**. ICT and other healthcare technologies are tools that need proper organization and skills to deliver. In other words, technology can just improve the chances if applied correctly.

**eHealth as a component of recovery plan.** It has the potential to boost the economy and **foster innovation** by developing the third industrial pillar in healthcare (after pharma and

medical devices) as well as by bringing a new edge to the above mentioned traditional health industries. Recently ICT for Health has been at the center of attention for its potential to bring innovation, societal and economic impact. An irrational exuberance on the role and expectations of ICT for Health could be detrimental to the whole cause of providing real benefits to all patients in EU.

The three major factors determining health status of an individual or populations are

- i) effectiveness and quality of health services to take us out of trouble when needed,
- ii) endogenous determinants ( nature)
  - our genetic blueprint and predispositions,
- iii) exogenous determinants (nurture)
  - physical, social and environmental factors, e.g. what we eat, drink, breath etc

The thrust of ICT research has focused on the first two categories through medical informatics and bioinformatics research. Isn't it time to invest also in iii) and the big picture?





# Legal Basis of eHealth and Telemedicine



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in Brussels

## Introduction

**H**ealth care players such as hospitals, sickness funds, organisations of health care providers, producers of medical devices or medicinal products etc. are becoming European Healthcare players. At the same time, patients do not hesitate to consult physicians using the internet, are in touch for tele-monitoring with European health care players etc. These tendencies do imply more European rules on e-health and telemedicine. Below we make clear that the Commission has enacted many rules that have an important impact on the creation of an EU legal framework for e-health. However, some current legal questions are still unanswered at EU level and therefore, more European action is needed.

## European Legal Instruments Related to e-Health and Telemedicine

The Commission has enacted several directives which have an impact on the legal aspects of e-health. Firstly, the Privacy Directive contains several important principles that require compliance from e-health players that process personal data concerning health. Secondly, the Medical Device Directives are also of importance for the e-health and telemedicine sector, especially with regard to medical software that

is used in many e-health/telemedicine applications. Thirdly, e-health business may involve the conclusion of contracts. A contract related to e-health concluded between professionals and consumers (for example, a contract between a patient and a tele-expert) may be the subject of a contract at a distance, in this case the Directive on Distance Contracting is applicable. Fourthly, the Directive on the recognition of professional qualifications guarantees that persons having acquired their professional qualifications in a member state will have access to the same profession and be able to pursue it in another member state with the same rights as nationals unless the latter member state has laid down any non-discriminatory conditions of pursuit, provided that these are objectively justified and proportionate. Fifthly, the European Union seeks to create a single internal market characterised by open competition. Therefore, community competition rules prohibit undertakings from participating in anti-competitive activities, such as agreements to set prices or abuse of dominant position. The rules of European Competition Law can apply, for example, to electronic networks. Finally, healthcare players that utilise e-health may be considered to be providing information society services and may have to comply with the Directive related to services, the European Directive on Certain Legal Aspects of Information Society Services in the Internal Market (the so-called E-commerce Directive 2000/31/EC).

## Patient Rights and e-Health

The Commission has launched several initiatives and invested in several research programmes related to e-

health. In spite of these efforts, the Commission has observed a low take-up of telemedicine applications in real-life medicine. It is now identifying the barriers and trigger factors for greater use of e-health applications, and, on 4 November 2008, issued a Communication on Telemedicine for the Benefit of Patients, Healthcare Systems and Society. According to the Commission, Member States should have assessed and adapted their national regulations by the end of 2011 enabling wider access to telemedicine services. Issues such as accreditation, liability, reimbursement and privacy should be addressed.

In its recent proposal for a Directive on the application of patients' rights in cross-border health care, the Commission referred also (albeit rather briefly) to e-health. Article 16 of this proposal stipulates that the Commission shall adopt specific measures necessary for achieving the interoperability of information and communication technology systems in the healthcare field, applicable whenever member states decide to introduce them.

## Towards More European Guidance on the Reimbursement Criteria for Telemedicine and on Liability and Telemedicine

Despite the existing European rules and the policy attention, the existing European legal framework is not yet complete. The current European rules often remain too vague and some important legal issues still need a clear legal answer. Specific attention should be given to the need to enact European criteria on the reimbursement of e-health activities on the one hand and on the (no-fault) liability



issue on the other hand. The recent Commission Communication on Telemedicine for the Benefit of Patients, Health Care Systems and Society of 4 November 2008 states clearly that the lack of legal clarity with regard to, for example, reimbursement is a major challenge for telemedicine. In some Member States, for a medical act to be legally recognised as such, the presence of the patient and the health professional in the same place is required. This condition is not fulfilled in the case of telemedicine and one may wonder whether requiring this condition for each type of telemedicine is in conformity with the EU-Treaty.

The EU should also play a more important role with regard to the liability issue if e-health players are submitted to different liability

schemes. Some countries recently enacted so-called 'no-fault' legislation related to healthcare while many other countries do not use the no-fault standard with regard to the treatment of patients by healthcare professionals. Some no-fault legislation of Member States is only applicable if the damages have been caused in that Member State. Such legislation makes cross-border telemedicine more difficult and one may wonder whether such legislation would be in conformity with the EU-Treaty. To avoid problems with regard to the relation of telemedicine and no-fault legislation European guidance should be encouraged if the Commission wants to promote European telemedicine.

<sup>1</sup> Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

<sup>2</sup> Directive 2007/47/EC amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EEC concerning the placing of biocidal products on the market.

<sup>3</sup> Directive 97/7/EC on the protection of consumers in respect of distance contracts.

<sup>4</sup> Directive 2005/36/EC on the recognition of professional qualifications.

<sup>5</sup> Articles 81 and 82 EC Treaty.

<sup>6</sup> Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal market.

<sup>7</sup> European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, health-care systems and society', COM (2008) 689 final, 4 November 2008.

<sup>8</sup> European Commission, 'Proposal for a European Parliament and Council Directive on the application of patients' rights in cross-border health-care', COM (2008) 414 final, 2 July 2008.

# The impact of telemedicine on the medical development of remote regions



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In the mountainous Midi-Pyrénées Region, which is more spread out than Belgium, and home to 2,315,319 people, the Regional High-Speed Telemedicine and e-Health Network (Réseau Régional à Hauts Débits de Télé-médecine et e-Santé) interconnects the medical potential of public, private, hospital and personal assistance facilities, as well as all independent practitioners.

The topography of the terrain, together with the appropriation by the Health and Telemedicine organisms - defined as a new form of medical practice by the French law of 13th August 2004 concerning the 'Medical Insurance' system and confirmed by the 'Hospital, Patient, Health and Territories' law currently under debate in the French Parliament - allow us to assess the impact of Telemedicine on the development of remote regions.

Telemedicine in the Midi-Pyrénées has been developed within the context of an interlinked, well-graded and co-ordinated network. This regional structure, which takes the form of a Public Interest Group, seemed indispensable to the integration of Telemedicine into the Regional Health Organisation Scheme, whilst also embracing regional development objectives. The purpose is to ensure equal access to quality care for all, at every point in the regional territory.

As part of this Midi-Pyrénées Regional High-Speed Telemedicine and e-Health Network, a Telemedicine Department has been created at the teaching hospital (CHU) in Toulouse, which is necessary to the operation of this new medical practice, so as to ensure:

**on the one hand**, support activities such as the operational co-ordination of the Network (support through the process of change, training, setting up of infrastructures, design and implementation of projects, co-ordination and regulation of exchanges,

and organisational, research, innovation and prospective processes, etc.)

**on the other hand**, primary activities, such as multidisciplinary medical exchanges (tele-consultations, tele-staff, tele-training, tele-expertise, health education, and tele-monitoring). Such sessions are conducted via support activities carried out by the medical profession, as well as by all health professionals in the Midi-Pyrénées Region.

In 2008, out of 1,189 sessions and 816 hours of telemedicine, regional exchanges stood at 63.5%, national exchanges at 32%, DOM-TOM (French overseas departments and territories) exchanges at 3.4%, European exchanges at 0.2% and international exchanges outside of the European Union at 0.6%. Exchanges between a referring professional and a consulting professional give rise to a modification in the medical approach of the referring doctor in 51% of cases. This enables the maintenance of patient care within the patient's home area - whether the patient is hospitalized, living in a nursing home, or at home. Quality of treatment is also optimized, through the reduction of non-quality. For the purposes of information, costs avoided through tele-consultations within the context of neuro-surgical emergencies treated in 2005 in the Midi-Pyrénées region were estimated to amount to 931,597€. Tele-training and tele-consultations contribute to giving medical professionals (including those in the remotest locations) a level of knowledge which enables them - through sharing of competences - to acquire quality ongoing training without having to travel. This is a substantial achievement both in the face of the distances involved and in terms of weather conditions, which may temporarily interrupt travel. 3,525 health professionals have had the benefit of participating in these training courses, up to and including those in isolated areas. Fifteen (or even more) sites can be connected for simultaneous exchanges. All medical specialties are involved.

Feedback received has allowed us to remark that telemedicine offers increased value for

## the patient:

- Better access to healthcare and to the required level of expertise
- Access to a network of multidisciplinary com-

petences combining topographical realities and therapeutical necessities

- A privileged contact person: the local practitioner
- Facilitated patient information
- Information and education of the patient
- Quality and security of locally-based health-care / Quality of life

## the health professionals:

- Competences are put to work in a complementary way
- Loyalty-building among regional partnering teams, around the patient
- Concerted collegial decisions / Dissemination of best practice

Optimization of practices: diagnostic approach, therapeutical indications, patient transfer indications, shared monitoring of patients

Optimization of treatment quality

Reduction in the cost of non-quality/ investigations, treatments, non-justified transfers and optimized duration of hospitalization


- Reduction in the isolation of professionals/ mutual aid
- Ongoing training integrated into everyday practice, an important vector
- Bonus of increased confidence in relation to the patient
- Reinforced credibility / prospective vision of the accreditation process

Telemedicine associated with the personal medical file will be the essential means of reaching the remotest Region. Telemedicine brings patient and doctor closer together, whilst the personal medical file ensures the continuity and co-ordination of treatment. For example, this method is currently being used to set up home-based anti-coagulant treatment at a variety of remote points in the Midi-Pyrénées region, through the Anti-Coagulant Clinic at the teaching hospital (CHU) in Toulouse.

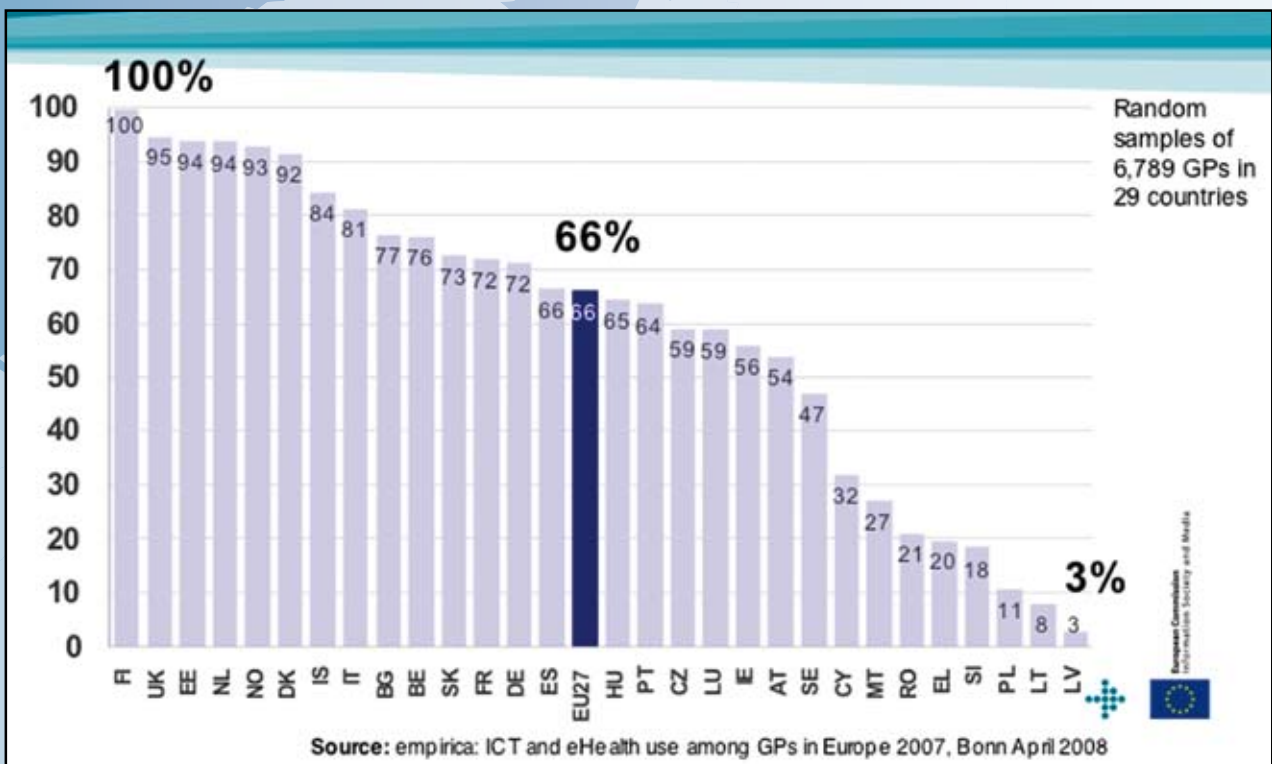
For today's citizens, the choice to live in a remote area partially depends on being able to guarantee a certain level of security in terms of health. Territorial development follows from this. Through telemedicine and e-Health, the global information society (whose progress is sometimes badly received) also brings about beneficial effects which contribute to bringing tomorrow's citizens even closer together.

## Electronic exchange of data for at least one purpose

Priorities in national eHealth Strategies	# of Countries	Examples
<b>Electronic Health Records</b> EHR, EPR, Medical Records, Patient Summary, Emergency Data Set	17	DMP - Dossier Médical Personnel (FR) BEHR - Basic Structure for the EHR (DK) NHS Care Records Service / Spine (UK), Patient summary (SE, FI) SumEHR (BE), eGP file (NL)
<b>Infrastructures &amp; Networks</b> Broadband communication networks and associated technology and basic services	12	MedCom – the Danish Healthcare Data Network (DK) Sjunet (SE) National Health Network (NO) National eHealth VPN (DE, AT)
<b>ePrescription</b> Management and implementation of ePrescribing	16	Apoteket (SE) ePrescription (DK, NL, SI) eRezept (DE)


  
<http://www.ehealth-era.org/>

## Electronic exchange of data for at least one purpose



# Public-Private Partnerships: an added value for online health



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GROSSETÊTE**

Member of the European  
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European People's Party  
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Online health in Europe should, to my mind, lean heavily on public-private partnerships – both for its development, and to offer the broadest possible set of advantages to patients. These public-private partnerships open up a new and promising alternative for research in pharmaceuticals, as well as in all other sectors of activity.

This co-operation - through large companies, small research centres, SMEs and universities - will allow them to make a reality of their research projects. Thanks to improved knowledge transfer within both universities and businesses, and the involvement of small businesses in European research, new projects in e-health will see the light of day.

Online health (or e-health) is a very broad sector which refers to Information and Communications Technologies (ICT) application right across the spectrum of functions operating in the health sector – from the doctor to the Hospital Administrator and from data processing to Social Security administrators, and patients. The objective is to improve the quality, access and effectiveness of healthcare for all.

As Ms Vassiliou, European Commissioner for Health, has reminded us, this is a matter of optimizing patient care and improving patient treatment. Still more important is the fact that, by reducing the potential for medical errors, lives can be saved. Although public-private partnerships need to be developed, we are also in need of a partnership between Health Ministers, technology suppliers, groups of patients and NGOs working

in the field of health – so that we can make the most of every aspect of online health potential in Europe.

Europe is planning huge developments in online health, through an i2010 European programme intended to stimulate both innovation and employment. The aim of this programme is offer IT systems that are both easy to use and interoperable for both patients and health professionals in Europe.

With regard to this, I am very proud of the recommendation adopted by the European Commission on cross-border interoperability of electronic health record systems, which refers to the necessity of providing adequate mechanisms in the field of public-private partnerships, as well as of using the approaches and achievements of pertinent initiatives within the sector as a foundation.

It is clear that we are going to have to be vigilant about the issue of data confidentiality. It is obvious that there is a significant danger of medical data being used ill-advisedly. In my opinion, this aspect is essential - and we must make sure its importance is recognised with the European Parliament.

For me, online health offers fabulous opportunities for patients.

I want to underline the major role I believe telemedicine and telemonitoring can play in offering extraordinary benefits to patients. Here again, public-private partnerships need to be developed.

Telemedicine encompasses a wide variety of services. The applications most often mentioned in peer evaluations are teleradiology, telepathology, teledermatology, teleconsultations, telemonitoring, telesurgery and teleophthalmology. Among other services that may be possibilities, we might also mention call centres and online information centres for patients, remote consultations or online check-ups, and videoconferencing between health professionals.

Telemonitoring could contribute to better allocation of healthcare resources – for example by reducing the number of hospital appointments, which improves the efficiency of healthcare systems.

Its beneficial effects on the quality of care received by patients, especially those suffering from chronic diseases are acknowledged. At a time when the population is aging and chronic disease is increasingly costly, the advantages related with its wider deployment may prove to be of vital importance. The European Commission referred to the use of telemonitoring in the event of heart failure, in a communication dated November 2008.

In Europe, more than six million people suffer from chronic heart failure. This condition has serious consequences - both in terms of quality of life for patients and in terms of mortality rates - and increases healthcare system costs considerably.

Telemonitoring for patients suffering from chronic heart failure offers them the advantage of closer monitoring of their state of health, as well as treatment from the earliest possible stage. Dyspnoea (difficulty in breathing) and/or rapid weight gain - which are determining parameters requiring daily monitoring – are often signs that the condition is worsening. Rapid adjustment of the treatment, on the basis of the data collected through monitoring, can enable stabilization of the patient's condition, rendering a consultation superfluous and avoiding (or shortening the duration of) hospitalizations.

These innovations should be encouraged, because for the moment there are only temporary projects. At European level, what is required in the future is the adoption of a consistent approach, and the establishment of a partnership bringing together patients, health professionals, care providers, funding bodies and the health sector - so as to guarantee the long-term sustainability of these services.

# Re-deploying eHealth in Europe



**Eric MAURINCOMME**

Vice President, Chief Strategy & Marketing Officer, Agfa HealthCare

The past years have seen a tremendous rise in the use of terms like “eHealth”, “Electronic Patient Record (EPR)” and “Electronic Medical Record (EMR)” in Europe. Their use has increasingly become synonymous with a vision of where healthcare is (or should be) going and as a benchmark for what countries and regions should be achieving in terms of overall improvements in the way patient care facilities operate.

eHealth is still a relatively new term in healthcare and is essentially about the integration of clinical and administrative patient information, across care facilities, hospitals, regions and, in some cases countries. The aim is to deliver improved information-based patient care, from general practitioners to specialists, through the availability of a unique “Electronic Health Record”. This record would follow the patient from birth to death and aims to improve the quality of care, reduce the risk of medical errors, enable faster physician communication and turn-around times, and so forth.

**So why argue we should be “re-deploying” eHealth?** The intent of this article is not to counter the concept or its ambitions, but perhaps to issue a small wake up call to some of the challenges we still face in Europe to achieve eHealth.

To do this we need to first look at the ingredients that make an effective eHealth solution: Administrative Information Systems, Clinical Information Systems (CIS) and a shared infrastructure (network, storage). Why these three? Simply because hospitals and physicians need to ensure they can adminis-

ter their patients (address, age, etc.), they need to be able to keep a record of their medical conditions (past diagnoses, allergies, medication, etc.) and, to be effective, be able to share this information with other treating health professionals who see the patient in different locations, for different reasons. Blend these three together, and you have a basis for a successful eHealth drive.

**So what is missing?** Recent figures from COCIR have revealed that, despite the fact that nearly 100% of European hospitals have administrative IT solutions (our first ingredient) to manage their organizational needs, a mere two out of three hospitals in Europe currently have a Clinical Information System (our second ingredient). More surprisingly, the figures reveal that roughly 80% of all hospitals in Europe still rely on paper as the main media to manage their clinical patient records. This figure is high because it also includes many facilities that already have some sort of CIS solution in place, but are not making effective use of them.

So we conclude that most hospitals in Europe today rely on IT for administrative support, but are managing their clinical information for those same patients separately. In short, too few are making effective, daily and consequent use of the full potential of IT solutions on this front.

From an infrastructure perspective, the third ingredient, there is progress across Europe. Today, comprehensive infrastructure facilities that can be shared by entire health communities are being rapidly deployed across the continent. The challenge is that infrastructure procurement is often a fragmented initiative, driven primarily by the local hospital or local physician needs. In order to really enable eHealth, such IT infrastructure would need to be shared across all healthcare constituencies: hospitals, private practices, General Practitioners, and so forth. Today, there is no central European approach to achieve this.

So in short, of the three ingredients we need to bake our eHealth cake from, one is esta-

blished, the second is in need of being established and the third ingredient often has various flavors which are not always complementary with the final result. Consequently, we still have some way to go before we can open for business.

**What needs to be done?** We know healthcare is under financial pressure and we understand that increased efficiency is a cornerstone to effectively deal with that challenge. Today, most healthcare professionals and industry agree that eHealth, if achieved, will not only have a positive effect on financial pressures over the medium and long term, but will additionally improve overall patient management, service and safety.

Steps now need to be taken on a policy level and by the industry to support standards and technologies that encourage an effective introduction of IT solutions to fill the gaps we are seeing. The stage has already been set by users and industry, with structures like IHE (Integrating the Healthcare Enterprise) and pan-European projects like ePSOS (European Patients - Smart Open Services). Such standards and technologies need to be continuously supported on a higher level to further drive their introduction that would, in turn, deliver cost efficiencies.

From a technological perspective, the industry challenge will be to deliver IT solutions that are interoperable and integratable with each other and with legacy solutions. Most hospitals, again for financial reasons, will introduce IT solutions to meet their varying needs in a piecemeal fashion. Industry and policy makers will need to focus on technologies which deliver on interoperability and integration, and not a collection of systems which will only push us further down the path of fragmentation, cost and workflow inefficiencies. Only in this manner will we be able to achieve a successful and affordable eHealth model.

<sup>1</sup> The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry



**Michael WILKS**

President, Standing  
Committee of European  
Doctors (CPME)

## eHealth

**I**nformation technology applied to healthcare – what is called “E-Health” – will bring revolutionary changes to patient care and to the doctor/patient relationship. CPME believes that E-Health must be used to assist and improve the doctor/patient relationship, rather than, as some would claim, replace it with “virtual” consultations. While in the future patients may have more contact with their doctors through remote technology, the central and essential relationship of trust between a doctor and a patient must remain. This is why the ethical and privacy aspects of systems will be so important.

How do we see technology improving patient care? In the USA politicians and advisers are struggling to decide how \$34 billion dollars of financial stimulus can best be spent on their healthcare system. In the EU, while we have a variety of provider systems, we do have a more co-ordinated approach. The rights of patients to move more freely from one member state to another for care, has focused attention on the interoperability of systems across borders. IT systems need to support flows of patient information, communication between doctors, and financial management, and systems that can do this will also improve the management of healthcare in their own member states.

While many patients and doctors are concerned about data security and privacy – and of course they should be – it is a fact that most of the well-publicised breaches of security and

losses of data have not been due to failures of systems, but of the humans using them. Memory sticks being lost, hard discs lost in the post, and laptops being left on buses are not faults of the systems, but of people being careless. Healthcare data should not be transferred to removable media, and should only be transferred through secure electronic pathways.

That said, patients need to know that what they tell their doctors is kept confidential, and will be shared only with their consent, and only with other healthcare professionals involved in their care. Current approaches to the security of sensitive information are expressed in legal terms – data protection, privacy and security. Inappropriate sharing of data is punishable through employment and/or criminal sanctions. A more constructive approach, and one far more familiar to doctors, is one based on ethics. This requires doctors to obtain informed consent for the collection, storing and sharing of data. When this information is used for the immediate care of a patient, doctors can usually assume that this consent is “implied”. But when data is shared with others, especially for purposes not directly associated with care, then much more specific and informed consent must be obtained. This approach is more likely to develop trust between patients and doctors than one based on sanctions.

The main successes in E-Health have been in teleradiology, where savings in time, and therefore improvements in the speed of reporting X-Rays, has transformed patient care. E-Prescribing has also simplified the prescribing, dispensing and safety of medication. Both are good examples of how technology can improve convenience, enhance and patient safety, and have been introduced with little

or no implications to confidentiality.

Increasingly, healthcare information can and will be used for a variety of other purposes. Chief among those is financial management, either the direct billing and/or reimbursement of costs, or for internal transfers of charges. These information flows will necessarily identify the condition for which the payment is being made, and these systems must be internally secure, and operated by people with an absolute legal duty of confidentiality. Data is the life-blood of health service planning, but information flows that help to improve the delivery of care do not need to include patient-identifiable information. Similarly, data used for research should not identify a patient without his or her specific consent. If this is not forthcoming, or cannot be obtained the information must be anonymised.

The future that E-Health promises are exciting, and will be based on a new use and purpose of the information available to both doctors and patients. Apart from data collected at the point of care, there are other sources of information that can be fed into the electronic record. These include clinical guidelines, protocols, drug warnings and patient information sheets. The future is one in which open access by patients to their (web-based) record will be commonplace, relevant and accessible information to improve self-help will be fed into the record, and warnings and electronic contacts between patients and doctors will be used to alert both to measurable changes in a patient’s condition. These changes will be acceptable to doctors and patients alike only if they are secure.

# Conditions governing cover by eHealth insurers



**Alain COHEUR**

Director of European  
Affairs-National Union  
of Socialist Mutual Health  
Funds - Belgium

**To many, telemedicine seems like a technology of the future. For the insurers - who will, sooner or later, be asked to finance it - either within the context of compulsory or complementary health insurance – this technology of the future will alter their relationship with the medical profession. In the same way, if we take a close look, the relationship between doctor and patient will also be altered, diminished – whence the importance of correctly identifying uncertainties, barriers - and the reasons which currently prevent telemedicine from really taking off.**

## **The complexity of health systems slows the spread of telemedicine**

“Why does such an innovative sector as health fail to prove more dynamic in adopting technology that is likely to offer solutions to some of the difficulties involved in the management of healthcare systems - such as how to achieve results that are as good or better - more cheaply ?” Within a context that is favourable, in which image and information superhighways have ushered in renewed interest in telemedicine, we are left with no choice but to accept that the applications are struggling to reach the stage of mass distribution.

### **1. An underestimation of the complexity of the operation of health**

**systems** The market potential for telemedicine applications seems very broad, but these are divided into sectors for which various commercial activities are necessary. The fact that assessment procedures for telemedicine applications are centred on technological and commercial considerations, rather than on analysis of the needs of populations and health professionals and the benefits that could be drawn from this, goes some way to explaining the failure of telemedicine to make significant inroads.

Research and development in this cutting-edge field demands heavy investment in return for a uncertain financial rewards. This is why we are seeing industrialists rapidly backing out, as soon as neither health structures nor financial backers are putting the development of experimental applications onto the market.

In the same way, public authorities will only agree to finance the development of applications if they offer both a solution to a major public health problem and improved transparency of the activities of the health system.

The problem of medical-economic assessment is the result of the still-experimental character of telemedicine applications, which makes the implementation of large-scale cost/effectiveness and cost/benefit analyses difficult. All real live trials being a delicate matter, these applications are difficult to fit into medical and healthcare practice precisely because of the existing organisational routines.

**2. The absence of a regulatory framework and specific financing** results in a great deal of confusion. There are several barriers to the development of telemedicine. Many diagnostic medical acts do necessitate the physical presence of the patient, either for clinical examination or for complementary feedback

of patient complaints in the light of the technical indications observed. A further barrier is the difficulty of reimbursement of the ‘telematic act’ itself. The reimbursement of a remote diagnostic medical act is a question that preoccupies the parties involved in the reimbursement process. The financing of a medical act is not just conditional upon its recognition, reimbursement is based on the physical presence of the patient – yet in telemedicine, this act takes place without any physical contact, even in the absence of the patient.

It is therefore necessary to prepare the remuneration modalities of these acts, in accordance with clear, simple rules (codification of acts, types of acts funded by health insurance, evidence of exchanges of medical information, specific system for hospitals per telemedicine act).

In order to finance networks of professionals, it is necessary to rapidly make sure they operate within those structures which will be the main beneficiaries in macro-economic terms – French Health Insurance Organisations, complementary cover insurers, and the state.

### **3. Remuneration of the medical act**

Several different situations arise: the doctors involved consist of a general practitioner and a specialist, both specialists in different disciplines or both specialists in the same discipline. However, diagnoses via telemedicine should be limited to the transmission of technical medical parameters (records of clinical biology, medical imagery, vital signs, etc.) - and not based solely on the description of symptoms. In this way, we would achieve a maximum level of medical safety for the patient. The act does rest on objective medical data, the first of which results from a clinical examination of the person.

To avoid any drift, and the multiplication of unnecessary acts of tele-expertise, it would doubtless fall to the



French Health Insurance Organisations to define a 'maximum' level of requests for complementary opinions, or to draw up rules for a posteriori checks on the real necessity of these requests for complementary opinions with reference to the normal competence of a diligent professional concerned by questions of quality and assessment of his or her practice.

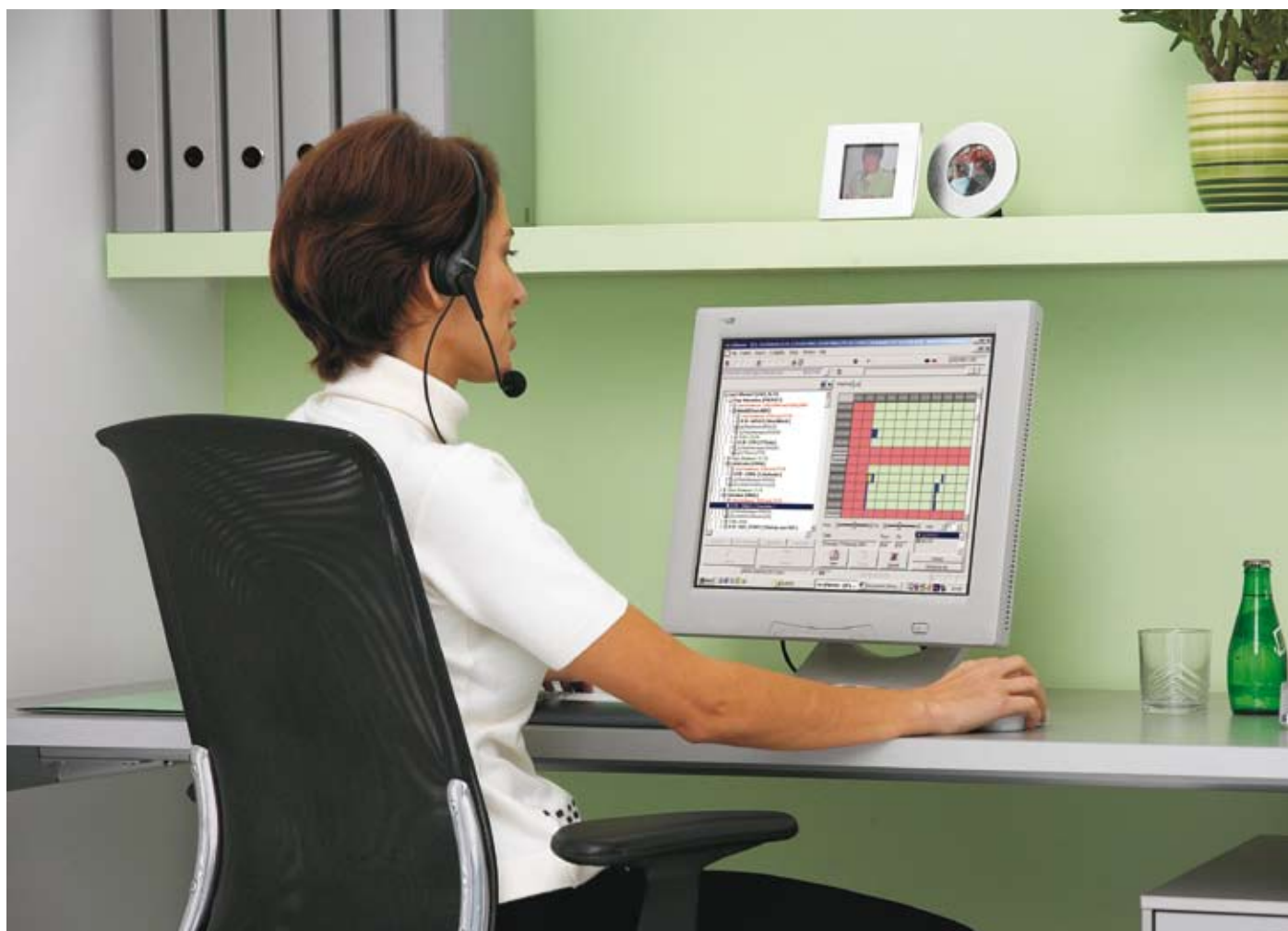
#### 4. Clear contractual relationships:

Independently of this inscription of telemedicine acts into the nomenclature, collaboration between doctors must be formalised in a contract clearly defining their respective responsibilities. The tele-expertise contract should

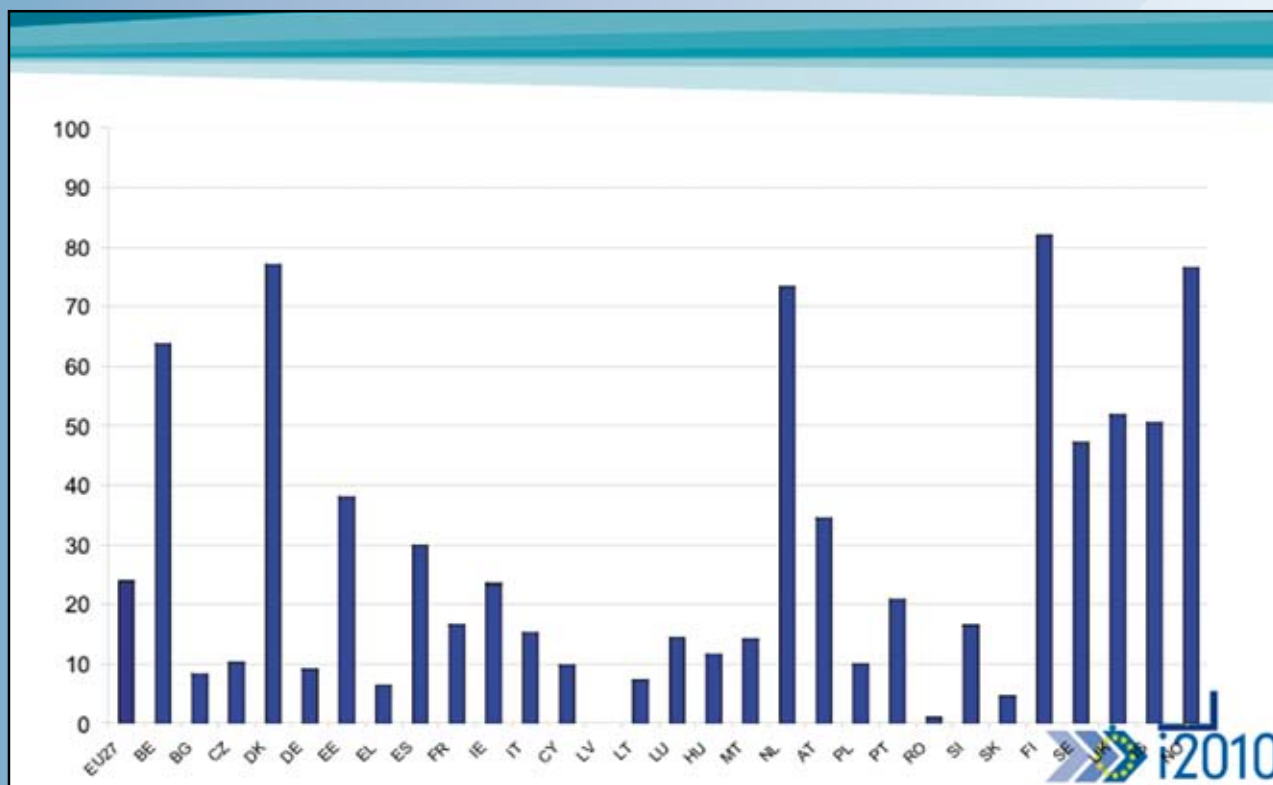
provide for doctors to send regular reports on examinations they have carried out to each doctor having requested an opinion. In return, the referring professional should pay the consulting professional the amount of acts carried out in accordance with the nomenclature in force, less the amount of actual expenses they have incurred for the management of samples, administrative documents and transmissions.

The number of requests for expertise should not exceed a given limit, to avoid any tele-expertise function creep and to avoid the creation of 'medical' structures which would be no more than reception sites for, for example, x-ray images.

**5. Investment by the public authorities** It goes without saying that without financial compensation, neither public hospitals, private establishments nor doctors in private practice are currently able to provide the necessary investment in terms of personnel and equipment required by the implementation of a tele-expertise system and the time spent on carrying out diagnostic acts.



## Electronic exchange of data for at least one purpose



## Electronic exchange of patient data by purpose (selected countries)

	Lab results from laboratories	Admin data to reimbursers	Medical data to care providers / professionals	Admin data to other care providers	Prescription to pharmacies	Medical data cross border
EU27	39.8	15.1	10.3	9.7	6.3	0.7
BE	73.5	2.5	12.9	12.9	1.6	0.9
BG	5.3	9.7	3.4	5.8	2.4	1.0
DK	96.2	47.9	73.6	74.0	97.3	1.9
EE	39.3	5.3	1.3	1.3	0.7	0.0
NL	83.8	45.4	26.0	27.5	71.0	4.7
FI	90.0	7.6	54.8	20.8	0.4	0.4
SE	82.4	8.2	13.1	15.7	80.9	1.5
UK	84.9	43.2	26.5	31.5	5.1	0.4
NO	88.2	18.6	34.8	25.5	2.9	0.5

Source: empirica: ICT and eHealth use among GPs in Europe 2007, Bonn April 2008

# eHealth and quality of care: what contribution should the Haute Autorité de Santé (French National Health Board) make?



Professeur  
**Laurent DEGOS**  
Chair of the HAS Board  
(French National  
Authority for Health)

**I**n an ideal world, e-health improves the whole set of healthcare processes. It facilitates access to information (via, for example, electronic medical files) – and this information is high-quality. These tools are effective in helping professionals in their practice (they are user-friendly, they make knowledge bases available, etc.). They also enable professionals to routinely assess the quality of care provided, and they enable the system to grow its epidemiological data.

In terms of e-health, what does the HAS (Authority for Health) do, in terms of these different processes ?

Which levers should it be instrumental in actioning within the coming years, to bring the health system closer to this ideal world ?

Firstly, to facilitate access to quality information, the HAS has established a certification process for websites, highlighting compliance with best practice rules in terms of both editorial policy and transparency. Entrusted to the HON – Health On The Net - Foundation, it relies on compliance with the HONcode. An impact evaluation by HAS and HON has shown great improvement in the quality of websites having implemented this process.

The HAS has also drawn up a drug database quality charter. This charter approves those drug databases which undertake to respect certain processes in the constitution of information, and makes a variety of data about the medication shown in this chart available.

Secondly, in order to improve the professionals' toolkit, the HAS has defined a certification procedure for software to assist

in the prescription of ambulatory medicine, which uses a database of approved drugs. This voluntary step is intended to contribute to the improvement of quality and security of prescriptions -facilitating the work of the prescriber - and to prescribe treatment of equal quality at the best cost. The certification frame of reference, which essentially deals with the prescription of drugs, makes sure that this software permits prescription by international non-proprietary name, provides information about contra-indication alerts and interactions as well as, at the doctor's request, the principal medical-economic information about the drug.

Next stage: the drawing up of a reference framework for the certification of software designed to assist with hospital prescription, and which takes into account prescription issues that are specific to the hospital sector, by supporting initiatives for the establishment of message formats for prescription, dispensing, and administration. Moreover, ulterior versions of the certification should also include therapeutic strategy support: this is why the HAS is currently conducting a study on decision support systems. Secondly, in order to boost their accessibility both online and in computerized environments, the HAS has undertaken to encourage the computerization of its productions, and to create an electronic environment which will lend itself to effective mobilization of its works (indexing, etc.).

Thirdly, in order to contribute to the achievement of the integrated professional practice evaluation processes, the LAP certification specification includes the option of extracting data from prescriptions. The HAS has also organised feedback of information about events considered as medical risks in the accreditation process for doctors exercising a «high-risk» specialism or activity in a health care institution.

However, e-health can only really improve the said healthcare process if the parties involved, including the HAS, manage to

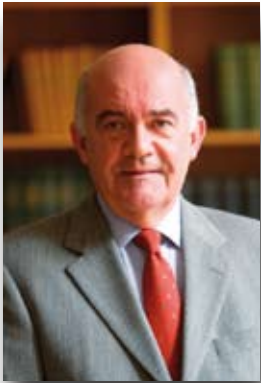
deal with the following issues better.

In synergy with the production of medical knowledge, the promotion of medical semantics is vital: promotion of formats which assist in both communication and storage of medical information, development of semantic resources which are lacking, development of knowledge management activities to update decision support systems, search engines, etc.

Next, the evaluation of the computerized tools should be mobilized. The evaluation of an intervention as complex as the introduction of a computerized tool calls for a thorough description both of the tools used and of the contexts in which it is used. Evaluation will improve the experimentation/evaluation loops, such as those which will be implemented within the context of the personal medical file in France. Up until now, the HAS has not addressed these issues in depth. It could offer its assistance, particularly in terms of process evaluations and treatment results. Evaluation of the potential risk resulting from the use of electronic tools is an important question: it is necessary to anticipate which recommendations are likely to avoid errors for professionals.

Lastly, the cultural and motivational aspects must move forward. The culture of the decision-makers on such matters as the computerization of productions, or semantics, must be developed. Because a certification constitutes a specification only if the publishers perceive a demand from their doctor clients, it is important to think about why doctors might buy certified software for prescription assistance. The definition of such motivations, is, it is true, filtered through efficient management of health IT, which certainly does take into account the objectives of those who are paying - as well as the need to reinforce what contribution to practice is being made by the tools professionals are using.

# Favouring the development of telemedicine, to respond to the issues of access to healthcare and quality of life for all



Docteur  
**Jacques LUCAS**  
Vice-President of the  
French National Medical  
Council

## **R**oselyne Bachelot-Narquin, French Minister of Health and Sport recently reminded us that

"e-health will, in the coming years, be called upon to transform medical practice - and even the way in which we conceive of our health system. Without weakening the link between patient and practitioner, health information systems facilitate both group and multi-disciplinary practice - sharing competences, accelerating exchanges, reinforcing patient safety and improving patient care. The effectiveness of these systems is proven. And their deployment is a priority."

These remarks echo the declaration made by the European Commission on 4th November 2008, which asked member states to integrate telemedicine into their national health strategies by 2010.

The 'Hospital, Health, Patients and Territories' law, currently under discussion before the French parliament, will include an article devoted to telemedicine: information systems working in the service of treatment and access to treatment - this is one of the issues addressed by the reform included in this law. In the pursuit of its objectives, the Conseil de l'Ordre des Médecins (CNOM - French National Medical

Council) published its recommendations in a Livre Blanc (White Paper) devoted to the development of telemedicine.

Telemedicine should be seen as a medical practice in its own right, even though it can be practiced remotely through Information and Communication Technologies (ICT). It also remains wholly subject to the principles of medical ethics and professional deontology. Telemedicine must contribute to the organisation of access to treatment where it is needed, and where the (general or specialist) facilities available in the immediate vicinity are lacking. With respect to this issue, the CNOM stresses that these new technologies are no more than additional tools in the service of medicine, which is itself in the service of patients.

In order to implement the deployment of telemedicine, this medical practice needs to be given a legal and economic foundation which recognises the possibility of remote diagnosis, of obtaining a specialist opinion, of taking and implementing a therapeutic decision, of setting up monitoring of the evolution of the medical condition of patients, of carrying out services and prescribing acts, treatments and drugs.

In the eyes of the Medical Council, this deployment must take place through validated protocols and co-operation agreements, both between establishments and between health professionals. Such agreements should enable telemedicine applications to be made available in line with both health needs, and the

territorial realities of 'real life'. A choice of 'administrated telemedicine' through the a priori definition of a nomenclature of recognised acts risks finding itself very quickly out of date. Indeed, new health or organisational needs are bound to appear, and technological progress is forever improving the quality of treatment, medical and socio-medical care.

The anticipated benefits of telemedicine take into account: improved access to treatment, prevention, maintenance at home, quality of care, and quality of life which would be to the credit of the enhanced organisation of this practice. From the point of view of public health and economic effects, the development of this form of medical practice should not be seen as generating additional costs, but as an investment for the benefit of all.

The CNOM therefore both accompanies and supports the development of telemedicine. It does so in the full awareness that the use of ICT must not affect the preservation of absolute confidentiality of personal medical data which may circulate as a result. This preservation (which is the expression of medical confidentiality applied to ICT in the field of health) renders absolutely necessary the constant co-operation of the Medical Council - with patient associations, with the Agence de Systèmes d'Information en Santé Partagé, created by the law, and with the Commission Nationale Informatique et Libertés (French Data Protection Authority).

# Telemedicine - an issue for practitioners



**Jean-François  
THÉBAUT**

President of the Syndicat National des Spécialistes des Maladies du Cœur et des Vaisseaux (French National Union of Specialists in Heart and Vascular Disease)

**T**elemedicine is not just about data transfer or technical parameters (implantable devices or telemonitoring), nor the transfer of personal medical data, nor yet the transfer of information and knowledge via the internet.

It can be broken down into a certain number of concepts that have become fairly precise, each very different from the others. What they share is that they are remote, and they use (New) Information and Communication Technologies (NICT).

In this way, they can be classified in line with a typology that is roughly shared by a great many analysts:

- **Tele-expertise** between doctors - either primary (interpretation of a remote examination such as telerradiology) or secondary (request for a second opinion, or virtual staff)
- **Teleconsultation:** the patient enters into remote contact with a doctor, either for a clinical, visual (dermatological) or paraclinical opinion (image, ECG, biomedical analysis, a specific interrogation made through the system)
- **Telemonitoring** of external vital parameters (activity, weight, BP, heart rate...) or **teletracking** of technical parameters collected by implantable devices (pacemaker, ICD) or not (teledialysis, Event ECG)
- Consultation of sharable or personal medical data: **the Personal Medical File (PMF)** which is at the heart of

the system - due to the obvious fact that in order to be pertinent, every act of telemedicine must be based on complete knowledge of the condition or pathology of the patient.

And to this, we must add:

- **Tele-assistance** by paramedical third parties, based on the Anglo-Saxon Disease Management (DM) model, as it has been adapted in France - for example in the French Health Insurance Organisations 'Sophia' coaching programme for Type 2 diabetics.
- Above all, without neglecting the irruption of the **internet** in knowledge and perception of disease by patients - whether this is through access to (Wikipedia type) encyclopaedical knowledge, through the transmission of information in real time (innovation, therapeutic, medical alert, epidemic, etc.) or even through **Web2.0**, which renders patients interactive amongst themselves - for better (forum) or worse (ratings sites..)
- And **Robotics**, which to date has been able to demonstrate the possibility of remotely acting on the patient in a physical way - to perform surgical acts, for example

Until the recent availability of broadband internet and the deployment of the information highway, each of these services or techniques was already feasible from 'point to point' through a classic switched telephone network: telemonitoring of old people, telephone platforms or call centres, and even the transfer of informative data (shared files) or techniques (ECG, for example) and even by fax (biomedical analysis - reports). The confidentiality, security, rapidity, reliability - and above all, the interoperability - of these exchanges was, of course, impossible.

The real revolution in NICT is first and foremost, to my mind, the ability to develop the interoperability of the various IT systems, which allows a 'convergent' interconnection of these different services and systems in record time, as well as the making available of information on a single IT platform. This ubiquitous availability offers responses to:

- the increasing complexity of medical competences
- the justified requirements of users for security and ever-greater effectiveness, even though knowledge and techniques are exploding
- the reduction of relative medical working time, at once secondary to medical demographic reduction (especially in France) and the expected reduction in working time of future doctors
- the increase in demand due to the explosion of chronic pathologies, corollary to the lengthening lifespan and the spectacular success of treatments for acute pathologies - the reduction by half of death through heart attacks in twenty years, for example.

This is therefore a major development issue for medical practice yet to come, which will call into question a certain number of habits - even if, in principle, IT doesn't add constraints but does increase stringency.

As an example, let's take the case of ethical requirements concerning the maintenance of the medical file: patient consent, integrity, confidentiality, availability, security, updating, accessibility. Each of these aspects can gain additional guarantees, through well-thought out and well-managed computerization. In terms of effectiveness and security, there is, for example, no comparison between the transfer of biomedical results by HPRIM standard



digital format and the (still far too common) fax.

In this way, the availability of personal information to the various actors is an obvious gauge of security - whether within the context of an emergency, treatment co-ordination, results interpretation or the DM's therapeutic education.

Last but not least, through their very essence these technologies enable traceability of interventions, and thus evaluation of the process.

The benefits - in terms of both security and quality seem obvious in themselves - yet there is no immediate medical-economic benefit. French leaders

of the years 2004-2007 had hoped to finance generalized PMF use through the savings made, and were sorely disappointed. These are extra services, rather than replacement services !

The diffusion of such technology will however be accompanied by additional organisational, regulatory, legal and ethical constraints, in view of the additional capacities of these interconnected networks:

- Patient consent and absolute respect for confidentiality
- Organisational change: Group medical work in a world that is highly individualist, and deployment of task delegation
- Modification of remuneration modes: the 'virtualisation' of NICT presents a real challenge to the traditional system of remunerating the act only where it is achieved within a unit of time and place
- Interoperability of different systems at the risk of creating a new 'Babelization of information', necessitating a real public policy
- Modification of responsibilities, with the appearance of 'technological trusted third parties' who share responsibility for the operation of the system.
- And above all, very significant investment at both collective and professional levels

This really is a revolution, in terms of modes of both practice and financing, and although the benefits may appear implicit, they are yet to be demonstrated - even though common sense leads us to believe that improved co-ordination in treatment and the transfer of information and skills can only result in quality, and a reduction in iatrogenesis, redundancy and pointlessness.



## epSOS

## EU-funded eHealth initiative to support medical assistance while travelling and living abroad



Fredrik LINDÉN

epSOS Project  
Coordinator

Travelling around the European Union is taken for granted, until something goes wrong. The Smart Open Services for European Patients project (epSOS) intends to remove linguistic, administrative and technical barriers within the EU, by making it easier for people to receive medical assistance based on their medical history, especially when they are away from their home.

### Patient summary and ePrescriptions

**P**atient summary and electronic prescriptions (ePrescriptions) are two key services that enable high quality medical care. Such health records are intended to provide health professionals with essential information on the medical and medication history of the patient. In many situations access to such information can save lives (for example in case of allergies to medications, chronic conditions and blood disorders).

The epSOS project is a step in addressing problems faced by doctors treating patients who seek health treatment when abroad. These problems include re-supplying essential medication that a patient has lost or forgotten, communicating medical situations to foreign-language doctors, diagnosing illness and prescribing proper medication with little knowledge of patient history.

Several Member States have implemented these services in their national healthcare systems and several others are about to do so. However, many of them cannot currently communicate with each other. These services will only be widely used if they are trusted by both patients and healthcare professionals. Appropriate data protection, system security and performance criteria need to be included in any cross border application.

### Objective

The objective of the epSOS project is to ensure that these national solutions can interoperate or with other words “talk to each other” so that the information can follow the patient. epSOS aims at enabling health professionals to access electronically the data of a patient from another country in their own language, using different technologies and systems. It will also make it possible for pharmacies to electronically process prescriptions from other Member States, so that patients travelling within the EU can obtain their essential medicine.

### The approach

The project follows a bottom-up approach; it builds on existing technical solutions, and develops a set of specifications to ensure the interoperability of solutions, including security and identification systems and performance criteria. There have been and are many other projects in the area that epSOS may collabo-

rate with and to reuse their findings such as STORK, EHIC/Netc@rds and HPROCard. Another important task is to Collaborate with Mandate403.

The project will examine the level of maturity and deployment of patient summaries and ePrescriptions in the participating countries, and explore legal questions and develop technical specifications covering all basic components for a secure use of personal health data. In a second phase, the project will define, test and validate these solutions in real-life situations.

The approach will form the basis for a longer term, pan-European approach to building service solutions that will be able to work with each other.

The project responds to the commitment of Member States and the European Commission to achieve full interoperability of eHealth services. This commitment, first mentioned in the eHealth action plan of 2004<sup>1</sup>, was reconfirmed in April 2007 at the Berlin eHealth 2007 conference, where the member states agreed on a common declaration which can be considered as the origin of the epSOS project. It will benefit from guidance provided by the Commission on how to make electronic health record systems work together.

### Participants

The Project Consortium consists of 27 beneficiaries representing ministries of health and national compe-



tence centres from 12 EU Member States (Austria, Czech Republic, Germany, Denmark, France, Greece, Italy, the Netherlands, Spain, Slovakia, Sweden and the UK), a research institute and an industry team of more than 30 companies.

The epSOS project has a total budget of over 23 million Euro for the next 3 years, 11 million of which is covered by the European Commission's Competitiveness and Innovation Programme, Programme to Support Policy (CIP-PSP).

### **Dissemination and awareness raising**

The project will work in close cooperation with the CALLIOPE network (Call for Interoperable eHealth services in Europe) to ensure that benefits can be shared with non-participant countries. CALLIOPE's activities will contribute to raise awareness and create consensus around the overall issue of interoperability of eHealth services.

### **Further information:**

<http://www.epsos.eu>  
[http://ec.europa.eu/information\\_society/ehealth/policy](http://ec.europa.eu/information_society/ehealth/policy)  
[www.calliope-network.eu](http://www.calliope-network.eu)

### **Authors:**

- Fredrik Lindén, epSOS Project Coordinator

<sup>1</sup> 2004 Communication on 'e-Health – making healthcare better for European citizens: An action plan for a European e-Health Area' - COM(2004) 356





# ICT – a strategic axis for the French Health Insurance Organisations



**Alain FOLLINET**  
CIO, CNAMTS

In its strategic project for the current and coming years, the *Caisse Nationale d'Assurance Maladie des Travailleurs Salariés* (CNAMTS, French Health Insurance Organisation for Employees) expresses its determination and ambition to really fulfil its role as a 'supportive insurer' within the health domain.

The corresponding plan of action is constructed around three focal points:

- the domain of risk management, to encourage best practice in the organisation and production of treatments, and to develop a policy of prevention, support and guidance of patients.
- the domain of service, to deliver information that is targeted and pertinent whilst simplifying relationships with sections of the public in contact with the Health Insurance Organisations
- the domain of efficiency, with the intention of producing the best service at the best cost

French Health Insurance Organisations consider Information and Communication Technologies to constitute a vital lever in attaining objectives, representing an opportunity to effect the transformation of its organisation, and guide its evolution.

The development of teleservices and the generalisation of internet usage

will facilitate co-ordination of the relationship between the various actors: insured persons, health professionals, employers, and Health Insurance Organisations.

Since 2007, deliberate action has allowed a bouquet of services to be made available through the AMELI website, which is one of the top five websites in France, with more than 4 million visitors per month.

200,000 health professionals have opened personal accounts, enabling them to access administrative information, the better to take the rights of their patients into consideration: declaration of the general practitioner and healthcare modalities.

A space that is totally secure, through the use of the *Carte Professionnel* and the *Carte Vitale*, which authorise access to information about the patient's medical history: reimbursement history, nature of medical examinations, stays in hospital or sickness leave – the consequence of which is to improve both the quality of dialogue with patients and the pertinence of prescriptions, by warning of the risks of drug contra-indications, or by avoiding redundant examinations.

The service is gradually becoming richer, to enable the drawing up of an interactive and completely dematerialized care protocol related to the treatment of heavy or chronic pathologies integrating medical reference frameworks produced by the Haute Autorité de Santé (Authority for Health). Such a dematerialized and secure process simplifies and optimizes the relationship between the

patient, his or her general practitioner and the medical examiner from the Health Insurance Organisations, in a significant way.

It is also intended to participate in the constitution of the Shared Medical File, which is to be set up within the next few years. These facilities, aimed at professionals, are consistent with the services offered to insured parties, 2.8 million of whom have an account open on [ameli.fr](http://ameli.fr), enabling them to find out the position of their reimbursement account at all times.

An information and prevention space in the various domains – pregnancy, dental health – will be offered to those insured persons who are interested.

The 'expecting a baby' section, for example, is designed in diary form. The information guide is updated every month. Examinations to be conducted, useful contacts, advice to be followed – pregnant women can keep track of the various medical events to be accomplished, from the first month to the birth.

It is possible to appreciate, through these examples, just how important the development of internet services is for the Health Insurance Organisations, because it allows a personalized service to be available 24/24 – which facilitates communication and co-ordination between the actors in the health system.

# RSI's preventive healthcare portal



**Philippe  
ULMANN**

Director of Health  
Policy, RSI

## **Towards better patient involvement in managing their own health: RSI's (National Healthcare Insurance for the self-employed) personal on-line preventive healthcare record**

**A**t a time where creating a European on-line healthcare space is one of the European Union's "seven eEurope action plan priorities", the RSI – the French national healthcare insurance scheme for some 3.5 million independent business leaders, craftsmen, retailers and the self-employed, both active and retired, and other beneficiaries - is improving its services by offering all its beneficiaries a personal on-line space dedicated to preventive healthcare, My Preventive Healthcare (Ma prévention santé).

As a national healthcare insurance scheme, RSI's mission is to promote healthcare, vaccinations and to screen for diseases. In order to provide services responding to its beneficiaries' needs, expectations and practises, RSI conducted a survey in July 2008, the results of which helped to focus the scheme's activities in these areas: 89% of RSI members think preventive healthcare is highly important, 8 out of 10 insured with RSI have internet access and of these, 64% use it almost everyday<sup>1</sup>. With this in mind, and the numerous expectations expressed by members

in terms of information and prevention campaigns, RSI at the end of 2008 standardized access to a prevention portal for all its beneficiaries in France.

This new service provides each individual insured and other RSI beneficiaries with a personal on-line healthcare record which includes vaccinations, tests and screenings recommended due to age, profession and, possibly, state of health. For example, a mother's personal on-line record will allow her to directly track her own medical examinations as well as those of her children. This personal file indicates different statuses following each test: action completed, action not completed, action recommended. In addition to postal reminders being sent for all tests recommended, the portal can keep track of all invitations for tests received by the patient. As part of a trial launched at the beginning of 2009, some individuals, such as those with type 2 diabetes, can now access a specific page containing all of their personal information with regard to examinations and consultations recommended so that they can monitor their condition. Everyone insured through RSI can check that they are up-to-date with prescribed tests from any location and at any time, with a view to taking responsibility for the illness. The personal healthcare record is secure: a log-in is created during the first visit providing each RSI member with a confidential password, which is sent by mail for maximum security.

In addition to the secure area of the portal, RSI has also made full preventive recommendations available to support its members and other beneficiaries in managing their

health. These include: dental care, nutrition, monitoring pregnancy and young children, vaccinations and stopping smoking, as well as preventing work-related diseases which are specific to the self-employed. Regularly updated, this area of the portal is also dedicated to relaying RSI's prevention campaigns, different healthcare insurance activities such as the flu vaccination campaign or major national prevention campaigns such as cancer screenings.

Remodelling administration services, which is a priority for national healthcare insurance schemes and for the State, enable customer service, which is at the heart of RSI's action plan, to be improved, cette phrase n'est pas très claire. The objective is to encourage on-line contact with the insurance provider, in addition to physical intervention, in order to facilitate procedures whatever the given situation. In addition to the information it provides, My Preventive Healthcare is a great direct tool which supports individuals in becoming more involved in their own healthcare. RSI is particularly attentive to the need to control Social Security's expenditure in the case of the self-employed for whom any health problem can have an immediate impact on professional activity

<sup>1</sup> LH2 study for the RSI "Enquête prévention santé auprès des assurés du RSI", July 2008.

# Progressive development of the European Card for health professionals



**Patrick FORTUIT**

Group Coordinator,  
HPRO Card

**H**PRO card project is based on the European directive 2005/36/EC relative to the recognition of professional qualifications. This directive mentions the necessity for a European card for health professionals.

The main objectives of the card will be to facilitate the free movement of health professionals in Europe while protecting patients from the small number of professionals that could be subject to severe disciplinary sanctions. In the future, the card could have other possible applications such as validation of continuing education, access to medical records ...

The health professional European card will show two sides: one side is national, solely designed by competent authorities in line with local laws, the other harmonized side is European and clearly states the contact details of the competent authorities of the country of origin.

Progressively, in function of the evolution of technology in the various member states the card will bear a microchip (that will be used as a key – with no data included inside). This chip will be used to connect to the data base of the competent authority of the country of origin of the health professional and will allow to know in real time if this professional is fit to practise or not (cf. example of architecture below). **There will not be a new European data base and the information will be constantly up to date.** More the European card will still hold all national functions and will

still follow the national legislation of the various member states.

In order to continue its work on the European card, a working group has been created in early 2007. This group is composed by members of each five health professions (Doctors, Pharmacists, Midwives, Nurses and Dentists). They do represent :

- European wide health professional associations
- Competent authorities from the five professions listed in the directive originating from different Member states, Candidate countries or from European Economic Area (EEA)

An agreement was reached by the HPRO Card working group in July 2007. This format was officially presented at the European Parliament during a special event in Brussels on October 17th 2007 in presence, in particular, of Mrs Bernadette Vergnaud and Evelyne Gebhardt, two MEPs.

The European side will be harmonized in all Member states. The name and address of the national competent authority will appear along with the European symbols. The card information will have to appear, at least, in the origin country language and in another language of the European Union. The following information will be mentioned on the card

- The profession,
- The logo of the competent authority,
- The name and contact details of the competent authority,
- A signature area.

The national side only will be different in each country and for each profession following the national regulations. At least, the name, the ID of the health professional and a security hologram will appear on the card.

While working on the graphical part, the group answered a call for tenders from the European Commission on July 30th, 2007 related to the mobility of profes-

sionals in the EU. In late February 2008 the European Commission has decided to give a grant of almost 300 000 euro to the group in order :

- To identify competent authorities of the health professional listed in the directive in each of the 27 Member states;
- To study the current state of the art of health professional cards through all European Union;
- To study the implementation conditions of health professional's strong authentication;
- To study the interoperability of the different health professional's strong authentication system;
- To communicate on the European health professional card project (HPRO Card)

On 28 November 2008, the HPRO card working group organised a conference on the European card for health professionals in Paris. The conference was attended by more than 200 people from 24 different countries and was organised under the auspices of the French Presidency of the European Union. The main topics were:

- Opening the European area, recognition of professional qualifications and harmonisation of diplomas, development of professional practices are some of the progresses that encourage mobility of health professionals
- The obligation to inform patients and the necessary safety at all stages of care require a precise identification of practitioners and increased exchanges between Member states.

Using the results of this work, which will be communicated to the European commission, a political decision ought to be taken to improve the implementation of the European health professional card.

A certain number of competent authorities have already started to implement this card.

# SESAM-Vitale: an infrastructure operator for secured electronic data exchanges between Health Professionals, Patients and French Health Insurance Organisations



**Jacques de VARAX**

General Director of GIE SESAM-Vitale (Economic Interest Group)

## 260,000 Health Professional Users

The GIE SESAM-Vitale infrastructure has enabled secured electronic data exchange between Health Professionals and French health insurance organisations since 1998. Every year, it processes more than a billion electronic medical claim forms, and the service is renowned for its quality. 260,000 Health Professionals accept the 'Carte Vitale' from their patients, who thus benefit from faster and secure reimbursement (2 to 3 days on average, as against about 3 weeks for a paper medical claim form). An undeniable success for a national system whose far-reaching scope is unique in the world.

## New online services in the field of care co-ordination

The GIE SESAM-Vitale (Economic Interest Group) operates the infrastructure –consisting of the many compulsory and complementary French health insurance organisations - designing and implementing shared solutions for exchanges with Health Professionals. Its success in dematerializing the reimbursement process has encouraged founding members to open up the GIE SESAM-Vitale infrastructure to a set of online services accessible from the Health Professional's workstation. The GIE SESAM-Vitale

expertise - in terms of smartcards, workstations and portals - now finds itself naturally oriented towards trust infrastructures, secured by smartcards. Amongst these planned online service projects is the option for doctors to consult (via the patient's Carte Vitale) reimbursements made by the French health insurance organisations so as to avoid redundant acts and prevent drug interactions.

This desire to develop services and reinforce the security of transactions also guided the design of the second generation Carte Vitale, which is currently being rolled out. Featuring a photo of the insured person and with a modernized visual, the Carte Vitale 2 offers reinforced security, equivalent to the security standards of bank cards. Its memory capacity has been increased by a factor of more than eight in comparison with the first generation card, so that new information can now be stored on it (complementary health cover, designated general practitioner, organ donor status, etc.). The first smartcard to comply with the standards defined by the state for the electronic administration, the Carte Vitale 2 will allow the general practitioner access to the future Personal Medical File, with the patient's consent. This new card is expected to unveil all its potential in the course of the coming years.

## Sharing know-how with 15 other countries

Very soon after its creation, the GIE SESAM-Vitale sought to establish contact with other European countries. This is now a reality, mainly through

the NETC@RDS project, for whose coordination it is responsible. This is a European-scale interoperability project, whose objective is to set up shared resolutions with a view to the gradual deployment of the Electronic European Health Insurance Card, associated with online checking of the entitlement of the insured person. The result of the determination of certain actors in public health (the French health insurance organisations, representatives of Health Professionals, hospitals and local governments) NETC@RDS aims to offer a response to the mobility of insured persons within the European Union and other countries of the European Economic Area. 16 countries are participating in this project: Austria, the Czech Republic, Finland, France, Germany, Greece, Hungary, Italy, Lichtenstein, Norway, the Netherlands, Poland, Romania, Slovakia, Slovenia and Switzerland. These works present a powerful opportunity for exchanges of expertise and skills for all the countries concerned.

## 200 partner companies

The GIE SESAM-Vitale develops its know-how around its specific knowledge of the French health insurance organisation /Health Information Systems. Through its major calls for tenders and the publication of frames of reference in phase with the standards and norms, it seeks to work with the main economic actors present on this sector; publishers of health software, smartcard industries, service provider companies. In France almost 200 companies contribute, in a partnership role, to the GIE SESAM-Vitale infrastructure.

# The Care Revolution: for the massive use of new technologies in personal services



**Martin VIAL**  
Chief Executive Officer  
of the Europ Assistance  
Group

**W**hilst life expectancy in our European societies and all industrialized societies is constantly extended, the question for our generations is that of 'living better'.

This new qualitative perspective is at the heart of the Care Revolution, which combines increased demand for services with an increased need for tailoring of these services.

The issue of dependency is becoming a policy priority in all countries concerned - for demographic, economic and human reasons - about the aging of their populations.

Demographic aging poses the question of the financing of dependency, corollary to the anticipated passage of a section of the European population from young elderly (often still active) to old elderly, often synonymous with loss of autonomy.

The financial side of dependency is one of the major short and medium term economic challenges for our public health policies: more than 20 million Europeans aged 60 and over will be in a situation of 'dependency' within the next decade - at the very time when the health insurance budget, particularly in France, is profoundly unbalanced, and just as it is necessary to manage the

emergence of mass neurodegenerative disease - although both hospital and specialist facilities have far less capacity than is necessary.

In response to these issues, two potential pathways are worthy of consideration: firstly, maintenance at home, for elderly people, does represent a real alternative to traditional hospitalisation or placement in a specialist facility, and secondly, recourse to new technologies offers fantastic opportunities for securing this care, in which such 'assisters' as Europ Assistance can contribute their experience and know-how.

There is no doubt that the combination of these two paths does partially clear the way for durable and rational management of the problem of aging.

With regard to the care at home of elderly and dependent persons, we know that this is 1.5 to 2 times less expensive than a specialist structure - this ratio even reaching 1 to 4 in the United States, where the cost of hospitalisation is very high. In addition, this most often matches the wishes of individuals and their families. Lastly, it is considered by health professionals to be a means of stimulating the people concerned, both physically and mentally, resulting in the delay of entry into major dependency.

The large-scale deployment of care at home presupposes a massive effort in terms of training, selection and qualification of personnel involved. In the same way, the organisation and integration of services of various participants - medical personnel, daily home help, relations with third par-

ties, logistics, home ergonomics, installation of equipment, maintenance, remote monitoring, etc. - must be provided by professional companies in the sector, in order to optimize cost, quality and safety. This is precisely the role of assistance companies, which have, for decades now, exercised this function of integrating services.

Above all, recourse to new technologies will enable us to reinforce this essential link in the care chain. Recourse to such technologies as the intelligent home, home automation, robotics, internet and mobile telecommunications enable us to make remote assistance secure and to increase quality.

Europ Assistance is, for example, a partner of the European MonAMI programme, which consists of developing - with the help of academics, researchers, industrialists or telecom operators or service providers such as EDF - 'ambient intelligence' systems to design the home assistance services of the future.

These initiatives are one of the responses to the issues of aging and more generally to the challenge of the Care Revolution. Demography, urbanization, the evolution of our way of life, transformation of the family unit and local support, increase in health expenditure, the quest for well-being...the world is changing, and in this new world, personal service is set to become a major sector in responding to this challenge.

The integration of new technologies must become one of the main objectives of European programmes in the personal services sector.

# eHealth in Europe, Towards a conceptual revolution ?



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**T**he implementation of technologies and services favouring the support at home and autonomy of aging or aged people is stumbling over the difficulty of economic models.

In the field of health, all European and developed countries are locked into an economic control logic which focuses on health risks in terms of individual or group severity. The emergence of technologies and services which are connected appear currently as a second line “disease management” technique – coming after the drug regime, hospital, and biological response. Economic tools highlight the reality of a health production and productivity that would in all likelihood be useful to the development of e-health and gerontechnology, but the indicators are neither taken into account nor developed.

In the medical-social field, if the logic consists of presenting the usefulness of technology as a tool for autonomy, it is necessary to be able to demonstrate that it compensates for the deficiency or the disability situation, or that it prevents the loss of autonomy. Again, the efficiency indicators, which are essential justifying the costs - within a “case management” logic - are neither used nor developed.

Yet, assuming civilisation remains constant, we must imperatively find a solution for the development of these technologies, which the European population can no longer do without. The number of ‘care givers’ will, within the next few years, prove insufficient, and technology will be there - both to assist the ‘human help’ and in the organisation of care at home, within a context of a considerable reduction in the number of hospital beds available.

## **Faced with this dilemma, a return to concepts is called for.**

The first paradigm – a constant of French policy ever since the 1962 Laroque report, is that of support and maintenance at home. Beyond a strict application of this principle - agreed to by all but yet to be demonstrated – it seems prudent and realistic to consider not only the individual home in the ‘home’ field, but to also enlarge it to include the group home.

The second paradigm, founder of our western medical education, is based on the identification of diseases, their diagnosis, their pathophysiology and their treatment. In the real world, the symbol of disease and of medical power may well be in the process of being toppled in favour of a new concept which is added to the previous one and which surpasses it – the concept of functioning. The World Health Organisation (WHO), after having produced 10 International Classifications of Diseases (ICD) has just, in 2001, after a long debate, established the International Classification of Functioning

(ICF). This new classification reduces the health part of disability in favour of the environmental aspect. Historically, this is the second of the WHO after identification of Philip Wood’s sequences of the 1980s, connecting disease to disability. This ICF – fairly complex, yet universal in its mission – represents raw material that is rich in applications to be developed, particularly to evaluate those needs in the face of which the technologies may appear to be choice solutions. Governments were not wrong - even though many have misjudged the significance of this revolution - since about fifty countries in the World seem to have adopted this classification as the basis of laws and regulations to encourage taking care of people in disability situations. In France, this is the 2005 law on disability.

In practice, this may correspond to the highly concrete remark made to me recently by an older patient: “You know, Doctor, I am aware that I have 7 chronic diseases at the same time and that I am unable to recover; but what is most important to me is to be able to function and to maintain my position in society for as long as possible...” This hierarchical change, this emphasis on functioning as a dimension which can equally well adapt to mobility, communication, and even to end of life projects, can offer precious help for means allocation decisions and the promotion of technologies and services in the field of health and autonomy.

# No e-health without privacy: securing health information systems



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**E**-health, which defines the information communication technologies underpinning the health sector, offers an important opportunity to rationalize soaring health costs and improve the efficiency and the quality of the medical system in many ways. However, the shift to an online health system also comes with a number of challenges regarding medical security and privacy for data which is processed, archived and shared across such an extensive, complex and decentralized network.

The new standard ISO 27799:2008 Health informatics fulfils this need. It deals with the management of health information security and sheds some light on the best ways to protect it. The standard specifies a series of detailed controls required for the management of security for this type of information and provides guidelines in terms of best practices to follow in this area. By encouraging the adoption of this new international standard by health organizations and other health information handlers, public authorities will be able to guarantee a minimum level of security required by patient in Europe which is adapted to the specific conditions and circumstances of the health sector.

Risks in protecting the infrastructure of health information systems are daunting because not only are they related to elements which can be controlled, such as terminals and access by identified users in the hospital, but they are also related to

uncontrollable risks such as those relating to the connectivity between health organizations, access to patient records by general practitioners working outside the hospital or the processing of reports by relevant third parties. Moreover, the legislator and public authority will likely want to ensure that preventive measures which guarantee proper protection patients and citizens records are in place before rolling out an e-health system.

The first step to take is to protect the information network of the hospital and its critical systems (servers, databases) from threats which could potentially be introduced by external elements and which the organisation is not responsible for conformity management.

The use of mobile end points is common practice in hospitals but mobility calls for the need to implement new tools and methods to secure and protect these end points.

Moreover, the multiplication of security and protection functions need to be managed and mastered by an IT team which resources are often limited or being reduced. Therefore a single solution for the protection of all items is a good way to reduce the costs.

Further, the management of risk coming from outside the organisation is necessary but not sufficient in the light of data loss, whether accidental or not, when the data loss originates from within the organisation. Hence for example, a USB key, memory card or other device should not enable the copying or distribution of patient data, even partially, by an unauthorized user.

These security policies are only applied effectively if they are audited in a system-

atic way. In the light of the vast number of terminals and devices connected or connectable to the hospital network, automation is an absolute necessity so as to adequately collect, correlate and report security incidents from which appropriate security measures will be taken to protect the critical network infrastructure.

By integrating tools to measure risks, network vulnerability and access points early on at the network policy setting stage, health organisation can guarantee to reduce cost and ensure compliance of their system.

It remains for public authorities to ensure the interoperability of the information systems of e-health at national and international level so that the European patient can fully enjoy a e-health system which is efficient, cheap and above all in which he/she can trust that his/her personal data will be protected.

## About Symantec

Symantec is the world leader in providing solutions to help individuals and enterprises assure the security, availability, and integrity of their information. Headquartered in Cupertino, Calif., Symantec has operations in 40 countries. More information is available at [www.symantec.com](http://www.symantec.com).

# e-Health: the benefits are clear, but the risks entailed cannot be ignored



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The EU Agency ENISA [European Network and Information Security Agency] has released its report presenting potential Emerging and Future Risks [EFR] in a possible remote health monitoring and treatment scenario, having deployed its recently developed framework on identifying such risks for emerging and new applications and / or technologies [EFR Framework].

e-Health is the first scenario that has been developed and analyzed by a group of interdisciplinary experts. The report identifies 14 potential risks, and underlines the importance of a cautionary approach towards e-Health solutions.

## Why an e-Health scenario?

The European Commission describes e-Health as the application of information and communications technologies across the whole range of functions that affect the Health sector.

Health care expenditure represents an increasingly large proportion of national budgets. Officials are paying attention to e-Health because it can help to limit costs and improve productivity in areas such as billing and recordkeeping, reduce medical error, alleviate unnecessary care and achieve savings in B2B e-commerce relevant to the health care sector. Nevertheless, e-Health remains somewhat controversial.

In this context, a scenario on the issue of e-health and on remote health monitoring and treatment in particular, provided excellent grounds for this analysis, the results of which could contribute towards discussions at EU level and have direct policy relevance.

## A cautionary tale: overview, scope and limitations

The initial scenario idea was derived from a proposal made by Philips Research (Netherlands), based on their existing research. Their suggested set-up on remote health monitoring and treatment formed the basis for this EFR scenario (for the complete text of the scenario, please refer to Annex I of the full report).

Ralph is our hypothetical diabetic, who signed up for a remote health monitoring and treatment programme. He goes about his daily business wearing a special vest with biosensors, which keeps track of his vital signs. This ensures rapid reaction from the doctors, while his personal data may be literally flowing around, in order to enable this kind of service.

This scenario also highlights the many important and beneficial advantages that e-health solutions offer for citizens' safety and quality of life. But what exactly are the risks entailed? Here lay some reflections regarding security, privacy, data protection and legal ones, as well as in the social, political and ethical area.

A series of assumptions were made in the development and analysis of the scenario, and in the identification of risks. The risks are factored into these



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assumptions, which means if the assumptions are changed, the validity of identified risks has to be checked or additional risks may emerge.

The scenario **does not** and cannot cover all possible aspects of this very wide area of applications and therefore the results produced and the risks identified are by no means exhaustive and cannot be considered as recommendations. The analysis leaves room for additional risks to be identified, especially if more effort would be invested in detailed technical aspects of the involved IT-Systems.

It does, however, present some of the potential risks and challenges posed by emerging e-Health applications. As such, it contributes to the dialogue on e-Health implementations and can hopefully fuel further study on social, ethical and technical issues of e-Health applications.

## So which are the identified risks?

Now on to the identified risks in terms of remote health monitoring and treatment.

Based on the assets identified, the most important risks regarding these assets are subsequently drawn up and analysed in detail. This followed a broad risk assessment approach, as identified the recently developed ENISA EFR Framework. Some of the risks, identified in the report, affect only the individual,



while others could affect all users involved in the treatment and monitoring application (e.g. doctors, nurses, etc.). The risks, prioritised according to their impact and probability, include the following:

- Failure to comply with informed consent and data protection legislation
- Data breaches
- Repurposing or secondary use of data (mission creep)
- Equipment is damaged or stolen
- The system could malfunction and/or break down
- Inadequate provision or availability of medical services
- Human error in emergencies

- The patient or medical staff might misinterpret or delete data
- Users may not follow instructions
- Data surveillance and profiling

### ...and what are we trying to protect?

The assets, i.e. what are we trying to protect against the risks mentioned above include first and foremost the human life, human rights and social values, autonomy, the national health care system, mobility of citizens and their personal data. We also considered any devices, technologies, applications, processes, data or anything of value to

the individual, organisation or, indeed, society. Some assets are more valuable than others, of course, and those values may vary over time and/or according to the context.

### Find out more:

[http://enisa.europa.eu/pages/02\\_01\\_press\\_2009\\_03\\_20\\_being\\_diabetic\\_2011.html](http://enisa.europa.eu/pages/02_01_press_2009_03_20_being_diabetic_2011.html)

