

TELEMEDICINE 2010:

Visions for a Personal Medical Network



THE TELEMEDICINE ALLIANCE



The Telemedicine Alliance

The TM Alliance was formed under the auspices of the European Commission (EC) within the 5th Framework Programme of the Information Society Technologies (IST) Directorate. The overall goal of this consortium was to formulate an underlying policy for the application of eHealth in support of the European citizen, and to create a 'Vision' for a personal healthcare network by the year 2010. The TM Alliance partners are renowned in their fields and are at the same time International Organisations representing a broad spectrum of nations, thus offering a unique platform of expertise while being neutral in approach. The partners are:

The European Space Agency (ESA)

<http://www.esa.int/telemedicine-alliance>

ESA holds a key position in Europe combining expertise on science and technology with that of satellite communications. Tele-operations and control and remote monitoring of and interaction with Earth-orbiting space crews has, over the last two decades, contributed to the building up of considerable experience in the area of medical monitoring and technology. ESA has also had long experience in coordinating and managing international projects spanning many disciplines across its Member States, quality assurance, functionality and reliability being the requisite trademarks of the Agency in this work.

Two main research groups at ESA's European Space Research and Technology Centre (ESTEC) are involved in this project:

- The ESA Human Spaceflight Directorate's aim is to implement Europe's participation in the development of space infrastructure, such as the International Space Station. It has expertise in the areas of life and physical sciences, advanced sensor technology, remote monitoring of health parameters and building and/or provision of related equipment, advanced software solutions for training, and applications of e-learning.
- ESA Telecommunications Department is responsible for coordinating, shaping and supporting innovation in satellite communications. Its role as a major facilitator of R&D activity enables European businesses in participating Member States to develop world-class products and services, and helps Europe's citizens to benefit from high-quality, cost-efficient telecommunications services.

ESA has its Headquarters in Paris, while the technical centre, ESTEC, leading the project, is based in Noordwijk, The Netherlands.

The World Health Organization (WHO)

<http://www.euro.who.int/telemed>

WHO is a specialised agency of the United Nations with primary responsibility for international health matters and public health. It has global experience in health matters, and a special interest in telemedicine for addressing issues related to remote health monitoring and disease control.

WHO/Europe (the WHO Regional Office for Europe) is one of six regional offices throughout the World, each with its own programme geared to the particular health problems of the countries it serves. The WHO European Region embraces some 870 million people living in an area that stretches from Greenland in the northwest and the Mediterranean in the south to the Pacific coast of the Russian Federation in the east.

WHO has its Headquarters in Geneva, Switzerland, while WHO/Europe's office in Copenhagen, Denmark, and its office for Integrated Healthcare Services in Barcelona, Spain, are participating in this project.

The International Telecommunication Union (ITU)

<http://www.itu.int/ITU-D>

ITU is the United Nations' specialised agency for telecommunications. It has produced thousands of worldwide telecommunications and radio communications recommendations (standards) and brings to the project its expertise in the area of telecommunication networks and applications, standardisation, development trends, and data security.

ITU's Telecommunication Development Bureau (ITU-D) has well-established programmes of activities to facilitate connectivity and access, foster policy, regulatory readiness as well as network development, expand human capacity through training programmes, and formulate financing strategies and innovative technology applications in developing countries.

ITU-D is located in Geneva, Switzerland.

Definitions of Telemedicine and eHealth

The terms *Telemedicine* and *eHealth* are sometimes confused or broadly used interchangeably. Telemedicine normally refers to the practice of medicine, or provision of medical services from a distance, while eHealth, broadly speaking, refers to the administration of health data electronically.

Telemedicine:

- Telemedicine is the use of telecommunication technologies to provide healthcare services across geographic, temporal, social, and cultural barriers.

(J. Reid, 1996)

- The delivery of healthcare services, where distance is a critical factor, by healthcare professionals using information and communications technologies for the exchange of valid information for diagnosis, treatment and prevention of diseases and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interest of advancing health and their communities.

(WHO, 1997)

eHealth:

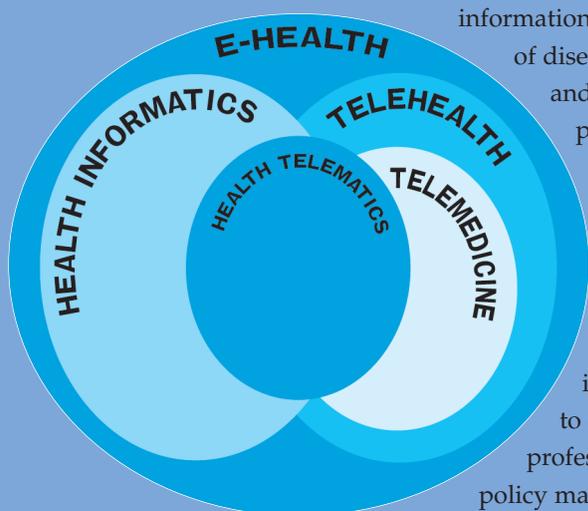
- eHealth refers to the use of modern information and communication technologies to meet needs of citizens, patients, healthcare professionals, healthcare providers, as well as policy makers.

(Ministerial Declaration, eHealth, 22 May 2003)

- The use of information and communications techniques including health-related activities, services and systems carried out over a distance for the purposes of global health promotion, disease control and healthcare, as well as education, management and research for health.
- (L. Androuchko, ITU-D, ITU Workshop on Standardisation on eHealth, 2003)*
- eHealth is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterises a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve healthcare locally, regionally, and worldwide by using information and communication technology.

(Journal of Medical Internet Research, 2001)

The relationship between the various terminologies associated with eHealth

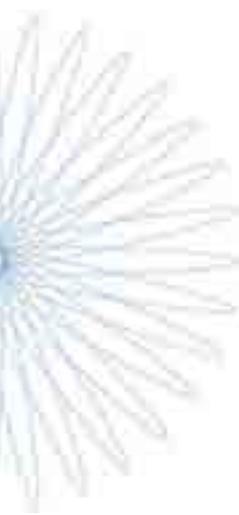


CONTENTS

	PREFACE	4
1	THE VISION	8
	1.1 A citizen-centred eHealth system	
	1.2 Key issues	
	1.3 The Roadmap	
2	THE DRIVING FORCE BEHIND THE VISION	12
	2.1 An ageing population	
	2.2 Quality of care and care delivery	
	2.3 Cost	
	2.4 Mobility	
	2.5 Technology	
	2.6 Consumerism	
3	REALISING THE VISION	18
	3.1 Systemic change	
	3.2 Key supporting actions	
4	IMPEDIMENTS TO REALISING THE VISION AND ACTIONS	26
	4.1 Cost	
	4.2 Lack of infrastructure	
	4.3 Non-adherence to adequate standards	
	4.4 Fear of change and globalisation	
	4.5 Fear of alienation of the medical service	
	4.6 The business aspects of Telesupport	
	4.7 The missing electronic health record	
5	RECOMMENDED ACTIONS FOR IMPLEMENTING THE VISION	30
6	CONCLUSIONS	36
7	FUTURE FOLLOW-UP	37
	APPENDIX – EXPERT INTERVIEWS : Summary of Results	39

PREFACE

The health of the citizen has always been, and will continue to be, a critical issue for all governments within and beyond the European Union (EU). The conversion from traditional health strategies to eHealth is a giant, but inevitable, step for which the EU Health Ministers have recently (in May 2003) given their unequivocal backing via the implementation of the eEurope 2005 Action Plan. ESA, WHO and ITU, with the support of the European Commission (EC), have formed the TM-Alliance consortium, with the express purpose of studying the challenges and opportunities of eHealth.



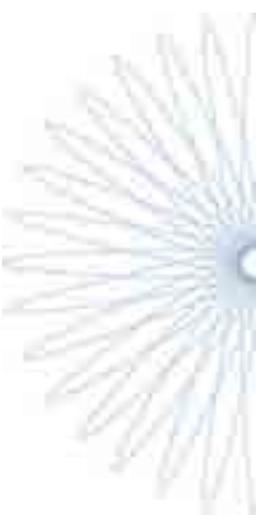
The TM Alliance has thoroughly examined existing documentation on the development of digitally supported health services in Europe and elsewhere in the World, notably in the areas of health cards, electronic health records, electronic prescribing, and IT support for telemedicine. It has consulted with representatives of national and regional governments, health-service providers, vendors and standardisation bodies, in order to glean their expert and representative opinions.

The EU Member States recognise the right of all EU citizens to healthcare provision, including accession countries, migrating workers and tourists within the EU countries, with not only local but also international health-service provision. Legal, ethical, regulatory and organisational issues, as well as the impact of conflicting economic and political interests, may represent barriers to the rapid deployment of eHealth strategies and services.

The TM Alliance recognises that the prerequisite conditions for the realisation of its Vision, such as international standardisation activities, need to be more coordinated and accelerated, avoiding competing standards and non-interoperable systems, and that in the interests of cost-saving 'open source'-based systems need be developed further and used in eHealth to avoid grossly repeated investment in the same systems.

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Ministers of the Member States have expressed a positive political will, as reflected in the Ministerial Declaration of 23 May 2003, and the TM



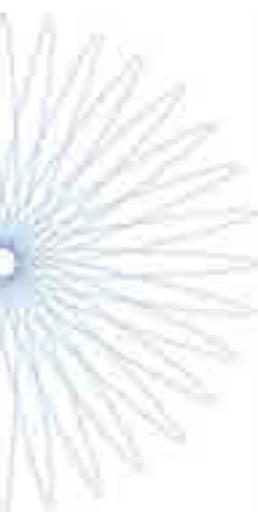


There is evidence in several countries that the use of information and communication technologies (ICT) improves access to care, increases satisfaction and supports access to a vast amount of biomedical and health information by both individual citizens and healthcare providers. However, the way to mass use of eHealth applications is not yet paved.

The TM Alliance's Vision, presented in this document, and supported by findings elaborated in greater detail in the project documentation, is addressed to the decision makers and other bodies who are in a position to make it possible or facilitate its realisation.

The Vision can be succinctly summarised as follows:

- Empower citizens and patients (e.g. choices based on knowledge, interactivity, participation in decision-making processes).
- Improve and support equal access to care (e.g. continuity of care, de-institutionalisation, tele-home care, second opinion, specialised care).
- Build capacity for health professionals (e.g. access to knowledge databases, second opinions, education and training).
- Increase quality and cost/efficiency (e.g. shorter waiting lists, safer prescription, diagnostics and treatment, shorter stays in healthcare institutions).
- Reduce burden of travel for patients (e.g. remote monitoring, second opinions, referrals).
- Support decision-making by improving information systems and surveillance (epidemiology, access to databases).
- Keep pace with and make use of the infrastructures that will be provided by other eEurope sectors, i.e. eGovernment, eBusiness, and eLearning. Otherwise, expensive duplication, loss of time and missed opportunities to improve health services may be the result.
- Overcome substantial barriers of a political, professional or economic nature. eHealth requires a different and more modern approach to healthcare provision, with new roles for the professionals and greater empowerment of the individual citizen. Economically viable deployment of eHealth requires substantial top-down leadership and bottom-up pressure and acceptance.



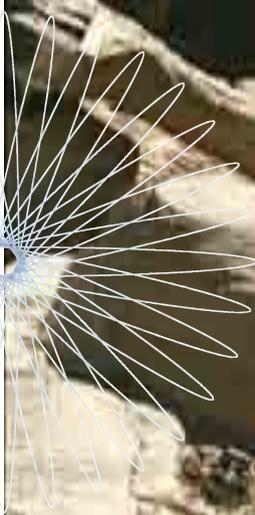
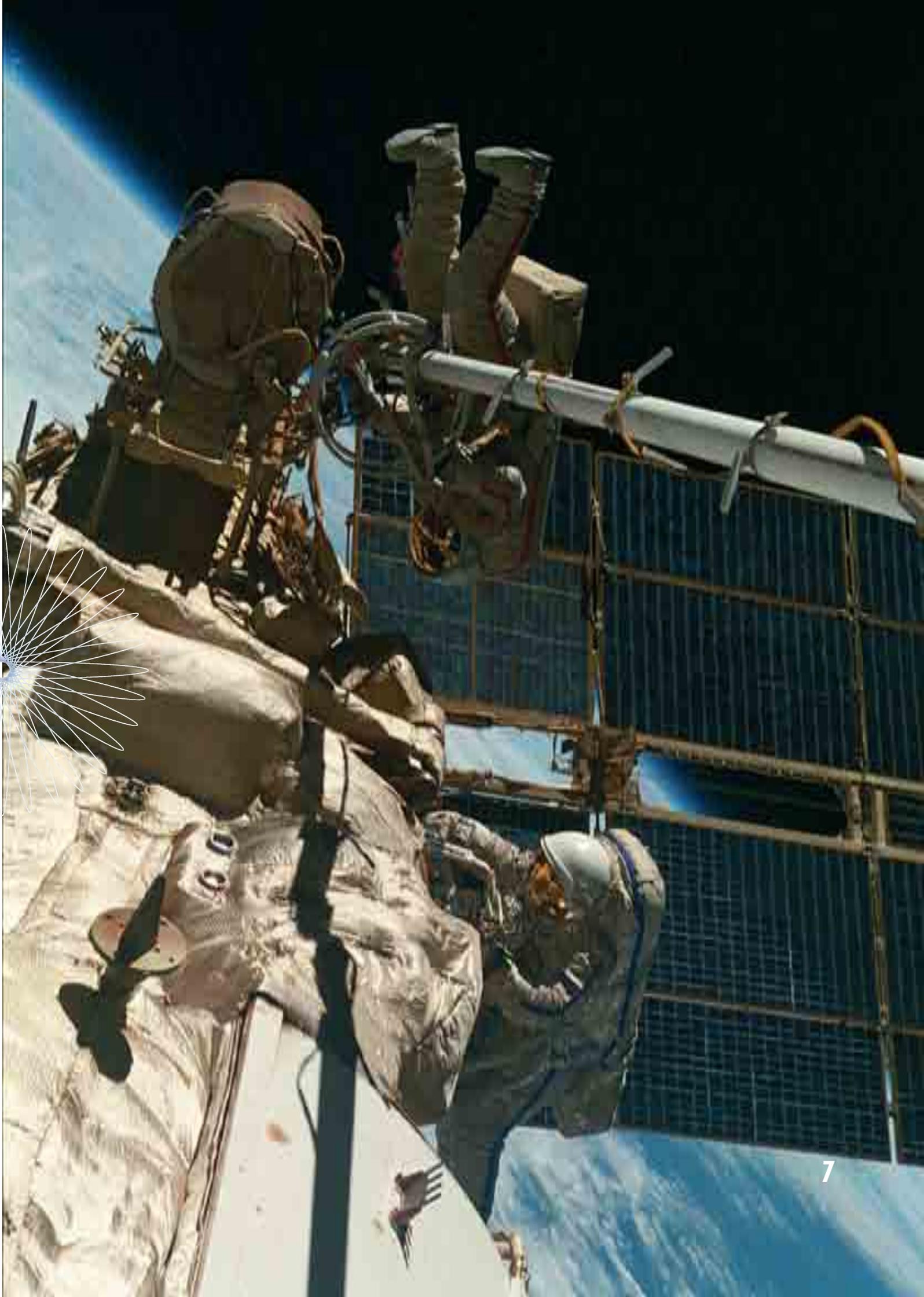
- Coordinate legislation on the use of electronic media now, as well as define financing and reimbursement systems.
- Promote and foster the worldwide standardisation and interoperability of applications and systems.

The members of the Telemedicine Alliance believe that through consensus and concerted action the creative resources of the EU can be harnessed and Europe can take and maintain a world lead in eHealth services technology, and thus also in the broader framework of the technologies of the eSociety. This effort needs to start now with political initiatives from the top, involving industry, the healthcare professionals and the patients. Any delay will be counterproductive, will damage Europe's competitiveness, and will leave any eventual progress to be technology-driven instead of politically and citizen-driven.



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1 THE VISION

1.1 A citizen-centred eHealth system

eHealth systems have the capability to significantly enhance the move towards citizen-centred healthcare. The Vision and Roadmap presented below clearly illustrate how the patient can become the focus of the healthcare system and be in a position to control his/her own care plan (Fig. 1).

Figure 1 -
The Vision



The key to the success of this move will be the creation of a network of data repositories associated with the citizen and used by the principle healthcare 'actors'. Via this eHealth system the patient will be able to interact with the healthcare providers, receive education and be empowered to take greater control of their own health and healthcare. The collected data will enable better planning and assessment of preventive measures and individual cases or care plans. It will enable the patients to be partners with their healthcare professionals in making choices between available treatments.

Finally, it provides the basis for payment/reimbursement systems. Its success depends on the trust of both citizen and healthcare professional. This has to be achieved by explicitly incorporating authentication, security and confidentiality measures so that the data is both legally and medically appropriate to the potential user. This model is particularly adapted to a world in which more and more of its citizens, because of their increasing life spans, will suffer one or more life-restricting conditions or chronic illnesses.

1.2 Key issues

The achievement of this Vision by 2010 will require significant resourcing and commitment from healthcare providers, governments, and funding agencies. The key issues that have to be resolved are highlighted with a star in Figure 2. eHealth has been divided into eCare, eLearning, eSurveillance and eAdministration to display more clearly the different impacts of the major factors on eHealth.

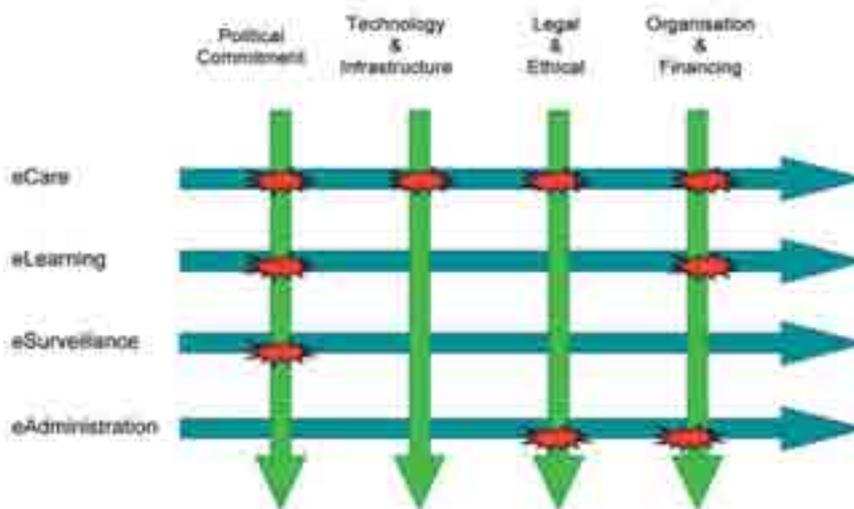


Figure 2 - Key issues



Figure 3 –
Fundamental
components of an
eHealth system

eCare Provision

- Electronically facilitated citizen self-help
- Remotely promoted and monitored preventive healthcare programmes
- Remote monitoring of health and biological signals
- Individual case management
- Electronically assisted health assessment
- Electronic health cards
- Remote professional consultation and sharing of data between professionals, especially the provision of second opinions
- Assisted interventions by healthcare professionals
- Online professional health groups
- Patients communication with health professionals
- Emergency-medicine and vital-sign monitoring for disasters such as earthquakes, floods, plane crashes, etc.
- Access to and updating of electronic healthcare records, providing the right information at the right time to the right person

eLearning

- Patient learning for preventive care and disease management
- Remote learning, development and competence monitoring for healthcare professionals
- Access to high-quality health information including current literature
- Access to evidence-based medicine
- Provision of preventive health education and health-enquiry services

eSurveillance

- Public-health and reporting of notifiable/infectious diseases
- Real-time epidemiological analysis
- Electronic health-information collection, analysis and reporting
- Research and electronic statistical health analysis
- Management of health consequences of natural/man-made disasters and wars
- Monitoring for peace-keeping purposes

eAdministration

- Patient and provider healthcare product purchases (prescriptions, glasses/contact lenses, etc.)
- Billing and administrative data management to support the healthcare process, including financing and reimbursement
- Aggregation and reporting of administrative data, including quality/performance, clinical outcomes, etc.



Figure 4 –
The Roadmap for citizen-centred eHealth care

1.3 The Roadmap

Achieving the TM Alliance’s Vision of citizen-centred eHealth will take several years and the key components will only be in place by 2010. Special attention will need to be given to the intersections highlighted by a star in Figure 2. The progression to this objective is shown in the accompanying roadmap (Fig. 4).

Healthcare is delivered and organised in a great variety of ways in Europe and so achieving the Vision will vary not only by country, but also in some cases with healthcare provider. The steps needed to achieve the Vision are nevertheless the same and are illustrated in the roadmap. The speed of implementation will depend on existing legal statutes, previous strategies and investments in infrastructure.

The key step is committing to the Vision in a political sense, so that it is recognised that eHealth will be able to deliver the benefits claimed and empower the citizens to take greater control of their own health destiny. It is only from this political commitment that the necessary legal, technical and organisational actions will come.

The conversion from traditional healthcare to eHealth will have to be planned carefully so that there is no disruption of services during the change. Adequate resources supporting training and maintenance will need to be available during the transition. The process will need to include opportunities to share experience and ‘lessons learnt’. Moreover, it is important that the introduction of eHealth does not impact negatively on the traditional care that the citizen is accustomed to receiving.

2 **THE DRIVING FORCE BEHIND THE VISION**

Over the last decade, the healthcare system has started to move from being health-professional-centred to being centred on and controlled by the citizen (if so desired). The general trend in politics is to recognise and support this trend. The vision of citizen-centred eHealth provides a key element, by providing a cohesive and economic solution to the complexities implied by a citizen-centred healthcare system.

eHealth provides the opportunity to change outdated working practices and support personalised care, involving the patient and his/her 'support group' in the decision-making and care-provision processes. This empowers citizens to move from being grateful recipients of healthcare services, to a knowledgeable consumers and partners, as they are in all other domains.

The key imperatives that support the TM Alliance's Vision are:

2.1 An ageing population

Currently, in Europe, between 16 and 18% of the population are over the age of 65. By 2010, 4 in 10 people will be over 65, and many will have at least one chronic medical condition and possibly two. Many of these individuals will require contact with several healthcare sectors to provide complex and sometimes expensive treatments. The human and financial resources and organisational effectiveness needed will be beyond today's stretched budgets and health-system competences. eHealth is well equipped to counter this growing and seemingly insurmountable predicament: it can supply the tools for seamless care, coordinating the activities of health and social care teams, thus achieving the ultimate goal of providing better quality of life at lower cost.

2.2 Quality of care and care delivery

Conventional healthcare delivery has not changed much over the last century. The working procedures are unnecessarily repetitive and



resource consuming. Today's working methods have been developed according to the wishes of the professionals, rather than those of the patients. Also, there is a growing literature showing that the care itself and the associated clinical interventions are flawed in about 30% of all cases. Some of these may be lethal. One report claimed that 90 000 persons die annually in the USA as a result of medical errors. Added to this there is increasing concern that best practice and most appropriate pharmaceuticals are not always used because it is difficult to communicate with the healthcare professionals and change their working practices.

eHealth provides tools to increase the quality of the system's performance and level of service without increasing costs, provided the change management is effective. It does this by improving workflows, reducing errors in data transmission, providing information about best clinical practice and assisting in pharmaceutical prescribing. It also provides a counterbalance to professional judgement by providing the same information to the citizen. It is especially useful to those citizens having chronic illnesses who have the potential to become expert on their condition.

Home care and 'hospital at home' are key elements in many efforts to improve the quality of care for all ages of patient. eHealth is again a critical component, keeping the patient's healthcare team up to date not only with the appropriate treatment, but also with the treatments being provided by others. It is possible with current technology for clients and their carers to keep in contact via interactive tools using familiar procedures. The same mechanisms allow the monitoring of persons living alone via devices with ambient intelligence embedded in their living environments.

2.3 Cost

Many governments, employers and individuals are already finding the cost of healthcare unsustainable. The result has been a critical appraisal by most western governments of their national healthcare system and its financial support mechanisms. Although the TM Alliance study did not provide an unequivocal answer as to whether eHealth would assist in reducing cost, there were strong indications that the initial costs of conversion would lead to better healthcare provision, but that the degree of improvement achievable would depend on local conditions.

The initial costs of establishing eHealth systems on a broad scale complete with re-engineered systems will be greater than leaving the system unchanged. However, the alternative is one of decreasing ability to fulfil the demands for skilled professional staff and the concentration of expertise in urban areas, with corresponding reductions in the quality of and access to care for citizens living in rural areas. If there were no planned move towards eHealth, then the results would certainly not only be expensive but also unpredictable, with a consequent rise in lack of equality in healthcare provision and access. Individual digital eHealth support to citizens and patients offers the possibility to reduce the need for new buildings and hospital beds whilst at the same time enabling isolated professionals to receive support and competence building from centres of excellence, however remote they may be.

2.4 Mobility

Individuals now live and work in a globalised environment, the EU encourages mobility of workers and services, and the western world experiences migration. Individuals enjoy tourism and many Europeans seek to spend the autumn of their lives in milder climates. They all expect the same quality of health services and that the reimbursement schemes will be similar to those in their home country. Moreover, they expect their health data to be available whenever and wherever needed. Only eHealth



can meet these requirements, by making an individual's health data available when and where it is needed. Digital transmission of entitlements to reimbursement for healthcare expenses is an issue that the EU Member States have dealt with in the context of decisions taken on the stepwise digitisation of the E111 Form on a health insurance card.

Mobility also implies mass transport of passengers in trains, vehicles, vessels, and planes. Personalised care would imply that such mass-transportation facilities need to establish, as some are already doing, a digital connection with centres of relevant expertise to provide guidance in individual cases and service support in mass emergencies.

2.5 Technology

The average western citizen now expects communications and information technology to be ubiquitous. A majority use the Internet and are aware of some of its capabilities. They are less and less tolerant of professions that make avoidable mistakes, do not use proven techniques, and cannot provide basic services because of delays caused by low-technology solutions. Use of the latest technology in other sectors is driving the need to introduce similar technologies into healthcare in order to achieve similar benefits.

These technology-driven changes could also destabilise the existing healthcare systems if not introduced only after careful trials and assessment. Their introduction therefore has to be backed by a method of trial that wins the confidence not only of the healthcare practitioner, but also of the citizen.

2.6 Consumerism

Another of the important trends in the western world has been towards a more consumeristic attitude, whereby the ability to choose a product or service is based on an assessment of its features, benefits and costs. Most

current healthcare systems are not transparent in terms of features, costs and risks. The citizen is therefore faced with the choice of either having to accept what is offered by usually well-meaning professionals, or making decisions personally with little access to data. This will inevitably impose tensions that could lead to patients making uninformed choices outside the healthcare system, rather than being able to make the same sorts of informed judgments that they make every day when selecting other goods and services.

eHealth supports not only an increased transparency of service quality, but also the ability to obtain second opinions. Whether it can go as far as being able to offer quality and cost comparisons of the sort found in many consumer magazines will depend on the prevailing political climate.





3 REALISING THE VISION

Each healthcare system will follow a different path in moving towards the goal of citizen-centred healthcare supported by eHealth mechanisms. The exact route and steps in each case will depend on the current established system, the financial strength of the major players and providers, the political will and the necessity of achieving the goals. However, the route for all will involve both systemic and detailed changes.

3.1 Systemic change

The acceptance by the main healthcare-system actors of the Vision of citizen-centred eHealth is the bedrock on which the detailed facilitating measures will be built. This can only be achieved through wide-ranging promotion to the significant decision makers of the benefits that the TM Alliance's Vision brings to the citizens of Europe and of how it reinforces the Lisbon Council (2000) Declaration about making the EU "the most competitive and dynamic knowledge based economy in the World ...". These promotional activities need to be supported with expert advice on the steps to be taken to realise the benefits.

Demonstrating the ability to achieve improved quality of healthcare provided with higher levels of client satisfaction whilst driving down long-term costs will be critical in gaining the confidence healthcare-system policy makers to signing up to the realisation of the Vision.

The exact implementation of the TM Alliance's Vision will of necessity have to be adapted to each country to meet the needs of the different healthcare systems. However, the increasing interaction between Member States and their citizens requires that the principles of implementation be sufficiently similar to allow fast and efficient transfer of data and support across national boundaries. This implies that critical legal and technical standards have to be identified and adopted to enable this goal to be achieved.



There are several key opportunities in 2004 and 2005 to realise the goal of gaining acceptance for the TM Alliance's Vision:

- The Spring Summit, organised under the Irish Presidency, includes *"the potential efficiency gains linked to the development of eHealth"* and how these might be *"further explored, especially in the connection with the eEurope 2005 Action Plan"*.
- The enlargement of the European Union, new Commission and Parliament in May 2004.
- The preparations that are underway for the mid-term review of the Lisbon Agenda which is due in 2005.
- The mid-term review of eEurope 2005 as part of the Lisbon strategy.

3.2 Key supporting actions

The systemic changes create the environment, but many detailed actions remain in order to ensure that the objectives of both the Lisbon agenda and the TM Alliance's Vision can be achieved. The key elements are outlined below.

Legal Framework

In conformity with the principle of subsidiarity, legal and ethical issues have up to now been dealt with at national level. The advent of eHealth throws into sharp relief the need for legal and ethical issues to be considered at a pan-European level. This becomes especially true when:

1. Europe's citizens are more mobile as workers, tourists and retirees.
2. Health professionals and services can move to where the need is greatest and the appropriate facilities exist.
3. Health-related data, whether of a personal or more general informative nature, need to be accessible from the place where the patient is being treated.

Some of the key legal issues identified are outlined overleaf.

Confidentiality, consent and privacy

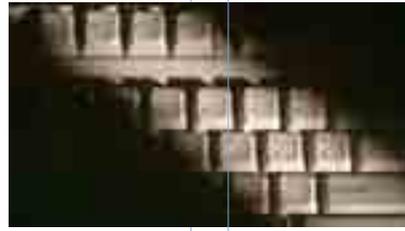
The results of the expert interviews and market survey put data protection and confidentiality among the top priorities to be addressed before the conversion to eHealth could be seriously and widely implemented. The guarantee of citizens' rights regarding the security of personal data is a prerequisite for the acceptance of eHealth. It is recognised that the Commission has tackled the issue of data protection head-on with a series of Directives on data-privacy, which most Member States have incorporated into national laws. Nevertheless, despite this supposed harmonisation across the European Union, the Directives still allow much leeway to national governments with respect to health. The result has been a rather varied gamut of guidelines across the Member States, with none at all in some cases. There are some sensitive areas, such as access to doctors' diagnostic notes, that beg for guidelines. Moreover, there are ten new States that still lag far behind regarding de jure and de facto respect for citizens' rights.

Protection of and access to health data

The issues raised by data protection and confidentiality are clearly accentuated and exacerbated when the movement of such data leaves the realm of dedicated hospital or local medical-practice Intranet systems and travels farther across networks and national borders.

Patient empowerment

The right of patients to participate in the decision-making regarding their own treatment is, at present, limited and unclear. Currently, most systems are centred around the healthcare establishments, with the patient having to fit into the system; the TM Alliance's Vision calls for the reverse – the infrastructure and processes should be centred instead around the patients' needs.



Licensing and accreditation of healthcare professionals and services
Cross-border medical practice requires that the qualifications and accreditation of the health professionals be easily recognisable across borders, whether the service is provided personally or via Telecare or Telediagnosis. There are presently many categories of health-service providers and professions that are without equivalence and not recognised across the EU. It is almost impossible at present for patients to verify the qualifications of foreign healthcare professionals offering treatment or advice from abroad. There are currently few legal guidelines for Teleservices, especially cross-border services. This can lead to complex issues of liability in the uncharted waters of cross-border eHealth.

Each Member State will need to incorporate laws for Teleservices (Telediagnosis, Telesupport and Telecare) to ensure that the rights of its citizens and the responsibilities of its healthcare professionals are clearly defined. They will also need to clearly identify the responsibilities where advice or services are provided externally to that Member State.

Liability, risks and responsibilities

There are increased risks for patients as well as health professionals as services are offered in the framework of eHealth applications and across national borders. This shift, together with unrestricted access to health knowledge and records of patient health and diagnostic data, could lead to increased litigation over malpractice and liability. Without supporting guidelines, there will be hesitation on the part of health professionals to move towards eHealth practice.

Interoperability

Lack of interoperability is the second barrier to realising the TM Alliance's Vision. It involves not only technical aspects, but also healthcare issues such as medical coding systems. To enable a personalised eHealth service

system to be constructed regardless of location, all these interoperability issues have to be resolved at least into European agreed and implemented standards, if global standards are not achievable. It is too important to be left only to the experts in each field. A key recommendation, therefore, is that the eHealth Standardization Coordination Group (eHSCG) already created be supported at top government level, and that the interest and competences of pertinent European healthcare-system groups, both public and private, be channelled accordingly.

This would provide the co-ordination between European Medical Standards and coding bodies, WHO, ITU, ISO, CEN, National Standards Bodies and other Standard-making bodies on eHealth matters. It would also create the timetable and programme for achieving interoperability. It would not duplicate the work of these other bodies, but rather ensure that their work was harnessed to the goal of achieving a pan-European personalised eHealth service.

One of its main contributions would be to provide guidance for applicable standards for existing bodies involved in healthcare standardisation and to disseminate their work by using web technologies.

Gaining Trust

The TM Alliance's Vision can only succeed if not only the key decision makers are committed, but also that 'the man in the street' – whether potential patient or healthcare professional – is confident that the investment is worthwhile and will lead to improvements in healthcare procedures and outcomes. Therefore careful planning, testing, outcome monitoring and widespread presentation of results are vital elements of the realisation strategy.

All healthcare-system policy makers will therefore have to ensure that each new technical component or organisational change is carefully tested



in their system prior to universal implementation. This will add substantially to the cost, but will avoid the cost of failed implementations and the non-costed reduction in trust that results from failure.

The other important aspect for gaining and maintaining trust is to ensure that all implementations are preceded by awareness programmes, training in the basic technologies, and continuing support and education programmes. Clearly, these will be different for each healthcare system and will require an action plan for all groups involved. Common technology education and training can be developed through cooperation between these groups to reduce costs and increase effectiveness.

Communications and Information-Technology Events

The TM Alliance's Vision does not require the creation or development of any specific technologies as it is built on the roadmap of evolving technologies; the technology itself will drive the Vision forward.

In the period from now until 2010, several key events are forecast that will drive the concept forward almost regardless of the other issues identified elsewhere in this chapter. The technologies critical to success are:

- Evolution of the communications networks by 2010 to:
 - Gigabit fixed networks with IPV6 addressing, offering almost unlimited addresses and improved security.
 - 3G and 3.5G mobile networks, offering permanent and high-speed connections so that multimedia content and Internet interaction become a reality.
 - WiFi, offering freedom from fixed connections at lower transmission powers than cellular phones, and hence being more suitable for use in buildings containing sensitive electronic equipment.
 - Bluetooth, offering the possibility of short-distance transmission and allowing greater capabilities for human monitoring equipment without the need for restrictive wiring.



- Nano-technology in the medical/sensor area.
- Implementation of the European Galileo Navigation System, allowing greatly improved responsiveness to manmade and natural disasters.
- Reduced cost and widespread availability of satellite services such as interactive digital television and high-bandwidth data transmission, giving a potentially vast increase in support for health-promotion programmes.
- Evolution of the Internet to much higher levels of capability.
 - The increasing use of XML for inter-system communications and data storage.
 - Semantic web towards 2010, whereby navigation will evolve towards machine comprehension rather than the current requirement for human interpretation. Search engines will therefore be able to provide 'correct answers' to questions, whereas at present they provide a wide range of answers, some of which might be useful but there is no way of knowing if they are correct.
 - High-access-speed technologies, such as ADSL and satellite communication, allowing greater multimedia content supporting both domestic and professional interaction, education as well as remote consultation.
- Evolving user interfaces will move towards ones in which all human senses are used and speech recognition will join touch as a common data-entry method. New interfaces such as virtual reality are likely to be perfected and become commonplace, enhancing and enriching the user capabilities.
- The continuing increase in power and capability of computing devices will support the enhanced user interface and provide computational ability enabling the multimedia medical record to become a reality. The maturity of data and knowledge grid computing will enable the personal data to be used for both preventive and responsive healthcare interventions in the fields of epidemiology and genomics.



- The reducing size of computing devices together with their increased power, improved human interfaces and communications capabilities, will help to make the much-discussed mobile pervasive computing a reality. This will be important in both facilitating and driving the creation of citizen-based healthcare records and health services, because it will allow the citizens and healthcare professionals to undertake measurements, collect data and work interactively with knowledge bases regardless of location.

Funding

The transition to eHealth and conversion of existing systems requires a massive initial investment in new technology, infrastructure and training. This is a burden that is difficult for the healthcare system owners to justify, especially with few immediate benefits and uncertain short-term harvesting of the potential returns. Notwithstanding this, such support should only be provided with the proviso that certain minimal predefined international interoperability standards – common across the entire EU, as a minimum – be followed. This will have the advantages not only of encouraging the transition, but also of ensuring that such changes have a long-term impact. There is also the added advantage that this philosophy would foster investment from the private sector, which would have more confidence that there would be a wide and long-term market for their applications and solutions.



4 IMPEDIMENTS TO REALISING THE VISION AND ACTIONS

With some notable exceptions, the established European healthcare sector has been tardy compared with other sectors in grasping the opportunities. Several factors have led to this situation:

4.1 Cost

Healthcare is expensive, and Information and Communications Technology (ICT) has been seen as an opportunity cost rather than as a strategic investment. Decision makers have given lower priority to ICT investments compared to those providing immediate medical benefits. Also, changes in financial allocations within the health sector in order to afford the introduction of eHealth would necessarily imply either a reduction in future staff numbers or a reduction in forecasted staff increases. Local reductions in employment are not popular, although the human resources liberated might well be used to good effect elsewhere within the sector. Add to that the fact that attempts in the past to introduce large IT systems have resulted in 'financial scandals' or have failed to deliver claimed benefits, and it means all potential investors will be doubly careful.

4.2 Lack of infrastructure

Many regions have not yet established a physically secure network infrastructure, not to mention national or trans-European networks that are interoperable and have sufficient capacity to meet today's and future demands. However, the commitment of governments to eEurope 2005 should lead to the establishment of the necessary highways to be shared by many sectors, and eHealth must jump onto that bandwagon, provided that it can satisfy the special needs of healthcare. The issue has been dealt with by the European Commission in a dialogue with EU Member States.

Ignoring the opportunities arising from the establishment of national information and communication infrastructures for the benefit of all sectors would be very costly and time wasting.



4.3 Non-adherence to adequate standards

One of the main reasons for the unnecessarily high costs and lack of flexibility of today's IT systems is that previous investments have been in systems that either do not comply with interoperable standards or use closed or proprietary turn-key solutions. The documents emanating from the TM Alliance study can facilitate the elaboration of a standard policy for the future.

4.4 Fear of change and globalisation

Healthcare professionals, administrators and local/regional decision makers have not all fully understood the potential of eHealth, or have even feared the challenges of the workload, the need for staff education, the changes in power structures, and the change of roles and restructuring. It is human to fear that your patients may disappear to some 'clinic in cyberspace'. In other words, the globalisation of the Internet can be seen as a threat. Also, the steps necessary to implement change management are cumbersome, and incentives for leaders to be the champions of change have been found to be inadequate.

This is also true for the citizens who have seen the reduction in local services from their banks and increasingly impersonal shops. They are also concerned that they will lose prized personal relationships with their local healthcare professionals. Therefore, any implementation of eHealth has to be in a context that reinforces the local relationships, whilst allowing them to be enhanced with expertise and experience from other locations.

4.5 Fear of alienation of the medical service

In contrast to national governments, regional and local politicians have failed to push for digital solutions because all parties involved have viewed healthcare as being based on a very personal face-to-face

encounter, ignoring the opportunities for improved services, the involvement of the patient in the decision-making process facilitated by access to data, and the improved continuity of care across different health institutions.

4.6 The business aspects of Telesupport

Currently, second opinions and Telesupport are provided on a friendship basis and in most cases no money changes hands. The legal and financial implications are therefore kept simple. With increasing volume, the reimbursement for Teleservices, especially across borders, has to be clarified, together with the legal responsibilities, before these services can take their place in standard healthcare practice.

4.7 The missing electronic health record

Full exploitation of eHealth opportunities necessitates the availability of the electronic health record. This is more complex than the basic records in other business sectors and although it is much discussed, in healthcare there are few extra-institutional examples. The creation of an electronic medical record will be a long process, for which at present we do not have much detailed evidence of national benefits; but medical experts have confidence and we know from other sectors' simpler implementations that it will be fundamental to success.



5 RECOMMENDED ACTIONS FOR IMPLEMENTING THE VISION

The EU Member States must seize the momentum to implement the TM Alliance's Vision. 2004 will be remembered as the year of major EU enlargement. It could also be remembered as the year when major commitments were made to pursuing the Lisbon Declaration about making Europe "the most competitive and dynamic knowledge-based economy in the World". Since the Lisbon European Council in 2000, the 'information society' in general and the different eEurope initiatives in particular have been acknowledged as being major tools for the enhancement of EU growth and competitiveness. At a time when Europe's citizens have access to more and more communication infrastructures and services, this is also a means of slowing down e-exclusion and narrowing the digital divide.

Against this background, one has to consider the specific context of eHealth. Health policy falls within the competence of each of the Member States, who define how eHealth services will need to be developed and how Europe's citizens will be able to benefit from the technology's added-value. eHealth needs a consistent approach across national boundaries, so that the technical, organisational and social aspects are included. Political willingness is the key to proper implementation of the Vision. Continuous political support from the Member States is the means to encourage eHealth development and to benefit fully from the gains to be derived from it.

The Vision has to be disseminated to the multiple healthcare decision makers in the Member States. In the spirit of Subsidiarity, better governance within the healthcare domain will facilitate the development of eHealth tools, while eEurope actions on eHealth will support further development in health services. It will help by clarifying responsibilities and actions at European, national, regional and local levels. This will help in the removal of inconsistencies (e.g. healthcare quality and procedures, technical interoperability and standardisation,...) that can prevent the Vision from becoming a reality.



Enhanced cooperation is a must in a world where citizens/patients have ever greater expectations from their healthcare systems - in terms of access to accurate health information, as well as patients' rights in other EU Member States - and more globally in terms of data security. The EU has a great responsibility for improving the lives of its citizens and should be proactive in doing so. While eHealth applications and services are moving forward, Member States should be ready to "meet the inevitable change". Although the market can provide solutions, it is up to the Member States themselves to provide a coherent policy (e.g. healthcare quality, technical interoperability and standardisation). Otherwise, the transition will be slow, uncoordinated, follow different standards, and in the long-run lead to increased costs for healthcare providers. Moreover, if the transition from conventional medical systems to eHealth systems is not supported financially by Member States, the direction and pace of change will be dictated from other more advanced countries and many of the market exploitation opportunities will be lost.

In a multi-level-governance Union, the Member States can learn from each other's experiences and exchange best practices. In that sense, they need to support enhancement of the Method of Open Coordination (MOC) in the health area. The MOC is a means of spreading best practice and achieving greater convergence towards the Lisbon Agenda. It has already proved effective in other social areas (e.g. employment) and can support the Member States in their willingness to coordinate their policies. As strengthened during the Lisbon summit, the MOC combines the logic of mutual learning, benchmarking, best practice and peer pressure to achieve commonly identified objectives.

Health has always cut across a wide range of EU policies. In order for Europe's citizens to benefit fully from the four freedoms guaranteed by the Internal Market, the Commission needs to look at the impact of other policies on health, to ensure that there is a coherent and consistent approach across all policies and activities. The Commission will need to present a Communication on eHealth legal issues, as foreseen in the eEurope 2002 Action Plan, by reviewing the current legislation relevant to the area.

Legal domain

Facilitating the Vision requires clarification of the legal framework in which eHealth is operating, and its practical implications. Although there are, for the most part, adequate supporting regulations in the EU Member States, with the conversion to eHealth and the resulting potentially greater flow of cross-border care, services and data, there are added complexities and uncertainties, which the present legal infrastructure is inadequate to deal with. It will be necessary to introduce modifications, clarifications and guidelines to match the increased complexities and demands of eHealth tele-consultation services, especially where they cross national borders.

It is therefore recommended that:

- consistent guidelines be developed and agreed across the EU regarding the processing of health data, with specific clarifications regarding diagnostic notes, which emphasise and guarantee its protection and confidentiality, as well as unrestricted access by the patients to their own data
- guidelines be created for the practising of telemedicine, and tele-consultation, and cross-border healthcare; this requires EU-wide-accepted standards and definitions of liabilities and responsibilities
- guidelines for accreditation and licensing of all categories of healthcare professionals throughout the EU who offer cross-border services be prepared so that they are transparent and recognisable across all Member States (to facilitate the provision of cross-border practices, and to enable the mobile patient to find the treatment to which they are accustomed)
- the missing support necessary for the legal framework to facilitate the realisation of the Vision be identified and put in place.

Information and communication infrastructure

Information and Communication Technologies (ICT) both provide the tools and create the opportunities that underpin the Vision statement of



anywhere-anytime eHealth services. The technology required builds on the roadmap of evolving technologies and does not need specialised tools. It does, however, need high levels of connectivity provided by universal, ubiquitous, equitable, secure and affordable broadband access. The application of this without creating a digital divide is a critical element in these recommendations.

This access must be derived from the integration of Internet and wireless technology with the development of eHealth services combining mobile, satellite and other wireless communications. It will have to be driven by European Industry together with healthcare decision makers, so that both Europe's healthcare professionals and its citizens can have their mobility needs satisfied.

Interoperable solutions in eHealth created by both private and public investments and supported by the deployment of secure health networks are fundamental to the success of eHealth for all citizens.

The crucial actions to be taken by the key players are as follows:

- Support from all European healthcare system groups, both public and private, to the eHealth Standardisation Coordination Group (eHSCG) created last year. eHSCG is an informal liaison between WHO, ITU, ISO, CEN and other Standardisation bodies to deal with the operational aspects of eHealth standardisation. Its main objective is to harness the work of these bodies for the common goal of achieving at least a pan-European, if not worldwide, personalised e-Health service based on recommended international interoperability specifications/standards.
- Identification of the most economic solutions and, where appropriate, open-source-based systems to be applied.



Education and training

Potential technical/knowledge difficulties can be overcome by ensuring that the application is both technically feasible and clinically acceptable. The human barrier to acceptability is the most difficult to overcome. All stakeholders (citizens, healthcare professionals and policy makers) must accept the introduction of eHealth for its implementation to be successful, and their concerns differ. Healthcare professionals are concerned about quality, cost (where they are accountable) and usability. Citizens are concerned about reliability (trust) and substitutability (effectiveness), and are highly influenced by marketing strategies.

The policy makers, concerned about the effect eHealth applications will have on societal and power structures, should provide adequate publicity, training and education to all stakeholders in order to achieve general acceptance of eHealth in the provision of health services. These services provided must be continuous and accessible by all, regardless of location or wealth.

Structural aspects

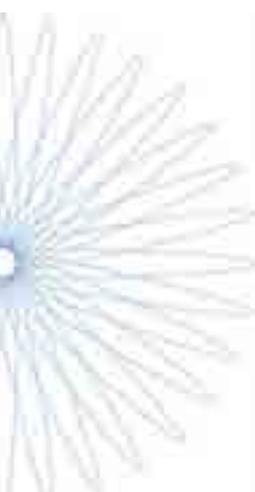
The aim of the TM Vision is not to harmonise the EU healthcare systems. On the contrary, the diversity of healthcare systems is intimately linked to the rich cultural diversity and traditions of the different regions of Europe and provides a unique test-bed for alternative approaches, methods and solutions. Each has advantages and disadvantages and the lessons learnt and shared will result in a broad market of tried and tested products. This approach also serves as a useful and necessary quality-control platform for the different solutions to be tried and tested.

With the current methods of healthcare-system financing and organisation, the cost of healthcare provision has become unsustainable for governments, employers and individuals alike. The investment needed to strategically align healthcare systems to include eHealth as one



of the pivotal pillars will be an inevitable cost, but the return on that investment will be even greater and the risks that would be associated with continuing with a non-aligned system will be minimised. To take full advantage of new technologies, such a change must also be accompanied by the appropriate change in process, otherwise there will only be added costs without the benefits of optimisation or added value:

- In order to facilitate the inevitably costly conversion to eHealth systems, it is recommended that government or EC funds be directed towards transition and conversion schemes.
- Such support should only be provided with the proviso that certain minimal predefined international interoperability standards – common at least across the entire EU - are followed.
- It is recommended that patients be empowered regarding decisions about their own treatment to ensure informed consent and choice of treatment (wherever they may be in the EU).
- It is recommended that the conversion to eHealth be implemented wherever possible using smaller projects with formal evaluation processes. Such thorough testing on a limited scale will allow 'wrinkles to be ironed out', easing the subsequent transition to a larger scale. This also avoids costly experiments and establishes confidence and a solid basis for broader conversion.
- It is important that guidelines are issued so that organisations will feel secure about making the costly investment in change/development towards an eHealth society.
- It is therefore imperative that there is a detailed 'eHealth Action Plan' in place, so that all parties can securely plan their own long-term changes.
- Procedures must first be in place for facilitating the reimbursement of Teleconsultation, Telediagnosis and Telemedicine services before they can be widely introduced.



6 CONCLUSIONS

The Telemedicine Alliance has developed a Vision for citizen-centred eHealth that is both comprehensive and achievable. The arguments for its adoption by all Member States of the European Union are persuasive from a healthcare perspective and in support of the Lisbon Accord.

The Roadmap for implementing the Vision includes actions that are realistic and build on the general trends in healthcare and information and communications technology. These steps require sensible changes in legislation, healthcare delivery and technical aspects. Although many of these changes are inevitable even without the TM Alliance's Vision, there is a high risk that their implementation would be uncoordinated and haphazard. The results of such an uncoordinated approach could be limited and incompatible limited approaches with lower benefits to the European citizen, while hindering the rational development of a pan-European approach and market for eHealth products with its accompanied benefits.

It now remains for key healthcare decision makers to adopt the Vision and apply it to their own healthcare systems. They will have to ensure that the increasing cross-border flows are facilitated by agreeing to binding international standards for the exchange of information and for legal safeguards. Implementation of the Telemedicine Alliance's Vision will result in healthcare systems based on integrated solutions where the investments made are fully in line with the resulting benefits. It will also ensure that the healthcare expectations of Europe's citizens, founded on comparisons with other industries, will be met, rather than facing their growing dissatisfaction with a deteriorating service as a result of a combination of ever-increasing demand and spiraling costs.

The Telemedicine Alliance believes that there are few alternatives to a citizen-centred eHealth system on the horizon and therefore recommends its prompt and vigorous adoption!

7 FUTURE FOLLOW-UP

In the course of the analyses performed and the activities undertaken by the Telemedicine Alliance consortium, the added-value of a supra-national, objective coordination alliance became very clear. The eHealth domain is so large, multifaceted, and complex that single 'sectors' work to a large extent in relative isolation from each other. The TM Alliance partners, together, have the collective experience, expertise and breadth, required to address the social, scientific, technical, and organisational issues associated with Telemedicine.

With the first phase of the consortium's work now complete, it has moved its focus to Phase II called 'TMA Bridge', building the bridge between the present state and the desired state. Building on the results of Phase-I, TMA Bridge will concentrate on verifying that the TM Vision and Roadmap are fully compatible with users needs, especially in terms of service interoperability and user mobility. A foreseen third phase will develop an eHealth platform for implementing and sustaining the Vision. The three phases of the overall project are depicted schematically in Figure 5.

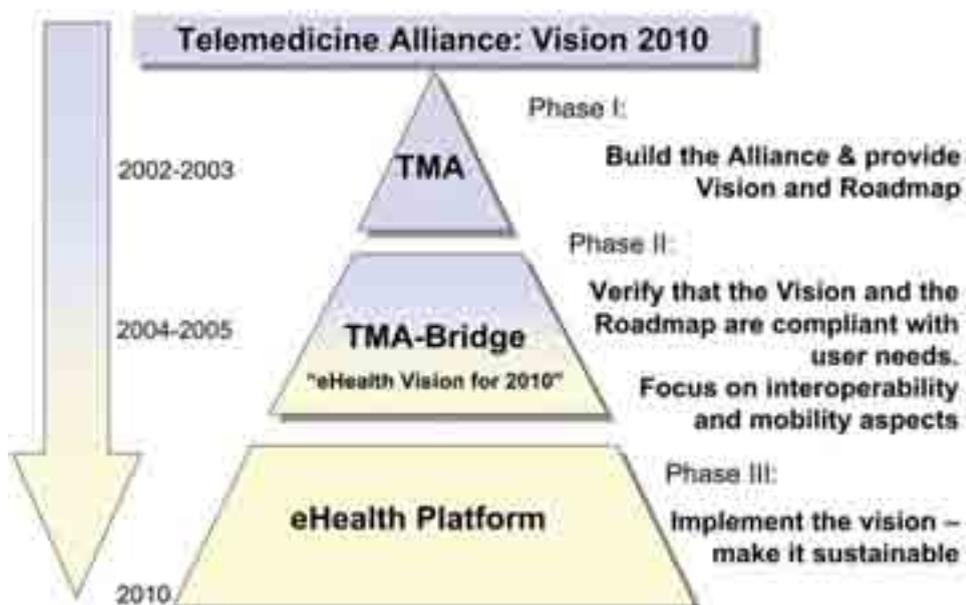


Figure 5 - The Telemedicine Alliance consortium's planning

Interoperability was one of the main concerns identified in Phase I of the study. Phase II, *"TM-Alliance - A Bridge Towards Coordinated eHealth Implementation"*, with the same consortium, funded by the EC 6th Framework Programme, a Specific Support Action of the Information Society DG, will therefore address all aspects of interoperability: communication, database structures, medical workflow, re-imburement, ethical and legal aspects.

The consortium, through its prominent member organisations (ESA, WHO, ITU) will also support the activities of an eHealth Standardisation Coordination Group (eHSCG), made up of nominated professionals from relevant national and international standardisation bodies, and will actively disseminate concrete proposals to eliminate the obstacles to the free movement of citizens/patients. The recent legislation adopted by the US government concerning eHealth standardisation activities are an additional sign that the European organisations must act to create the conditions necessary for European companies to be competitive and successful in the world healthcare market.

ACKNOWLEDGEMENT

The main authors and contributors to this work were:

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APPENDIX

Expert Interviews – Summary of Results

The following summarises the results of interviews carried out in the context of this project. These interviews have been used as one of the inputs for the proposed Vision of eHealth 2010 (the final goal of the Telemedicine Alliance Project).

54 experts in eHealth and telemedicine from a variety of fields were interviewed. They were asked to give their view on potential benefits and risks with eHealth and also on difficulties that might hinder its implementation. In addition, they were asked to give their input on the concept of the Telemedicine Alliance and on the proposed vision of a citizen-centred eHealth system.

In general, there is firm support for patient/citizen-centred eHealth. Healthcare professionals feel that it might be unfeasible with the citizen as the one with ultimate access to medical data – as described in the ‘Vision for a Personal Medical Network’. The latter has therefore been adapted in accordance with some of the experts’ inputs, as expressed in the interviews, and now includes more dynamics and interactions.

There is strong support for any development that would have applicability for home care and that would increase the feasibility of getting remote second opinions from healthcare professionals. The added values that could be acquired with ePrescription were also highly appreciated. It was emphasised that the applications to be used in an eHealth setting should be developed in close cooperation with the end-users.

The implementation of eHealth in Europe should be performed by the simultaneous use of top-down and bottom-up approaches. Central top-down implementation would be adequate regarding issues like Interoperability and Standardisation, whereas bottom-up approaches

would be more suitable when dealing with applications, acceptability and awareness. Overall interoperability in a multitude of areas, across national borders, is regarded as the main obstacle when aiming at European and International eHealth implementation. With regard to the implementation of European eHealth it was notable that the two most important potential showstoppers (Fig. A1), the problem of interoperability and acceptance of a 'new' health system, are obstacles that should be handled with a top-down and bottom-up approach, respectively. This confirms that implementation has to be accomplished by using several different methods/tactics simultaneously. It should also be noted that interoperability embraces not only the issues regarding technological standardization, but also encompasses areas such as languages, database structures, medical workflow, reimbursement and legal aspects.

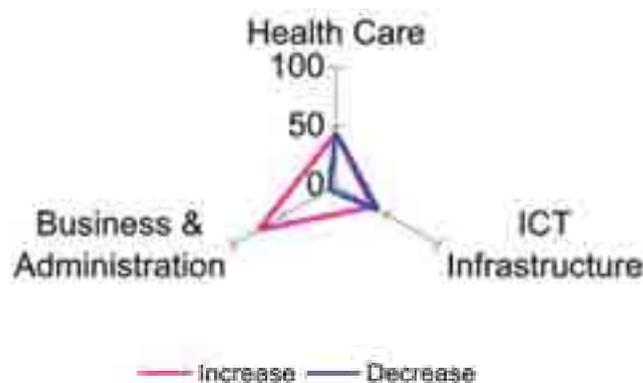


Figure A1 –
The key obstacles to
eHealth implementation

There is a great uncertainty regarding the economic impact of eHealth. A multitude of reasons were given why eHealth would bring increases/decreases in cost. Equal numbers of medical-care and ICT-infrastructure experts predicted that cost would increase and decrease. However, almost none of the business & administration experts thought that the cost would decrease, and about 85% predicted that it would increase (Fig. A2). The conclusion is that the estimation of eHealth-related costs is a highly complex issue, as reflected in the diverse responses from the interviewees. This should not be interpreted as reflecting an adverse attitude towards eHealth; on the contrary a great majority emphasised the added-value of eHealth and concluded that eHealth would give more for the money, i.e. it would be more cost-effective.

The expansion of the European Union will definitely push the development of eHealth forward, but it will also make its implementation more difficult. It will be an opportunity for newcomers to the EU to build on the experience of those already involved in eHealth. The speed of eHealth implementation in accession states will depend on the disparate infrastructures in the different countries.

Experts with different backgrounds perceived problems and opportunities associated with different eHealth topics in different ways. This emphasises the importance of having representatives from different professional areas both when assessing and implementing eHealth.

Decision makers have a strategic role to play in convincing users of the interest and added value of eHealth. Europe's citizens not only have to be aware of the existence of the new information and communications technologies (ICT), but also have to understand their inherent added-value.

The concept of ESA, ITU, and WHO teaming up in the Telemedicine Alliance was endorsed by a large majority of the experts.



Figure A2 – Predictions of cost by the three groups of experts

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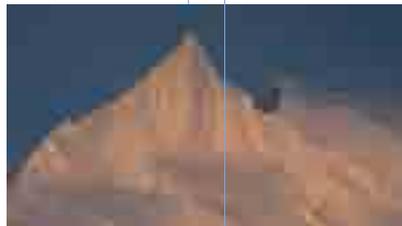
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BR-229
July 2004

Prepared by: TM Alliance team

Published by: ESA Publications Division
ESTEC, PO Box 299,
2200AG Noordwijk
The Netherlands

Editor: Bruce Battrick

Design & Layout: Leigh Edwards

Copyright: © 2004 European Space Agency

ISSN: 0250-1589

ISBN: 92-9092-799-2

Printed in: The Netherlands

Price: 5 Euros

