



# Implementation of eHealth in Europe Position Paper

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## **Executive summary**

This document is a publicly available deliverable from the PROEHTEL Consortium to the European Commission.

The development of an EU-wide provision of digital applications and services via a secure interoperable network is the eEurope vision of the member states. By 2005 member states have committed themselves to introduce transnational health cards that should become digital over the following couple of years.

This document highlights what is expected from eHealth by citizens, health professionals and care providers and by industry over the next decade. It describes the necessary actions and changes of attitudes needed to move from present reality to what is expected.

Throughout the text there are Recommendations clearly marked, and these are considered to be the future contributions of EHTEL eHealth.

*Section 1* confirms that the vision of the EU is strongly supported by member state leaders. It also describes the elements of eHealth, namely the digital provision of clinical services, educational and training applications including those for the general public, and administrative and financial services.

*Section 2* relates to society, citizens, health professionals, and health services, summarising the demands. It describes the changing demographic, disease and therapy patterns, which are increasing life span, more chronic diseases and complex and costly therapies leading to increased consumer and access demands. Patients are being treated closer to home and will, together with the family, become responsible for themselves.

The EU, which may soon be seen, also, as a common market for health services, is undergoing enlargement and migration across its borders will grow further and a number of threats to health will be widespread. All these factors indicate that health services will become more global and need IT-support. The section gives a description of the consequences for eHealth, of the development of genomics and bio-informatics; results from these areas will be available, soon, as eHealth elements. However, in the associated recommendations, it is suggested how the new data could or should enter the electronic medical record and highlights the role of EHTEL as a vigilant observer.

The section closes with a description of citizens' needs and demands, as well as those of health care providers, administrators and researchers.

Empowerment of the citizen, services such as ePrescribing, homecare and individualised care are prioritised topics.

*Section 3* addresses the evolving technologies; it propounds that even simple, mass produced electronic support devices will pose problems in healthcare, either because of incorrect or unsafe use or construction. There are also cutting edge devices emanating research which can be used for complex procedures in health, such as robotics, bioinformatics, image manipulation, haptics etc. Ubiquitous (or pervasive) healthcare is ambient, and pervasive computing applied to health gives new possibilities to monitor patients at a distance. This technology and proper infrastructure will allow for much improved telemedicine services, provided that regional or national electronic health record systems are deployed. The transition from institutional EPR systems to trans-institutional EHR systems are huge and will demand integration platforms, only recently developed. Without the capability to feed information obtained by telemedicine services into a record structure, important data may get lost.

*Section 4* deals with the education and training that is part of the eHealth services to both professionals and citizens, individual and in communities.

*Section 5* is concerned with the market and the vendors. Based on analyses in different member states, it claims an insufficient investment in health ICT in the past for the industry to penetrate a market, the size of which is not known, precisely. It is encouraging to note that collaboration between EHTEL and other health initiatives may drive the debate, but more work is needed. To open the market positive, political decisions at all levels will have to be taken and a number of other barriers broken down. Public/private partnerships must be formed and technical interoperability between systems, via open standards, established by industry. There is a potential to reach markets outside EU.

Implementation of the EU vision on eHealth is the subject of *Section 6*, which describes a number of initiatives necessary to overcome hurdles that are more of a political/professional nature than technical. The positive political attitude must mature and result in decisions being taken; security and PKI issues must be solved, international interoperability of infrastructure and systems are needed and regulatory ethical issues must be in place. Many of these issues can be supported by national organisations, demonstration sites of best practice should be updated and enlarged continuously, and quality criteria set up. Evaluation of benefit and cost is essential and a set of evaluation elements for telemedicine is given in a separate annex as an illustration.

## **SECTION 1 Introduction and Background**

Within the framework of the EU-funded PROEHTEL project, the EHTEL eHealth Working Group was commissioned to write this publicly available document. At the European level, the recommendations of this paper are directed to the European Commission and all health-related parties (including the Health ICT Industry), and globally to the supra-national organisations that are active in European and international health politics.

The Working Group presented a "Position Paper for the development of eHealth Europe" in February 2002, and this document complements the analysis of the state of the art with suggestions for the comprehensive implementation of eHealth in Europe.

### **1.1 Vision for the EU and Member state policies**

Advances in technology and particularly the provision of security measures for IP-based communication networks allow for seamless transmission of medical data, which, in synergy with the widespread provision of public education on healthcare matters, facilitates equal access to high quality healthcare services by all European citizens. European citizens are poised to benefit from the ubiquitous provision of quality healthcare services through a healthcare reform transformation brought about by the widespread deployment of eHealth practices and solutions.

This process is already taking on a Pan European perspective with national borders between member states becoming less of a barrier both for access and the provision of healthcare services. This is especially important with candidate countries applying to join the European Community, where healthcare provision is very different from that achieved by other European member states. The EU documents eEurope 2002 and eEurope 2005, adopted in May 2003, mark a significant change of attitude amongst European politicians. They signify that health care delivery and services are also an element of eGovernment, which should simplify administrative procedures and increase access of citizens to relevant information and interactive handling of matters pertaining to the individual. It also demonstrates that health services should be delivered electronically, via a national infrastructure interoperable with those of other Member States with, at least, the same security precautions and demands for quality of applications and content, that apply in other domains, such as eBusiness.

For 2005, the common goals are to stimulate secure services, applications and content over a widely available broadband infrastructure.

For healthcare, the emphasis is on

- ⇒ health cards,
- ⇒ health information networks and
- ⇒ on-line health services.

Clearly, this is a top-down approach activating governments. However, in order to materialise, it must be combined with a bottom-up approach because healthcare delivery is often a local or a regional responsibility.

The evolving changes, with new member states coming into the European Community and their special needs for restructuring care provision, highlights the need for collaboration and interoperability.

At the recent EU ministerial conference on eHealth (May 2003), the Commission's plea was for interoperability, standardisation and integration of systems. Also, the conference issued a declaration on eHealth which was referred to as "the use of modern information and communication technologies to meet needs of citizens, patients, healthcare professionals, healthcare providers, as well as policy makers."

eHealth is analogous with eBusiness, eBanking and eLearning in that it comprises a range of services and applications with the purpose of improving access, quality and cost efficiency.

Broadly, eHealth can be conceived as:

- ⇒ clinical applications including telemedicine, decision support with access to databases, vital signs monitoring and home telecare,
- ⇒ individualised professional education and training,
- ⇒ information and education for the public,
- ⇒ health services, such as cost reimbursement, prescribing and nursing.

It is considered that eHealth not only enables healthcare staff, but brings the citizen into a higher focus and empowers them to become co-responsible for their health status and choice of treatment of disease: *"The ePatient is part of the therapeutic team"*.

Monitoring of chronic diseases, which is showing an upward trend and accounts for as much as 60 % of health care costs, can be moved, partly, out of large institutions into smaller units or to the home. Indeed, there is a strong trend towards home telecare. The ubiquitous access supported by mobile links and services and by "pervasive computing" will

push this trend as well as apply pressure for the implementation of new working procedures in institutions.

The recent EU Ministerial conference also demonstrated that it is now a common aim within the European Countries (including candidate countries), that eHealth should be a central structuring factor of healthcare provision, in addition to preventive and other health related activities of citizens and patients.

Some quotations from that declaration illustrate this point:

"Ministers expressed their commitment to the development of national and regional eHealth implementation plans as an integral part of eEurope 2005. Ministers declared their willingness to work together towards best practices in the use of Information and Communication Technologies (ICT) as tools for enhancing health promotion and health protection, as well as quality, accessibility and efficiency in all aspects of health care delivery."

and

"The ministers recognised that efficient national planning and evaluation of health policy, as well as cost effective delivery of health care, require speedy, accurate and comprehensive exchange of data. Ministers noted that the accessibility to appropriate health information can be enhanced through the use of secure shared eHealth applications, such as those described in the objectives of the eEurope 2005 Action Plan<sup>1</sup>, and agreed in the Council's Resolution<sup>2</sup> of 18 February 2003 on the implementation of the eEurope 2005 Action Plan."

Accordingly, individual statements from several of the European National Health Ministers and government leaders have demonstrated that this is not only policy at EU-level, but also policy at member state level.

eHealth also has a role as an integrating element and as the common denominator in other major policies of the EU in sectors, such as pharmaceuticals production, food and agriculture and the measures against disaster, bio-terrorism and terrorism, as in military affairs.

## **1.2 Objective and Scope of the Document**

This paper is intended to demonstrate how EHTEL will be supportive to the aspirations of Europe to become the leading voice for eHealth implementation in the world by

- ⇒ demonstrating the state of the art in eHealth in Europe and worldwide
- ⇒ defining short and long term priorities for the transition to "eHealthcare" in Europe

- ⇒ devising Guiding Principles and defining Milestones for the European Commission as well as the Member states for the transition to "eHealthcare".

## **SECTION 2 Societal and Healthcare Issues**

### **2.1 Demographic Changes and other driving forces**

Demographic and socio-cultural changes with an ageing population and a growing share of chronic diseases are responsible for the increased and modified demands for healthcare, nursing services etc. These demands confront the already challenged European healthcare systems with additional tasks and the need for restructuring and re-organisational measures. In addition, progress in medical research and medical technology, like the advent of biogenomics and bioinformatics are leading to a radically changing reference framework for health professionals and provider organisations; eHealth offers solutions to cope with and manage the challenges.

The major drivers which are forcing change (and a paradigm shift) are:

- ⇒ obligatory search for cost containment,
- ⇒ changing demographics, i.e. ageing population,
- ⇒ changing disease and therapeutic patterns requiring continuity of care and/or collaboration between various health professionals and healthcare provider organisations (e.g. diabetes, cardiovascular and respiratory diseases, locomotor ailments, epilepsy etc),
- ⇒ more therapeutic opportunities,
- ⇒ impact of information technology including ICT support for clinical decisions and telemedicine,
- ⇒ more informed and expectant patients,
- ⇒ equal access for all citizens to all levels of care,
- ⇒ health care delivery close to the patient,
- ⇒ responsibility shift into patients hands and to the communities,
- ⇒ organisational and administrative issues.

One of the biggest challenges facing the healthcare sector is to manage the change in practices and roles as a result the ongoing de-institutionalisation of healthcare delivery. There is already evidence that healthcare services, which have been traditionally available only within physical institutions, such as hospitals and clinics, are increasingly moving out of that space into the retail environment as evidenced by the reducing numbers of beds and the moving of services to make them accessible and deliverable in an ambulatory setting (day-care surgery, ambulatory diagnostic clinics, etc).

This trend will increase and accelerate with the deployment of home telecare services. Sentinel devices are being fitted into homes, making them "smart homes" or safe environments allowing the more vulnerable members of our community (elderly citizens and the like) to live alone, but with instant access to appropriate healthcare services.

## **2.2 European Integration in a common market for health services**

There are new challenges and also some responses already, in particular:

- ⇒ The upcoming enlargement of the EU will encourage increasing migration movements calling for satisfactory solutions for the provision and reimbursement of cross-border healthcare for patients and citizens travelling into or working within other European countries.
- ⇒ The rise in cross-border healthcare has already led to the initiative of the European Commission to introduce a European health insurance card. Yet beyond a pure administrative solution for access to healthcare and reimbursement issues, health professionals will need authorised, patient granted access to personal health related data, to be able to provide the best possible diagnostic and therapeutic measures suited for the patient's health problems.
- ⇒ The increasing mobility of the citizens is also reflected by the need for telemedicine services to be provided on airplanes and on ships and ferry boats.
- ⇒ New international health threats, e.g. related to new infectious diseases (SARS) or to the threats of bio-terrorism need quicker responses than hitherto, to limit the spread of health hazards.
- ⇒ In addition, the information hunger of a well-educated world population demands comprehensive and quality assured health information to be made accessible.
- ⇒ Taking into account the increasing cross-border use of health services quality-assured health information must be made available beyond national borders to support mobile citizens and patients across Europe.

Recent rulings of the European Court of Justice support a Europe-wide common market with respect to free movement of persons, services and goods including health services.

## **2.3 Millennium Megatrends and Emerging Health Opportunities**

### **2.3.1 Biogenomics & Proteomics**

Biogenomics research is rapidly increasing our understanding of how genes function in normal and disease states. In medicine, the identification of gene sequences involved in disease and complex traits will provide a basis for the study of individuals' and populations' susceptibility to diseases, the pathogenesis of disease and the development of novel (including transgenic and gene modification) therapies and preventive measures. Proteomics has existed as a distinct discipline since the mid-1990s. It encompasses protein identification, characterisation, and expression studies (comparison of protein expression levels between healthy versus diseased samples or control versus treated samples), studies of protein function and roles in biological pathways and structural studies.

Massive volumes of data are involved. Substantial effort is now being applied to methods by which the resulting information can be usefully stored and accessed by computer systems. HKIS (IST-2001-38153), for example (part of Healthgrid – see below), a project to investigate the use of genomic and proteomic data for the prediction, diagnosis and treatment of cancers.

### 2.3.2 Bio-informatics

Europe has a lead in the science of bio-informatics. In 1980 the European Molecular Biology Laboratory (EMBL) established the world's first nucleotide sequence database at its Heidelberg laboratories. In 1992, the European Bioinformatics Institute (EBI) was established and there followed a gradual transition of the activities from Heidelberg, till in September 1995 the EBI occupied its current location on the Wellcome Trust Genome Campus. The EBI serves researchers in molecular biology, genetics, medicine and agriculture from academia, and the agricultural, biotechnology, chemical and pharmaceutical industries. eHealth networks can augment the efforts of the EBI by providing base data and feedback - demographic and epidemiological patient data and near real-time information on the effects of therapies.

There are massive benefits for eHealth to be gained from harnessing bio-informatics. The key to ensuring that these benefits are realised is the roll-out of eHealth systems that can be developed to accommodate and interface with the immensely data intensive environments.

The importance of these systems is recognised in European Union's Sixth Framework Programme (FP6) which has life sciences, genomics and biotechnology for health as one of seven major thematic priorities. Initial interest is in combating cardiovascular disease, diabetes and rare diseases; combating resistance to antibiotics and other drugs; studying the

brain and combating diseases of the nervous system; and studying human development and the ageing process.

### **Recommendations**

- ⇒ EHTEL should ensure that infrastructure and service providers are mindful of likely network capacities as systems mature.
- ⇒ EHTEL should articulate a clear position not only on privacy and security issues but also on ethical and societal matters in respect to the outcomes of bio-informatics.
- ⇒ EHTEL should particularly ensure that players are mindful and vigilant when bio-informatics generated under FP6 projects are incorporated into Electronic Health Records.

## **2.4 Citizens needs and demands related to healthcare provision**

### **2.4.1 Empowerment of the citizen and the patient**

Public and private sectors have both realised the necessity and the benefits of providing services that empower the citizens and consumers to decide for themselves on an informed basis over a wide range of issues. The advent of interactive digital communication via the internet with sources of information stored in databases or retrieved from centres of relevant expertise has opened new horizons not yet fully explored and exploited.

In the healthcare sector this has become the case in relation to the individual citizen's management and promotion of their well-being, the choice of diagnostic procedures, treatment and care in case of illness including the free and informed choice of medical expertise. Monitoring of chronic diseases, with an upward trend, and accounts for as much as 60 % of health care costs, can partly be moved out of large institutions into smaller units or to the home. The healthcare personnel can act as advisers together with the patient, the relatives and the local community. These opportunities should make the citizen co-responsible for their health and add to their general satisfaction, providing the health sector with a reduced financial burden, in spite of increasing consumerism.

On the other hand, there is the danger that information sought by the individual could be wrong, and could increase the risk of breaching ethical rules and good practice, by the providers of digital communication.

### **Recommendations**

- ⇒ Breach of safety and confidentiality rules and regulations must be prevented, effectively.

- ⇒ EHTEL should support the "IT for ALL" and work for personalised advice and care for persons in need and for handicapped or IT-illiterate persons.
- ⇒ EHTEL should discourage 'dehumanisation' by eHealth, by all means. This implies that face-to-face contacts must be available when needed and, consequently, ICT is used only as a tool to deliver a personalised service, instead of the reverse.

EHTEL should continuously support the work and achievements, that have been established by its active *patient and consumer protection group*. Over the last year this group has analysed a number of issues stemming from digitised healthcare delivery. The assessment of issues arising from proposed and implemented digital healthcare issues in Europe will continue and conclusions will be presented to all stakeholders at European, national and local level.

#### **2.4.2 Electronic prescribing and the unique personal identifier**

IT support to medication is highly recommended to reduce the considerable risk of incorrect medication and, clearly, electronic prescribing is related to electronic medication - next to the electronic health record, electronic prescribing is the most discussed subject in eHealth.

There are wide variations in use of electronic prescribing across the EU. Denmark established a nationwide system in the mid-nineties and, today, 50 % of all Danish prescriptions from general practitioners are electronic, with a remarkable cost saving as a consequence. Only Belgium has come close to these figures. The rest of the EU member states are now determined to proceed; conferences and studies are on-going in all countries. Among the elements needed for success are:

- ⇒ a fully reliable and secure physical infrastructure
- ⇒ one digitised prescription format
- ⇒ a legal framework in place
- ⇒ integration of communication system into all pharmacy and medical record systems

In that context, it is worth mentioning that it is crucial that the personal identification is correct for electronic prescribing, as for any other eHealth service use. One of the contributory factors in Denmark's success in using a nationwide health network, is undoubtedly the long existing unique personal identification system. Similar systems have been in use also in the other Nordic countries.

#### **Recommendation**

EHTEL could contribute to the exchange of information now taking place among member states and be supportive in solving the problems of individual regions and countries

### **2.4.3 Individualisation/personalisation of healthcare**

This topic covers a range of different concepts. It may be care in the immediate daily surroundings of the patient, or the establishment on the internet of the individual's personal "electronic safe" portal containing all personal health information for access either by the patient alone or together with the doctor. It may even include the use of statistical evidence from genomic research to counsel or treat the individual patient or relatives.

ICT supported homecare has been the subject of a large number of projects over the last 15 years and some are used regularly on a routine basis. The technical support may be required for the homecare nurses to stay in contact with the headquarters to retrieve updated information on patients they visit and treat. Videophones for contact between a patient and the care center have proved valuable, and messaging via mobile telephones or Interactive video have been demonstrated to be a user friendly solution.

Two examples of monitoring different patient categories are:

1. Throughout Europe, many local or regional cardiology centres monitor cardiac patients in their home and give (automated) advice.
2. In contrast, one health company has established a single global server to receive, daily, digitised information on the clinical and laboratory status of patients, world wide, suffering from the rare haemophilia disease and feed back, via mobile phones, appropriate advice. The benefit for the patient is the steady expertise provided by the server and the knowledge database, and for the company, the benefit is information on the efficacy of the product.

In the long term, such a haemophilia service may become regional. It would then be possible to control the medication of large numbers of patients in anticoagulation treatment, once the monitoring and the reporting technique had become widespread.

More recently, sensors to register vital biosignals have been optimised and refined to monitor and transmit cardiovascular signs together with other vital parameters. Combined with ubiquitous technologies which permit service delivery into individuals homes, workplaces or to personal area networks there is scope to increase productivity and economy in health-care delivery. Ultimately, eHealth technologies could permit a shift in emphasis to delivering 'wellness' to individuals, rather than the episodic treatment of illness.

At the other end of the spectrum of personalised care are the needs created by new bio-medical knowledge. The development of disciplines such as genomics, bio-informatics and proteomics and the increasing availability of simple testing techniques are beginning to allow the understanding of disease on a molecular and individual level. In addition to better focused therapies dispensed in an episodic fashion these technologies are also permitting predictive medicine. In theory, and soon in practice, it will be possible to test individuals for susceptibility to diseases, understand how they might react to therapies, and model personalised prophylactic and treatment regimes.

However in order to realise the benefits, eHealth in Europe must be implemented in such a way that practitioners can interface with outputs from 'big science' research (outlined above) and act as effective intermediaries on behalf of their patients.

### **Recommendations**

An updated European Inventory of Best Practice Examples of Individualised care should be established.

#### **2.4.4 Demands and needs of health providers.**

The responsibility for delivering care and service of quality ultimately lies with the health professionals. Therefore, they also have needs and demands of the ICT systems, some of which they share with citizens and patients:

The members of the health professions share with the patients the need for immediate access to all relevant clinical data, necessary for the given situation, irrespective of time and location. Patients expect – and rightly so - the service and the care is seamless. For the clinical decision to be correct, the information must be complete and non-corrupted. The whole concept of e-health builds on the fact that information and knowledge, and not the patient, should be available immediately to wherever needed.

It is paramount that information is consolidated and that the clinical status of the patient and acts of the professionals are always documented in a user-friendly structured, standardised and integrated way. Medical images and biosignals must be available in multimedia format. The electronic health record (EHR) is the ultimate integration of technical systems, concepts, coding and classifications and semantics. EHR's integrate or federate several electronic patient records (EPR) covering only events in one institution. EPR's exist, in various forms, in about 10 % of the institutionalised health care. They are more commonly used in primary care, and are being deployed at an ever-increasing rate, with improving quality. The

demand of doctors and nurses, for high quality systems will spur further developments over the years.

Clinicians must have immediate access to databases of instructions and guidelines applicable in any situation. Often, such support is accessible locally but not always in the form of an electronic "library" or database. Other situations demand access to global databases and knowledge support systems. The appropriate use of existing and evolving systems is essential for the safe practice of medicine. An example of how clinical ICT systems support doctors and other health personnel, is medication. Alarming figures from all over the Western World have shown that the medication of hospital patients was wrong in about 30 %, but fell to less than 2% following the introduction of IT supported medication in daily practice.

Also the aim to practice evidence based medicine and to comply with best practice, can only be fulfilled if knowledge based systems and databases are used.

The need for health professionals to consult other colleagues, peers and experts and request a second opinion, has always existed and dealt with by written correspondence or by telephone. Now, the immediate support to a medical colleague can be provided on an improved basis, with telemedicine solutions allowing all types of medical data, text, images etc to be accessed. The needs of medical professionals for such services, however, can only be fulfilled if it is realised that the most difficult aspect is the organisational part. Only when the organisation around telemedicine services has been established will the benefits be realised in daily work.

Daily workflow planning, scheduling and booking in health institutions by means of ICT systems are all now commonly done with the support of ICT systems. It has been a challenge to establish and make use of systems that are shared across various types of health workers like doctors, nurses, secretaries etc. These systems have added, greatly, to the efficiency of the work. In addition, the positive effect of deploying such systems has been the development of team spirit.

The medical researchers share the needs of all other health professionals for ICT systems that will support their work and consolidate their data. The difference may be that they experience a more focused and yet more complex set of problems to be solved. Examples of that could be genomic or pharmaceutical research or neuroscience. These disciplines produce large amounts of data that must be stored, structured and retrieved. Their proper use requires ethical and legal regulations.

All medical professions share a need for continuous education and training. In some countries elements of a national ICT-based educational programme for specialists are underway, but there is a long way to go before the medical professions have picked up the possibilities for ICT-supported coverage of the learning needs.

The financial and the administrative aspects of healthcare provision have been covered by ICT systems for many years. The IT connection between administrative, clinical, reimbursement and other financial systems to support one-stop shopping, smooth transactions and documentation of efficiency is still a demand not fulfilled. However, the widespread use of DRG, or DRG-like ranking of production, is a strong incentive to make shared use of relevant information which, traditionally, has been available either to the clinical or the administrative processes. Likewise the demand for automated reimbursement has driven the development.

## **SECTION 3 ICT support now and in the future**

### **3.1 Evolving technologies**

Technological development has rarely been driven by eHealth demands so far, although it may be so in the future. The time taken for a completely newly designed technology to mature to the necessary robustness can often be protracted. Hence, for the time being, eHealth has to take on mass technologies that are already in existence and can be used at a feasible cost level. Many exciting new technologies, however, emerge from diverse fields of science and can be directly used or adapted to eHealth purposes with relatively simple measures. The RAND-report (Anton et al. 2001), forecasting technology developments from 2001-2015, focuses on nanotechnology, smart materials, and genetic manipulation as key technologies under development. These technologies, together with improved computer and communication technologies, pave the road for new eHealth solutions.

The ethical implications, which may be significant, cannot be disregarded. As a counterpart of new potential for improvements in the ability to prevent and treat diseases, threats to the principle of equal access to healthcare technologies are encountered and may be seen as an analogous trend to the digital divide in society.

### **3.2 Typical scenarios of technology use in healthcare**

At a given point in time, technologies may be separated broadly into "technologies for the masses" and "technologies for the few" – the few being ideally selected not on economic criteria but on personal health needs. These options also place different requirements for technological implementations to support eHealth. Mass-technology can become a tool to deliver more and/or higher quality services with the same amount of financial resources as today, i.e. increasing the quantity and/or quality of health care delivered per Euro. A further eHealth technology path is described by the usage of large, sophisticated, possibly highly individualised resources on a single patient e.g. to cure rare diseases. This path requires cutting-edge technology both in the communication and tools, e.g. nano-technology that allows automatic measurements of biodata from within the body. The implementation of both types demands careful planning, training and education to understand the best use.

#### *Path 1 - Massive deployment of technologies:*

To allow for widespread usage, devices must be user-friendly, robust and have inbuilt security. If multiplied through massive deployment also small technical problems may lead to massive negative effects when multiplied through widespread use. Since standard tech-

nologies are used, which are also in use in other industrial fields, there is a dependency on industry trends. Hence, a sophisticated specialised healthcare specific development might become useless by the simple withdrawal of the underlying product by the industry due to changing consumer needs.

Typically, the technologies in this scenario allow sharing of information, reduce bureaucracy, improve documentation, empower patients to look after their own health, and enable relatives to give healthcare to their parents and children when needed. Clearly, there is a need for robust, cheap and simple technology that can be used regardless of technology skills; however, there is a demand for cutting edge skills to organise new ways of delivering health care services.

For this scenario, the technological trends today are characterised by small hand-held devices, blue tooth communication, sensors to automatically measure biodata and Internet applications for information retrieval and organisation.

Three major issues must be considered for this type of eHealth technology:

1. One major challenge in eHealth is to ensure that technologies can be used by technically unskilled persons, either the patient themselves or health personnel.
2. Another main challenge, especially with small hand-held devices that are easily stolen, is to maintain the privacy of patients while giving the healthcare worker access to relevant data. There is a need for authorisation of the health professional by secure techniques, such as employing certificate and/or biometric based authentication and logging facilities to trace access to health data.
3. Technology which is to be used, widely, in the healthcare sector must be robust and mature. One reason why eHealth only emerges slowly from the phase of pilot projects, may be that funding organisations (as well as venture capitalists) demand "innovative technology", which can be expensive, hard to use and prone to errors. Thus, mature technology and its innovative use in innovative organisations, is needed.

*Path 2 - Massive use of cutting edge technologies on single patients:*

Large resources may be used on a single patient to cure rare diseases, to perform surgery using satellite communication, robotics and full-body 3D imaging, to develop and deploy bioinformatics or to use GRID technologies. This path requires cutting-edge technology, e.g. nanotechnology, which allows automatic measurements of biodata from within the body. By stressing the term "point in time" in the introductory remarks, it has been taken into account that enormous and unforeseen technological developments, as well as specific

demand situations, might lead to a mass-deployment of former niche technologies. This situation was experienced with the technologies underlying the internet, which hardly existed 10 years ago. This path may also lead to enhanced medical knowledge to the benefit of the patients.

Leading edge technologies will prove of great value in 'Virtual reality' as used, for example, in training surgeons and planning operations. 3D software and haptics allow trainee surgeons to practice laparoscopy with the correct tools on the computer before being allowed to practice on the patients.

### **3.3 Ubiquitous healthcare**

Ubiquitous healthcare, pervasive healthcare are expressions for applications of ambient intelligence within healthcare. These applications typically deliver health services to citizens within their own daily environment and limit any adverse effects of the technologies used to the practical minimum. Thereby not disturbing the lives of the citizens themselves but opening up new fields such as home telecare.

The technologies used are small-scale low-power unobtrusive hardware including sensors, actuators and computing power; low-power ubiquitous wireless communications; intelligent user interfaces and applications. These are used to monitor an individual's normal activities and their ability to carry out tasks for normal living. Technologies will necessarily be tailored to the individual and their daily environment whether at home or on the move. It is paramount that such technology be deployed as non-invasively and unobtrusively as possible with the ability to alter each installation in a modular manner as the individual's requirements change.

Whilst the home environment has been in the initial focus of this activity the home itself must not act as a physical constraint. The phrase 'virtual prison' has been used to describe a scenario whereby the individual feels unable to leave home because of the fear of losing the support they enjoy. This is "institutionalisation" on the smallest scale.

It is essential, therefore, that the individual can enjoy the same level of support whilst "on the move" or at least outside the home as they do whilst in the home.

There are a number of moral, ethical and security issues related to the introduction of ubiquitous health, especially issues of private freedom/rights versus public good, unless genuine personalisation of the technologies exists. An example may be the use of a key (equivalent of an electronic car key) which turns on devices in public places.

There is a feeling that this area of healthcare is possibly the least understood and appreciated amongst both healthcare professionals and patients/consumers and therefore one which requires considerable analysis.

### **Recommendations**

For the use of ubiquitous healthcare (technologies) to be adopted widely both healthcare professionals and patients/consumers have to be made aware of their existence, capabilities, costs and future developments. A scoping study should be initiated into the best means of enabling this. Issues such as

- ⇒ the personalisation of devices in public places for the provision of healthcare
- ⇒ implants/wearables/etc for the citizen
- ⇒ decision points for the switching on of ubiquitous devices e.g. should the concept of enduring power of attorney (UK) be extended to this arena.

### **3.4 Interactivity**

eHealth solutions designed for healthcare professionals can rely on a high level of user expertise, i.e. IT literate people familiar with advanced technologies. eHealth for the masses, i.e. citizens and patients must take into account the diverse abilities of populations as a whole. Many will not have computer skills or internet connectivity and may lack the dexterity or cognitive abilities to cope with complex electronic form navigation. eHealth solutions can be deployed over more familiar platforms – telephones, television – or specially designed simple interface units. In all cases, the full benefits of systems may only be harnessed through ensuring effective interactivity. Thus health information can usefully be broadcast over a satellite system - but in order to emulate the one-to-one patient/carer relationship a separate backchannel (typically a telephone land line but not precluding mobile systems) must be provided. There are infrastructure cost implications but EHTEL should where practicable encourage the development and deployment of genuinely interactive solutions.

### **3.5 Broadband, Infrastructure, interactive digital television**

As previously stated, the prime and immediate goal for the EU is to have user friendly health services and applications over safe and interoperable communication routes.

Over the next 5-10 years, healthcare services will increasingly be delivered into European Citizens homes through the use of interactive video and home monitoring devices (vital signs monitoring), linked to nurse led call centres (health contact centres).

This transformation covers the full spectrum of eHealth including the increasing demand led need for access to healthcare services via additional eHealth supported channels.

### **3.6 Clinical applications, telemedicine**

The type and range of clinical applications ranging from telecare, tele-consultations (previously referred to as telemedicine) to clinical decision making support software – surely the medical encyclopaedia of the modern age; is increasing rapidly in both number and variety. What is generally lacking is a rigorous evaluation of their clinical, financial and organisational implications.

The components of a eHealth system are:

- ⇒ telecommunication and computer technology
- ⇒ appropriate staffing
- ⇒ geographic separation
- ⇒ development of an organisational structure

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- ⇒ clinical protocols
- ⇒ standards of behaviour

The following actions are therefore suggested as a means of ensuring the most rapid dissemination and uptake of knowledge and experience on clinical applications.

#### **Recommendations**

- ⇒ There should be a European register of eHealth clinical applications listing suppliers, demonstration sites (virtual and physical) and supporting evidence (trials, academic papers etc)
- ⇒ A sustainable mechanism for creating, disseminating, reviewing and discontinuing clinical guidelines on a European basis should be created.
- ⇒ A European code for the conduct of tele-consultation et al should be synthesised from current best practice

### **3.7 Electronic Health Records**

EHTEL can endorse the following quotation from the EU project PICNIC's final report from 2003:

An "Electronic Health Record" (EHR) links together a number of Electronic Patient Records (EPR) systems to provide a complete history of episodes of care [...] EHR systems, and their counterpart within healthcare provider institutions, the EPRs, are a common theme in all European national healthcare ICT strategies. There is still a long way to go, however, before the concept is implemented on a European-wide level. However, the push towards EPR (within healthcare organisations) and EHR (across healthcare organisations) will both generate a major requirement for systems integration [...], to enable applications to be integrated and data to be exchanged across Regional Health CareNetworks.

Standardised Electronic Health Records should be deployed throughout Europe as a means of recording personalised healthcare events from conception to death. This information must be provided on a standard platform, although there may be individual variations between member states (like with the Euro). In addition to longitudinal healthcare event recording, it will be possible to add personalised genomic finger print data, socio economic data accumulative throughout life and environmental data, etc. When such datasets are de-personalised and clustered in different population groupings, the data makes a rich mine of information to predict healthcare trends and thus assist in the development of European e-Prevention strategies."

### 3.8 New GRID technologies

GRID<sup>1</sup> aims to promote the development and advancement of technologies that provide seamless and scalable access to wide-area distributed resources - a type of parallel and distributed system that enables the dynamic sharing, selection, and aggregation of geographically distributed "autonomous" resources. GRID technologies will allow individual users access to unprecedented processing power.

GRID technologies are supported under IST work programmes. The Healthgrid initiative ([www.healthgrid.org](http://www.healthgrid.org)) contains projects such as Mammogrid (IST-2001-37614) provides mammography diagnostic assistance, DEVASPIM (IST-2001-52101) provides a telematic service to surgeons and manufacturers of lumbar implants, and GEMSS (IST-2001-37153) provides advanced simulation and imaging to allow for better pre-operative planning and near real-time surgical support.

Promoting the GRID technology remains a key action in the IST Work programme under FP6 with the objective to develop an intelligent environment that enables ubiquitous man-

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1. I. Foster and C. Kesselman (1999) The Grid, blueprint for a new computing infrastructure, Morgan Kaufman, San Francisco, 1999.

agement of citizens' health status and to assist health professionals in coping with some major challenges, risk management and the integration into clinical practice of advances in health knowledge. Specific focus will be given to research into user-friendly, fast and reliable tools providing access to heterogeneous health information sources, and also to new methods for decision support and risk analysis. The use of GRID technology and open source is encouraged where appropriate. The programme also addresses networking of researchers in the areas of medical informatics, bioinformatics and neuroinformatics with the objectives of advancing health knowledge leading to a new generation of eHealth systems assisting in the individualisation of disease prevention, diagnoses and treatment.

### **Recommendation**

There is a role for EHTEL in ensuring coordination is maintained with other relevant FP6 thematic priorities, and non-EU national and transnational initiatives.

## **SECTION 4 The field of Education**

Education is equally important to citizens and the healthcare professionals. That covers both the education and training in the use of ICT as well as using ICT as a tool for education and training. The importance of the role of education in the development of knowledge based economies has been emphasised within the action plan eEurope 2005 "An information society for all".

The Internet can be used for life-long learning and as a supplement to student education, thereby sharing the teaching resources in special subjects. Cultural and linguistic barriers are still important inhibitors for broad international programmes, but for subspecialities and special topics there are large possibilities. Resources can also be shared between countries using automatic translations and advanced language tools, and the next generation Europeans have better language skills than their parents. Thus, in the future we can foresee a completely new way of education and life-long learning which will benefit a knowledge intensive field such as medicine.

An evaluation of the action plan eEurope 2002 reported that progress towards an eEurope was slow and that there were considerable differences between countries. In addition there was a marked differential in the effective use of the technologies. Examples cited included people using computers in work whilst having received no formal training, schools having Internet connections but not using the connectivity to any great extent.

The action plan eEurope 2005 will be concentrating on the effective usage and availability of the Internet and has four components:-

- a. Identifying areas where public policy can provide an added value with a focus on priorities such as interactive public services, deployment of broadband networks and a cyber-security taskforce.
- b. Using demonstration projects and other means to help in the dissemination of experiences and practices (good and bad)
- c. There will be better monitoring and benchmarking of the progress within eEurope 2005
- d. A steering group will be set up so as to provide a better overview of policy developments and a communication channel between European and national policy makers and the private sector. It is hoped that improved co-ordination of existing policies will provide some value adds.

eLearning is one of the three priority areas where the eEurope 2005 Action Plan will focus its enhancing of online public services. It is hoped that by 2005, Europe will have modern online public services with a special focus on eGovernment, eLearning services and e-health services, as well as a dynamic e-business environment. To achieve this widespread availability of broadband access at competitive prices and a secure information infrastructure are considered essential.

#### **4.1 Use of interactive Media and Channels for Health Information/Education**

There is good international consensus that by the provision of appropriate and widespread education on health matters to defined populations, it is possible to change radically health-care demand patterns with patients self treating more conditions and thus providing a more focused demand profile for healthcare services when required.

Political decisions will have to be made as to the mix of "push" versus "pull" in the provision of healthcare information to the consumer (including "consumers" that have little or no consumer power e.g. children and many elderly).

There has been much research around the use of Websites for the provision of healthcare information, perhaps less on other means such as SMS messaging (which would be a particularly appropriate means of imparting information to "difficult" groups such as adolescents) and some on "old media" e.g. TV (and in its new guise – DiTV). However this research has not translated into practical use and shortening this loop (and others) should be a priority of the strategy.

#### **Recommendations**

- ⇒ If National Governments find the use of focus groups and polling to be effective means of ascertaining the views of consumers then consideration should be given to using it on a European scale on a regular basis; a scoping study should be undertaken
- ⇒ Work carried out in such projects as TEAC-H should be used as a basis for the registration/licensing of "health (in its broadest sense)" Websites.
- ⇒ Studies should be initiated into the use of "push" technologies e.g. SMS as opposed to "pull" technologies e.g. Websites for Public Health Information.

#### **4.2 New Forms of web-based CME/CPD**

Healthcare professionals require maintenance of their knowledge levels throughout their careers, and this is achieved by the provision of continuing medical and nursing education.

The European Lifelong Learning programmes apply equally to the healthcare professionals as they do to the traditional targets of these programmes.

Using web based technologies, such programmes can be personalised for the individual healthcare professional and delivered over the web, thus removing the requirement for time out from existing working patterns to seek education in another perhaps distant institution, which is wasteful in terms of human resource.

## **SECTION 5 Market**

### **5.1 Financial Investments for ICT in Healthcare**

Communication and computing costs have been reduced substantially and broad bandwidth networks have now been deployed, hence the widespread deployment of such technologies and solutions has become timely.

The healthcare sector has traditionally invested very little in IT in comparison with other major sectors, such as banking, manufacturing, etc, where investment levels run between 10-14%. The healthcare sector in some countries has invested less than 1% in IT and it is this differential that provides one of the key market elements for eHealth in Europe.

The study "The Emerging European Health Telematics Industry" (commissioned to Deloitte Touche Tomatsu by DG INFSO at the onset of the IST-Programme) already demonstrated that the European countries invest less than half of the US-average into ICT in the hospital sector. Furthermore a comparative study on eHealth in eight countries worldwide (comprising five countries in Europe) commissioned by the Dutch Ministry of Health, Welfare and Sports to PriceWaterhouseCoopers published in 2001 demonstrated again the "1 %-rule" and hence deficiencies of the financial investment in Healthcare ICT in all the analysed European member states. The potential of this market is also well documented in research conducted by Silicon Bridge, with a number of others, based on experience from the UK.

Various Thematic and Actor Working Groups representing the range of eHealth stakeholders under the umbrella of EHTEL are contributing greatly to the process of demonstrating the potential for eHealth solutions and services and the scope for market growth is now being better understood as a result of work already achieved.

### **5.2 Market size**

At the present time there are no consistent country figures from which to aggregate an accurate estimate for the size of the eHealth market in Europe. Understanding of the scope of this market varies widely but it is generally considered to include IT hardware, software and professional services together with a growing component of e-services but not including medical equipment or medical devices. This distinction is becoming more difficult to sustain as the boundaries between IT, telecommunications and medical devices become progressively less distinct.

The development of eHealth, the explosion in availability of information, the recognition of the significant complexity of healthcare and the growing trend to treat medical equipment and devices as a part of the IT infrastructure, are pointing towards a much broader technology assistance market extending far beyond the bounds of existing conventional IT.

A review of currently available European figures indicates a conventional ICT baseline spend for 2002 of between € 10bn and €11bn, representing about 1.4 % of total healthcare expenditure (€ 724 bn). This is considered low from the point of view of industry and financial sectors (2.5% is regarded as the minimum effective figure for manufacturing with 8% or even 10% in high usage sectors such as financial services). It is also relatively low as a proportion of total European ICT spend (2% of a total market of € 643bn) as opposed to healthcare which accounts for more than 8.5% of the total EU GDP.

UK figures were researched as part of the European HINE project, part sponsored by EHTEL. These indicate that healthcare has been underinvesting so far in ICT and yet there are huge changes emerging in the way in which care will be delivered and in market expectations for developing an increasingly mobile and IT articulate Europe [needing further investment].

There are strong indicators that a key factor in commercial productivity per employee is capital investment. OECD has already identified that ICT investment per employee in the health sector per employee is low even compared to other government services. [half of the investment being training/human resources: 25% hardware/infrastructure, 25% software, 50% human resources]. [a number of drivers to increase productivity by health professionals]. [st: Meiningen]. Concern over the conflict of increasing citizen demand driven by demographic change together with pressures on health professionals to increase productivity (for example more patient contacts, shorter length of stay, earlier appointments) means that ICT investment per employee may become a key measure.

Sufficient ICT investment is expected to create a 'knock on' effect in eHealth investment as technology assist becomes a prerequisite for delivering more effective healthcare services and transformation of delivery processes starts to gain momentum, e.g. by deploying mobile infrastructures and pervasive computing.

If government are not only doing lip service, they have to form reliable partnerships/alliances with industry, basis for investments in infrastructure, reliable platform, engagement of governments, setting the ground rules, public-private partnerships, agreement on standards, industry has to demonstrate its ability to deliver, The need for some form of Government intervention, in terms of investment or other incentives in order to create an

effective platform for the rapid evolution of eHealth, is expected to feature strongly in all major European country markets. On this basis, European projections derived from the HINE project (using UK figures as the template) indicate a rapid growth from €11bn to € 22bn by 2005 and to € 50bn by 2010 as eHealth starts to take off in a major way.

During the first years of EHTEL, it is encouraging to see the growth of collaboration between EHTEL and other eHealth initiatives. The EC INFISO Health Information Network for Europe project (HINE) is one of the important steps forward where close links of EHTEL and its Working Groups with other players (Deloitte&Touche, Silicon Bridge, HCON) have been incorporated from the outset. These and other initiatives will keep EHTEL at the forefront of an eHealth debate which is broadening to include the business transformation aspects as well as the clinical eHealth areas.

More work has yet to be done in order to provide more accurate means of measuring market growth and providing new models, which are less dependent on conventional systems extrapolations and are more closely based on transaction monitoring to reflect the complexities of electronic interactions inherent in a technology assisted healthcare market. With these new tools, development of value chain models for IT assistance and soundly based commercial business plans can be used to promote the need for more aggressive investment in eHealth".

### **5.3 Opening the market place**

#### **5.3.1 Political decisions**

For 2005, the common EU goals are to stimulate secure services, applications and content over a widely available broadband infrastructure. The healthcare emphasis is on health cards, interoperable health information networks and on-line health services.

It is a striking fact that European countries, where nature or disasters have made equal access difficult, and countries with an obvious need and wish to (re)-establish a health delivery system are more advanced. In contrast, countries with a long-standing tradition for service delivery appear to have difficulty realising that a delivery system which worked well for a century now needs modernisation.

#### **5.3.2 Public/Private Partnerships**

Europe must move from isolated projects to Europe-wide operations 24 hrs x 365 days a year. To achieve that, solid public/private partnerships with industry should be created. Us-

ers must learn to specify requirements better than in the past, and industry must understand the needs of the market segment better, as with the pharmaceutical industry.

### **5.3.3 Interoperability as a prerequisite for an open market**

Despite of a variety of harmonisation processes already in place, the status of European-wide or even national interoperability is still disappointing: Although world-leading technical components and system solutions for electronic data interchange are now available nearly everywhere in Europe, isolated national solutions still dominate the landscape. The emphasis on European and international interoperability is crucial. Highly secure and yet interoperable cryptographic procedures ensuring confidential data transmission are an additional significant prerequisite for applying the aforementioned technologies in healthcare. The extensive and interoperable use of e-Health applications requires specific societal regulations and infrastructure measures. Hence, a more intense promotion of the harmonised use of e-Health applications in Europe is necessary. This should involve the Health-IT-industry, health policy makers and health care actors in joint actions.

## **5.4 Exporting Health Services outside Europe**

Successful implementation of eHealth across Europe will enhance the ability of European based solutions providers, indigenous or global, to penetrate non-European markets. The diversity of health markets within Europe - with models ranging from full economic cost recovery to full service free at point of delivery - combined with expertise in communications networks and proven history of innovative service development and delivery suggest that European eHealth solutions could be readily replicated in other territories.

There are already significant exports of medical technologies/expertise into regions such as the Africa, the Middle East and parts of Asia. There is a negative balance of trade in healthcare technologies between the EU and the USA but nonetheless inroads are being made.

First world economies are subject to the same market drivers as the EU. e.g. ageing populations - in these territories the proportion of citizens aged 60 or over already exceeds 20% and is rising. The need to obtain better value in healthcare delivery; in the USA the cost of healthcare is approximately equal to 14% of GDP, up from 7% in 1980 [Espicom Medistat]). In developing economies eHealth solutions can address issues such as distributed populations' access to healthcare in addition to promoting economical delivery. Health considerations may be different, such as younger populations with consequent public health issues like maternity care provision or immunisation programmes, but European eHealth solutions are demonstrably capable of addressing these.

International standardisation - or at least interoperability with legacy systems - would reduce a key barrier to market entry. In developing economies legacy systems may not be present. This presents both an opportunity for technology providers but also presents a challenge as these territories can and do 'leapfrog' legacy infrastructures. It is therefore likely that some will acquire communications infrastructure that is superior to some parts of the EU (by moving directly to UMTS systems, for example).

### **Recommendation**

- ⇒ EHTEL should ensure that eHealth standards are developed in an international context and
- ⇒ eHealth solutions providers should be prepared to deploy advanced solutions into developing economies.

## **SECTION 6 Implementing the European eHealth Vision**

### **6.1 The role of governments and politicians**

The healthcare sectors of Europe have been tardy applying ICT compared with other sectors, especially banking and financial services.

The reasons for this include:

- ⇒ The regulatory and remuneration environment with respect to healthcare services across Europe will require further changes to facilitate the necessary processes.
- ⇒ Healthcare is costly and ICT is considered an opportunity cost, which decision makers have given lower priority than investment in immediate medical needs.
- ⇒ All healthcare professionals have not fully understood the potential of eHealth or even have feared it, seeing it as an extra work load and the basis for change of roles.
- ⇒ Regional or local politicians, responsible for a fraction of the sector have failed to push for digital solutions because all parties involved have viewed health care as a personal face-to-face encounter. In doing so, the opportunities have been overlooked for improved services, involvement of the patient in the decision process by access to data, and the better quality of continuity of care across health institutions.

However, ignoring the chances arising from the establishment of national physical infrastructures for the benefit of other sectors would be very costly and time wasting.

Now, it is the obligation of national and regional politicians and other decision makers to provide solutions that fit into the national infrastructure and security systems and demand content and applications (notably such as personal health records) that are interoperable nationally and in conformance with European standards. Standards that are not yet available although needed must be developed. A very basic and pertinent example is the work needed to standardize the content of health insurance cards and card readers before the third and digital phase of European Health Insurance cards is introduced [Com2003 73].

#### **Recommendations**

- ⇒ A knowledge network should be established of eHealth experts within Europe, who can assist European member state governments.

- ⇒ The EHTEL (A1) group of government administrators have been instrumental in providing the commission's services (SANCO and INFSO) with material for a strategy for the introduction of interoperable health ICT solutions.
- ⇒ EHTEL should continue to offer advice on this issue collaborate with the commission on these issues. EHTEL is in a good position to anticipate the needs of governments and local decision makers and may support them in this field because of the expertise of its diverse membership.
- ⇒ EHTEL should offer its support to projects in the health area emerging from the present call for proposals by eTEN, the 6<sup>th</sup> framework IST programme and similar programmes.
- ⇒ EHTEL should offer collaboration and support to relevant on-going projects in order to harmonize solutions to be proposed. One example is the accompanying measure TM-Alliance by the European Space Agency, WHO Regional Office for Europe and ITU.

## **6.2 Elements of a secure infrastructure including regulatory aspects**

The establishment of a "health telematics infrastructure" implies not only establishing Internet connections of outpatient and in-patient healthcare institutions, but the systematic foundation of information, communication and security infrastructures suited for the transmission for patient-related health data in compliance with European and national laws and data protection regulations.

As a guiding principle the rules of the "Krefelder Memorandum on the Endorsement of the Implementation of Standards and interoperable Applications" (Krefeld, Germany 2002) for open standards and open source usage should be applied:

- ⇒ "Support the usage of standards and interoperable, secure methods for documentation, communication, processing and archival of health data
- ⇒ Compulsory use of open standards, prefer international developments
- ⇒ Open specifications or usage of open source software
- ⇒ Employ sustainability as a basis for reliable planning and safe-guarded investments for users and software manufacturers"

### **6.2.1 Security and PKIs**

Highly secure encryption procedures are deemed necessary elements of adequate security infrastructures for the healthcare sector. Accordingly, the use of digital signatures<sup>2</sup> and

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<sup>2</sup> Here used as the synonym for "qualified electronic signatures" in accordance with the EU directive and the new German Digital Signature Law.

asymmetric encryption has been planned, whereby no country in Europe has a specific Public Key Infrastructure (PKI, which also comprises certification services providers and directory services) for the healthcare sector in place.

### **6.2.2 Electronic IDs for Patients and Health Professionals**

The introduction of electronic IDs "Health Professional Cards" with cryptographic functions (digital signature, encryption, authentication) into European healthcare systems requires a Public Key Infrastructures and other measures that enable the use of chip cards. In addition the respective legislative bodies must clarify the situation with respect to the reliability of substituting paper-based documents by electronic ones. So, with respect to the European Directive on Electronic Signatures the conditions for the validity of electronic signatures in healthcare must be determined.

### **6.2.3 Register of ehealth professionals**

The importance of a register of eHealth professionals will become even more evident as citizens exploit the potential of the net to resolve critical health problems. At the present time there are a number of ways that citizens can assess the worth of healthcare professionals but these institutional models of registration do not yet apply to the net. Additional security on the net is required for public confidence in the professional practice of ehealth. For ehealth to prosper the following needs to be done:

- ⇒ To ascertain the various methods by which patient identification can be established to allow the secure movement of clinical data across borders.
- ⇒ To consider the many ways by which national institutions identify their healthcare professionals, wherever and whoever they might be, and propose how such identification can allow both citizen and fellow professional to judge the veracity of data communicated via the internet.
- ⇒ Establish a European representative body for ehealth registration
  - Representatives of physicians and hospitals
  - Representatives of other healthcare professionals – nurses and pharmacists
  - Representatives of patient interests
  - Representatives of government

It has been apparent in the work of EHTEL that national representatives are aware of the nature of professional registration in their own country but unclear whether their understanding is sufficient to contribute effectively to a generic model of registration in their own country let alone throughout Europe. A better understanding of all healthcare institutions

and methods of professional registration is crucial if eHealth registration is to become a reality and be of use to both professional and patient.

The particular reasons for considering professional registration in eHealthcare are:

- ⇒ A citizen's need to recognize the professional accreditation of eHealth providers on the internet
- ⇒ A similar need for professional institutions and governments to consider the credibility of professional eHealth entries on the internet
- ⇒ The easy access to the internet allows a broader healthcare community to provide eHealth advice – a community that is not necessarily under the auspices of national institutions
- ⇒ The ethical and secure movement of clinical information between either citizen and professional or professional and professional
- ⇒ The combining of patient and professional registrations as an aid to the secure control of health gateways and patient care pathways
- ⇒ There are no national boundaries for eHealth

#### **6.2.4 International Interoperability**

In view of the progressing convergence in the European healthcare sector and the freedom of providing and using healthcare services in Europe and worldwide, eHealth services and applications should be designed with the goal of their international interoperability. Otherwise, as opposed to the language barriers resulting from paper or film-based procedures, which can be overcome, at least in part, insurmountable technological barriers will emerge that completely prevent access to existing medical information. This might have considerable negative impact on the patients involved.

When eHealth applications have been established in an internationally interoperable form, they may facilitate care across borders, since the language barriers of digital data can be overcome with comparably simple means (multilingual classifications etc.).

### **6.2.5 Legal Binding Data Transmissions, Privacy and Security**

In Europe and world wide, approaches for the electronic transmission of findings and other patient data can be recognized. Qualified electronic signatures in accordance with the EU Directive are an important element to give such transmissions a legally binding effect. Means for ensuring data protection and data security during data transfer and storage are secure cryptographic encryption procedures.

### **6.2.6 Promotion of eHealth-Standards by Implementation**

European (CEN etc.) and worldwide (ISO etc.) standardization activities are often experienced as unnecessarily complex and are implemented insufficiently. Advanced EHR-standards such as the four-part European draft standard on Electronic Healthcare Record Communication (prENV13606-1-4) offer a conceptual basis for software systems without specifying these in detail. The potential benefit of these standards can only be exhausted by concrete realisation. Based on such implementations, valuable experience and qualified support of the European standardization activities.

The meaningful electronic collection, transmission and storage of patient-related health information must be based on minimum standards for medical documentation. In addition, standardized data formats are necessary to ensure that the patient-related health data can be integrated consistently in the relevant electronic patient records.

A key issue for that process is the collaboration between Healthcare and eHealth industry in order to ensure that standards, solutions and implementation plans are available in line with the requirements, budgets, skills and transformation of the industry. EHTEL will support European wide developments through its unique position.

### **6.2.7 Shaping the Regulatory Environment in Europe**

Healthcare provision in each of the European member states is the undivided responsibility of member state governments and in many ways independent from European regulations. Hence one of the major barriers in the deployment of eHealth across Europe is the complex regulatory environment and the lack of uniform statutes, which would allow for eHealth practices to be legal, ethical and reimbursable. The European Commission will issue a publication on "Legal aspects of e-Health" to clarify the framework for the practice of eHealth and hence accelerate market development in the field of eHealth. While this communication is still in preparation, the EHTEL Association has done complementary work on legal and privacy issues and published the White Paper entitled "Breaking Down Barriers".

### 6.2.8 Support of national and European umbrella organisations

Many European member states have established national forums and other activities in support of the promotion of eHealth and the establishment of nationwide eHealth infrastructures. In some nations actors in the healthcare sector and health policy makers have established umbrella organizations like for instance the "Health Telematics Action Forum" (ATG) in Germany, IPZorg/NICTIZ in the Netherlands, MEDCOM in Denmark and the UKeHA in the UK. EHTEL is proactive in supporting the foundation and the work of these umbrella organisations by providing a common framework ("EHTEL-like-organisations") for these kind of activities.

### 6.3 eHealth Best Practices and Quality criteria for the Health Internet

Much dynamic activity at the European level has been undertaken since the "eEurope 2002 Action Plan" was established by the European Council and the European Parliament. One of the most demanding features is the provision of an eHealth infrastructure in all the member States throughout Europe. Furthermore best practice projects should serve Europe-wide as models for emerging eHealth services.

While many eHealth solutions are still in their infancy, they are already recognized as possible remedies for the increasing strains seen in healthcare services.

eHealth solutions that work have two main components

- ⇒ effective and powerful technology as well as
- ⇒ successful organisational changes.

The European Commission and European policy makers and policy makers in the member states and the ICT-industry in Europe should be guided by systematic planning based on a European long term e-Health Strategy (eHealth Europe 2010).

EHTEL will attract professional and citizen interest by displaying examples of best practice that is presently in use in Europe. To do so, EHTEL has merged a number of initial thematically distinct activities into one working group, the *eHealth Working Group (eHWG)*, which has the mandate to follow as well the emerging opportunities for digital health care services and delivery as providing demonstrators of best practice. Already its members monitor the development and contribute with a range of solutions. Individualized care is demonstrated at the Best Practice Demonstrator at the EHTEL web site managed by the eHWG.

Furthermore, it is evident that with the rapidly increasing number of Internet users in Europe and with such information available on line, this will become an increasingly important re-

source of healthcare knowledge for the European Citizen of the future. The content of such health-online websites needs to be accurate as well as informative and should meet the requirements of the patient population as well as conforming to individual member states' healthcare educational strategies.

The eEurope 2002 Action Plan proposed that the Member States, the European Commission and the private sector (industry) should establish a set of quality criteria for Web sites offering health information<sup>3</sup>. Since in Europe various parallel approaches exist on this topic, there is a need for communication and harmonization on a European level. The European Commission has already initiated significant activities and organised a European wide meeting at Brussels in June 2001. As a result Draft Quality Criteria have been written and a communication to the Member States is awaited. EHTEL actively joined these activities and supported a second meeting on this issue held at Paris in September 2001. Based on a firm interest of it's membership EHTEL is to take a proactive role in this field and will support the harmonisation of quality criteria and their implementation on a European wide level through its knowledge network.

### **Recommendations**

- ⇒ Best Practices should be promoted throughout Europe by EHTEL, the European Commission and others, so that European institutions and healthcare organisations planning to implement eHealth practices and solutions can draw on the experience of others and thus avoid costly mistakes.
- ⇒ European member states need to look at eHealth deployment in other countries around the world, where lessons can be learnt from existing successes (and failures).
- ⇒ To promote interest amongst those involved in research and development appropriate authors should be offered web site services to publish work in this domain on the EHTEL web site.

Quality criteria for medical web sites should be promoted by the following actions:

- ⇒ Follow up the Commission initiative and by doing so, maintain its momentum
- ⇒ Promote the criteria by a published communiqué
- ⇒ Support similar national initiatives.

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<sup>3</sup> "Establish a set of quality criteria for health related websites."

## References

Anton, PS, Silbergliitt R, Schneider J (2001) RAND Report: The Global Technology Revolution: bio/nano/materials trends and their synergies with information technology by 2015

### **Annex: Evaluation of eHealth and telemedicine services (4)**

In Europe, few large scale implementations of eHealth solutions have been evaluated for cost-effectiveness and impact on the large scale delivery of healthcare. This is a necessary step to get beyond the pilot project phase. In order to compare the various initiatives and projects that emerge within each country or between a few countries, a European task will be to define uniform methods of evaluation. The evaluation must look at the processes as well as the outcome of the projects. In order to fully understand not only the magnitude of the effects, but also what causes those effects (inhibiting and encouraging factors).

The following themes for evaluation are identified:

#### **A.1 The telemedicine solutions**

Is telemedicine the best possible solution, and is it adequate to deliver the medical service across distance? Before this argument is settled, it is difficult to conduct large scale trials on socioeconomic effects. This evaluation is best done in smaller studies where the patient is examined both by the doctor directly, and using telemedicine. When doing this evaluation, however, organisational issues must be taken into account as well as medical. Patient satisfaction and working conditions of medical personnel must be taken into consideration as well as the actual diagnoses made.

#### **A.2 Education and training**

It is always necessary to include training of the users into a telemedicine project. When evaluating the project performance, the quality and scope of the training

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4 Annex was provided by Gunn-Hilde Rotvold, Norwegian Centre for Telemedicine, Tromsø

must be part of the evaluation. It is important to understand what the transition to routine operation will require in terms of training, and it is important to understand to what extent inadequate training of the project participants is contributing to the project results. How vulnerable is the solution to the quality of the training? Will this be effecting the routine solutions in any way, given the normal turnover of medical staff? What levels of general technical skills are required, and are these realistic for real life settings? This is the kind of questions evaluators should be asking.

### **A.3 Organisation**

Organisational problems are predominantly mentioned as the main cause of the failure of the introduction of telemedicine into routine services<sup>5</sup>. The evaluation of the projects must bear in mind the requirements for transition from project to service delivery, when it comes to organisation of the service. Who will have to adapt their organisation and in what way? Are there any power shifts as a result of the telemedicine solution? (Power transferred from specialist to GP, from doctor to nurse, from health care professional to patient or vice versa)

### **A.4 Relations and identity**

Introducing new ways of delivering a service to a citizen will change the way the patients relate to the health. The terms "patient empowerment" and "digital divide" are often used in the context of telemedicine. When evaluating a telemedicine service, it is important to look at the changes in the identity and how the service will mitigate increasing of the digital divide. Also, empowered patients will place new demands on the quality of the health care service that is delivered, and in parallel with the new services and the new service delivery methods, there must be evaluations on how this affects the relation with the patients.

### **A.5 Socio-economic effect**

The problem with evaluating the socio-economic effect of telemedicine services is the selection of factors to be considered. What is the socio-economic benefit of reduced waiting lists? If the patient pays his own travel, what is the effect on the savings? For this part of the evaluation to have a meaning on a European level, with so many different health care models, there should be a set of rules for doing this, and how it shall be documented. What succeeds in rural districts of Norway, Sweden, Finland and Scotland, may be not so economically viable in central Germany. The reduction in sick-days, must be valued and described. Often it will be more valid research to define the criteria for socio-economic sustainability of a ser-

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<sup>5</sup> The Norwegian Centre for Telemedicine, [www.telemed.no](http://www.telemed.no)

vice rather than make a conclusion as to whether or not a specific service is economically viable. Hardware prices are not stable; they tend to go down each year. What is published using 2002-prices will not be valid in 2003. Salaries of health-care workers vary; the value of an hour saved of specialist time is dependant on whether or not nurses or specialists are most in demand. Thus the most important issue when carrying out a socio-economic evaluation of a service is to identify the relevant variables and state how each variable affects the outcome.

## **A.6 Comparison to other projects**

It is important that EU research money is not used to reinvent the wheel over and over again. An important issue when evaluating a project, both before it is granted funding and during its execution, is how the project results relates to other projects of the similar type. A comparison of the similarities and the differences affect the outcome. This requires that not only previously finished projects are known to the evaluators and auditors, but also as many ongoing projects as possible. Clustering activities and best practice databases can be a help, as well as good networks across professions and countries within Europe.