

THE EUROPEAN FILES

The Telemedicine challenge in Europe



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SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE
EUROPEAN COORDINATION COMMITTEE OF THE RADIOLOGICAL,
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FOR A BETTER DEPLOYMENT
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- 1. **COCIR 5 key recommendations** toward policy makers.
- 2. **Glossary of terms** including all key definitions.
- 3. **Compilation of references studies**, focusing on:
 - > Chronic Obstructive Pulmonary Disease
 - > Diabetes
 - > Multiple Chronic Diseases
 - > Congestive Heart Failure

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EDITORIAL

Telemedicine - or medicine that is remotely administered – is not a particularly new idea. We were already talking about it in the very first framework programmes financed by the Commission, and it did give rise to several sample and pilot projects - which rapidly demonstrated their limitations, either for technical reasons (network performance and medical devices) or because of acceptance issues among health professionals. Twenty years on, telemedicine is making a big comeback, and seems to offer solutions that are credible which have been tested in real medical situations, to the main challenges facing our society, such as:

- the ageing of the population, which leads to an aggravation of chronic conditions (which represent about 70% of healthcare costs)
- the growing need for patients to become actors in monitoring their own health
- the necessity of controlling healthcare costs whilst maintaining high quality care
- the lack of availability of qualified personnel in certain branches of professional healthcare

To avoid readers becoming lost in a sea of complicated definitions, let's just say for sake of simplicity that telemedicine is remote medicine. Teleconsultation, teleradiology, tele-ophtalmology, telepsychiatry, telemonitoring (so useful in monitoring patients with chronic conditions) – are just particular forms of telemedicine (for precise definitions, please consult the article by COCIR on page 34 in this special issue). Some of these forms (teleradiology, for example) are more developed than others, and yet others are still subject to dispute among professionals (teledermatology, for example). In any case, it is clear that hundreds of pilot projects now exist in all member states – and that telemedicine is not yet entitled to be cited at national level in any one of them. The situation is evolving fast: the number of legal barriers is falling and professionals are increasingly interested - occasionally even becoming promoters.

The aim of this special edition is to help you take stock of the development of telemedicine, in all its diverse forms, and in a range of different environments. It is a collection of accounts and analyses by political and industrial decision-makers, patients and professional healthcare representatives, who seem to us to be those best-placed to communicate messages that are both brief and easily understandable to all audiences. It also aims to clarify the problems which are still holding back the development of telemedicine, and to outline a sketch of what the medicine of tomorrow might look like. Lastly, it demonstrates that only an effort on the part of all actors in medical care will be necessary in order for telemedicine to be accepted by all, and that it will be the role of the political decision-makers to ensure that inter-ministerial mechanisms are developed in such a way as to take into account its multidisciplinary nature.

Gérard Comyn

Vice-President CATEL,

(former Head of Unit 'ICT for Health', DGINF50, European Commission)



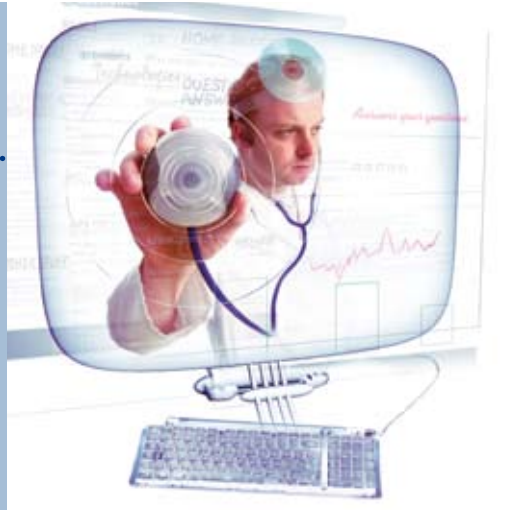
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Telemedicine and Infrastructures in Europe



Neelie KROES

Vice-President of the
EC and Commissioner
in charge of the Digital
Agenda for Europe

A new era for eHealth

Europe's eHealth sector is in line with the European Commission's vision for the future: knowledge-based, experience-driven, and continuing to grow in tough economic times.

The European Commission has long understood the potential of information and communication technologies (ICT) to have a positive impact on the lives of patients. Having invested over one billion euros in eHealth research over the past twenty years, we have many evidences of how bringing together ICT and health can save and improve people's lives. The time has now come to turn the research results into real large-scale benefits. Our finances demand it. Our citizens expect it. And we absolutely need to maintain the strength of this growing industry and the high-paying jobs it supports.

In March this year, the European Commission launched its strategy for smart, sustainable and inclusive growth known as «EUROPE 2020¹». At the heart of the strategy is an economy based on knowledge and innovation. It promotes a more resource efficient, competitive and greener environment and fosters high employment via economic, social and territorial cohesion.

The European Commission's new flagship initiative, the Digital Agenda² for Europe, builds on the foundations of EUROPE 2020. It represents an important step on the road to transforming eHealth from a research activity into an integral part of our daily lives leading to improved quality of care, reduced medical costs and increased independent living for the elderly and people with disabilities.

Importantly, the Digital Agenda for Europe acknowledges that if we want eHealth services to reach their full potential, we need to provide user friendly tools and services directly to our citizens and patients. It also recognises that to reach this point, we must pull down the legal and organisational barriers that are preventing progress and build up cooperation between the EU Member States.

We should not get stuck at the stage of delivering electronic patient records only. That is, no doubt, a huge challenge in itself. But we also need to work together to deliver tools for patients that prevent health problems and personalise the healthcare services they receive.

Patient Power

Our research has shown that a common element of many successful eHealth solutions is their capacity to bring into play what are arguably the two most undervalued resources of the healthcare sector: information and patients.

We already know that Europe's citizens have a thirst for knowledge when it comes to their health. According to a recent study, in 2009, 85% of online citizens in the United Kingdom, Germany, France, Italy and Spain turned to the internet and other technologies for health and prescription drug information².

Our vision is that eHealth systems across Europe should channel this enthusiasm for information. Through secure and practical ICT based tools and services citizens can take greater control of their health: whether it be making an appointment online with their doctor, or getting a second opinion on test results, or learning how to take preventive measures to stay healthy. This is a feasible step and can make a real difference for the efficiency of health systems, and for patients' lives. To help achieve this vision, the European Commission will be active in supporting the deployment of projects that provide Europeans with secure online access to their own health data and enable online health services. An important first step to achieving this will be agreeing on a minimum common set of patient data that can be accessed in a secured way wherever and whenever necessary.

Unlocking the Market Potential

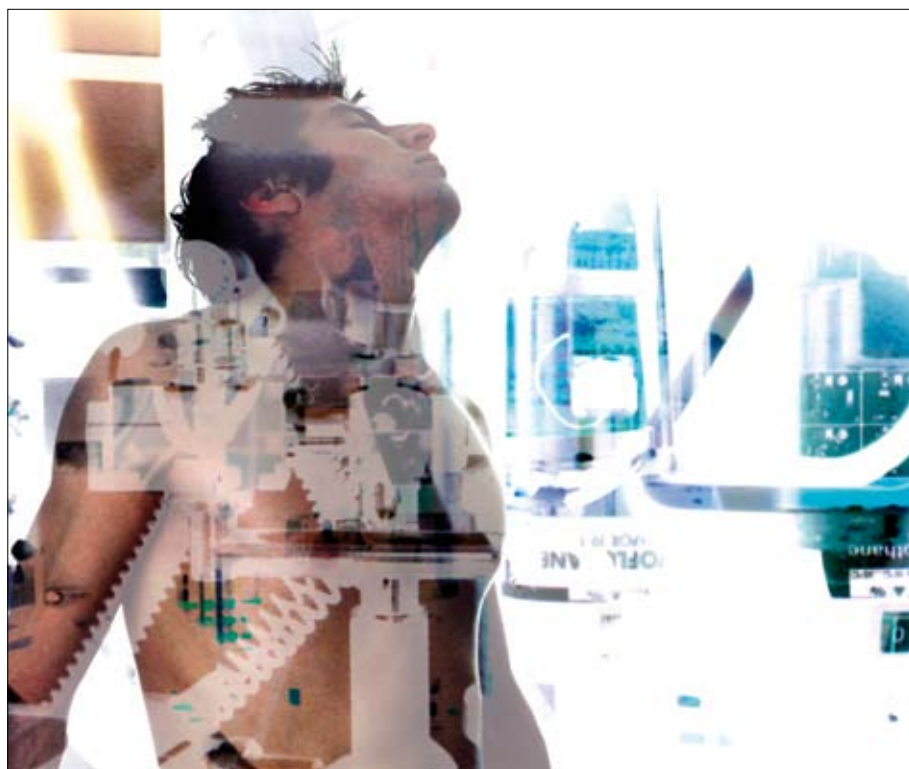
eHealth is the fastest growing of the three main healthcare sectors in Europe (eHealth, pharmaceuticals and medical devices). I would like to see the maturity of this market match the maturity of the technology itself. Health is not like most other

markets – change depends heavily upon political will. So spreading the benefits of eHealth to all Europeans cannot happen without the support of all stakeholders, health authorities professionals and the industry in particular, with the underlying trust and demand by patients.

In line with the EUROPE 2020 vision, eHealth has great potential to create new businesses, jobs and save taxpayers' money. Designated by the European Commission as an EU «Lead Market», coordinated efforts have already been made by some eHealth stakeholders to address the legal and organisational barriers that are holding back innovation and progress. The Digital Agenda now provides an extra stimulus to progress with the necessary standards, interoperability testing and certification processes that will consolidate the eHealth market and ensure transparency, growth and procurers' trust. By bringing stakeholders together to take these often complex but necessary steps, we will foster competition at EU level and guarantee better quality and safer eHealth solutions at a lower price for the benefit of all.

eHealth without Borders

eHealth services put patients at the centre and can only work if patients and practitioners have the tools and the trust to be fully engaged. If eHealth is going to work across Europe, we need to ensure that we have secure and interoperable systems in place that enable safer care across borders. An important first step to achieving this



will be agreeing on a minimum common set of patient data that can be accessed or exchanged electronically across the Member States. In practice this would mean, for example, that in the future any EU citizen with a chronic condition or allergy needing medical assistance in another EU country could be reassured that local health-care professionals can have access, if the patient agrees, to the basic vital information to make potentially life-saving medical decisions.

The benefits of eHealth are clear, but large scale eHealth success and corresponding benefits for all patients and our industries will only come as a result from a truly collaborative effort. We must now seize the oppor-

tunity to step up a gear and enter this exciting new era for the benefit of all.

I am fully aware of just how difficult it will be to achieve this agenda. My new portfolio is very horizontal in nature, and eHealth is among the most horizontal of all the parts of this agenda. It involves not only every layer of government, but also many industries, many Commission policy areas and huge amounts of money!

¹ <http://ec.europa.eu/eu2020>

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52010DC0245:EN:NOT>

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



**Göran
HÄGGLUND**

Swedish Minister
for Health and
Social Affairs

The 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 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 programmes. 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 aimed to make substantial progress in this area. The main strategic goal was 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 in this area, and create a strong political mandate for a closer and more concrete European cooperation 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 eHealth¹. This report will try to visualize the value based costs for healthcare if 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 coordination 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 in this area have also been launched during 2008, namely the eSOS² Large Scale Pilot and the CALLIOPE³ Thematic Network. Through 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.

¹ http://www.se2009.eu/polopoly_fs/1.8227!menu/standard/file/eHealth%20for%20a%20Healthier%20Europe.pdf

² www.epsos.eu

³ www.calliope-network.eu

Telemedicine and hospital reform in France



**Roselyne
BACHELOT-
NARQUIN**

French Minister
for Health and Sports

Like all European countries, France finds itself facing a double-edged challenge: to adapt its health system to guarantee equal access to quality healthcare for all citizens, whilst controlling the public spending devoted to it.

To this end, France passed the «Hospital, patients, health and territories» Act¹ in July 2009, profoundly reforming the way in which healthcare is organised. This law brings with it three major evolutions.

The setting up of regional health agencies will allow us to bring all public health services together, under a single authority, at regional level. This will enable us to implement a health policy appropriate to the needs of the territories.

The establishment of cooperative structures both between public hospitals and between public and private establishments will allow resources and skills to be shared, and will also provide coherence and complementarity in healthcare at territorial level.

New forms of cooperation between healthcare professionals will also be promoted, so as to facilitate the development of a medical practice that is interdisciplinary, as well as more collegial.

Shared IT systems - and telemedicine in particular - will prove indispensable tools, both within this sharing process and in the search for effective territorial coverage.

Numerous telemedicine experiments have been carried out in recent years. Telemedicine technology and uses are now mature enough for their use to become widespread. This is why France is currently preparing a national plan for the deployment of telemedicine - and beyond that, for telehealth.

Among the various priorities, I will be placing particular emphasis on the care of patients with chronic conditions, and those located in remote or less well-served areas. Today, we estimate that five million people in France suffer from a chronic condition, and because of increased life expectancy and evolutions in lifestyles, we think this number could reach 20 million in ten years time. ICTs can contribute to the optimisation of patient care, whilst also helping patients maintain a certain level of autonomy in the management of their condition. For example, home-based telemonitoring of simple clinical indicators - such as weight, blood pressure, respiratory condition, electrocardiogram - transmitted to a first aid centre could enable us to not only prevent the appearance of acute complications in patients suffering from chronic heart failure, but also to save them from having to travel to consultations, and prevent unplanned hospitalisation.

France is beginning to face problems of access to care in areas in which the number of healthcare professionals is becoming fewer. In these areas, telemedicine services must enable us to offer all citizens quality healthcare.

Lastly, the development of telemedicine services will be accompanied by the development of the use of remote tools designed to assist decision-making, within the context of a reorganisation of healthcare. The fall in medical demography, the demand for better quality healthcare and economic pressure will lead to a regrouping of technical facilities in healthcare

establishments. It will therefore be necessary to set up a response that is measured to meet medical demand. For example, treatments for stroke patients will benefit from the setting up of teleradiology and videoconferencing services - in deciding on the most appropriate therapeutic treatment, in guiding patients to neuro-vascular units, and by doing so as quickly as possible.

Yet the natural tendency of telemedicine is to go beyond frontiers - be they administrative or territorial. We must, therefore, clarify the legal framework required at European level, so as to encourage the development of trust and the emergence of new services. In order to do so, we need to adopt a framework for European interoperability, founded on standards which will allow us not only to respond to technical issues in terms of security, but also to facilitate the emergence of a truly pan-European market. This is an indispensable condition - and one which will enable European actors and businesses having acquired a veritable know-how in the domain of telemedicine to accelerate their development, achieving competitiveness at world level.

In its 2004 action plan for a European ehealth area, the European Commission proposed initiatives related to the development of experimentation in telemedicine in Member States. In its communiqué of late 2008, it reaffirmed its support for the deployment of such services on a widespread basis.

Within the context of the reform of its health system, France is resolutely committed to the development of telemedicine in its territory, in close collaboration with European initiatives on this subject.

¹ http://www.assemblee-nationale.fr/13/dossiers/reforme_hopital.asp

Online health



**Trinidad
JIMENEZ**

Spanish Minister
for Health
and Social Policy

In Spain, health is the public service that citizens most value. It is for this reason that the continuous improvement of its quality and safety is a constant social demand. The use of information and communication technologies is particularly relevant in this context, not only because they make it possible to offer better care, but also because they optimise the use of resources and efficiency in public spending.

In a health system like the Spanish one, which consists of 18 Regional Health Services that work in coordination, 4.5 million people are looked after each year away from their usual place of residence, and so the application of these tools is making geographical mobility and cohesion between regions easier.

This is a clear Spanish commitment that has been in operation for over a decade and which we are promoting in the framework of the Presidency of the European Union, following the recommendations adopted during the Swedish Presidency for developing digital services in order to improve healthcare for Europeans.

This year, 2010, means the start of a political and institutional era for the EU in which the new European agenda must face challenges of our

societies, such as economic recovery, employment growth, population ageing or the sustainability of public services. All this must be done with the basic principle of promoting the social and economic inclusion of all citizens.

Digital health is one of its instruments. The knowledge accumulated tells us that when the new information technologies are applied to health they help to get healthier citizens, in a framework of innovation that improves their living and working conditions and with more possibilities of social and territorial cohesion.

After the heavy boost given by the Swedish Presidency, during the Spanish Presidency of the European Union eHealth held an outstanding place in our lines of work and was the object of a ministerial conference that was held in Barcelona, between 15th and 18th March 2010, organised jointly by the European Commission, the Spanish Government and the Regional Government of Catalonia.

We hope that the conference represents a milestone in building a health system based on innovation and knowledge, through the use of information technologies that make it possible to improve the quality of care and which, in turn, are an element of competitiveness for the economy of the EU countries.

The work that we, as the Ministry of Health and Social Policy, base ourselves on today has allowed us, together with the autonomous regions, to have the full introduction of the individual health card for every citizen, the individual digital clinical history and

others still being developed, which are the digital history, the network for the whole of the National Health System, and electronic prescribing of medicines, which are expected to be ready in the course of 2010.

In the first place, all citizens and health professionals benefit from its advantages. It means that our citizens can travel from one autonomous region to another to be cared for appropriately by professionals with safe access to their clinical data; for us, it means that the medicines prescribed can be dispensed at any pharmacy, without the need for prescriptions in paper format; and it allows us to have better management of services, avoiding the duplication of tests and mistakes that occur because of incomplete information.

The availability of an information exchange system in the whole of the system has been essential for developing the project, with a flexible, top security central node and a common health card database.

In the second place, digital health is a source of wealth for any country. These developments improve the quality, safety and accessibility of the Spanish health service while at the same time generating innovation and competitiveness for the companies that have participated in them.

As a basic tool for an improved management of our welfare policies, the new information technologies are a huge investment for employment and innovation. They represent a profitable investment that produces quantifiable benefits in the economy, increasing productive potential and employment. Their implementation in the Spa-

nish health system has been possible thanks to the institutional collaboration of the Government and the autonomous regions, all of which are sure that this is the road to follow: a model based on research, development and new technologies, that will allow us growth and, above all, to guarantee rights that are characteristics of the Welfare State, which we Europeans have invested thirty years in building.

However, the various Spanish autonomous regions have been developing instruments for an online health system for over a decade, with the great boost coming from the so-called Avanza Plan, through an agreement signed between the Ministry of Health and Social Policy and the Ministry of Industry, Trade and Tourism.

With a budget of 448 million euros – 205 million of which were put up by the autonomous regions – for the 2006-2012 period, the plan has made it possible to strengthen the basic infrastructures necessary for digitalizing the health system. Among other things, it has become a material fact in the installation of over 60,000 pieces of computer equipment in 6,000 health centres, that provide health care to over 33 million citizens and in which 250,000 professionals work.

Consensus between the various State Administrations, both central and autonomous regional, has been essential in order to guarantee that the circulation of data is secure, flexible and of quality standard, as this is a fundamental element for efficiency in the Spanish health system which is decentralised and of a capillary nature. It has allowed us to reach agreement on mechanisms for an unambiguous identification of

each person in the health system, as the principal key to accessing clinical information, and also to agree on minimum common contents in the information provided and secure conditions for its access and use.

After a first development phase, new efforts in the development of knowledge await us in new instruments that enable us to share information safely and efficiently.

Spain is also participating with determination in the European epSOS project **which has the backing of 12 European Union countries (besides Spain, Austria, Sweden, the Czech Republic, Germany, Denmark, France, Greece, Italy, Holland, Slovakia and the United Kingdom) and represents a first step towards improving the health care of European citizens who are away from their own country, thanks to the fact that health professionals will be able to access relevant information about their health (what medicines they are taking, allergies, chronic illnesses, etc.), in confidence and in their own language, which will make it possible to know more about the casuistry of each patient and speed up the action to be taken.**

What the Project aims at is to guarantee the compatibility of the different healthcare delivery systems regardless of the language used and their technological slant, without making it necessary to adopt a single system in the whole of Europe.

Our commitment in this field during the European Presidency leads us to propose and carry out actions that integrate digital health more in European policies.

What we want is to strengthen lea-

dership and political commitment to online health and convince citizens and professionals alike of its advantages. To achieve this, it will be essential to provide legal clarity and to guarantee data protection.

In short, what we want is to take yet another step on the road to innovation that Europe has already started to tread, by contributing our own experiences and our view of the future.



Europe, in the age of Telemedicine



**Françoise
GROSSETÊTE**

Member
of the European
Parliament

The potential benefits of telemedicine are so far-reaching that it is developing fast, and becoming increasingly well-known. But what is telemedicine, and what are the issues underlying these innovations?

The notion of telemedicine covers a range of aspects. It is all about using information and communication technologies to – depending on the circumstance – consult a fellow practitioner for an opinion, remotely monitor a patient, or even intervene remotely (in which case, a veritable interaction exists, whether this is a remote examination or – in more technologically advanced situations – a teleguided operation).

These developments do, of course, make it necessary to redefine the nature of the contact with the patient – since the relationship becomes, in this case, literally ‘virtual’. The patient’s condition must justify the use of telemedicine, and healthcare quality imperatives must be complied with. The patient must be provided with the information necessary to giving fully-informed consent; patient confidentiality must of course be respected in compliance with deontological norms, and data of a personal nature must be protected.

The potential benefits are immense. For example, populations living in remote areas – particularly in developing countries – can be offered faster, cheaper, and better-quality healthcare access.

Yet the populations of poor countries are not the only ones who stand to benefit:

these technologies are also applicable within the European context – especially in the current situation (fewer medical staff in rural hospitals, reductions in the number of practitioners in certain specialities, etc.). For example, these technologies allow recourse to assistance with difficult diagnoses, by calling for the opinion of a fellow practitioner, or by sending x-rays taken at a rural establishment with low staffing levels to another radiology facility for interpretation.

In today’s Europe, we must cope with multiple economic and demographic constraints – and telemedicine allows us to offer an effective response. Our population is ageing, and therefore increasingly affected by chronic conditions requiring constant monitoring. Telemedicine enables us to meet these challenges, even though it would clearly be impossible to assign a nurse to every senior citizen!

Other, more specialised applications are also possible; for example, treatment for people held in penitentiary establishments – which accommodate ‘high-risk’ populations subject to major security constraints – can be difficult to manage at the casualty department.

In addition, this sector has excellent potential for growth, and encourages the setting up of new sectors for innovation – in terms of both technologies developed and services on offer. Medical information networks, electronic medical records, transportable and portable systems... these are just a few of many ideas, each of which has potential for development within an emerging market – a point which is not being neglected in the current context of economic crisis. According to Vice-President of the EC and Commissioner in charge of the Digital Agenda for Europe Neelie Kroes, the eHealth market is currently worth €15 billion per year.

By taking the necessary legal measures, we can act to facilitate the setting up of telemedicine that is fit to face the challenges of the 21st century health

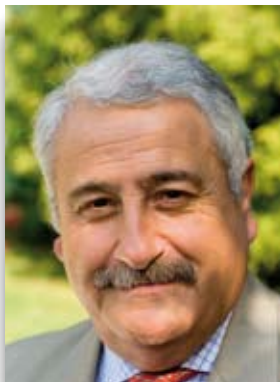
system. In particular, we need to know into which legal framework trans-border telemedicine will be brought. It is urgent that we take these new elements into account in our outlook, and Member States must therefore act together, in order to face up to this new challenge.

On 2nd November 2008, the European Commission published a communication on this theme, aimed at clarifying this issue, and preventing the development of telemedicine from being hampered by legislation that is stuck in the past. It is also a matter of making sure that patients are better informed and more accepting of these new practices, and of acting on interoperability between the various European systems, so that this telemedicine really is border-free. This is where cross-checking comes in, with legislation concerning trans-border treatment – a law which is particularly close to my heart because I am the spokesperson for it. Because telemedicine healthcare often has a trans-border dimension – in spite of the absence of physical movement across the border – elements of reflection on this theme were integrated into the directive project.

‘The eHealth week’ was held in Barcelona from 15th to 18th March 2010, in the course of which European leaders were able to acknowledge the ‘strategic value of eHealth’. The ‘eHealth2010’ and ‘World of Health IT’ conferences took place simultaneously – an event organised by the Spanish Presidency of the European Union and the European Commission, with, on 15th March, an interministerial meeting addressing these themes.

It is essential that we continue our efforts in this direction, so as to set up wider political coordination. By integrating these objectives into the set of European policies concerned, we will promote economic growth, technological innovation and social and territorial cohesion in the EU.

The evolution of telehealth



**Pierre
LASBORDES**

Representative of
Essonne, French National
Assembly

Advances in Information and Communication Technology have resulted in the availability of new and innovative healthcare applications: telehealth, or eHealth.

Telehealth – involving the use of the tools of production, transmission, management and sharing of digitalised information – is beneficial to both medical and medical-social practice. It encompasses applications which allow the practice of remote medical acts (teleconsultation, tele-expertise, medical tele-monitoring, medical tele-assistance) as well as remote monitoring and data devices (televigilance, teledata, etc.).

Faced with an ageing population, a constantly-growing increase in chronic conditions, and increasing specialization in medicine – with the consequent multiplication and increasing complexity of treatments, as well as a fall in the number of doctors – telehealth is an ambitious and adapted response to the new issues of the healthcare system.

The benefits this new approach is expected to offer are multiple: improvement in remote treatment and diagnosis of patients, reinforcement of the patient role and increased patient responsibility for the treatment of their own condition, as well as the development of collaborative work between the professionals concerned. This application could also become a very effective tool in offering guidance and support in situations of loss of autonomy, by equipping users with devices that will provide monitoring, continuity of treatment and reinforcement

of social ties. ‘Remaining at home’ is now the desire expressed by most of our fellow citizens, and one which could be satisfied through the widespread dissemination of gerontechnologies.

In time, telehealth should also offer our fellow citizens healthcare that is both improved, and easier to access.

Moreover, the deployment of this new tool to serve all also represents an excellent means of restructuring healthcare organisation: the emergency and medical imagery facilities at local healthcare establishments will be able to remain operational, whilst being linked to reference establishments – providing true equality of opportunity to patients in the smaller establishments.

It is, under no circumstances, a matter of replacing the a doctor’s presence with a computerised tool, but rather of better meeting the needs and expectations of patients – people who are vulnerable, dependent and/or disabled.

Our country was one of the first to invest in telehealth, and experiments have multiplied in the different territories, resulting in the shared observation that there is a clear improvement in terms of both healthcare quality and access to healthcare, as well as improved social well-being among patients. Yet, in spite of this generally positive context, a number of problematic elements concerning legal issues, pricing, and organisational aspects – as well as cultural considerations – persist, holding back optimal telehealth development.

This observation led me, last October, as part of the task entrusted to me by the Prime Minister, under the authority of the Minister of Health, to submit a report aimed at encouraging the development of telehealth in France. This mission clearly demonstrates the interest the public authorities have in this type of tool, as well as their determination to remove the obstacles standing in the way of its full implementation.

Several imperatives follow:

The telehealth project should be founded on the basis of a national specification, with implementation at local level, via the new regional health agencies.

Healthcare professionals (whether doctors, nurses, pharmacists, or other...) must practice within a framework of controlled, equitable remuneration, whilst allowing practice to evolve towards increased co-operation – both between themselves and in healthcare coordination. It is also of crucial importance that actors are offered both reassurance with regard to security and encouragement to take on further responsibility, through the implementation of a new legal framework, notably to inspire the confidence of patients/users in the deployment of this new tool.

Industry should be associated with the deployment process, because its involvement is essential to the proper functioning of telehealth.

Lastly, strong and acknowledged national governance, with the ability to co-ordinate and federate all parties concerned, as well as to proceed with the operational roll-out in the regions – is an absolute must. The presence of a strong piloting authority is seen as essential to the success of the project.

In terms of technical considerations, the networks must be capable of covering the whole of the national territory.

Finally, the success of this project will depend on its ability to be as simple, legible and appraisable as possible.

The telehealth perspective offers benefits we have come to expect of 21st century medicine, and combines increased efficiency with greater humanity. Making it available to all will depend on the concrete actions to be carried out on the ground, as well as on the willingness of each of us to rise to this new challenge – so as to make it a real success in the service of improved quality and greater accessibility to healthcare for our fellow citizens.

eHealth in Catalonia



Marina GELI

Catalan Minister
for Health

Situated on the Mediterranean, **Catalonia** is one of the 17 Autonomous Regions of the Spanish State. Catalonia has its own history, language – Catalan – and culture. It covers an area of 32,000 km² that is home to over 7.5 million inhabitants and over the years its geographical location has favoured a close, active relationship with the other countries in Continental Europe.

For centuries now, Catalonia has been renowned for being a pioneering, highly dynamic territory in the fields of commerce and industry. This entrepreneurial tradition projects itself towards the 21st century with the firm commitment to being a European reference in the sphere of innovation, information technologies and know-how, as a means of being fully integrated into the knowledge society and economy.

The Catalan Government, an institutional system into which the self-government of Catalonia is organised in political terms, holds broad powers and manages different spheres ranging from education, social affairs and transit to the determination of economic and trade policies. In the sphere of health, Catalonia holds full powers regarding management of the health system. The Catalan Administration's Department of Health is the institution that is responsible for managing Catalonia's health policy. Besides this, other bodies attached to the Department of Health are responsible for providing, financing and purchasing services to

make the principles of health as a public service and universal healthcare a reality.

The Catalan health model is a combined one that integrates all health resources, regardless of whether they are publicly owned or otherwise, into a single network for public use. It is a system that has been decentralised into seven health regions, and this makes it possible for more to be known about the health needs of the population besides forging a closer relationship with service providers.

Context

These days we have to deal with the changes that are occurring in the environment and are affecting the sustainability of the health system. Population growth, ageing and the increase in chronic and cardiovascular diseases, together with epidemiological changes, give rise to increased pressure on healthcare and health expenditure. Besides this, we also have to deal with the difficulty of having insufficient numbers of qualified professionals, integrating healthcare levels and managing resources efficiently. In this context, progress in medical science and technologies must help us guarantee the sustainability and quality of the system. We have to aim at a sustainable model that enables us to deal with the new challenges and requirements.

Information and Communication Technologies (ICTs) in health services are a strategic pillar for all health systems to help improve their efficiency and offer better quality in the provision of services. ICTs provide users, professionals, health centres and the system itself with great benefits. For citizens, this means gaining access to the necessary information and services that enable them to be jointly responsible for their own health, as well as immediate access to the results of diagnostic tests and a

reduction in the risks associated with the duplication of tests and treatments. As regards professionals and health centres, ICTs mean faster transfers of information at lower cost, greater flexibility in the coordination of resources and, as a result, improved clinical and economic management as well as better service for all citizens.

SITIC 2008-2011 Strategic Plan

The Department of Health is strengthening the development and incorporation of ICTs for providing health services. This has been done by equipping itself with instruments such as the **SITIC 2008-2011 Strategic Plan**, the TicSalut Foundation and the future Agency for Health Information and Quality Assessment, which will make it possible to give the final boost to these technologies that aim at improving and providing citizens with the management of their own health processes, and guaranteeing the sustainability of the Catalan health system. The main aim of the SITIC 2008-2011 Strategic Plan is to promote the Department's targets and strategies through ICTs in the service of health (SITIC), thereby guaranteeing the **citizen's** right to access information and facilitating the task of **professionals** in improving healthcare quality. It is also designed to position the Information Systems and ICTs at a strategic level for improving the health sector. The plan consists of 6 strategic lines and 35 action plans.

Main Projects

Among the main projects being deployed in Catalonia we have the Catalan Shared Medical Record (CSMR), the Personal Health File (PHF), the Medical Image Digitalization Plan (MIDP), Telemedicine and the Electronic Prescription (EP). The **CSMR** brings together the set of documents that contain data, informa-

tion and clinical assessments regarding the situation and evolution of a patient throughout his healthcare process. The CSMR is the result of the digitalisation and application of ICTs with the aim of improving citizens' healthcare through a tool that makes it possible for any doctor to access all available relevant information concerning his patients, regardless of their healthcare level or their geographical location. The CSMR also promotes continuity of healthcare by integrating all information, thereby avoiding mistakes and having to repeat examinations and/or procedures. The CSMR is a decentralized model that uses interoperability and standards systems to make it possible for the different systems, initiatives and projects that have been developed (PHF, MIDP, Telemedicine and EP, among others) to interconnect.

The **Personal Health File** is a digital space that allows citizens to have and use their personal health information in a way that is safe and which guarantees their rights. A first phase of the project provides for all citizens to be able to access the most relevant data in their CSMR: medication and vaccinations that have been prescribed and dispensed and medical reports and test results, as well as the complementary examinations that have been generated in healthcare processes. In a second phase, citizens could gain access to other fields of information regarding their health with customized access to all the e-services and procedures carried out through Internet such as: making appointments via Internet, changing the personal details shown on the Health Card, monitoring the status of claims and requests for health certificates.

The **Medical Image Digitalization Plan** provides a reduction in costs as a result of the generation of economies of scale, improved efficiency and productivity and increased image quality, as well as permitting remote access to medical images. The health centres are currently provided with equipment and software for digitalising radiological images. At the present

time, two thirds of the over seven million radiological studies carried out each year at Catalan health centres are available in digital format. As regards non-radiological images, the first projects have started to be carried out and a technical support office has been made available. The creation of the central repository for medical images, which is a medical images back-up, is currently nearing completion.

The **Telemedicine and Medical Telecare Plan** aims at speeding up the implementation of state-of-the-art technological applications which optimise, through telecommunications, the quality, efficiency and fairness of health services in Catalonia.

The plan prioritises communication in real time between the professional in a reference centre and the patient, promotes telemonitoring in the case of chronic patients suffering from diabetes, respiratory deficiencies and heart disease and, lastly, it makes communication between professionals from different healthcare levels much easier when diagnoses have to be made. One of the most important proposals in telemedicine is the Catalonia Teleictus Network. This project consists of the implementation of a telematic system that provides specialized care for ictus patients during the early hours of the acute phase, in the reference territory, according to the criteria of the Department of Health's Outline Plan for circulatory system diseases and cerebrovascular disease.

The **Electronic Prescription** facilitates prescription and dispensation processes and improves their efficiency, besides reducing the numbers of routine visits and increasing prescription control. The Electronic Prescription is in its final phase of implementation, which is expected to be completed in mid-2010. After that, it will be providing service to over seven million people, with the participation of 4,500 doctors and 410 primary healthcare centres, and will handle a volume of 140 million pharmaceutical prescriptions per year.

Conclusion

In the same way as in other European Union countries, the integration of ICTs is being developed in earnest in the Catalan health field, as they are a strategic pillar for tackling the challenges of today's environment and achieving a sustainable, efficient, fair, safe and high quality health model.

The apparent difficulties that stem from the complexity of incorporating ICTs into a diverse system such as the Catalan health system are being transformed into strengths. It has been possible to integrate the ICTs while at the same time respecting the information systems attached to each centre and/or agent. This highly satisfactory integration has been achieved with the use of standards. It is a solution that could be valid for the Spanish State and for Europe: Interoperability based on Standards.

The application of ICTs in health faces great challenges that will gradually shape the future of healthcare for us: the ability of citizens to take responsibility for their own health, the possibilities of biomedical research, changes in the way professionals work and, above all, improvement in the quality of healthcare.

This evolution in the use of ICTs will allow us to evolve from eHealth, with the application of ICTs in health practice, to iHealth, with the customisation of health services. iHealth means more individualised healthcare based on a better knowledge of the patient. iHealth means adapting health services and information to the characteristics of the population, shared responsibility and the patient's participation in caring for his own health, immediacy in access to information and services and improved safety in medical care and interventions. iHealth is the future before us.



Living at home with the new technologies



**Prof. Alain
FRANCO**

Professor
of Internal Medicine
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President of the ISG
and President of
the CNRSDA (France)

Living at home for a long time – if possible, right to the end – and being treated at home!

This two-fold assertion expresses the predominating desire of the European citizen. If we add to this the commonly-held economic view that it is less expensive, particularly given the technological progress made, we have enough to explain the current interest – from both public authorities and actors on the market – in the use of information and communication technologies for the benefit of home-based healthcare and the autonomy it can provide.

Living, ageing and being cared for at home: higher quality, increased safety, and reduced costs – this is a prospect that, whilst raising hopes, also presents certain difficulties to be overcome.

Hopes

NICTs capable of improving safety are envisaged. Home automation – which brings the electronic, computerised and robotic equipment of the household together – was originally security-oriented. The security of doors and windows from theft or attack, safety from the risk of excessive consumption of water, electricity or – and most importantly – gas,

the safety of vulnerable people who are liable to falls – by adjusting their architectural and furnishings environment, adapting lighting and its automatic activation when the person finds themselves in a hazardous area, and by equipping people with tele-alarms to warn family, neighbours, the emergency services or a 24/24 call centre.

The mobility of a person in their own space is also related to the architectural environment of the home, accommodation, building or neighbourhood – particularly if technical aids, or a manual or motorised wheelchair, are required.

Familial and social inclusion become a priority for the 30% of elderly people who feel lonely, or isolated – and who often are, objectively. Communications equipment – a telephone, videophone, or videoconference system – can provide an excellent opportunity to fight exclusion for those who are equipped, who know about and are able to use it, and who are motivated to do so.

Everyday assistance with domestic chores, where personal or basic needs should soon be able to reap the benefits of information and communication techniques – especially those which emit contact-free signals – so as to help better manage, co-ordinate and pay for home-based interventions.

Telemedicine should make a huge contribution to the home-based care of patients; particularly those afflicted with single or multiple chronic conditions, and terminally-ill patients at home. Research has certainly shown their usefulness in reassuring patients and improving the quality of care.

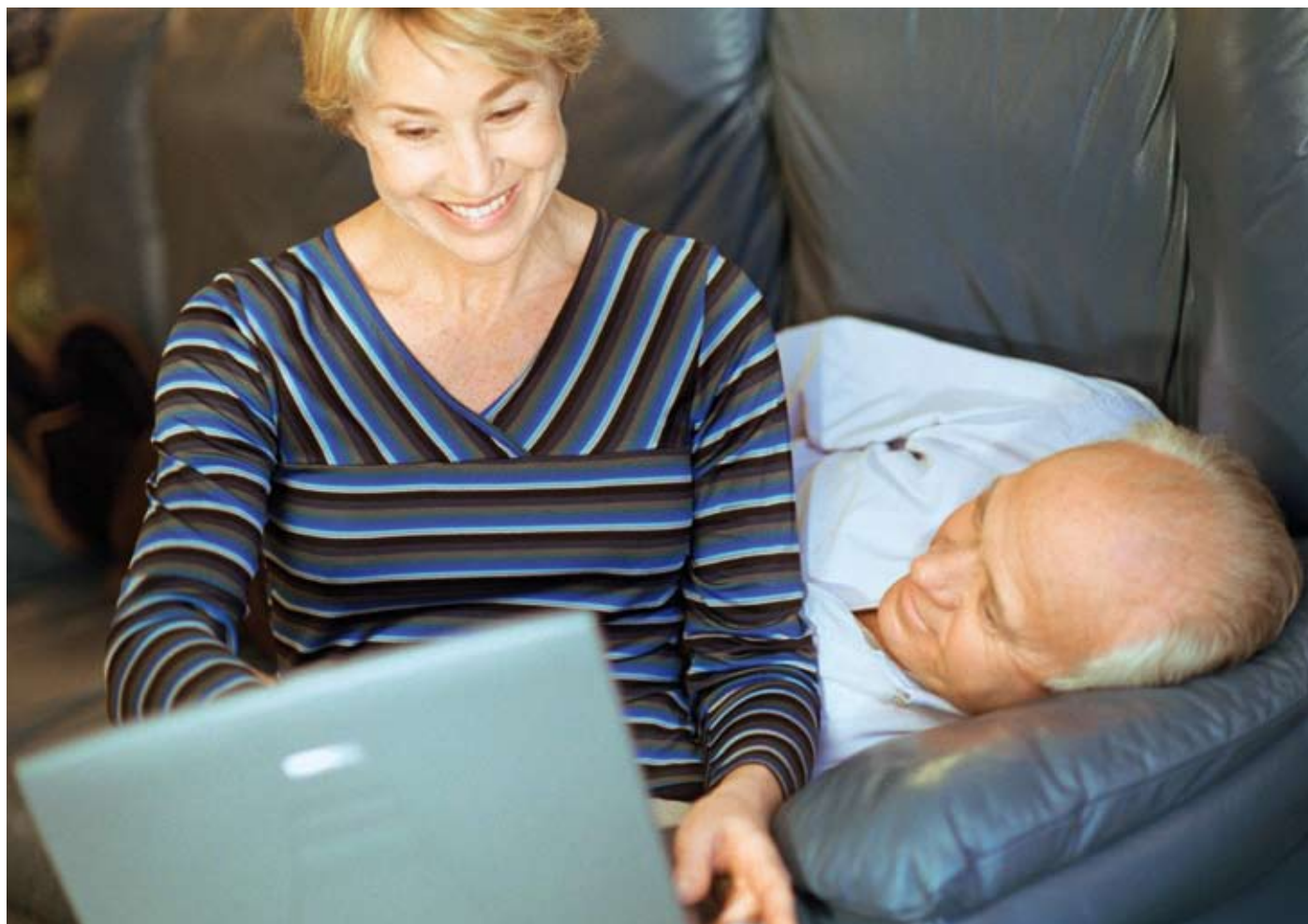
Difficulties

The technology is, in general, already available – so why are our countries so slow to implement it?

This is certainly the result of a failure to sufficiently take into account the fact that a technology is only useful if it renders service, or if it is associated with a service. A person – especially if they come from a generation not involved at the time of the emergence of a new technological generation – might recognise the value of a new technique but not necessarily decide to use it, because culturally – or by force of habit – they turn to other alternatives that are both closer to them, and older. This remains true even if the equipment is provided to them free of charge by the environment, family, social or healthcare services. On condition that appropriate training is provided, and that there is either emotional motivation or a dimension of fun, a certain number of people can certainly be re-integrated in the use of new technologies.

Friends and family can move forward – or hold back – the use of technology at home – for reasons that are extremely variable. Sometimes family and professional carers develop opposite strategies. This underlines the indispensable phase of appropriation by the entourage (and the professional entourage, in particular). Yet, carers working in people's homes are often not very highly-qualified and/or are essentially motivated by human contact – which opposes them to the use of technologies. Sometimes, professionals are anxious about the technology-related control function, preferring to protect their





independence. Where this is the case, the work of establishing these new technologies and services entails an intense effort on the part of the promoters in terms of training and assistance with innovation, so as to render usage habitual and useful. But above all, use of these new technologies, when both well-understood and well-accepted, can present an opportunity for an in-depth reorganisation of the service and for the co-ordination of aid to the patient, whilst respecting and encouraging human contact.

The ethical dimension is ever-present, and technologies and services must now - to a greater extent than they previously did - encourage charitable

endeavours and contribute to equity, whilst respecting the humanity and autonomy of the people they serve. The ethical education of professionals and ethical advice must represent crucial objectives in a development policy.

The difficulties of financing technologies and services may of course be a significant obstacle to their development. The economic model in European countries - all of which are borrowed from the 'welfare state' model - cannot liberate itself from a framework of assistance or participation of the public authority, and the citizen is, doubtless neither ready nor financially capable of paying for

the cost of the system and its operation. A major and large-scale effort will be required to demonstrate both the social and economic usefulness of the quality of life, and the quality of the assistance made possible through these wonderful technologies, and to integrate them into a place of their own within the health system, in social support and in economic and cultural life.

Telecardiology: Evolution and Prospects



Prof. M. COWIE

Professor of Cardiology,
Imperial College London

and Dr. A. ACOSTA LOBOS

Clinical Research Fellow, Imperial College London

Telecardiology ('cardiology at a distance') aims to widen access to high quality healthcare, with good diagnosis and management closer to home. The potential benefits appear obvious, with less inconvenience for patients and their families, less geographical inequity in service provision, closer monitoring of chronic conditions, and the potential to improve outcome at a reasonable cost. However, adoption of telecardiology has until recently been slow, related to technological issues, lack of policy drivers, a relatively weak evidence-base, and cultural resistance amongst some healthcare professionals to the necessary organisational change.

Telemonitoring, the use of communication technology to monitor the patient's clinical status from a distance, has been examined in several clinical trials, particularly in the area of heart failure. This is a chronic condition that leaves people feeling breathless and tired, and can deteriorate usually over a period of days to weeks to the extent that an emergency hospitalisation is required to restabilise the symptoms. Self-monitoring of variables such as body weight, blood pressure, and symptoms is the cornerstone of modern management, but can be a challenge for

many, often elderly, patients. Telemonitoring can improve this situation, and enable deterioration to be picked up earlier, and treatment modified to reduce the need for hospitalisation.

Telemonitoring can also be used to assist the proper and speedy introduction of life-saving drug therapies, the dose of which can be increased if there are no harmful side-effects without the need for multiple face-to-face clinic visits.

Such telemonitoring can be done simply via telephone contact, or by the use of stand-alone measurement equipment in the patient's home that is used daily to collect and transmit information to the medical team. At the most complex end of the spectrum detailed measurements can be transmitted wirelessly from a patient's pacemaker to a bed-side unit that then transmits the information by broadband to a central server that can be accessed by the healthcare team. Sensor and communication technology advances rapidly.

Small randomised controlled trials have shown promising outcomes. Although there is some variation from trial to trial, results suggest a reduction in mortality. Although hospitalisation rates may not change, they tend to show a reduction in emergency or unplanned hospitalisations¹. Disappointingly, few robust economic analyses have been performed, but the data suggest that such technologies are unlikely to save money, but are probably cost-

effective, and certainly allow more patients to access higher levels of expertise than is currently the situation in most European countries. Importantly, these studies have shown that current technology is acceptable to patients, with adherence to daily monitoring above 80%^{2,3}. There are several ongoing trials assessing the use of implanted devices to monitor heart failure, where many more variables can be assessed. Making sense of the mass of information that can be accessed is a challenge, and further work is necessary to see which combination of variables are the most useful to measure, and how often to provide this information to the healthcare team. There is undoubtedly a steep learning curve for those who adopt remote monitoring – with too low a threshold for intervention in the early stages of monitoring.

One major issue is the lack of national and international guidelines with

¹ Clark RA, Inglis SC, McAlister FA, Cleland JG, Stewart S. Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis. *BMJ* 2007;334(7600):942.

² Dar O, Riley J, Chapman C et al. A randomized trial of home telemonitoring in a typical elderly heart failure population in North West London: results of the Home-HF study. *Eur J Heart Fail* 2009;11(3):319-325.

³ Cleland JG, Louis AA, Rigby AS, Janssens U, Balk AH. Noninvasive home telemonitoring for patients with heart failure at high risk of recurrent admission and death: the Trans-European Network-Home-Care Management System (TEN-HMS) study. *J Am Coll Cardiol* 2005;45(10):1654-1664.



respect to the implementation of telecardiology, particularly telemonitoring. This reflects the relatively small evidence base and marked differences in operating procedures from one study to another. Pooling of experience, and larger more international studies, are undoubtedly needed. The future is bright for telecardiology. It enables patients, wherever they live or however frail, to access diagnostic and management expertise. As the technology becomes simpler to use, and as we learn how to analyse the data more appropriately, it can sup-

port expert teams in reaching out to many more patients. It does require a change in working practice, with less face-to-face interaction, and more remote data-driven action, and thus can be a challenge for healthcare professionals. Education and training are essential. Patient and family acceptance of such technologically-facilitated care is unlikely to be a major barrier in Europe. Challenges do remain. Differences between systems and poor interfacing between systems and users can confuse and demotivate. Funding

issues can be tricky, particularly in systems that pay hospitals for admissions, but do not recognise the cost and effort of providing telecare. The locus of monitoring is also problematic – most studies have been co-ordinated from hospital practice, but the technology lends itself to co-ordination from the community. Such barriers are certainly surmountable. Telecardiology will never replace face-to-face interaction between patients and their healthcare teams, but it will become a standard part of cardiology within the next decade.

Telemedicine activities at the Centre National d'Études Spatiales



Dr. Antonio GÜELL Head of the Application and Valorisation Department

Murielle LAFAYE Environment/Climate/Health Programme Coordinator

Nathalie RIBEIRO VIEIRA Health Care For Remote Regions and Telemedicine Coordinator

Pascal FAUCHER Humanitarian & Risk Activities Coordinator

The French space agency CNES (*Centre National d'Études Spatiales*) develops the use of space and encourages the emergence and dissemination of new applications. It has, since 1998, developed pro-health applications in consultation with health authorities, professionals and users, as well as with industry and the scientific community. Space industry technologies improve our ability to observe, measure, compare, and understand health-related phenomena. They ensure continuity in quality information. The services offered are unique, providing access to communication resources to as many people as possible, in all matters and in every circumstance, and at the lowest price - as well as planetary coverage for localisation and earth observation services.

The CNES is thus supported by its partners in the development of telehealth applications around four themes: health care for remote regions, environment/climate/health, crisis management, therapeutic education and ongoing medical training for health professionals.

The telehealth offer is rich and varied, integrating the mastery of space industry technologies associated with innovative solutions into a technical and organisational health plan.

In the field of **health care for remote regions and telemedicine**, satellite communications links thus offer the possibility of consultations (cardiology,

paediatrics, gynaecology, dermatology, parasitology, and so on) for sites deprived of permanent or occasional earth-based communications resources.

Thanks to the range of facilities developed and validated by the CNES and its partners, teleconsultation represents a promising channel for the improvement of existing healthcare networks: patients can be treated better and faster, the medical isolation of practitioners is broken, access and equality of healthcare for all.

There are also specific collaborations aimed at enhancing the telemedicine system on board aeroplanes. Other systems of information and localisation in the course of medical-economic evaluation (nursing terminal, localisation of dependent persons, etc.) improve patient care via the more effective intervention of health professionals in keeping patients at home (acquisition of biomedical data, monitoring of treatment and diagnoses).

In terms of tracking epidemics, the merging of health data with environmental and climatic data collected either on the ground or via observation satellites (water, air, vegetation, soil) allows identification of conditions that are favourable to the development of the disease and to better understand how it is transmitted.

In this domain, the use of space industry techniques constitutes a major step

forward in combating diseases that are water-borne, air-borne or transmitted via vectors (malaria, Rift Valley fever, yellow fever, dengue,...) - channels which are responsible for millions of victims every year, worldwide.

Within the context of projects issuing from the working groups and consortiums in which it participates, the CNES is involved in Africa (Senegal, Niger, Burkina Faso, and very soon, Benin), in South America (Argentina, Paraguay, Bolivia), in Asia (China, India) in the Maghreb (Algeria, Tunisia, Morocco), as well as in the Dom-Tom (French overseas departments and territories) such as Guyana and Réunion, setting up epidemic monitoring networks through co-operative arrangements. The ultimate aim of this work is to set up alert systems which will prevent epidemics.

In the domain of **humanitarian crisis management**, telecommunications satellites for observation of the earth and localisation/navigation can be mobilised anywhere on earth, at any time, to contribute to humanitarian action. They provide secure communication and data exchange with remote centres (hospitals, ambulances, civil security, etc.) Humanitarian containers allow medical assistance to be remotely dispatched to victims and populations. This is why the SAMU (Emergency Medical Service) in Guyana has equipped itself with a PSMA (Advanced Emergency Medical Station - *Poste de Secours Médical Avancé*), a very hi-tech



communications and control tool that is both autonomous and tropicalised, easily deployable in disaster zones and remote areas. This facility allows a tactical network of communications to be set up, and a very broad range of data collected (medical, epidemiological, environmental, etc.) to be transmitted, via satellite, to an emergency centre for the preparation, support and co-ordination of an emergency operation. This health crisis management tool could therefore be put to use in the Amazonian forest or in any other 'hostile' environment.

The International Space and Major Disasters Charter is another tool set up by the CNES and the European Space Agency. It aims to provide a unified system of satellite data acquisition in the event of major disasters, whether natural or man-made in origin. It can be triggered by bodies responsible for civil protection, defence or security in any of the member states.

In January 2010, the International Space and Major Disasters Charter was activated by France for the supply - to local authorities and the COS - of high-

resolution satellite images of the disaster zone in Haiti. The re-establishment of satellite telecommunications facilitated the treatment and evacuation management of victims in the hospitals of Haiti and the Antilles. A certain number of multi-point video-conferences were organised between the various intervention services (on-the-ground team with the rear bases). A cybercafé was also created, which was invaded with victims anxious to get news to their families, as well as by journalists. Lastly, in the domain of therapeutic education and ongoing medical training, the CNES is interested in the development of new interactive television services by satellite. As such it has created a complete system including sections for a services portal and satellite telecommunications, and a terminal allowing people suffering from a diabetes-type chronic condition to receive specific information at home, aimed at teaching them the best lifestyle to adopt.

The software content, which was specially developed and adapted by specialist doctors, is made available to users in the form of interactive games, Questions and Answers, or themed conferences.

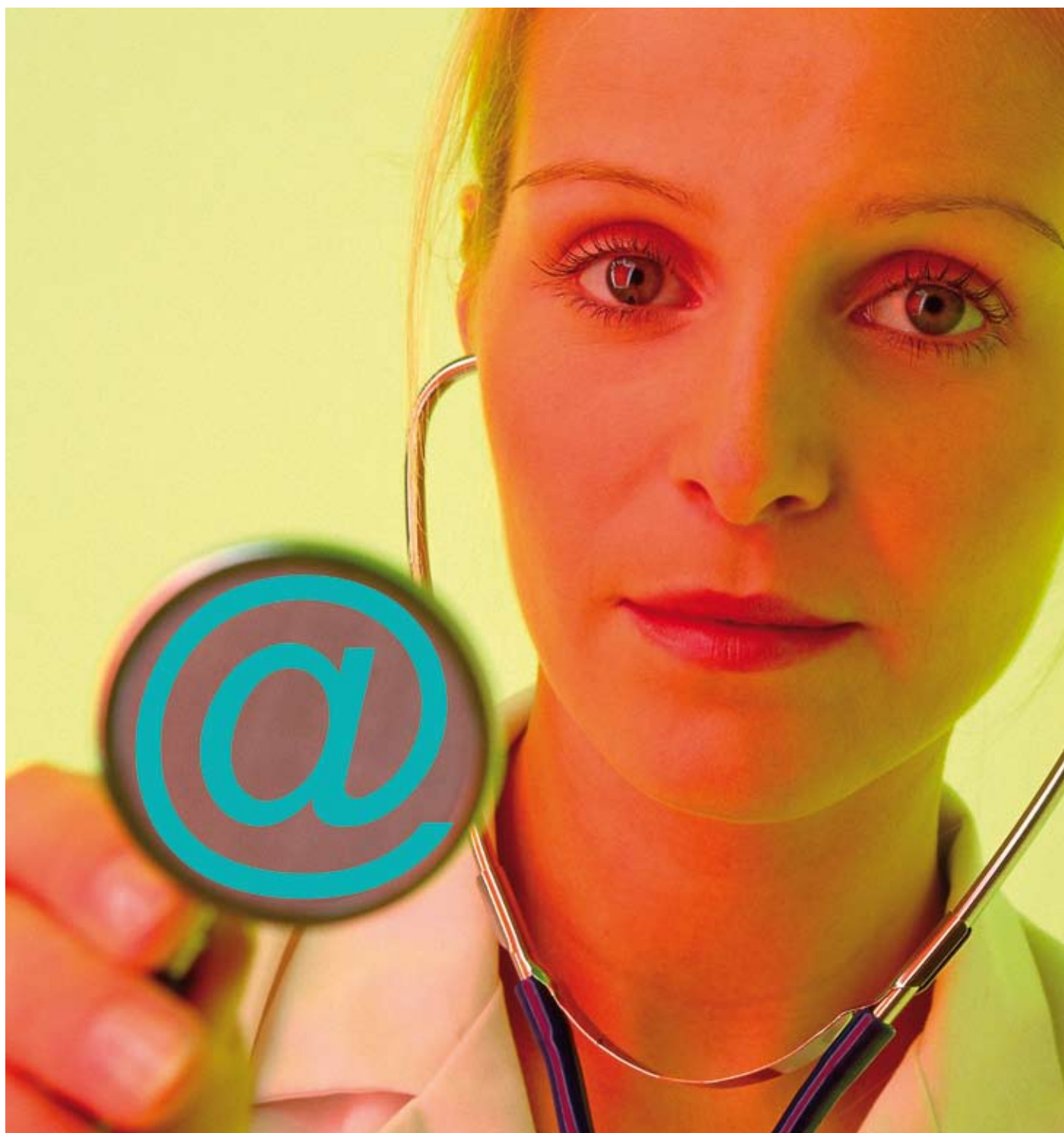
Space industry applications also enable the development of remote medical training projects, through the creation of communications and applications platforms and through the setting up of teletraining networks.

In this way, within the context of the UMFV (Virtual French-speaking Medical University - *Université Médicale Virtuelle Francophone*) which now brings

together all the medical schools in France, 31 CHU (teaching hospitals) and several African universities, the CNES plays an active role in testing out new uses (interactive training sessions via satellite, dissemination of educational content) liberating all actors from the constraints imposed by distance and by inadequate means of accessing the internet.

To date, many pilot projects are operational and durable: for example, the telemedicine network in Guyana, with 16 remote health centres connected by satellite with the Teaching Hospital in Cayenne, or the Ecological Monitoring Centre in Senegal, which uses satellite image-supplied data and products to improve the quality of monitoring agricultural and breeding campaigns (bovine grazing).

As a resources agency, the CNES can contribute in a variety of ways (financial, technical, and expertise-based) to the definition of specifications for solutions that are suited to users' needs. It offers users guidance and support throughout the phases of development, validation, deployment and technical evaluation of performance - both economic and medical and thus acts as a lever to transfer innovative technologies towards a public or private entity for the dissemination or commercialisation of new end-to-end services.



Impact on the restructuring of healthcare



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Physicians, health managers and technological companies envisage that telemedicine will play a key role in future approaches to healthcare provision. However, the business model to deploy this technology is still uncertain. It has been relatively easy and profitable to implement tele-imaging utilities because giving remote opinion about X-rays, a dermatological picture, or an ECG has few risks in terms of providing misleading information. Moreover, these telemedicine services are extremely useful for healthcare providers in rural areas or in environments facing a shortage of physicians. It is also relatively simple to set up telementoring services to improve the skills or the knowledge of trainee health professionals. The simplicity of this approach lies in the fact that it involves one-to-one communications or information transactions. A completely different issue is when we are talking about telemedicine as a tool to be used in a multilateral process where physicians and nurses from different healthcare levels and patients themselves have to share and contribute to fulfil an IT-system. How to solve the difficulties of that systems' use can be an organisational challenge rather than a technological problem. This may explain the common failure of technology companies manufacturing health software trying to solve a complex problem with a very naive approach often not taking into account the health professionals'

views or the real organisational needs. For example, it is now feasible to pick-up remote information by monitoring vital signs from a patient with chronic disease at home, but this information can be worthless if it is not properly matched with recent complementary information stored in the hospital, emergency room or family physician records and if a multidisciplinary and coordinated team is not in place to take care of the patient's need in any particular situation.

The questions are: what do we need to do to ensure that telemedicine facilities can be efficiently implemented? And in what way can IT-systems be helpful as a tool to push forward organisational changes in our healthcare systems? The answer to the first question is that we need interoperable systems based on standards that are able to connect electronic health records (EHR) from the different health providers involved in order to offer a personalised solution to the patient. Secondly, improvements in semantic interoperability and new developments in ontology workflows are needed to guarantee efficient communication between different IT-systems and to prevent errors when sharing and interpreting information coming from different sources. Thirdly, we need to build an EHR structure which not only provides information based on episodes or different health level encounters, but also provides transversal information over time, related with each specific health problem of the patient. Only when a problem-oriented architecture is available can decision-making support tools be efficiently applied. This means clinical guidelines and pathways with repository data enabling quality control of the process. And fourthly, the payment systems need to develop to support new transactions based on virtual appointments and on health outputs, in contrast with cur-

rent payments which are mostly based on traditional hospital or GP appointments. In addition, each health system, public or private, has to decide which telemedicine service should be included in its insurance coverage as it is important to establish which services are considered essential and should be reimbursed, and which are an «added value» for the comfort or convenience of the patient, for which s/he should incur the cost.

Regarding the impact of IT-systems and telemedicine on the restructuring of healthcare systems, several critical points should be outlined. The most obvious is the possible impact on human resources needs and the location of health professionals providing care. Often with the help of IT-systems and electronic decision-making tools, tasks traditionally undertaken by physicians can be satisfactorily covered by nurses, and telemedicine may avoid unnecessary movements of both patients and professionals with the consequent cost reduction. But the most relevant impact is related to improvements in the quality and safety of care. There is overall agreement that to increase quality we need to structure healthcare in coordinated multidisciplinary teams and on transparent and reliable information. These teams could belong to a single institution but often are part of different institutions and different healthcare levels. As these teams are organised around a disease or group of diseases the compilation of the information supplied by different members of the team coming from different institutions can not be done without an efficient interoperable IT-system. Moreover, only with an electronic data repository and using a datamining approach can the information be processed to evaluate health outputs or to detect safety warnings.

eHealth – exporting to new markets



**Jorgo
CHATZIMARKAKIS**

Member of
the European
Parliament

Europe has established itself as a leader in eHealth. Over the past 20 years it has benefitted from EU research and development funding and leadership. Europe has emerged with strong potential to become a powerful global player with innovations and successes which can play a strong role in addressing the major problems facing health systems across the globe. We now have an EU eHealth market that is currently worth around €15 billion representing more than a third of the global market.

Industrial solutions that are deployed in real life setting include electronic health records, regional health information networks with online services such as ePrescription, personalised health systems for improved management of chronic diseases, ambient intelligence systems supporting independent living, health education and lifestyle of a choice. More advances systems are continuously developed by European and national R&D such as the 7th Framework Programme (FP7) or Innovation programmes such as the Competitiveness and Innovation programme (CIP) that are strongly supported and monitored by the European Parliament.

A good example of the sort of progress that has been made is the MyHeart¹ project, bringing together 29 partners from across the EU, to help prevent and diagnose Cardiovascular Diseases (CVD) - the leading cause of death in developed countries. In the EU alone, Cardiovascular Disease costs €192 billion a year and contributes: 57% health care costs, 21% productivity losses, 22% informal care of people with CVD, 42% of all deaths in the EU. The

personalised, easy-to-use solutions and tools that MyHeart has developed (such as portable mobile devices, web-based support, and sensor-equipped clothing) promise to help citizens adopt a permanently healthier lifestyle and look after their hearts for life.

In my home region - the Saarland in Germany - we might explore the opportunities of eHealth in the next years since the demographic changes urges to cut expenditures on health. Some rough plans foresee that an old mining area will be populated and equipped with eHealth features specially targeting «elderly people».

eHealth has not just benefitted from funding, it has also achieved «Lead Market²» status, being recognised as a market with high economic and social value, in which European companies could develop a globally leading role, and where action should be taken to remove burdensome regulation or incoherent policy which could hamper its development. This has already led to steps being taken to: reducing market fragmentation and lack of interoperability, improving legal certainty and consumer acceptance, facilitating access to funding, and improving procurement of innovative solutions.

Of course, more can be done, and policy initiatives such as EUROPE 2020³ and its ICT chapter the European Digital Agenda⁴ should help to provide additional encouragement for Member States, industry, health sector workers and patients to work together to find solutions that will help the market develop further.

If this policy drive is to be effective and reach the anticipated results of smart, sustainable and inclusive growth, we need to be even more ambitious. A European market for eHealth will doubtless bring with it many benefits, not least: facilitating market growth, improving patient care, and allowing continuity of care across borders. But now is the time to think beyond Europe's borders and make a concerted effort to export our eHealth technology to new markets.

For example, in the US we can see that eHealth is a priority area for the Obama

administration and large budgets have been allocated for the implementation of the Electronic Health Records. The fact that several EU countries have already implemented some of the goals of the current US programmes should also provide competitive advantage to the companies operating in EU.

Exporting eHealth is not simply about addressing the problems related to an ageing population in developed countries. If we consider the many savings and benefits that eHealth can provide, we should also look at how we can share our knowledge and expertise with developing countries. As we have seen in recent years, ICT can have an enormously positive impact on people's lives in developing countries, bringing people - often in remote locations - and services closer together and raising awareness on important issues. Developing countries, often facing a high incidence of communicable diseases and a «brain drain» of their healthcare workers towards developed countries are increasingly looking towards eHealth solutions.

eHealth builds on the best assets of Europe: its health systems, its knowledge and its technologies. We have benefitted from investment, we have the political impetus to make progress, now is the time to open dialogue and cooperation on a global scale so that we can reach new markets, improve healthcare for more patients and achieve smart, sustainable health systems for all.

The European Parliament plays an important role in tackling challenges such as sustainability of healthcare systems and can contribute to the necessary consensus among all the stakeholders to bring benefits of eHealth solutions to patients quickly and safely.

¹ <http://www.hitech-projects.com/euprojects/myheart>

² http://ec.europa.eu/information_society/activities/health/docs/publications/lmi-report-final-2007dec.pdf

³ http://ec.europa.eu/eu2020/index_en.htm

⁴ Page 11 and 12 of the Commission's Communication http://ec.europa.eu/information_society/digital-agenda/documents/digital-agenda-communication-en.pdf

The impact of telemedicine on the medical development of remote regions



Prof. Louis LARENG

Director of the European Institute
of Telemedicine in Toulouse

and **Dr Monique SAVOLDELLI**

CHU Toulouse

In the mountainous Midi-Pyrénées Region, which is more spread out than Belgium, with 2,315,319 inhabitants, the Regional High-Speed Telemedicine and eHealth Network (Réseau Régional à Hauts Débits de Télémedecine 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 organisations - 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 (July 2009) - 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 eHealth 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 coordination of the Network (support through the process of change, training, setting up of infrastructures, design and implementation of projects, coordination 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 main-

tenance of patient care within the patient's home area - whether the patient is hospitalised, living in a nursing home, or at home. Quality of treatment is also optimised, through the reduction of non-quality. For the purpose 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 terms of the distances involved and 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. 15 (or even more) sites can be connected for simultaneous exchanges. All medical specialities 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 competences combining topographical realities and therapeutic necessities
- A privileged contact person: the local practitioner
Facilitated patient information



- Information and education of the patient
- Quality and security of locally-based healthcare / 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
- Optimisation 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 optimised duration of hospitalisation

- 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 coordination 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 derives from this. Through telemedicine and eHealth, the global information society (whose progress is sometimes badly received) also brings beneficial effects which contribute to bringing tomorrow's citizens even closer together.





Telemedicine – Bringing health closer to citizens



Marina GELI

Catalan Minister
for Health

In the sphere of health, Catalonia is divided into seven health regions and this makes it possible for more to be known about the health needs of the population, as well as forging a closer relationship with the service providers.

The Catalan health model is a combined one that integrates all health resources regardless of whether they are publicly owned or otherwise, and includes a tradition of organisations (provident societies, foundations, consortiums, church-related centres and town councils) that, historically speaking, are devoted to healthcare.

The Catalan Administration's Department of Health is the institution that is responsible for managing Catalonia's health policy. Besides this, other bodies attached to the Department of Health are responsible for providing, financing and purchasing services to make the principles of health as a public service and universal healthcare a reality.

These days, information and communication technologies (ICTs) in health services are a strategic pillar for all health systems, to help improve their efficiency and offer better quality of services, with the final goal of improving citizens' health.

The Department of Health is strengthening the development and incorporation of ICTs for providing health services. This has been done by equipping itself with instruments such as the SITIC 2008-2011 Strategic Plan, the TicSalut Foundation and the future Agency for Health Information and Quality Assessment, which will make it possible to give a final boost to these technologies that are aimed at improving and providing citizens with the management of their own health processes, and guaranteeing the sustainability of the Catalan health system (Shared Electronic Medical Record, Personal Health File, Electronic Prescription, Teleradiology and Telecare).

The telemedicine and medical telecare plan, which is one of the core parts of the above-mentioned SITIC plan, aims at speeding up the implementation of state-of-the-art techno-

logical applications which optimise, through telecommunications, the quality, efficiency and fairness of health services in Catalonia.

The plan prioritises three courses of action. Firstly, communication in real time between the professional in a reference centre and the patient, accompanied by another professional in a remote centre, through teleconsultation, in the special fields of cardiology, dermatology, neurology or psychiatry. Secondly, it promotes telemonitoring in the case of chronic patients suffering from diabetes, respiratory deficiencies and heart disease. And thirdly, it makes communications between professionals from different healthcare levels much easier when diagnoses have to be made in the special areas of radiology, pathological anatomy and ophthalmology, among others.



In this context, one of the most important proposals in telemedicine is the Catalonia Teleictus Network¹. This project consists of deploying a telematic system that provides specialised care for ictus patients during the early hours of the acute phase, in the reference territory, according to the criteria of the Department of Health's Outline Plan for circulatory system diseases and cerebrovascular disease.

Several teleictus projects are currently underway in the health regions of Barcelona and Gerona, where more than 130 experiences per year have been recorded: Vall d'Hebron Hospital, the reference centre for the Barcelona Health Region, shares its experience in ictus online with the hospitals in Vic and Granollers. In turn, the Josep Trueta Hospital in Gerona provides the hospitals in Figueras and Palamós with its knowledge.

In parallel with teleictus, the Department of Health is promoting other projects in the field of telemedicine such as teledermatology, the tele-electrocardiogram, teleophthalmology and telediabetes, always following the guidelines and priorities of the Outline Plans issued by the Planning and Assessment Area of the Catalan Government's Department of Health.

Besides this, and as an innovative territory, Catalonia is one of the nine

European regions that participates in the Renewing Health Project². This telemedicine project for providing home care for chronic patients suffering from pathologies such as diabetes or cardiovascular and respiratory problems also forms part of the Competitiveness and Innovation Programme (CIP)³ for policies regarding ICTs in the European Union.

In Catalonia, the Health Technology Assessment and Research Agency (AATRM) and the TicSalut Foundation coordinate the development of the Renewing Health project, promoting a project that focuses on chronic obstructive pulmonary disease that affects over 300,000 people in our territory and is highly prevalent in the active population.

In short, telemedicine and the application of ICTs in health face great challenges that will gradually shape the future of healthcare for us: the ability of citizens to take responsibility for their own health, the possibilities of biomedical research, changes in the way professionals work and, above all, improvement in the quality of healthcare.

¹ <http://www.i2cat.net/en/projecte/catalonia-tele-ictus-network>

² <http://www.renewinghealth.eu/>

³ http://ec.europa.eu/information_society/activities/ict_psp/index_en.htm

Making patient-centred Telemedicine happen – why involving patients matters



Walter ATZORI and Liuska SANNA

European Patients' Forum

Founded in 2003, the European Patients' Forum (EPF) has grown to become the key interlocutor representing the European patient community to the EU institutions. Through its EU-wide membership of 47 national coalitions and pan-European disease-specific patient organisations, EPF advocates for equitable, patient-centred healthcare across Europe. As part of its work, EPF has been focusing on investigating the potential of Telemedicine as an alternative and/or complement to face-to-face patient care. There is a general consensus that telemedicine solutions can contribute significantly to meeting healthcare's present and future challenges. Issues such as demographic change, rising chronic diseases, growing healthcare costs, shortage of healthcare providers, and higher patients' expectations are putting increasing pressure on Member States' healthcare systems. The priority for policy makers is, therefore, to make healthcare systems more sustainable without this resulting in less quality, safety and accessibility of care. Available studies show that care through Telemedicine can contribute to improving patients' quality of life, enable continuity of care and the provision of equal access to medical expertise regardless of the geographical location, while producing cost savings for both the users and taxpayers in terms of reduced workflow and administrative cost (Chou C., Brauer D., 2005 and Grosset K., Grosset D., 2005). With the emergence of Telemedicine solutions the role of patients is changing from passive recipients to empowered actors increasingly responsible for the daily management of their own disease. From a patient perspective, one of the key challenges of remote patient care is the shift from traditional face-to-face types of patient-physician relationships to stronger two-ways partnerships in which trust and mutual understanding are fundamental prerequisites.

Over the last 10 years a growing body of research across different medical fields has attempted to better explore patient's satisfaction with telemedicine-based healthcare and confirmed that the attitudes of patients in this area play a significant role in determining health outcomes (Whitten P, Love B, 2005). While these studies seem to suggest that sacrificing face-to-face contacts is worth the improved access to medical care, they also show that patients have major concerns about the confidentiality associated to telemedicine services and tend to perceive the clinic as performing a "monitoring" function.

Patients will be much more inclined to use Telemedicine if they believe they can do so privately and safely and trust both the physicians and the technical provider. To the best of our knowledge, however, there are no scientific EU-wide studies assessing the perspective of the main end-users – both patients and health professionals – in terms of trust and acceptability of Telemedicine services.

Building trust in Telemedicine solutions must go hand in hand with any further technological advancement in this area. Patients and healthcare professionals can have different understandings of health and illness and this represents the major hindrance to patients' acceptance of Telemedicine applications. While investing in health-literacy and strengthening communication channels between end-users is required in any healthcare environment, this is even more important in Telemedicine where the quality of health outcomes depends, to a large extent, on patient's ability to play a more responsible role in his/her daily healthcare.

In this context, the launch of the new eHealth Governance Initiative¹ is strongly welcomed. It is an unprecedented platform for political cooperation between Member States and the European Commission on eHealth jointly supported by DG INFSO and DG SANCO, involving also user stakeholder groups, including EPF. Apart from providing user input into mainstream activities,

one of the key purposes of the stakeholders' involvement is to look specifically at trust and acceptability of eHealth among end-users with a view to producing concrete evidence to better inform decision makers and policy developments in this area.

Why involve patients in Telemedicine?

The added value of patients' involvement in Telemedicine is the integration of health professionals' theoretical and methodological expertise with patients' real knowledge and individual experiences into a mutually reinforcing partnership. Despite significant improvements towards more collaborative patient-centred healthcare, technological progress in telemedicine continues to be, to a large degree, technology and physician-driven processes whereby the patients are involved only in a late stage to obtain feedback when the application has already been developed.

Involving patients in telemedicine is a challenging and complex exercise, but failure to do so may result in significant mismatches between real patients' needs and the ability of the healthcare system to recognise such needs and respond in an efficient way. This in turn will result in less patient satisfaction, poorer health outcomes and hence lower quality of care.

EPF will explore the patient perspective in the context of the RENEWING HEALTH, an EU-supported project aiming at implementing large-scale real-life test beds for the validation and subsequent evaluation of innovative telemedicine services. Through participation in this project EPF will gather evidence on whether and how these services improve the quality of life of chronic patients, promote their meaningful empowerment while increasing their acceptance and satisfaction.

¹ http://ec.europa.eu/information_society/newsroom/cf/itemlongdetail.cfm?item_id=5447

Telehealth: Making House calls



Jeremi BONFINI

Senior Vice-President,
Himss Global Services

and **Chuck PARKER**

Executive Director,
Continua Health Alliance

In April 1924, "Radio News" magazine promised readers that the Radio Doctor would soon be arriving in their homes. Some eighty-six years later and telehealth is still seeking critical mass. Thanks to three organizations that are working to facilitate the widespread adoption of telehealth, the radio doctor just might finally make good on his promise: healthcare may soon be arriving in your home.

Continua Health Alliance, Healthcare Information and Management Systems Society (HIMSS) and Integrating the Healthcare Enterprise (IHE) have partnered to promote global convergence of health information from clinical environments to the home via telehealth.

Until recently, the move toward telehealth has been somewhat inhibited by concerns regarding integration into the continuum of care, inclusion in healthcare payment systems, scalability, and interoperability. What is changing now is that most healthcare systems in the developed world are now simply unsustainable due to rising costs, an aging population, and chronic illness. Many advanced healthcare systems are taking extraordinary leaps to modernize the hospital and the general practitioner's office. The home is next. What is even more encouraging is that in healthcare systems such as in Lothian, Scotland, the Spanish Region of Andalusia, and the U.S. Veteran's Administration, there is demonstrated evidence that telehealth saves money and improves health.

Bringing the Hospital and the Home Together

Healthcare professionals and other industry stakeholders are becoming increasingly aware that in order to effectively and efficiently provide the quality of healthcare that is demanded by an increasingly aged population while coping with a shortage of physicians and keeping costs down, healthcare services must be extended to the home. Personal connected health solutions—telehealth, can deliver information and services outside of hospitals and directly to healthcare consumers in their homes, allowing an alternative method of care.

"Technology is allowing us to move toward a consumer-centric model that focuses on improving individual quality of life and controlling the total cost of healthcare. A host of personal connected healthcare services and devices have been and are currently being developed to extend care beyond the traditional hospital and clinic walls and into the home, empowering individuals to take responsibility in managing their own health and wellness as well as relieving the stress on the healthcare system due to extraneous visits to ERs and provider offices." (Chuck Parker, executive director, Continua Health Alliance)

These solutions will allow advanced healthcare systems to cope with the growing shortage of healthcare professionals and skyrocketing associated costs, while addressing today's most pressing healthcare challenge: improving healthcare consumer outcomes while enhancing access.

Combating Challenges

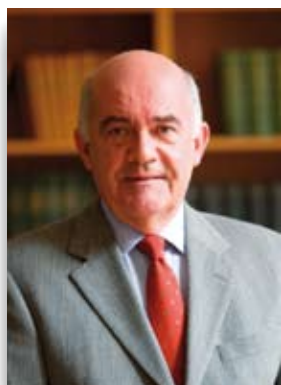
Payment systems, especially fee for service systems, have hampered clinician usage of telehealth solutions. Often healthcare providers are not rewarded for treating patients

unless there is an in-person consultation. This is changing, as recognition of the need for alternative healthcare solutions is becoming more widespread. Clinicians are often being offered additional options, even incentives to use telehealth solutions.

Telehealth equipment costs have also been historically high. Continua Health Alliance, an international industry organization formed in 2006, is working to develop interoperable devices that will allow more affordable personal connected health solutions. Continua Health Alliance has brought together more than 230 leading healthcare and technology companies to develop guidelines for a system of personal connected healthcare solutions. The Alliance defines personal connected health use cases and creates design guidelines based on open industry standards to provide framework for the development, certification and implementation of personal connected health solutions. Continua has drawn from the expertise and core competencies of its members to outline how to use existing standards to establish interoperability guidelines to build upon. The standards ensure that Continua Certified™ devices are interoperable, allowing for seamless data exchange and communication between individuals and physicians.

HIMSS, through its representation of clinical health IT managers and IHE through its Interoperability Showcases at HIMSS events has been leading the way in the adoption of interoperable IT systems. "Now, through Continua's participation in Interoperability Showcases, we are proud to demonstrate what is possible when data flows from hospital, to home to healthcare consumer and back again. This is the sort of demonstration that will be repeated around the world and fulfill our shared goals of higher quality, efficient healthcare," Bonfini added.

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



**Dr Jacques
LUCAS**

Vice President for Health
Telematics
French National Medical
Council

Roselyne Bachelot-Narquin, French Minister for Health and Sport reminded us that *“eHealth 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, Patients, Health, and Territories’ Act (July 2009) includes 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 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 Medical Council 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 Medical Council 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)

Telemedicine 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 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, etc.) 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) encyclopaedic knowledge, through the transmission of information in real time (innovation, therapeutic, medical alert, epidemic, etc.) or even through **Web2.0**, which renders patients interactive among 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 of 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.

Telemedicine: A Tool for Patient Empowerment



Nicole DENJOY

Secretary General
of COCIR (European
Coordination Committee
for the Radiological,
Electromedical and
Healthcare IT Industry)

Telemedicine is an emerging technology in the field of healthcare and one which has huge potential to help healthcare systems respond to today's challenges such as the demands of the ageing population, an increase in chronic diseases such as diabetes and health disease, a shortage of healthcare professionals and rising healthcare costs which put a strain on national budgets. COCIR, the association which represents the healthcare IT industry in Europe as well as the radiology and electromedical sectors of the medical industry, recognised the importance of telemedicine early on, working since the past decade on eHealth and its promising future as a key enabler to sustainable healthcare model. We then formed a dedicated focus group in 2009 to work on a smooth introduction of telemedicine into society and the need for an appropriate legal framework.

Our member companies have considerable expertise and have invested heavily in R&D in this area. We count pure IT companies as well as healthcare companies among our membership. Company representatives contribute their time generously to COCIR's activities, both on technical areas and in policy discussions in order to promote the development and deployment of eHealth solutions in Europe.

We believe that telemedicine can improve the quality of life of patients, empower the patient to manage their health, reduce hospitalisations and prevent exacerbations. Telemedicine can contribute to disease prevention and can leverage

information technology. This view is also supported by policymakers. A speaker from the European Commission told participants of the COCIR Focus Group that telemedicine has the potential to alleviate some of the pressure on healthcare systems, for example the demographic changes which will lead to more patients needing long-term care. As a tool for prevention and care, telemedicine can empower patients to take control of their care and to shift more patients from the hospital to home, therefore improving their quality of life, the Commission speaker said.

This vision was outlined in the COCIR White Paper 'Towards a sustainable healthcare model' which is available on our website. Taking this concept forward, we produced the Telemedicine Toolkit. The Toolkit contains a Position Paper, a Glossary of Terms and a Database of Referenced Studies on the effectiveness of telemedicine solutions and is designed to be the essential reference guide to telemedicine.

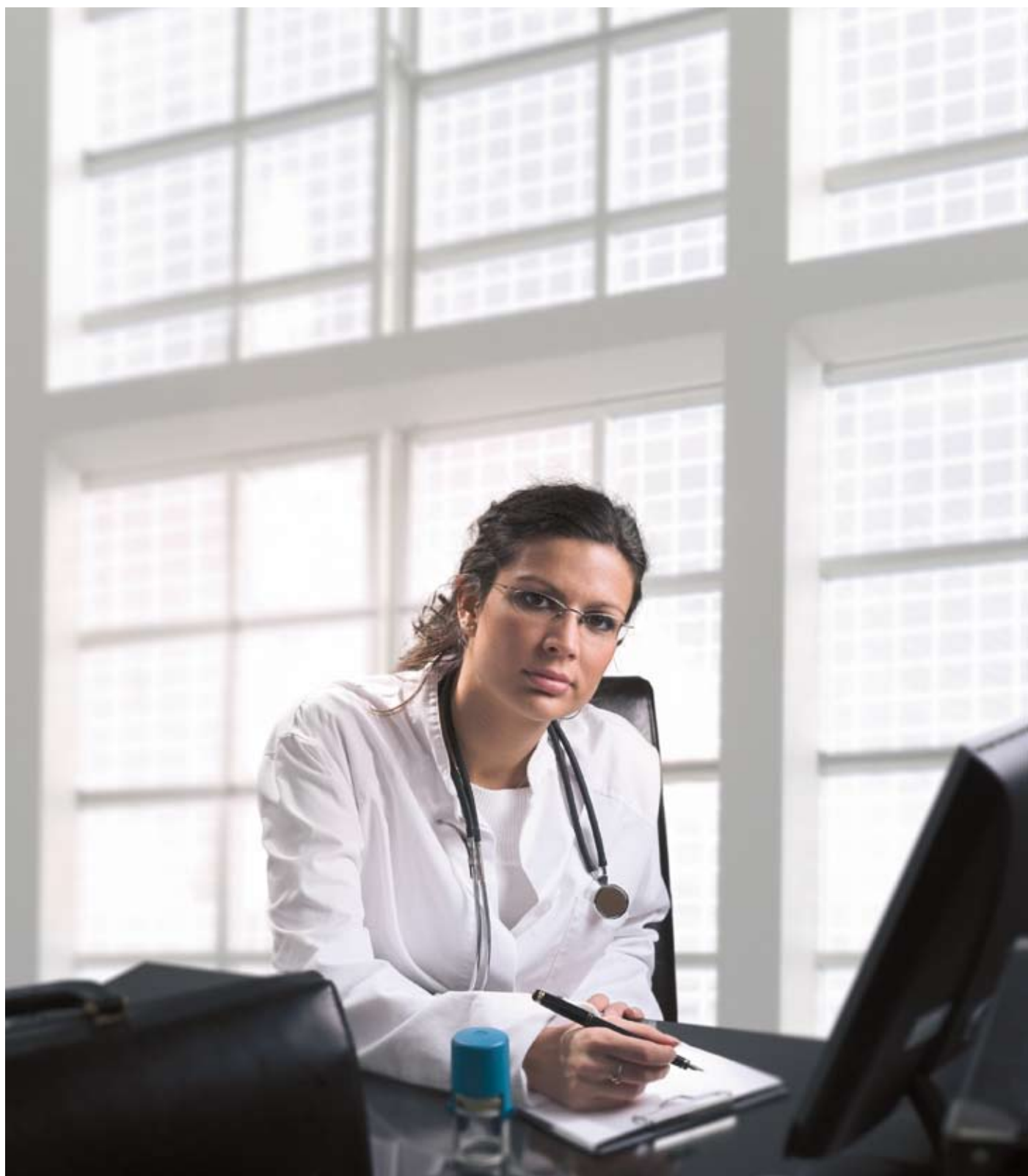
All of these tools respond to the need to clarify telemedicine – what it is, which technologies are included and what is needed for its widespread take-up. We have no doubt that telemedicine presents opportunities for empowering patients, particularly in the better management of chronic diseases. Patients who can be monitored from their home, for example, do not suffer the inconvenience and potential ill-effects of travelling to a medical facility for a regular check-up. This is particularly helpful for patients in rural or isolated areas and for elderly people.

The Position Paper includes five concrete recommendations for a stronger telemedicine sector in Europe, identifying the combined role of various stakeholders and the importance of working together to secure better access, empower patients, reduce health inequalities and optimise efficiency of the total healthcare system.

The Five Recommendations for Better Deployment of Telehealth are:

1. European Commission and Member States to establish an appropriate legal framework with effective transposition at country level
2. Strengthen cooperation between healthcare stakeholders to "best practice health strategies" supporting telehealth adoption in routine clinical practice
3. Finance more and sustainable large scale projects with health economic evaluation to assess the impact of telehealth solutions
4. Integrate telehealth into existing care delivery structures and ensure interoperability of telehealth solutions
5. Establish sustainable economic model for telehealth by starting dialogue between healthcare stakeholders

One of COCIR's goals with the Telemedicine Toolkit is to define common terminology as different terms are already in use. In all areas of our activities, we work towards internationally-recognised standards for efficiency for our members and to prevent the creation of trade barriers. The COCIR Glossary of Terms proposes clear definitions for the terms used in telemedicine and we encourage all stakeholders to use these definitions to ensure a better understanding among all actors. Not only does telemedicine have huge potential for patients but it is also a market where Europe excels and has excellent potential for growth and job creation. We understand the balancing act policymakers face as they strive to improve the quality and efficiency of healthcare whilst managing costs and promoting innovation. Telemedicine can contribute to meeting these needs and as an industry we will continue to work with all stakeholders towards a more patient-focussed sustainable healthcare system for the future.



Telemedicine for the benefit of patients, healthcare systems and society



Flora GIORGIO
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Unit ICT for Health, DGINFSO, European Commission

and former colleagues **Christoph Steffen**
and **Gérard Comyn**

Telemedicine - the provision of healthcare services at a distance - can help improve the lives of European citizens, both patients and health professionals, while tackling the challenges to healthcare systems.

European citizens are getting older and are increasingly living with chronic diseases. Their health condition often requires enhanced medical attention. Medical support may not be available in remote areas and for certain specialities as easily or as frequently as their health condition would require.

Telemedicine can improve access to specialised care in areas suffering from a shortage of expertise, or in areas where access to healthcare is difficult. Telemonitoring can improve the quality of life of chronically ill patients and reduce hospital stays. Services such as teleradiology and teleconsultation can help to shorten waiting lists, optimise the use of resources and enable productivity gains.

The benefits go beyond improving patient care and healthcare system efficiency. Telemedicine can also make a significant contribution to the EU economy. This sector, where European industry - including thousands of small and medium sized enterprises (SMEs) - is well placed, has been

expanding rapidly in the past decade and is expected to continue to grow at a fast pace.

Despite the potential of telemedicine, its benefits and the technical maturity of the applications, the use of telemedicine services is still limited, and the market remains highly fragmented. Although Member States have expressed their commitment to wider deployment of telemedicine, most telemedicine initiatives are no more than one-off, small scale projects that are not integrated into healthcare systems.

It is recognised that integrating these new types of services in healthcare systems is a challenging task. The aim of the European Commission Communication on Telemedicine¹ to support and encourage Member States in this endeavour, by identifying and helping to address the main barriers hindering the wider use of telemedicine and by providing evidence to build trust and acceptance. The Communication defines a set of actions to be taken by Member States, the European Commission and the broader stakeholders' community. It focuses in particular on:

- Building confidence in and acceptance of telemedicine services
- Bringing legal clarity
- Solving technical issues and facilitating market development

Regardless of the efforts in which the European Commission and other stakeholders are willing to engage, it is the Member States' health authorities, primarily responsible for the organisation, financing and delivery

of healthcare, that remain the principal actors with the ability to make telemedicine a reality in the life of European patients - in full respect of the subsidiarity principle.

By 2020 the European Commission wants to achieve widespread deployment of telemedicine services. It will do this by supporting deployment projects and implementing the Telemedicine Action plan as proposed in the communication. This includes providing support to EU Member States by helping to clarify legal, technical and operational issues and launched a large scale pilot «Renewing Health»² which will work across nine regions across the EU to test the efficiency and cost-effectiveness of telemedicine services and provide guidelines for consistent assessment.

The plans are ambitious and can only work with the cooperation of all stakeholders including governments, industry, healthcare sector workers and patients. The positive collaboration achieved with all partners to date resulted in fruitful achievements of many EC funded research projects³ over the past 20 years that are evidence of how effective this type of cooperation can be. New telemedicine services such as online medical consultations, improved emergency care and portable devices which monitor the health condition of people suffering from chronic disease and disabilities now show their potential to offer a freedom of movement that patients have never before enjoyed. Another notable success has been the creation of the eHealth Governance Initiative⁴ during the high-level



meeting on eHealth in Stockholm in October 2009. By building a structure which brings the governance, strategy and operational pieces of the eHealth jigsaw together we have a unique opportunity to put in place common standards for eHealth solutions and change the way eHealth in general, telemedicine in particular is perceived and used by our healthcare systems.

In addition, at a Ministerial Summit in Barcelona in March 2010⁵, EU Member States renewed their commitment to driving forward the further development of eHealth in Europe through enhanced cooperation. In March 2010, the European Commis-

sion launched its strategy for smart, sustainable and inclusive growth known as «EUROPE 2020»⁶. The strategy aims to achieve Smart growth – developing an economy based on knowledge and innovation; Sustainable growth – promoting a more resource efficient, greener and more competitive economy and Inclusive growth – fostering a high-employ-

ment economy delivering economic, social and territorial cohesion.

The eHealth sector: knowledge-based, efficiency-driven, continuing to grow – despite the economic downturn – and an area where Europe is a leader, is perfectly in tune with this vision for the future.

Building on this momentum, the European Commission has just launched one of the «Flagship Initiatives» of Europe 2020, the «Digital Agenda for Europe»⁷. The Digital Agenda for Europe puts the flesh on the bones of the Europe 2020 strategy when it comes to the EC vision for eHealth.

Firstly, it builds on the past results that demonstrated that eHealth can improve quality of care, reduce medical costs and foster independent living. Secondly, it acknowledges that if we want eHealth services to reach their full potential, we need to provide user friendly tools and services directly to our citizens and patients and at the same time pull down the legal and organisational barriers that are preventing progress and build up cooperation between EU Member States. The European Commission believes that this approach will help Europe to bring the two most undervalued resources to play: information and patients.

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52008DC0689:EN:NOT>

² <http://www.renewinghealth.eu/>

³ http://ec.europa.eu/information_society/activities/health/research/index_en.htm

⁴ http://www.epsos.eu/fileadmin/content/ppt/EHTEL_21_Oct_2009_-_Daniel_Forslund.ppt

⁵ <http://www.ehealthweek2010.org/>

⁶ <http://ec.europa.eu/eu2020>

⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52010DC0245:EN:NOT>

Legal aspects of cross-border telemedicine



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The growth of international telemedicine has spurred greater interest in its legal implications. Professional-to-professional telemedicine services include telepathology, telecardiology, teledermatology, and especially, teleradiology, which is the most developed example of cross-border telemedicine. Yet, legal uncertainty about cross-border teleradiology limits its further expansion. Legal uncertainty makes local radiologists hesitant to hire teleradiology services abroad.

The Member States themselves have called for European-based legislation on international telemedicine. In the summer of 2006 the EU health ministers called for clarity regarding cross-border healthcare and international telemedicine and instructed the European Commission to make proposals for necessary EU laws. The European Commission then proposed a Directive for cross-border healthcare¹ that has been accepted in first reading by the European Parliament in April 2009 with the adding of some crucial amendments². Not surprisingly for a matter of European legislation that infringes on the national autonomy regarding healthcare, this voting has been contentious. At the time of publication, the Directive has not yet been finally approved.

The amended Directive's articles-5 and -19 contain some important provisions about telemedicine:

Art. 5: Responsibilities of authorities of the Member State of treatment

- (a) when healthcare is provided in a Member State other than that where the patient is an insured person, such healthcare is provided in accordance with the legislation of the Member State of treatment;
- (b) healthcare referred to in point (a) is provided in accordance with standards and guidelines on quality defined by the Member State of treatment;
- (c) healthcare providers provide all relevant information to enable patients to make an informed choice;

Art. 19: eHealth

The Member States shall ensure that the use of eHealth and other telemedicine services:

- (a) adhere to the same professional medical quality and safety standards as those in use for non-electronic healthcare provision;
- (b) offer adequate protection to patients, notably through the introduction of appropriate regulatory requirements for practitioners similar to those in use for non-electronic healthcare provision.

Art. 5 establishes that the Member States where the patient seeks treatment is responsible for the entire chain of medical treatment, and that this country's law applies whenever medical examinations are outsourced to other EU Members States (assuming that these examinations are a part of the overall treatment); provision (b) holds that the Member States of treatment's standard on quality apply concerning qualifications and credentialing of medical specialists. And provision (c) leaves no doubt that patients should

be provided with adequate information regarding the outsourcing of their medical data. The emphasis on same medical quality and safety in Art. 19 again implies that telemedicine should be done by fully trained medical specialists accredited in the country for which they make their reports and that reporting is done in the language of the referring doctor. It also implies that the telemedicine specialist should make use of all available medical information when interpreting the medical data - which includes earlier radiology examinations. The directive in its present form comes a long way to meet the expectations of the medical professionals and is commensurate, e.g. with the joint position paper on teleradiology (2006) by the UEMS radiology section and the European Society of Radiology and with the view of the UEMS on data security and protection of privacy^{3, 4}. Several issues, though, await further clarification:

- (1) It needs to be unequivocally established that telemedicine is a medical act.

¹ European Commission. Proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare. COM(2008)414. Brussels; 2 July 2008. http://ec.europa.eu/health/doc/com2008414_en.pdf.

² European Parliament. Resolution on the proposal for a directive on the application of patients' rights in cross-border healthcare. Amendments to the text proposed by the Commission, Strasbourg; 23 April 2009. <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2009-0286+0+DOC+XML+V0//EN&language=EN>.

³ European Society of Radiology. ESR brochure-VII. Teleradiology in the European Union-white paper; November 2006. <http://www.myesr.org/html/img/pool/ESR 2006 VII Telerad Summary Web.pdf>.

⁴ Union of European Medical Specialists (UEMS). Bratislava declaration on e-medicine. UEMS 2007/19; 2007. <http://admin.uems.net/uploadedfiles/1111.pdf>.

A self-evident and perhaps trivial detail. Yet, in some EU Member States, e.g. Austria, telemedicine cannot be considered a medical act because according to Austrian law a medical act requires that the patient and his treating doctor are physically present in the same room. If telemedicine is not considered a medical act, this could mean that the legal protection offered with regard to medical procedures shall not apply;

- (2) Should patients give informed consent for telemedicine and can they opt to refuse its use?
- (3) A system for quality control or auditing telemedicine services should be developed;
- (4) Rules governing reimbursement of telemedicine services need to be agreed.
- (5) The proper legal procedures to follow in case of conflicts over telemedicine services.
Legal experts agree that the only possibility to sue should be before a court in the EU member country where the patient receives treatment, and not in the country where the telemedicine specialist resides⁴;
- (6) EU law does not apply whenever telemedicine firms are located outside of the EU.

In these cases, legal certainty can only be obtained by clear contractual agreements between provider and customer (e.g. which national law applies, in what country disputes should be settled before court, etc.).

A potential pitfall of too complex regulations

Extensive existing EU legislation is in place that also applies to crossborder inter-European telemedicine, e.g. with regard to the protection of individuals and processing of personal data, and



to the delivery of commercial electronic services within the EU (Table 1)⁵. A formidable problem of the legal aspects of cross-border telemedicine is in the complexity of integrating these existing rules which may be daunting even for the judicial expert. The legalities contain elements of national health law, national civil law, information technology law, international civil law, European law, competition law and consumer law, which may or may not be internally consistent. The legal field is fragmented in specialty domains and only few lawyers complete oversee all laws that apply to teleradiology (telemedicine). A real problem here, as voiced by a leading judicial expert, may be in the access to and dissemination of the required legal knowledge for its deployment⁵. The current article has been adapted from ref.⁶.

Table 1

Existing EU legislation with relevance to cross-border teleradiology within the European Union (modified from Ref.⁵).

With regard to data protection

- Directive 95/46/CE on the protection of individuals with regard to the processing of personal data and on the free movement of such data (24 October 1995)
- European Convention on human rights, art. 8
- Charter of the fundamental rights of the EU, art. 7 and 8

- Convention for the protection of individuals with regard to automatic processing of personal data (Council of Europe, European Treaty Series, no. 108, Strasbourg, 28 Jan 1981)
- European Court of Human Rights rulings, I versus Finland (17 July 2008)
- Etc.

With regard to delivery of electronic services within the EU

- Directive 2000/31/EC on e-Commerce (8 June 2000)

With regard to regulation of electronic communications and quality criteria for health related electronic data transfer

- European Commission Recommendation COM(2008)3282 on the interoperability of electronic health record systems (2 July 2008)

With regard to promotion and selling of products and (distant) services

- Directive 2005/29/EC on unfair business-to-consumer commercial practices (11 May 2005)
- Directive 84/450/EEC on misleading advertising (10 September 1984)
- Directive 1997/7/EC on the protection of consumers in respect of distance contracts (20 May 1997).

⁵ Hervé J. Introduction to the European legal framework for eHealth telemedicine services. Presented at the legal workshop on telemedicine, 7th Ministerial eHealth 2009 Conference. Organized by the European Commission/Czech Presidency. 18 February 2009.

⁶ Pattynama PM. Legal aspects of cross-border teleradiology. Eur J Radiol 2010; 73:26-30.



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Legal issues on the agenda in telemedicine

Towards personalized medicine and personalized health monitoring

Today's medicine is challenged by some important developments that have the power to change dramatically the role of the patient, hospitals, industry and other healthcare actors. Medicine is becoming personalised medicine with medicinal products designed to take into account the specific genes of patients and hospital care for patients is organised through clinical pathways to the patient. A similar tendency is emerging in the field of telemedicine whereby personalised health monitoring is attracting increasing attention. Personalised health monitoring covers a very wide area of products, services, procedures and techniques and refers to systems and services aimed at health status monitoring. It includes e.g. the use of implantable, wearable or portable ICT systems which facilitate remote monitoring of people with chronic diseases and the use of body scans at the airport to control if someone is contaminated with influenza. Personalised health monitoring devices may aim e.g. to monitoring the patients' clinical status as well as the early detection of several diseases. They may improve the quality of health care and make it possible for a healthcare professional to react more pro-actively. Personalised health monitoring will change the current role of physicians, hospitals, patients and industry.

Towards new European rules for hospitals

These recent developments in telemedicine may lead to benefits for patients if some important legal questions regarding the new role of the healthcare actors are answered. Monitoring devices will lead to changes in the way physicians and hospitals usually work. Physicians and other health care professionals as well as hospitals will have to always be on standby for the patients they monitor in case of an emergency. This implies that they will have to organise a guard duty probably with many other health care professionals and hospitals especially in view of the increasing shortage of physicians in several Member States. This guard duty to monitor and follow up can find its place inside or outside a hospital. These hospitals will play a new role in the future. Nowadays physicians are working inside the hospitals and examine and treat the patients who arrive in the hospital. When it comes to monitoring, one physician may monitor a lot of patients that are not (yet) in a hospital. The physician who is monitoring the patient may be working outside the hospital. So, by applying telemonitoring services there may be a huge increase of patients to follow. Moreover personalized health monitoring simplifies cross-border health care and the chances are high that reference centres will treat more patients (from several countries) than in the past. It seems also obvious that this field of telemonitoring will – in view of the shortage of physicians – urge

health care players and hospitals to work together beyond national boundaries to follow patients through telemonitoring. This activity of telemonitoring leads to important questions concerning hospital legislation such as: Who will be responsible for the organisation of guard duty? Who will have access to the information arriving in the hospitals? May a physician delegate the processing of data to a non-physician? What is the status of a physician that is participating in a guardsystem for telemonitoring organised by a hospital? Is this status different if the physician who is monitoring a patient at a distance, is working outside the hospital, participates in the "medical council" representing the physicians in the hospital? Is the hospital still the central contact point in case wrong information or bad care was given by the tele-physician? Can a hospital which works with independent physicians at a distance be held liable if the physician causes harm to a patient? It would certainly be in favour of telemonitoring if the basic answer to these questions would be similar across all EU Member States.

Relation between patients and industry

The aim of (home-based) (tele) monitoring is to promote patient self-care through education, so that patients get into the habit of self-monitoring and are empowered to play a more active role in their own health care management and variation in daily intake. Patients will become more



involved and accountable for the management of their (chronic) diseases. The role of the industry will change too. Delegates and employees from the medical device industry will have to be in direct contact with the patients to e.g. implant the personalised device, give information about how it works, to repair the device etc. As nowadays the industry only has contact with the physicians, there is in principle no direct contact between the industry and the patient. This situation will change when applying telemonitoring. Specific rules at the European level will be needed to regulate the relation between the industry and the patient for example to avoid illegal advertising or to avoid overconsumption.

Reimbursement of telemedicine

Another challenge will be drawing up a European regulation concerning the reimbursement of personalised health monitoring. The applications of personalised health monitoring will increase if the cost of the monitoring device, the cost of the implant of the device, as well as the cost of the treatment at a distance would be reimbursed by the (national) insurance companies. With regard to the reimbursement of medicinal products, the EU has enacted specific rules (see e.g. the Transparency Directive 89/105). It could also be a good idea to enact basic principles with regard to the reimbursement of telemonitoring devices

and/or activities at a European level. Some important (legal) questions and challenges in this context will be examined in a 7th Framework Project of the European Commission called "Personalised health monitoring (PHM) – Interdisciplinary research to analyse the relationship between ethics, law and psychosocial as well as medical sciences".¹

¹ <http://ethics.p-h-m.org>

Telemedicine: from technology demonstrations to sustainable services



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Telemedicine: a crossroad where space can meet health

The European Space Agency (ESA¹) is actively involved since years in promoting the development of Telemedicine² applications. More than 120 health-related projects³ have been carried out so far by ESA, half of which dealing with Telemedicine. ESA's interest in Telemedicine comes from two different perspectives:

1. **astronauts' health:** the potential support of Telemedicine during manned spaceflight missions, especially to avoid (whenever possible) the re-entry of a flight crew, whenever a medical problem arises during a mission
2. **terrestrial applications:** the potential role which different space assets can play in facilitating the provision of telemedicine services to citizens and organisations in different terrestrial utilisation scenarios

On one hand, telemedicine has led to series of development projects tightly associated with the very specific domain of space medicine, to prevent and manage medical emergencies during missions of astronauts in spacecrafts or crews of space analogue habitats (e.g. Concordia station in South Pole).

On the other hand, telemedicine using space assets to facilitate the provision of services on the ground has trigged

red a significant number of activities in different domains of eHealth (e.g. tele-consultation, second opinion, tele-education for healthcare professionals, tele-homecare). These activities have exploited the capabilities of:

- **satellite telecommunications**, to link healthcare professionals and patients wherever they are placed
- **satellite navigation**, to localise and help guiding medical emergency teams on the field
- **earth observation**, to extract environmental data relevant for health aspects and contribute to building up health risk maps
- sometimes **a combined use of these above capabilities together with technologies initially developed for manned space flights** but also useful on Earth (e.g. robotized tele-echography).

Potential of space-based Telemedicine

ESA's terrestrial telemedicine applications have raised strong interests among different actors such as medical doctors, healthcare organisations, systems suppliers, service providers and research institutions. Potential opportunities for new businesses have been catalysed by the sequel of benefits that are typically associated with telemedicine, such as:

- the ability to improve the access to healthcare services (e.g. access

to specialist healthcare for second opinion or tele-consultation from remote areas, or via tele-homecare for elderly people at home)

- the possibility to foster a better utilisation of healthcare system resources (e.g. infrastructures, medical equipment and healthcare professionals, that can be centralised and reached by telecommunications means rather than being geographically scattered)
- the possibility to reduce indirect costs while improving comfort for the patients (e.g. avoiding patients to travel to healthcare structures when not strictly needed)
- the opportunity offered by distance learning for continuing medical education, pursuing the paradigm of moving knowledge rather than moving people

Associated barriers yet to overcome

In spite of such potentials, telemedicine is not developing as quickly as expected. The success of many demonstrations projects contrasts with the slow uptake

¹ www.esa.int/health

² Telemedicine is here understood as the provision of medical services at a distance through the use of Information and Communications Technologies (ICT)

³ <http://iap.esa.int/iap-themes/Health>

experienced by many initiatives aimed at delivering operational telemedicine services. This is often claimed to be caused by a number of barriers, which so far have proven to be very difficult to overcome. Such barriers include:

- **the lack of awareness:** telemedicine is still an untapped area to a great extent.
- **the lack of mature products:** the immaturity of demands and the lack of consolidated offers (e.g. mature products) get often trapped into a vicious cycle. Modest market opportunities indeed hamper the consolidation of mature solutions (technically and operationally).
- **the resistance to changes** in the healthcare area. This can be a combined effect of a conservatory approach, lack of incentives, chronic lack of resources (including time) of healthcare professionals, and scepticism of patients who sometime perceive telemedicine as a “surrogate” of a medical act.
- **the difficulty in working out a convincing telemedicine evaluation** providing evidence of the actual benefits brought by telemedicine and able to convince the right stakeholders. This is probably one of the most difficult hurdles to overcome as there are no or few adequate methodologies for such purposes.
- **the lack of reimbursement schemes.**
- **the lack of interoperability** (technical, legal administrative) of telemedicine systems and services at national and trans-national levels.
- **the lack of a coordinated approach:** the many barriers make extremely difficult the uptake of initiatives beyond exploratory pilot projects with local characterisation. Such pilot projects are certainly good instruments to create and demonstrate innovative telemedicine applications in lead



markets. However, they contribute to generate a rather fragmented mosaic of very interesting initiatives, but with high mortality rates. Therefore, this lack of coordination does not really facilitate their migration towards sustainable operations and reach of a sensible economy of scale.

How to improve?

Although some of these barriers cannot be overcome without actions at European level, there is space for improvements at project level. This requires to:

- well assess user needs and define operational scenarios as this contributes to create a coherent consensus-based vision of the problems within end users communities
- identify the right stakeholders, understand their agendas, their needs and expectations, and find a suitable way to involve them
- properly familiarise with technical solutions, avoiding “technology

drop” (demonstrate and walk away) approach

- run real pilot utilisations, evaluation and field trials to understand whether innovative solutions are suitable for end users to perform medical acts, or not. It is fundamental to collect and analyse indicators (e.g. adoption and utilisation intensity) on continuous basis during projects and not just at their end when adaptations and/or re-steering cannot be implemented anymore. Moreover, delegating to the users the debugging phase of the solutions has serious counterproductive effects.
- involve the right users and stakeholder, in a holistic way to better lie within the global Telemedicine framework
- perform a comprehensive outcome and impact assessment to provide evidences of actual Telemedicine benefits.

Telemedicine and reimbursement, the way forward



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Telemedicine, defined as a delivery of healthcare services through the use of ICT in a situation where the health professionals and patients are not at the same location, encompasses a broad range of applications¹. According to some evaluations, telemedicine can improve access to healthcare in remote areas, the quality of life of chronically ill patients through telemonitoring for example, as well as overcome shortages of health providers. There is much less evidence on return on investment (ROI), like diminution in hospital bed days. The reality shows that telemedicine remains limited to numerous small pilot projects. The reasons to the lack of deployment of telemedicine are multiple, like technical, organizational, regulatory and legal issues. The absence of consistent, comprehensive reimbursement policies is often cited as one of the most serious obstacles to the integration of telemedicine into health care practice. But the reimbursement barrier, like the other barriers, can be solved, providing some conditions are filled.

The first one is the need to convince payers and healthcare providers that telemedicine has an added value. Different tools can be helpful like providing information on evidence based cases. There is a need to develop health technology assessment for telemedicine with appropriate tools, where the role of the European Commission is to coordinate the development of European quality standardised tools. Even if the majority of the projects failed to give evidence on that, one should continue to provide information on cost benefit analysis (ROI)

and to develop business cases for telemedicine applications, while clarifying the definition of business case.

There is also a need to provide a definition of telemedicine within the national health law and/or the Medical Association, like the report on telemedicine made by the French Medical Association. The procedures of telemedicine should be described (standards, guidelines) and the training, accreditation, authorisation of healthcare providers are to be well established, as well as quality assurance for telemedicine. It is obvious that all the legal questions, including the personal data protection, liability, tax and competition issues, have to be clarified.

When the conditions of deployment are satisfied, the reimbursement issues depend of course of the health system. It is a matter of revision of the national nomenclature of healthcare activities (standard tariffs) in a health insurance-based system or of integration in the national health financing system, like in a national health system. Different reimbursement and financing models exist, like fee for services, lump sum or capitation models for doctors, as well as DRG for hospitals, or mixed models. In different systems, incentives or pay-for-performance can be developed to increase the telemedicine services. There is no one-size-fits-all solution among the 27 health systems in the European Union, different systems need different solutions, but one can learn from best and bad practices in each country.

For example in the Netherlands, since 2006 a special fee for e-mail consultation was introduced, but the reimbursement occurs provided that the doctor has seen the patient before (tariff: 4.5€). The health insurers reimburse also consultations of teler dermatology (tariff: 30-55€) and other consultation forms are in preparation, like teleophthalmology and telespirometry. According to press releases, 8,000 practitioners are involved in the process.

For the specific question of cross border Telemedicine, the liability, health professional registration and reimbursement issues are to be taken into account. The successful example of cross border teleradiology applications are very helpful for this purpose.

Lastly, ehealth and telemedicine will have substantial effects on healthcare organisation, in addition to the shortage of healthcare providers and the need of new role within the health workforce and new jobs, the trend towards more home and personalised care of chronic diseases, as well as the need to better coordination between long term care and health care, between primary and secondary care. The challenge for the government, the health professionals and health protection bodies is to rethink together the organisation of healthcare delivery: a new visionary healthcare model towards patient coordinated healthcare.

In conclusion, telemedicine is part of the digital agenda of the Europe 2020. In order to pass from small pilot projects to national deployment of telemedicine, as stated by the ehealth declaration during the eHealth Ministerial Conference 2010 in Barcelona, there is a need of political will. It is the reason why showing evidence on the added value of telemedicine applications is vital, in order to convince the health authorities and the health professionals. Once the legal barriers are solved, the reimbursement question is an issue of integrating telemedicine in the health delivery system. Ehealth and telemedicine are catalyst for the adaptation of healthcare delivery to an evolving environment.

¹ For example: tele-Diagnosis for radiology, ultrasound, EKG, Holter, remote monitoring of chronic patients, tele-consultation (videoconference), tele ophthalmology- dermatology- neurology- pathology, teleconsultation, e-prescription, sms, medical support by call center. Electronic health records and health information portals are not included from the purpose of this article.

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