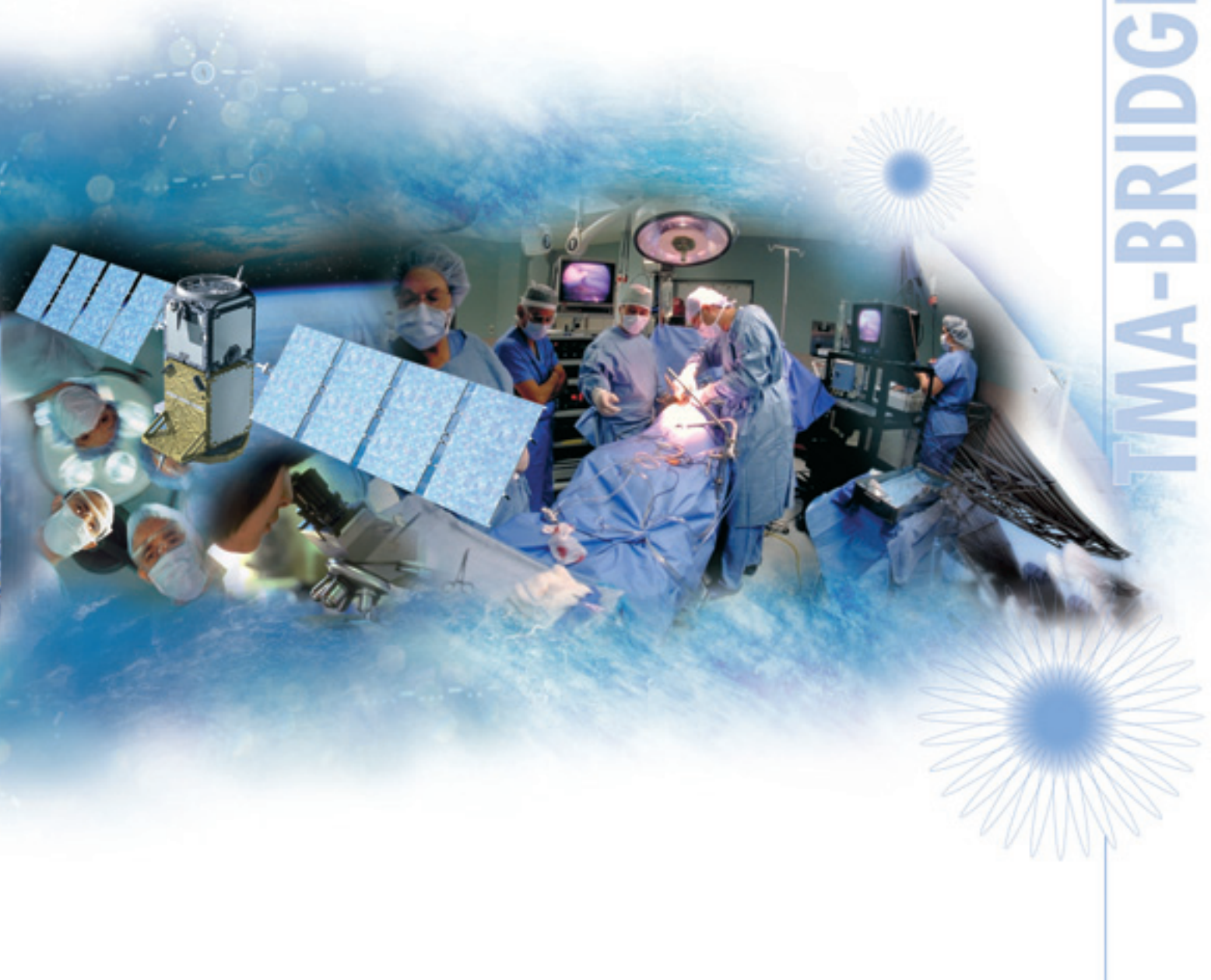


# *Towards Interoperable eHealth for Europe:*

**TELEMEDICINE ALLIANCE STRATEGY**

**TMA-BRIDGE**



**THE TELEMEDICINE ALLIANCE**



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# 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. This Alliance, now in its 2nd phase within the 6th Framework Programme under the project name 'TMA-Bridge', is a partnership of ESA, WHO, and ITU. This team comprises partners renowned in their fields and being 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 European Space Agency (ESA)**

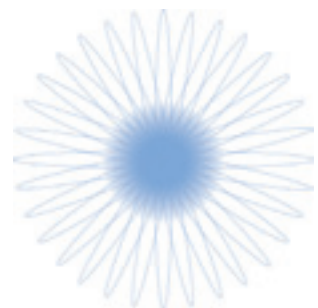
ESA holds a key position in Europe combining expertise on science and technology with that of satellite communications. Tele-operations and control and remote monitoring of and interaction with Earth orbiting space crews has contributed over the last two decades to building up robust experience in the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

Furthermore, ESA's Telemedicine activities are now more concerted than before, with the Telemedicine activities of two Directorates, located at the European Space Research & Technology Centre (ESTEC), working closely together (ESA has its Headquarters in Paris, while the technological centre, ESTEC, leading the project, is based in Noordwijk, The Netherlands). These two main research groups involved in this project are:

- The ESA Human Spaceflight, Microgravity & Exploration Directorate, with special 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 (development and testing of TM monitoring devices), advanced software solutions for training, and application of e-learning.
- The ESA European Union & Industrial Programmes Directorate, responsible for co-ordinating, shaping and supporting innovation in satellite communications and providing bandwidth and telecommunication facilities for Telemedicine applications. It helps European businesses in associated Member States to develop world-class products and services, and helps European citizens benefit from high-quality, cost-efficient telecommunications.

Recent EC-ESA agreements foster the TMA by providing a broad base of support.

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



### ***The World Health Organization (WHO)***

WHO is a specialised agency of the United Nations with primary responsibility for international health matters and public health. It has worldwide experience in matters of health, and has a special interest in the area of TM in addressing issues related to surveillance, remote 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 also sees a convergence in its global and European eHealth strategies in Headquarters (Geneva, Switzerland) and European activities (WHO/Europe offices in Copenhagen, Denmark, and an office for Integrated Health Care Services in Barcelona, Spain). Its public health approach emphasises that any action to improve health must take into consideration that eHealth is a tool to support health systems and it requires four functions in Member States: provision, financing, resource generation & stewardship. The Headquarters and European offices are now united in these efforts, with a common policy of working with the Ministers of Health, Information Society and Finance to facilitate the development of appropriate eHealth policies in health system reforms; and in partnership with the TMA to facilitate the achievement of political harmony and define a strategy for eHealth in Europe to support countries in improving their health.

ESA and WHO have also been cooperating in the Telemedicine area. WHO has notably been involved in the recommendations issued by the ESA Telemedicine group, actively contributing to the preparation of an ESA satellite telemedicine programme.

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

### ***The International Telecommunication Union (ITU)***

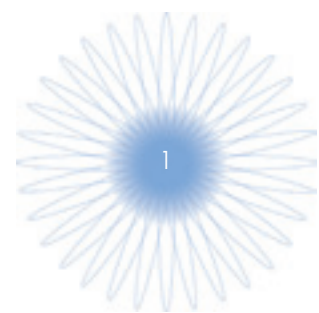
The ITU is the United Nations' specialised agency for telecommunications. It has produced thousands of world telecommunications and radio communications recommendations (standards) and brings to the project its expertise in the area of telecommunications networks and applications, standardisation, development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

ITU is supporting the activities of TMA-Bridge in the appropriate E-Strategies Unit of its Telecommunication Development Bureau (ITU-D), located in Geneva, Switzerland. The ITU Activities in e-Health fall within the framework of decisions adopted by the ITU Member States and ITU-D sector Members at the Third World Telecommunication Development Conference 2002 (WTDC02) in Istanbul, which outlines a clear action plan with regard to e-services for health, government, and education. The 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. Although traditionally the ITU's work has concentrated on developing countries, its objective is to assist all ITU Member States in adopting e-policies to foster the development of e-applications (including e-health). ITU is collaborating with WHO and in working groups on standardisation issues in Telemedicine and eHealth, as well as with other related domains such as e-Trust and e-Security. ITU is in a good position to assess and disseminate the work of TMA-Bridge especially in the domain of technical interoperability, which is its key area of contribution.

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

# CONTENTS

<b>PREFACE</b>	<b>2</b>
<b>1. WHY SHARED eHEALTH SERVICES IN EUROPE?</b>	<b>6</b>
<b>2. A VISION FOR TRANS-EUROPEAN CITIZEN-CENTRED eHEALTH</b>	<b>8</b>
<b>3. A STRATEGY FOR TRANS-NATIONAL eHEALTH INTEROPERABILITY</b>	<b>10</b>
3.1 Long-term Objectives	10
3.2 Methodology	11
3.3 A Strategic Plan in Perspective	12
<b>4. A RECOMMENDED ACTION PLAN</b>	<b>14</b>
4.1 Preconditions for Success	14
4.2 Taking Concrete Action	17
<b>5. CONCLUSIONS</b>	<b>34</b>
<b>6. LOOKING AHEAD</b>	<b>36</b>
<b>APPENDIX</b>	<b>38</b>
Definitions	38
Acronyms	39
Acknowledgements	40



# PREFACE

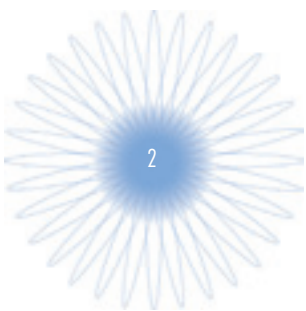
*In order to ensure that Europe's citizens can benefit from their right to live, work and visit other European countries knowing that their health needs will be met safely and affordably, the eHealth elements of Member States' national health systems must be interoperable. Currently, much remains to be done to achieve this interoperability.*

The Telemedicine Alliance (TMA), comprised of the European Space Agency (ESA), the World Health Organization (WHO) and the International Telecommunication Union (ITU), in its first phase of work, formulated a **Vision** for citizen-centred eHealth services by 2010\*. A key outcome of this study was that a major obstacle to the implementation of eHealth was the issue of interoperability. In its second phase of work, the TMA presented a **Strategic Plan** for trans-national eHealth interoperability with creative, citizen-centred, action-oriented strategic actionable recommendations. This aims to empower (promote and foster) stakeholders at all levels - political, organisational and social, and technical - to take action in order to achieve actual and sustainable interoperability. Moreover, two Workshops with experts from many fields related to eHealth were held in conjunction with this project, at which these experts reviewed the work done and provided valuable inputs.

The Strategic Plan and its recommendations are intended for the European Commission and the EU Member States, but are relevant for all stakeholders, in order to:

1. Ensure the delivery of trans-national health services with high efficiency, quality and equity of access for European citizens.
2. Create an environment in which eHealth is an integral part of health services across Europe.
3. Ensure that the European system of trans-national health services is adaptive to changing demography (population profiles, geographical location) and other major impacts.

\*Telemedicine 2010: Visions for a Personal Medical Network, TM Alliance, ESA BR-229



4. Ensure that proven (good) practice is shared both in terms of eHealth infrastructure and trans-national Health Services.
5. Ensure that trans-national eHealth and Information and Communication Technology (ICT) supported health services put the citizen at the centre of healthcare.
6. Ensure that all supporting actions are in conformance with the explicitly expressed political objectives of Europe, such as European Directives, the Lisbon Declaration, eEurope, the Nice Declaration, etc.
7. Provide guidelines for the Member States so that they can ensure that their national and regional strategies support the implementation of trans-national health services.
8. Ensure that the strategy builds on the strengths found in Europe both in healthcare and the supporting industries and infrastructures.

Achievement of these objectives will benefit citizens, public-health institutions, healthcare workers and insurers, and increase citizen mobility. It will also support pan-European research, the development of European industry and European markets, and the planning of the European response to epidemics.

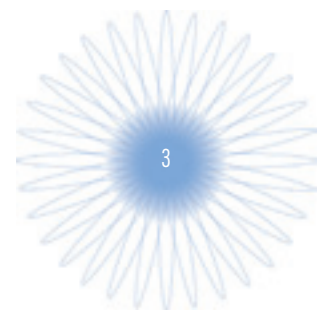
Trans-national health services should be supported by eHealth as described in the TMA Vision for citizen-centred eHealth by 2010, to improve efficiency, quality and equity of access for European citizens. For health services to be effective between Member States, interoperability challenges to the development of eHealth, and eEurope in general, must be actively and urgently addressed.

In its new strategic ICT framework for the coming five years – i2010\*, a European Information Society for growth and employment – the European Commission states that interoperability remains a main challenge to the development of a ‘Single European Information Space’ and therefore urges the EU Member States to “develop modern and interoperable ICT-enabled public services”. According to the EC, “identifying and promoting actions on interoperability” will help Europe accelerate “the economic pay-off from digital convergence” and consequently support the renewed Lisbon strategy†, a partnership for growth and employment.

To address these challenges, in support of the eHealth Action Plan, the Telemedicine Alliance Strategic Plan recommends action from three perspectives (or levels of influence): political, organisational and social, and technical.

\*EC Communication: “i2010 – a European Society for growth and employment”, 1 June 2005, COM(2005)229 final.

†Communication to the Spring European Council “Working together for growth and job, a new start for the Lisbon strategy”, COM(2005)24, 2 February 2005.



### *Political Perspective*

#### 1. Take Legal and Regulatory Action:

- Develop a legal framework (common guidelines) for health-data transfer.
- Bring Member States' confidentiality and privacy laws into harmony.
- Develop a clear statement on the legal liability for treatment.

#### 2. Create and implement a framework for monitoring and evaluation.

### *Organisational and Social Perspective*

#### 3. Develop a workflow model that will incorporate organisational and social models into trans-national systems.

#### 4. Create an environment for sharing knowledge of proven (good) practices and build up the knowledge and capability of health professionals.

#### 5. Create the facilities and the content to ensure that eligibility to receive treatment can be known at the point and time of care.

#### 6. Ensure that relevant data in electronic form are available to both the treating healthcare professional and the citizen.

#### 7. Ensure that language and cultural differences are incorporated into the system and available at the point and time of care.

### *Technical Perspective*

#### 8. Create a European telecommunications infrastructure as part of the eEurope initiative that will provide the technical support for the transmission of data in a manner conforming to the data-protection legislation in place, and which meets the needs of eHealth.

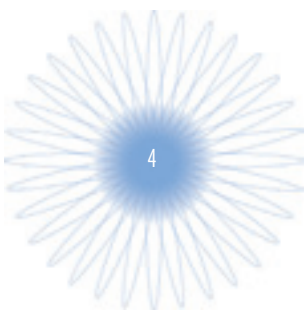
#### 9. Encourage the building of a set of value-added services incorporated into this infrastructure, including:

- Technical security components.
- Semantic and code translation to enable transferred data to be understood and used by the receiving clinician and the patient being treated.
- Ensure that data interchange standards are known, understood and implemented in both the supplying and purchasing organisations.

Successful and sustainable implementation of this strategy can only occur when the following underlying conditions are met through actions taken by the Member States of the European Union via the Council of Ministers and within their own countries, by proposals from the European Commission and by active interest and action by the European Parliament, which should have a role of oversight regarding progress towards achievement of the overall strategy.

- **A European Union response:** "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"\*.
- And indeed, there is a general political consensus that eHealth is the appropriate tool.

- **Appropriate investment:** Financial support by the European Union for trans-national eHealth interoperability development and implementation, preferably through a separate programme to support concrete and sustainable actions by Member States, is needed. Support





should only be given provided eHealth is implemented as an integrated element of eEurope to avoid a separate and expensive set of 'rails'.

- **A single coordination body integrated into the overall strategy of eEurope:** The newly created eHealth Working Group<sup>†</sup>, gathering representatives from all of the EU Member States as well as acceding countries, could be the appropriate forum in which to address interoperability matters. Support from its users and professionals' sub-group, the industry body as well as the eHealth Standardisation Focus Group, will allow the eHealth Working Group to address interoperability in an holistic manner, i.e. from a social and organisational angle as well as a technical one. The eHealth Working Group's work on interoperability will certainly help the eEurope Advisory Group get a better overview of interoperability and achieve better integration between eEurope domains. This would help avoid redundancy, and build a stronger eEurope based on the experiences in eSociety, eGovernment, eCommerce and eBanking.
- **Legal and regulatory action:** Although the European Court of Justice (ECJ) has listed the conditions within which EU Member State nationals could seek reimbursement of costs of medical treatment obtained in another Member State, the right of patients to benefit from this still needs some clarification. The practical details of entitlement and reimbursement of cross-border

health services need to be made transparent to health consumers.

- **A stepwise approach:** Implementing of cross-border interoperability should be done using a stepwise approach, e.g. through an initial implementation within a specific diagnosis or disease group and/or amongst a small patient group, and across a given number of countries. This would allow better follow-up, identification of the hurdles, and thus the initiation of immediate actions to correct them. Once refined, based on the lessons learned in each test case, other groups and additional countries would be included.

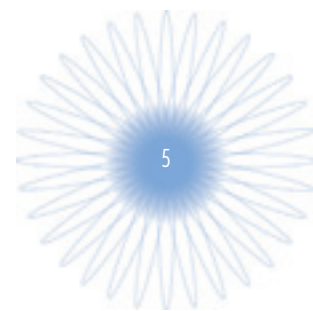
This strategy and supporting recommendations provide the necessary framework for a political climate in which Member States of the European Union can pool energies and funds effectively to create interoperable trans-national eHealth for European citizens.



Daniel Sacotte

ESA Director of Human Spaceflight, Microgravity and Exploration, ESTEC, Noordwijk

<sup>†</sup>The eHealth Working Group of the eEurope Advisory Group was created in February 2005, and held its first meeting in June 2005. Composed of nominated Member States' representatives from Ministers of Health, Telecommunications or Prime Minister's offices, this group advises the eEurope Advisory Group on the eHealth action plan. The eHealth Working Group is supported by other complementary sub-groups with an interest in eHealth, e.g. a stakeholders' group representing industry, standardisation experts, health professionals and users.



# 1. WHY SHARED eHEALTH SERVICES IN EUROPE?



*European citizens are becoming increasingly mobile. In 2003, more than 400 million tourists travelled around Europe for short-term stays for both business and pleasure. 320 million of these (roughly four-fifths) were Europeans travelling to other European Member States.\**

*The free movement of persons is one of the four fundamental rights for citizens of the European Union's internal market, and gives the citizens of Europe the opportunity to live, work, establish a business, and study in all EU Member States.†*

Health policy-makers must ensure that the healthcare available for EU citizens who move and are on the move is at least equal in terms of access, quality and cost to that of the Member State in which they normally receive care. They must provide emergency services for people travelling on short-term stays for tourism (pleasure or business), non-emergency services for those residing for the mid- or long-term (immigrants, migratory labour, students, retirees), and monitor and evaluate the numbers of mobile citizens, their healthcare needs, the treatment they receive while in another Member State, and the true cost of that treatment in order to better plan health-system resources.

eHealth provides a means by which the needs and demands of citizens who move around can be addressed, and offers the underlying tools to support all four recommendations of the EC Communication on Patient Mobility‡ through:

- European cooperation to enable better use of resources.
- Information requirements for patients, professionals and policy-makers.

\*World Tourism Organization, available: [http://www.world-tourism.org/market\\_research/facts/highlights/Highlights.pdf](http://www.world-tourism.org/market_research/facts/highlights/Highlights.pdf).

†A proposal has been made for a Directive on services and internal market ("Balkenstein Directive"), where services are defined as any self-employed economic activity normally performed for remuneration, which need not, however, be paid by those for whom the service is performed. COM (2004) 2(03): "Proposal for a Directive of the European Parliament and of the Council on services in the internal market".

‡Communication from the Commission, follow-up to the high-level reflection process on patient mobility and healthcare developments in the European Union, Brussels, 20 April 2004, COM(2004) 301 final.

- The European contribution to health objectives.
- Responding to enlargement through investment in health and health infrastructure.

Since 1999, eHealth has been one of the focuses of the European Commission within the eEurope Initiative. Further commitments in support of the setting up of a European eHealth policy were taken in 2000 and 2002, with the eEurope 2002 and eEurope 2005 action plans. To properly support EU Member States, and associated and candidate countries, in the adoption and implementation of eHealth within their health systems, the 1st High-Level European eHealth Conference was launched in Brussels in 2003. In the Declaration at the end of the Conference, Ministers expressed their commitment to the development of national and regional eHealth implementation plans as an integral part of the eEurope 2005 Action Plan. They also declared their willingness to work together towards best practice in the use of ICTs as tools for enhancing health promotion and protection, as well as insisting on quality, accessibility and efficiency in all aspects of healthcare delivery.

The eHealth action plan<sup>§</sup> was presented during the 2nd eHealth Ministerial conference held in Cork, Ireland in 2004, with the theme “Empowering the citizen through eHealth tools and services”. During the following Health Council Meeting, the Ministers recognised that eHealth could help improve health status and “empower people and patients to take greater control of their health”\*. Health Ministers also invited the European Commission to support the EU Member States in further developing “secure and interoperable information-technology systems and data networks throughout Europe as a means of facilitating e-Health development and the possible collection of public-

health data across the Community, including data on the mobility of patients and health professionals”.

With the eHealth action plan, the European Commission proposed an agenda for the implementation of eHealth, leading to among other things:

- Greater support for the mobility of patients.
- Facilitating citizen-centred health systems, and
- Providing health professionals and administrators with the tools and systems required to improve the quality and efficiency of healthcare.

The main challenges identified for action in the eHealth action plan are:

- The lack of interoperability of health information systems and electronic health records.
- The need to enhance infrastructures and technologies, notably to help health authorities collaborate with each other.
- The creation of appropriate legal and regulatory mechanisms.
- The need to share and disseminate best practices.

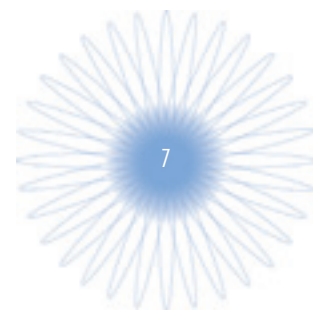
Most recently, the 3rd eHealth Ministerial Conference<sup>†</sup> in Tromsø, Norway in 2005, once again concluded that “special attention should be paid to overcoming some of the major challenges to the implementation of eHealth applications, such as organisational issues, interoperability, availability of funding, lack of long-term planning, and difficulties related to the overall assessment of ICT applications in the health-care field.” It was also stressed that “In a Europe in which our citizens are increasingly mobile - whether within the borders of their own Member State or between different countries - we need to raise awareness of the pressing need for a more integrated and interoperable European health-information space”. This is also very much in line with the European Commission’s new strategic ICT framework, i2010, where it is underlined that interoperability remains a main challenge to the development of a ‘Single European Information Space’.



<sup>§</sup>E-Health – making healthcare better for European citizens: An action plan for a European e-Health Area, Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of Regions, Brussels, 30 April 2004, COM(2004) 356.

\*2624th Council Meeting Employment, Social Policy, Health and Consumer Affairs Brussels, 6-7 December 2004, Conclusions. <http://ue.eu.int>

<sup>†</sup>Building on the strength of the eHealth Conferences of 2003 and 2004, and in support of the eHealth action plan, the eHealth Ministerial Conference concentrated on 1) Facilitating the mobility of patients and professionals, 2) Supporting more responsive health services, 3) Improving access, quality, safety and productivity. High-level Ministerial eHealth 2005 Conference, conference conclusions <http://www.ehealth2005.no>



## 2. A VISION FOR TRANS-EUROPEAN CITIZEN-CENTRED eHEALTH



### A Vision is formulated

During the period since the eEurope 2002 Action Plan, the Telemedicine Alliance first formulated a vision for citizen-centred eHealth, and subsequently a strategy to face the challenge of creating trans-national interoperability, which was identified by the team as being one of the main barriers to successful eHealth implementation.



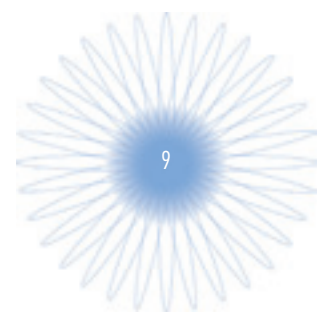
Figure 1.  
TMA's Vision for citizen-centred eHealth



This vision, which addresses the problems encountered in healthcare provision across Europe, puts the citizen in the rightful place of being at the centre of policy making and healthcare provision, and will facilitate him/her benefitting from the rights that are granted to the Internal Market. In short: The TMA's vision is of citizen-centred healthcare across Europe, where services are centred on the citizen rather than on the healthcare provider or other stakeholders, and where the citizen can easily receive this care wherever and whenever it is needed.

At the same time as the Ministerial Conference Declaration was published, following an independent process\*, the Telemedicine Alliance (in the 2nd phase of its work) came to similar conclusions regarding the dire need for trans-national interoperability. The Strategy suggested herewith by the TM Alliance to this end is based on a detailed Interoperability Study†, a systematic analysis of the current European initiatives in this arena, and an analysis of stakeholder expectations.

\*These recommendations were reached through studies and a series of workshops with eHealth experts from many different disciplines across Europe.  
†TMA-Bridge Deliverable 4



### 3. A STRATEGY FOR TRANS-NATIONAL eHEALTH INTEROPERABILITY



*The eHealth components of Member States' national health systems have to be interoperable to ensure that Europe's citizens can benefit from their right to live in, work in and visit other European countries, knowing that their health needs will be met safely and affordably. Currently, much remains to be done to achieve this interoperability. The following strategy has been developed by TMA Bridge to provide the foundation for the development and implementation of plans for eHealth interoperability.*

#### 3.1 Long-term Objectives

The objectives of the European trans-national eHealth interoperability strategy, as proposed by TMA Bridge, are to:

1. Ensure the delivery of trans-national health services with efficiency, quality and equity of access for European citizens.
2. Create an environment in which eHealth is an integral part of health services across Europe.
3. Ensure that the European system of trans-national health services is adaptive to changing demography (population profiles, geographical location) and other major impacts.

Figure 2. Multi-dimensional structure of interoperability for eHealth



4. Ensure that proven (good) practice is shared both in terms of eHealth infrastructure and trans-national Health Services.
5. Ensure that trans-national eHealth and ICT-supported health services put the citizen at the centre of healthcare.
6. Ensure that all supporting actions are in conformance with the explicitly expressed political objectives of Europe, such as European Directives, the Lisbon Declaration, eEurope, the Nice Declaration, etc.
7. Provide guidelines to the Member States so that they can ensure that their national strategies support the implementation of trans-national health services.
8. Ensure that the strategy builds on the strengths found in Europe both in healthcare and the supporting industries and infrastructures.

Achievement of these objectives will also:

- Benefit citizens, public-health institutions, healthcare workers and insurers.

- Support pan-European research.
- Support the development of European industry and European markets.
- Support planning of the response of Europe to epidemics.
- Increase mobility of citizens.

### 3.2 Methodology

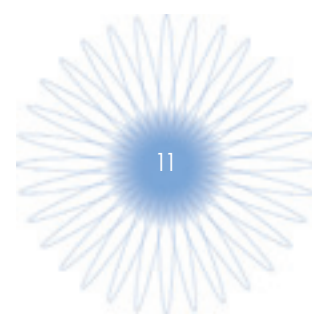
#### *A holistic approach should encompass all of the healthcare domains*

The TMA divided the broad arena of eHealth into four domains: Care, Education, Surveillance and Administration\*. For the purposes of this study, priority actions for the citizen were identified for each domain, as shown in Table 1. Moreover, the strategy resulting from this analysis provides a framework for action in three dimensions: political, organisational and social, and technical (as illustrated in Fig. 2).

eHEALTH SERVICE	PRIORITY FOR TRANS-NATIONAL ACTION
Care	Structured and harmonised messages and trans-national Electronic Health Record
Education	Web Community Services; Reliable health information webs for the citizen
Administration	Reimbursement
Surveillance	Early Warning Systems (comparable public-health data)

*Table 1. Domains of eHealth and priority trans-national services*

\*The TMA's holistic approach is consistent with the WHO's recently adopted eHealth strategy at its 2005 General Assembly, which urges Member States to pursue the potential benefits and provide the necessary infrastructure, connectivity and interoperability needed, according to the situation of the region or country. WHO, 2005d, available: [http://www.who.int/mediacentre/news/releases/2005/pr\\_who06/en/index.html](http://www.who.int/mediacentre/news/releases/2005/pr_who06/en/index.html)



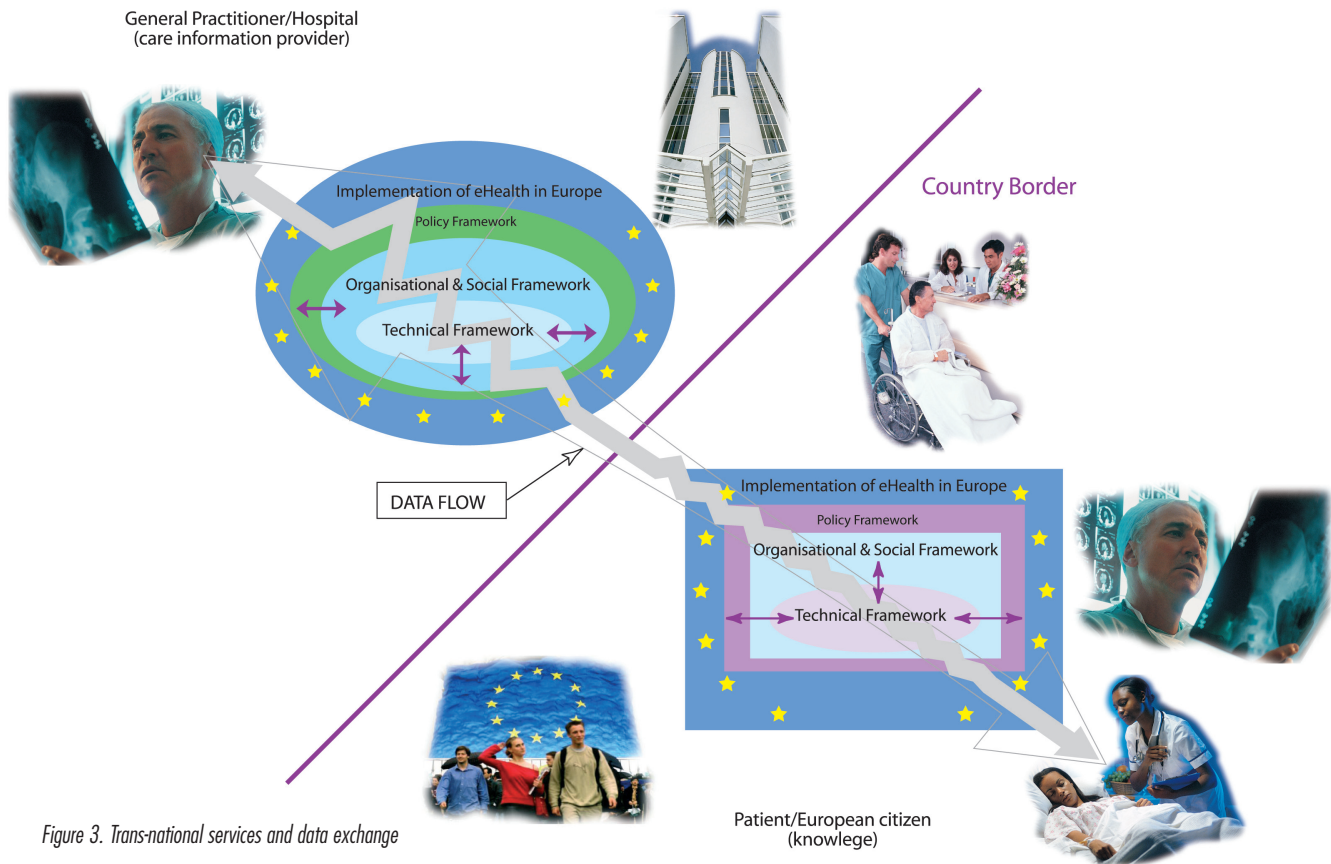


Figure 3. Trans-national services and data exchange

### 3.3 A Strategic Plan in Perspective

This strategic plan, designed to meet the objectives defined above, is recommended to be implemented in the European Union through actions taken by the EU Member States via the Council of Ministers and within their own countries, by proposals from the European Commission and by active interest and action by the European Parliament, which should have a role in overseeing progress towards the achievement of the overall strategy.

The strategic plan has three groups of actions: political, organisational and social, and technical. Implementation of these actions from the three mutually complementary perspectives will ensure that progress can be made without encountering insurmountable barriers, when supported through the following underlying conditions:

- Encourage the involvement of the European Parliament and the Council of Ministers in the planning and deployment of trans-national health services and their supporting eHealth components.
- Include all developments in eHealth as part of eEurope and ensure that there is co-ordination between other eEurope initiatives and those of eHealth; specific examples could include security, authentication and authorisation procedures.
- Commit financial resources to support trans-national interoperability via an explicit programme for trans-national eHealth.

This strategy was evaluated against existing initiatives of the main groups and organisations working on eHealth interoperability in Europe. Further action will be needed to ensure that proposals originating from other eEurope initiatives are supportive and not contradictory to this strategy; this was considered outside the immediate scope of the TMA Bridge project.



## POLITICAL PERSPECTIVE

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### 1 Take Legal and Regulatory Action

- 1.1 **Develop a legal framework (common guidelines) for health-data transfer.** This will enable the bi-directional transfer of data between electronic healthcare systems in different Member States.
- 1.2 **Bring Member States' confidentiality and privacy laws into harmony** to ensure health data is protected and access is authorised according to European Data Privacy Legislation.
- 1.3 **Develop a clear statement on the legal liability** for treatment to cover both bilateral and European-wide agreements. These must specify which country's liability laws are applicable in each health-service scenario.

2 **Create and implement a framework for monitoring and evaluation** to measure progress towards meeting trans-national citizens' needs, including basic statistics, benchmarking and indicators, for the number of mobile patients, the quality of care provided, the cost of care provided, etc.

## ORGANISATIONAL AND SOCIAL PERSPECTIVE

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3 **Develop a workflow model** which will incorporate organisational and social models into trans-national systems, so that clear and unambiguous guidelines can be developed for all aspects of trans-national eHealth and communicated to those involved, including, but not limited to, administrators, providers of healthcare, citizens and insurers. These procedures should also include actions to mitigate the impacts of the digital divide, to ensure that over time all providers can have access to electronic health information. Special attention needs to be paid to the treatment of vulnerable populations (e.g. migrant workers, people living in remote areas, disabled persons, elderly persons, (ICT) illiterate persons, etc.).

4 **Create an environment for sharing knowledge of proven (good) practice and build up the knowledge and capabilities of health professionals.**

5 **Create the facilities and the content to ensure that eligibility to receive treatment can be known** at the point and time of care. This should also include knowledge of reimbursement regulations for the patient and the provider, and a mutual recognition of the availability of health services provided by both Member States and those to which the patient is eligible.

6 **Ensure that relevant data in electronic form is available** to the treating healthcare professional and the citizen. This means that transfer between electronic health-information systems or allowed access from one system to another must be implemented.

7 **Ensure that language and cultural differences are incorporated** into the system and available at the point and time of care. This should include a European Union-wide agreement on minimum basic data sets (including, but not limited to, an emergency data set), language and terminology translation, and recognition of cultural sensitivities.

## TECHNICAL PERSPECTIVE

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8 **Create a European telecommunications infrastructure** as part of the eEurope initiative, which will provide the technical support for the transmission of data in a manner conforming to the data protection legislation in place, and which meets the needs of eHealth.

9 **Incorporate a set of value-added applications into the infrastructure**, by identifying and implementing a set of achievable key applications.

10 **Develop a central access point for health information standards**, by establishing one access point for health information standards for the semantic content, coding classification and ontologies.

11 **Increase awareness of the importance of existing interoperability-related standards for eHealth**, by ensuring that data-interchange standards are known, understood and implemented in both supplying and procuring organizations.

## 4. A RECOMMENDED ACTION PLAN



*The recommended action plan embraces two types of recommendations: the first includes conditions that must be met for the successful implementation of the strategy, while the second includes detailed recommendations for actions that support the achievement of the strategy.*

### **4.1 Preconditions for Success**

#### ***Conditions that must be met for the successful implementation of the strategy***

These actions help to create the overall environment in which the strategy is set.

#### ***Active political support from the European Union***

Active political support from the European Union is needed to ensure that plans are made and implemented in Member States to support an efficient and effective system of trans-national healthcare for European citizens. To achieve this, Member States\* and the European Parliament need to be aware of what needs to be done and what the resulting benefits will be.

Examples of proven practice in terms of concrete benefits of eHealth services and knowledge of the supporting technologies need to be provided so that Member States can ensure that appropriate funds are assigned, the legal systems are harmonised, and the citizens are involved.

The following benefits can be achieved:

- Visible political support for implementing trans-national eHealth.

\*Identified in the document Telemedicine 2010: Visions for a Personal Medical Network, TM Alliance, ESA BR-229.

- Clear political guidance on the importance of conforming to trans-national standards in the legal and technical domains.
- Clear European stance on eHealth and its importance in maintaining the health of European citizens when away from their home countries.

#### *Integrate eHealth into plans for eEurope*

It is important that eHealth is understood to be part of the eEurope initiatives to ensure that there is no duplication of effort and, more importantly, that components are jointly used between all the initiatives emanating from the Lisbon Accord. This necessitates knowledge-sharing between eBanking, eGovernment, eAdministration and eHealth.

To achieve this, it is recommended that Europe-wide eHealth developments continue to be conceived and implemented in the same framework as other eEurope actions. This would include development of standards, infrastructure, European Directives and co-ordination between individual countries. It is also recommended that separate eHealth developments should not normally be undertaken unless absolutely necessary.



The benefits that this could provide are:

- Greatly reduced implementation costs.
- Transferable, and exchange of, experience between different domains.
- Common standards for industry to follow.
- Larger market for industry in providing various components and applications.
- Large market for services to be provided on a European-wide basis.
- Extensions to the eEurope initiatives to meet special eHealth requirements with minimal delays.

#### *Create a single coordination body to guide the overall strategy of eEurope and eHealth*

A single coordination body should be established to harmonise the interests of all of the stakeholders as regards private and public implementation of eHealth in Europe. Such a body would bring a comprehensive view and approach to directives, applications and technical issues already developed.

The newly created eHealth Working Group of the eEurope Advisory Group is an appropriate body to be used for this function.

The eHealth Working Group\* includes representatives from all of the EU Member States and three acceding countries. It has been created to provide a forum in which to address interoperability matters. The group is served by a sub-group including: health professionals, industry, users and probably representatives from the eHealth Standardisation Focus Group.

\*The eHealth Working Group of the eEurope Advisory Group was created in February 2005. It met for the first time in June 2005. Composed of nominated Member States' representatives from Ministers of Health, Telecommunications or Prime Minister's offices, this group advises the eEurope Advisory Group on progress made in relation to the eHealth action plan. The eHealth Working Group is supported by other complementary sub-groups with an interest in eHealth, e.g. a stakeholders' group representing industry, standardisation experts, health professionals and users.

It is recommended that the eHealth Working Group's tasks should also include:

- Collecting feedback on national/regional roadmaps and Member State responsibilities in areas of interoperability.
- Acting as an interface between its sub-groups and their national ministries responsible for eHealth, and as such facilitate their work.
- Analysis of the inputs from sub-groups and issuing of recommendations in the field of interoperability.

The European Commission, with the support of the eHealth Working Group, should liaise between healthcare stakeholders and EU decision makers to ensure that eHealth interoperability concerns are properly addressed and well-integrated into eEurope policy.

Eventually, the eHealth Working Group should also work with the Health Agency<sup>†</sup>, one of the tasks of which is to "achieve synergies between national health systems" by generating and disseminating "more and better health information to citizens, health experts and policy makers" using eHealth tools. A close relationship between the Commission and the Health

Agency will help strengthen the Union's actions in the health area.

The benefits include:

- Integrated strategy and implementation guidelines for all aspects of eEurope (eSociety, eGovernment, eAdministration, eCommerce or eBanking).
- Policy guidance on all 'e-prefixed' domains.
- Shared experiences from all aspects of eEurope guiding future strategy and implementations.
- A strong basis for industrial development of innovative products and services.

#### *Allocate appropriate funding for eHealth developments*

eHealth has progressed beyond the realm of research, though much still remains to be done. It is an essential component of any Europe-wide trans-national strategy and, as such, needs designated funds for implementation. Unlike banking and commerce, healthcare services\* are mainly provided by governments\*\*, so it is appropriate that the European Union should provide funds for interoperability elements. The details of the most appropriate form of funding and degree of involvement of private funding are not elaborated here, but are left to the European Commission and the Council of Ministers.



<sup>†</sup>The Executive Agency for the Public Health Programme has been created in January 2005 in Luxembourg, for the management of Community action in the field of public health. Commission Decision of 15 December 2004 setting up an executive agency, the "Executive Agency for the Public Health Programme", for the management of Community action in the field of public health – Pursuant to Council Regulation (EC) No 58/2003, (2004/858/EC) – OJ L 369/73

\*Article 152 of the Treaty

\*\*Clearly among the Member States, there are different balances of public-private provision within the various health services.

Support should be provided by EU Member States at national level for:

- Infrastructure development.
- Supporting Standards bodies.
- Encouraging European industry to develop cross-border eHealth applications in support of the strategy.

#### *Allocate funding for standardisation*

To support the European approach to eHealth, it is essential that European interests are represented on international standards-making bodies. This requires funds.

It is recommended that funds be found to support the work of CEN and its involvement with the eHealth Standardisation Coordination Group (eHSCG) and other relevant groups such as the IHE.

The benefits would be:

- Rapid development of high-quality standards.
- Standards appropriate to European eHealth.
- Greater involvement of European industry in building interoperable systems to meet European requirements and healthcare models.

#### *Implement the recommendations in a stepwise fashion*

Implementing of cross-border interoperability should be done at the pace of the fastest and not the slowest Member States. This dictates an incremental approach to the implementation of the strategy, starting with smaller groups of Member States and for specific aspects of eHealth, which provides for the following benefits:

- Implementations will be smaller and lessons can be learnt at an early stage.

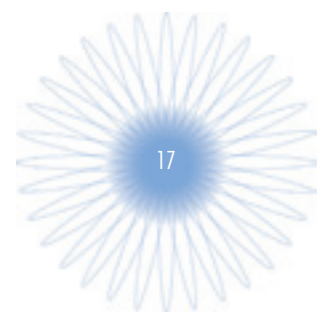


- Experience gained in early implementations can be shared, with significant economic advantage for later countries.
- Countries can progress at the rate that is appropriate to their stage of development and state of internal eHealth preparedness.
- Disease or demographic groups can be selected for early trials in implementations involving a smaller number of countries.

## **4.2 Taking Concrete Action**

### *Recommendations for action*

These recommendations, grouped under the strategy that they support, are addressed to the European Commission and to all other decision makers who influence the path towards a European eHealth area. Despite this, they will only be successful when supported by the conditions described above.



## **Strategy 1: Take Legal and Regulatory Action**

- 1.1 *Develop a legal framework (common guidelines) for health-data transfer. This will enable the bi-directional transfer of data between electronic health-care systems in different Member States.*
- 1.2 *Bring Member States' confidentiality and privacy laws into harmony to ensure health data is protected and access is authorised according to European Data Privacy Legislation.*
- 1.3 *Develop a clear statement on the legal liability for treatment to cover both bilateral and European-wide agreements. These must specify which country's liability laws are applicable in each health-service scenario.*

### **Action 1: Produce guidelines for cross-border data transfer**

The European Commission, supported by the eHealth Working Group, should produce legal and regulatory guidelines for cross-border data transfer. These should include recommendations for harmonising existing national confidentiality and privacy laws, and a clear statement of legal liability for treatment. This would help achieve interoperability between health systems for mobile citizens or cross-border consultations.

Thus create a single unified eEurope Telecommunications infrastructure based on consistent standards. This would provide a linkage between national infrastructures, which should include the legal framework related to secure transmission, authentication of receiver and transmitter, authorisation to use the data, liability when data is used and privacy issues.

### **Steps already taken**

Actions are underway to make laws for data confidentiality and privacy interoperable across the European Union to ensure that health data is protected and access is authorised according to harmonised European Data Privacy Legislation. However, they are uncoordinated and usually only address particular cases.

The ITU-T is working on a detailed description of international laws on data transfer, including the current European Directives: Data Protection Directive (95/46/EC), Electronic Communications Data Protection Directive (2002/58/EC), Council of Europe: EU Recommendation on the Protection of Medical Data. Additionally, Member States' special circumstances are described with a table of relevant laws and their status. The eHSFG recommends that a study be conducted of the business requirements for services to support the management of patient identification and control of access to patient-identifiable data by patients and by professionals with patient authority (with emphasis on Public Key Infrastructure and data cards for professionals and citizens/patients).

WHO has urged its Member States to mobilise multi-sectoral collaboration for determining evidence-based eHealth standards and norms, in respect of the principles of confidentiality of information, privacy, equity and equality. In parallel, the EC has asked EU Member States to provide a framework for greater legal certainty regarding eHealth products and services and plans to address confidentiality and privacy issues through the EC project I2-Health.

*Although these recommendations have been made, no group has been appointed with this responsibility and allocated the required resources at a European level to carry them out.*

#### **Benefits to stakeholders**

All stakeholders will benefit through greater privacy and security in ICT systems and telecommunications infrastructures.

Citizens (patients) will reap the greatest benefits from this action allowing for increased access to and control of personal health data.

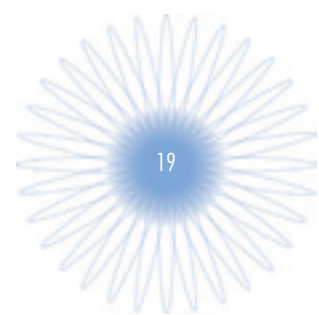
Healthcare professionals and healthcare organisations will also benefit from clear authorisation and authentication codes, and safer electronic-health-system purchasing guidelines.



Electronic-healthcare-system suppliers will benefit from data privacy and confidentiality legislation applicable to trans-border transfers and technical specifications for processing authorisations of persons requesting data.

Telecommunications service providers, supplying either a complete package or an element of a package of telecommunications services, and telecommunications equipment providers will benefit from clear security requirements to be applied to the transmission of data between countries and the opportunity to use value-added services for authentication and other common requirements for trans-national eHealth.

Governments, both national and regional, will have greater security when transferring data between Member States through harmonised data protection legislation and data-transmission requirements and a framework for issuing authorisation and authentication codes.



## **Strategy 2: Create and implement a framework for monitoring and evaluation**

*This will measure progress towards meeting trans-national citizens' needs, including basic statistics for the number of mobile patients, the quality of care provided, the cost of care provided...etc.*

### **Action 2: Establish comparative indicators for the quality of care**

Web-based, trans-national comparative information on the quality of care by healthcare stakeholders should be made available to citizens to enable them to make more informed and empowered decisions about their own health care. In that context, a template for patient-driven comparative indicators\* should be established in order to collect data and compare them in a meaningful manner.

This action, supported by the European Commission<sup>†</sup>, should be set up by patient organisations. In the first instance, it would be best applied only to a specific diagnosis or disease group, and across a given number of countries. In later stages, once the template has been refined, other disease groups can be added and additional countries included. The end goal would be to have a general template for all diagnoses and across all EU Member States.

### **Steps already taken**

Until recently, very few steps have been taken to measure the needs of trans-national citizens in relation to eHealth to serve as a basis for suitable indicators. Progress on initiatives to meet these citizens' needs is slowly emerging. A first step towards this vital strategy is required where basic comparative indicators for quality of care are established.

The EC has asked Member States to agree on an overall approach to benchmarking in order to assess the quantitative, including the economic, and qualitative impacts of e-Health by the start of 2005. The EC plans to have an assessment of e-Health developments completed ahead of the second part of the World Summit of the Information Society to be held in Tunis in December 2005. The EC project ERA-eHealth plans to study and research benchmarking with regard to the evaluation of best-practice.

WHO plans to provide technical support to Member States in relation to eHealth products and services by widely disseminating experiences and best practices, in particular on: telemedicine technology; devising assessment methodologies; promoting research and development; and furthering standards through dissemination of guidelines.

Other actions include extension of such mechanisms as the Health Academy to and within Member States in order to: promote awareness of health and healthy lifestyles through eLearning; analyse the evolution of eHealth and its impact on health; anticipate emerging challenges and opportunities; and provide evidence, information, and guidance in support of policy, best-practice, and management of eHealth services.

The eHSFG recommends that the Member States with the Commission should mandate the European Standards Organisations to develop a standard for communicating the priority indicators of quality of care, based on measurements of health-care outcomes and patient-safety issues, as well as the definition and matching of data elements.

\*The completeness of these will vary by country. This should not prevent the start of the work and publication of the results even if there are gaps.

<sup>†</sup>This could be done in cooperation with the Health Executive Agency according to which health indicators should be used as a means to collect data and as such to generate and disseminate more and better health information to citizens, health experts and policy-makers. Proposal for a decision of the European Parliament and of the Council establishing a Programme of Community action in the field of Health and Consumer protection 2007-2013, Brussels, 6 April 2005, COM(2005) 115 final.



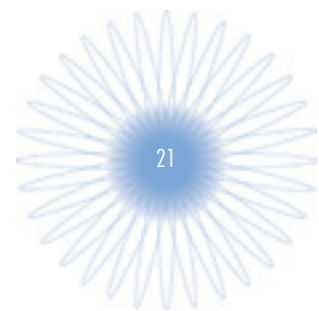
They also recommend, in parallel with ITU-T, the consideration of an EU Directive addressing the need to control the safety of health informatics products in a similar way as for medical devices, and mandate the European Standards Organisations to prepare the safety standards that should be applied to improve quality of care.

#### *Benefits to stakeholders*

Governments, both national and regional, as well as supra-national bodies are those ultimately responsible for the quality of care received by citizens when abroad or when received from abroad. Monitoring of the status of trans-national eHealth transactions to better identify problems, quality reporting on treatment accorded to their citizens in other EU countries and the ability to disseminate more relevant, complete and timely information to their citizens related to quality of care are the main benefits for these stakeholders.

Citizens are ultimately the stakeholders who gain the most from this action. Easy access to information about the accreditation of healthcare providers and institutional centres of excellence, assistance in accessing and obtaining treatment and informed choice when requesting care abroad are all great benefits for the citizen.

Insurance companies will have better information on the institutions that they recommend their clients to use, and comparative measures for other organisations with which they contract or reimburse.



### **Strategy 3: Develop a workflow model to incorporate organisational and social models**

*So that clear and unambiguous guidelines can be developed for all aspects of trans-national eHealth and communicated to those involved, including, but not limited to, administrators, providers of healthcare, citizens and insurers.*

*These procedures should also include actions to mitigate the impacts of the digital divide, to ensure that over time all providers can have access to electronic health information. Special attention needs to be given to those treating vulnerable populations (e.g. migrant workers, people living in remote areas, disabled persons, elderly persons, (ICT) illiterate persons, etc.)*

#### **Action 3: Perform a workflow analysis**

The European Commission should perform a practical workflow analysis applied to trans-national health services as a prerequisite for designing and implementing interoperable eHealth systems to support mobile citizens. Benefits of using an industry-standard workflow method include the provision of a well-defined separation of activities, responsibilities, sequences of activities, transitions between activities and data sets required for the transitions.

Create USE cases for trans-national treatment to provide a clear overview of the workflow between different systems. This will provide answers to questions such as “Who are the involved participants, who is responsible, and which sets of data need to be transferred at which times?”. The workflow process definition can be used to establish a common vocabulary between the participants involved.

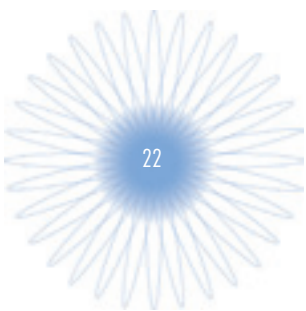
This workflow analysis would be based on a well-defined scenario, tested throughout Europe in different combinations of countries with the aim of achieving a better understanding of cross-border workflows for health services. It is not only the undertaking of the analysis that is important, but also the development of a proven method that will allow comparative analyses to be carried out.

#### **Steps already taken**

The EC aims to improve information on patient mobility and mobility of health professionals at European level, and work is being taken forward in particular through the information strand of the public-health programme. However, no work is specifically planned to study the related data and information flows and transactions between Member States.

The eHSFG recommends that the European Standards Organisations prepare standard workflow models and clinical pathways that would facilitate the application of ICT and improve efficiency. Similarly, the ITU-T stresses that the ways in which technical, clinical and administrative processes are actually implemented should delineate how the processes are intended to work in the future, assuring most relevant issues like quality, accessibility, cost effectiveness and patient and clinical acceptability.

Despite these intentions, a clear understanding of each stakeholder’s role and responsibility in relation to trans-national eHealth, including data and information flows across borders, is yet to be studied and understood.



### *Benefits to stakeholders*

Implementation of this action would benefit all stakeholders by ensuring that current and future initiatives to address the challenges to trans-national eHealth interoperability are built on a solid understanding of how health systems can work interoperably and on an evidence-based, citizen-centred workflow model.

Governments will benefit through an ability to tune their systems to better meet the needs of international eHealth services. There is also the possibility that the information could be used to greatly improve the efficiency with which these services are provided and place the citizen at the centre of their thinking.

Citizens will be better able to understand how to obtain eHealth services whilst visiting or resident in another EU country.

Industrial organisations will be able to develop applications that address needs identified in the analyses.

Providers of healthcare services will be able to better meet the needs of their clients through an understanding of the role and application of trans-national services.

Insurance companies will be better equipped to understand the processes involved in trans-national care and provide better advice to their clients travelling abroad.



## **Strategy 4: Create an environment for sharing knowledge of proven (good) practice**

### **Action 4: Create a repository of existing proven practices**

*Create a repository of examples of successfully implemented applications as well as suitable projects for inclusion in a database of 'existing proven practices' involving trans-national interoperability; this should be maintained as an accessible reference source.*

Candidates for inclusion in this repository should be either self-nominated or recommended by reputable industry, user or professional bodies. This activity should be clearly positioned as providing a potential showcase for proven practices, rather than a systematic review. Entries in the repository should be structured and presented in a standard and easily readable format, which will be available to interested parties via a website. No attempt should be made to judge the quality or sophistication of individual entries, or to accredit them in any way other than checking for completeness and clarity of presentation.

Creation, maintenance and dissemination of this material should be the responsibility of a representative pan-European stakeholder organisation and will need to be funded either from EC sources (the preferable solution) or by a combination of sponsorship and entry fees.

### **Steps already taken**

The necessity for sharing knowledge of good proven practice to facilitate capacity building of eHealth interoperability stakeholders has been identified in all strategic plans analysed. Resources have been committed in some cases; however, no unified central platform has yet been established where examples of good proven practices of interoperable eHealth systems can be found. The challenge is to develop a set of criteria for proven practice in order to evaluate systems fairly and attract interoperability stakeholders to participate in these activities.

The EU aims to produce a summary of European good practices as guidance for Member States in 2005 and is organising special events such as high-level conferences in order to disseminate best practices. It plans to publish a study on the state of the art in deployment, examples of best practices, and the associated benefits of e-Health.

Similarly, WHO's Secretariat has established a networked global eHealth observatory\* to document and analyse developments and trends, inform policy and practice in different countries, and report regularly on the use of eHealth worldwide. The observatory will help to identify best practices and opportunities for policy coordination, and identify needs for the provision of technical support and capacity building.

The eHSFG identifies certain models and solutions that have been demonstrated to be successful, where implementation was done, and whether industrial or user-driven. These include the IHE integration experience worldwide over the past 6 years and PRoREC and EuroREC in the area of EHR.

### **Benefits to stakeholders**

Electronic healthcare-system suppliers and telecommunications service providers are the direct beneficiaries of this action, with the growth of the market based on the selected standards for the exchange of data across borders in Europe, used by a critical mass, ensuring a non-proprietary approach to making systems interoperable.

A central repository for sharing proven practices will ultimately indirectly benefit all stakeholders (purchasers, developers and end-users of eHealth systems and services) by increasing the number of good, interoperable eHealth systems. Governmental decision makers will be able to use this to guide their policy making.

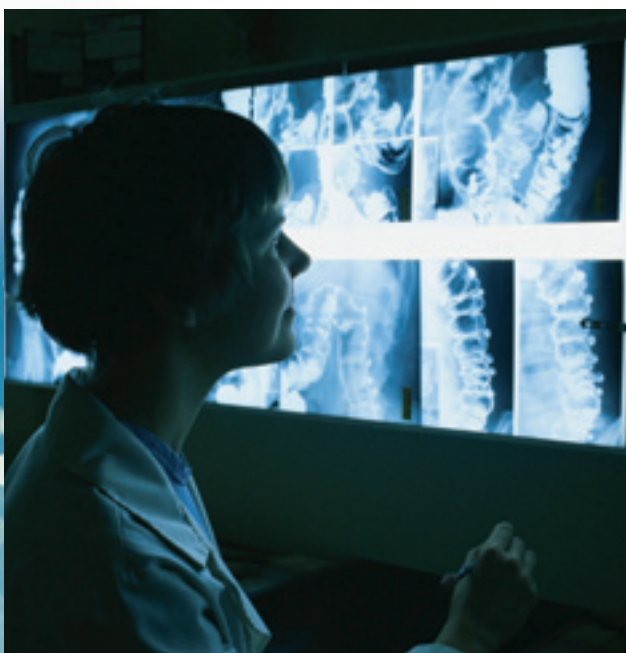
**Strategy 5: Ensure that eligibility to receive treatment can be known at the point and time of care**

*This should also include knowledge of reimbursement regulations for both patient and provider and a mutual recognition of availability of health services provided by both Member States and those for which the patient is eligible.*

**Action 5: Issue national entitlement and reimbursement statements for trans-national health services from each EU Member State**

The European Commission should encourage EU Member States to state – via an appropriate mechanism – their expectations and the actual situation regarding entitlement to and reimbursement of trans-national health services for their citizens in other Member States. These statements should be disseminated to the public to increase citizens’ awareness of their entitlements.

This statement, which should follow a common template, should be prepared by the end of 2006, and be produced by the most appropriate organisation selected and resourced by each Member State.



**Steps already taken**

Despite the EU Directives on free movement of goods and services and the EU Parliamentary rulings related to cross-border health-service provision, citizen and professional awareness about eligibility for treatment is still not widespread.

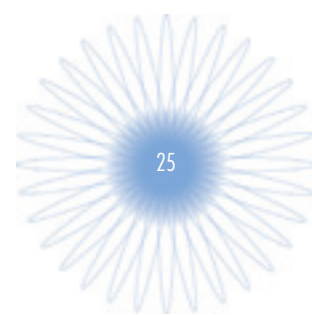
The EC has recommended the adoption of the electronic health-insurance card by 2008 and that all Member States develop a national or regional roadmap for eHealth that addresses such issues as the reimbursement of eHealth services. Additionally, the eHSFG recommends that data-card applications be considered in relation to access through portals to the relevant and actual information.

Many similar initiatives to support the electronic health-insurance card as a means of sharing entitlement information have been proposed, but the organisational-level changes (human and process) required to take these actions have not been studied, nor the resulting information disseminated.

**Benefits to stakeholders**

Making the practical details of entitlement to trans-national health services and related reimbursement transparent to health consumers would help European citizens obtain healthcare services trans-nationally (receive care abroad or receive care from abroad by making use of the tools of eHealth to facilitate such services).

National entitlement and reimbursement statements will also benefit health-insurance organisations and national governments by simplifying the exchange of claims for health services and providing a mechanism to better ensure fair exchanges.



### *Strategy 6: Ensure that relevant data in electronic form is available*

*This means that transfer between electronic health-information systems or allowed access from one system to another must be implemented for the treating healthcare professional and citizen.*

#### *Action 6: Provide a citizen driven trans-national web space for health*

The European Commission should support the creation of a personal health web-space for mobile citizens to empower the citizens/patients with access to their health data wherever they are and whenever they need it.

In this web space, the citizen will decide what data is included and what not, what data can be made accessible and to whom. The information and data can be added to the web space by the citizen, and may also be fed from other systems with the citizen's permission.

A format for this web space should be created that will maximise interoperability and ease of depositing, accessing, and reading data, whilst preserving security.

This web space would be accompanied by advisory guidelines regarding access to and control of data, as well as adequate warnings regarding security and privacy, especially where this may not totally conform to safeguards of data-privacy laws based on the EU Directives regarding protection of personal data.

This project could be supported by the EC, and eventually also by national governments interested in

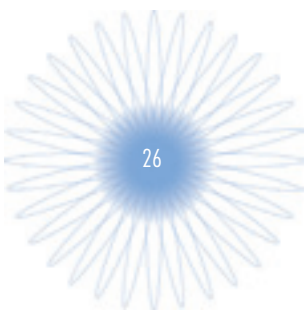
participating. It is recommended that a patient group with a specific disease be used to test the idea in two to three countries. The web space should be ready for testing by the end of 2007.

#### *Steps already taken*

Even though national ICT infrastructure for health is a high priority and a significant amount of resources have been committed (highly variable by Member State), the European Union has not achieved the situation where health data and information are universally or routinely stored in electronic form. Providing relevant data in electronic form to the treating health professional or citizen either through transfer between electronic health information systems or allowing access (web access) from one system to another is a basic requirement for interoperable eHealth.

Although the EC has asked Member States to develop a national or regional roadmap for eHealth, focused on deploying eHealth systems, setting targets for interoperability and the use of electronic health records (including issues such as the reimbursement of eHealth services, and citizen-centred control of electronic health data) is not addressed.

WHO has urged its Member States to consider drawing up a long-term strategic plan for developing and implementing eHealth services in the various health-sector areas, including health administration, which includes an appropriate legal framework and infrastructure and encourages public and private partnerships.



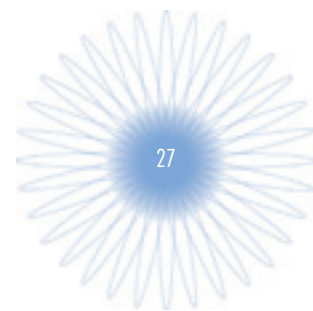
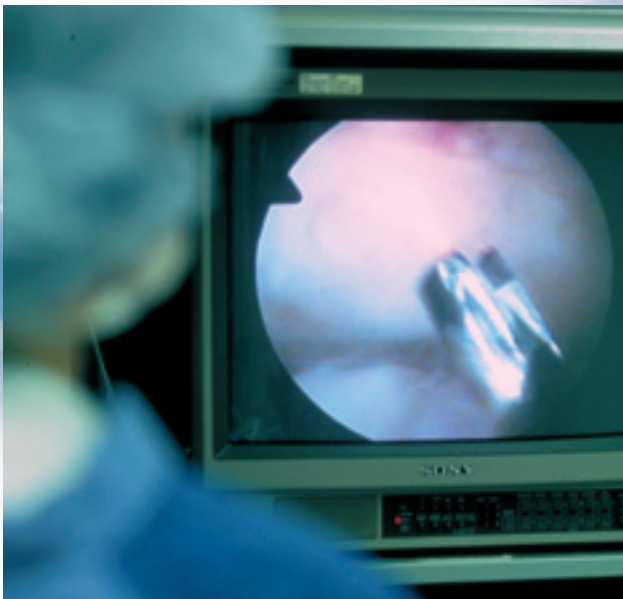
The eHSFG requests that the EC and Member States give significant momentum to national and Europe-wide secure access to clinical records, and to achieving full semantic interoperability of personal health data and information through strong support for existing and emerging European standards for electronic health-record communication. They recommend that the Member States together with the EC should provide the necessary means to exchange interoperable information structures such as those for electronic health-record extracts, patient referrals, discharge summaries, and laboratory results, also integrating point-of-care medical and test devices.

#### *Benefits to stakeholders*

Citizens are moving from grateful receivers of health services to demanding consumers. To support this

trend, they need data and information about their own health. A personal web-space application will help empower citizens to make their own health decisions and assist in their joint decision making with clinicians.

Health providers and health professionals would also benefit from this action by gaining greater access to patient health data and information. Lessons learned and experience gathered from this initiative could usefully be transferred to the creation of a future Europe-wide trans-national EHR.



### *Strategy 7: Ensure that language and cultural aspects are incorporated*

*This should include a European Union-wide language and terminology translation and recognition of cultural sensitivities incorporated into the system and available at the point and time of care.*

#### *Action 7: Create a repository of national health system procedures and customs for mobile citizens*

In line with the previous recommendation, and in order to help citizens in navigating health services whilst abroad, the European Commission should create a repository of national health-system procedures and customs for mobile citizens. This should include a European Union-wide minimum basic data set (including but not limited to an emergency data set), language and terminology translation, and recognition of cultural sensitivities.

#### *Steps already taken*

Incorporating language and cultural differences into systems at the point and time of care as been acknowledged as an important aspect of system interoperability, but little or no resources have been applied to make this a reality. The two main difficulties here are the large number of languages and cultures present in the European Union, and the fact that absence of consideration for these aspects usually affects vulnerable groups with less political power.

WHO has urged its Member States to endeavour to reach communities, including vulnerable groups, with eHealth services appropriate to their needs.

#### *Benefits to stakeholders*

Citizens are the direct beneficiaries of this action, which makes information and knowledge about health services more accessible to the citizen through language and cultural translations.

Indirectly, health-service providers benefit from this action through improved access to information about different cultural sensitivities related to health, leading to a greater ability to provide culturally sensitive services.

Providers and citizens will benefit by having access to data, which will improve communication systems for administration and delivery.





## **Strategy 8: Create a European telecommunications infrastructure as part of eEurope**

### **Action 8: Use existing infrastructures for eHealth**

*Create a European telecommunications infrastructure as part of eEurope and thus utilise such existing infrastructures for eHealth, which will provide the technical support for the transmission of data in a manner conforming to the data-protection legislation in place and which meets the needs of eHealth.*

Although eHealth encapsulates all the main themes of eEurope with its dependence on bandwidth, security, privacy, and user-centred service provision\*, healthcare standards are usually not incorporated into current telecommunications infrastructures and basic services. In order to facilitate early adoption by Governments, the special needs of the health sector should be taken into account and should benefit from the trans-national experiences of other sectors.

This approach, making use of the required broadband, wireless communications and current technical capabilities, will push Member States to use the general-purpose infrastructure adapted to their needs. A 'smart' infrastructure allows the transmission of different forms of healthcare information via web services and IP technologies.

#### **Steps already taken**

The current European telecommunications infrastructure available in Member States provides adequate support for the transmission of data across borders. The difficulties in terms of interoperability are not at the physical or logical level, but in the applications and semantics. Ensuring the level of quality and security required for health services when using general-purpose network services is still an issue that has not been sufficiently considered.

The EC has asked Member States to support the deployment of health information networks for e-Health based on fixed and wireless broadband and mobile infrastructures and Grid technologies by 2008, and detailed technical standards on types of networks are described and available in the ITU-T report.

Additionally, the ESA Telemed Programme identifies terrestrial or satellite communication as only one open part of the solution to the problem of the introduction, installation and maintenance of ICT in health. The applications and services should be independent of the underlying communication carrier. The software has to be transparent and user-friendly for the maximum number of users.

Terrestrial infrastructures are nowadays supporting the majority of existing and future applications and services in the eHealth and Telemedicine market. Only by developing competing financial models will satellite technology be able to demonstrate its value. The programme describes a Global Health Over Satellite (GHOS) system "with global coverage as communication platform for the concerted development and implementation of tools and services for health authorities and professionals, as well as for personalised health systems for patients and citizens", which is the goal that ESA wants to achieve. This will be a Health Grid system that should "provide Global Health Over Satellite (GHOS) dedicated 24/7 (i.e. 24 hours per day, 7 days per week) eHealth and Telemedicine services, offering interactive multimodal and multimedia communications"<sup>†</sup>. The system should support both point-to-point and multi-point communication in a fully meshed topology.

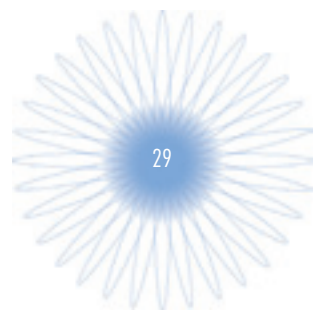
#### **Benefits to stakeholders**

This action provides direct benefits to all stakeholders including:

- Easier updating and maintenance of services
- Possibility of reconfiguring "virtual" enterprise entities
- Seamless evolution process
- Increase in patient safety
- Option to subsidize costs by central funding
- More flexibility in terms of different rates of uptake
- Tailoring of the telecommunication infrastructure to the eHealth requirements
- Driver for pan-European/global security infrastructure.

\*Communication "eEurope 2005 Mid-term Review" Brussels, 18 February 2004, COM(2004) 108 final.

<sup>†</sup> Eur. J. Med. Res. Supplement Proceedings of ESRIN-Symposium, 5 July 2004, Frascati, Italy, Opportunities and Challenges of eHealth and Telemedicine via Satellite, C. Dario, A. Dunbar, F. Feliciani, M. Garcia-Barbero, et al.



## *Strategy 9: Incorporate a set of value added applications into the infrastructure*

### *Action 9: Identify and implement a set of achievable key applications*

In order to increase citizens' comfort in the reliability and safety of trans-national eHealth systems, a selection of key achievable trans-national applications with appropriate security infrastructures should be identified and implemented. Relevant stakeholders (political, technical and end users) should be involved in the process of application selection and implementation where selected applications are those with a visible impact for citizens related to trans-national health services. The necessary standards and profile developments should be provided by a technical/industrial subgroup as well as a reference implementation and specification guidelines for the Member States.

### *Steps already taken*

To date, there are few examples of technically secure, trans-national eHealth systems. Despite a number of national public key infrastructure (PKI) initiatives<sup>†</sup> including eVoting, eAdministration and authentication of doctors, the issue of data security, including the recognition of PKI and the technical fulfilment of the different data protection laws, is still a tremendous roadblock for the interoperability of trans-national health services. Although further impetus may come from the introduction of the biometric-based passports and identity cards, to date little resources have been allocated to analyse international requirements and the impact of this action for the deployment of trans-national eHealth makes this issue of the highest urgency.

The eHSFG recommends that the EC with the Member States should consider an EU Directive addressing the need to control the safety of health informatics products in a similar way as for medical devices, and mandate the European Standards Organisations to prepare the safety standards which should be applied.

They emphasise Public Key Infrastructure and data cards for professionals and citizens/patients.

Concerning the mutual recognition of PKI, electronic signatures and trusted third parties, the EC Directive 1999/93/CE refers to Electronic Signatures, followed by "the legal and market aspects of the application of Directive 1999/93/EC and practical applications of electronic signatures in the Member States, the EEA, the Candidate and the Accession countries"<sup>\*</sup>. The EC I2Health project includes tackling security issues in their agenda.

### *Benefits to stakeholders*

Different stakeholders will benefit from this strategy: incorporating a set of value added services into the European telecommunications infrastructure in the following ways:

- Governments will benefit from the guidance they receive on priority application implementations and the creation of an environment encouraging their industries to build applications and provide services that meet both national and trans-national eHealth needs.
- Industry will see a larger more consistent European market that will encourage the development of innovative applications that can be interoperable. They will also see a much-increased market for value added services.
- Healthcare providers will be able to offer eHealth services at lower costs than previously as well as innovating in the provision of eHealth.
- Citizens will of course benefit through improved services that are more accessible wherever and whenever needed.

## *Strategy 10: Develop a central access point for health information standards*

### *Action 10: Establish one access point for health information standards for the semantic content, coding classification and ontologies*

A virtual or physical single-access-point for health-information standards in terms of semantic content, coding classification and ontologies based on open standards as an international public good\*, should be established.

This would help simplify the search for relevant standards and foster the coordination of eHealth implementation. A unique focal point is needed for the implementation and maintenance of international health-information standards. The following tasks should also be carried out:

- Development and publication of the most needed new-generation concept and terminology systems for clinical use based on ontological research, integrating the legacy terminology initiatives (GALEN, SNOMED, ICD, DRG, etc.).
- Annual publication of the rate of uptake of these standards.
- Maintenance of a list of developments and updating of standards with the latest versions released to facilitate the choice of coding, integrating a transparent process of drafting new standards.

### *Steps already taken*

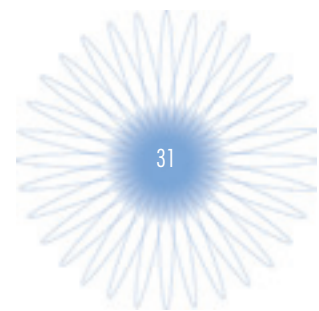
Semantics and coding are identified as major roadblocks to trans-national data exchange in most strategic plans. Some commercial and international initiatives in bringing a common terminology and in the definition of interoperable ontologies have been successful, although there is a long way to go before there are interoperable coding systems at European and international level. Clear recommendations for actions have been formulated and included in the section on 'Recommendations for Action'.

The eHSFG recommends that an agreement should be reached on international multilingual reference terminology, ensuring the Europe-wide referencing of and easy access to the content of existing health coding systems based on registration of such systems by the Eurorec Institute; support the international convergence towards a common framework for formal representation, and eventually the development and maintenance of a multilingual clinical reference terminology. This effort should build on existing efforts in formal forums such as GALEN and SNOMED, and be carried out in liaison with the WHO Family of International Classifications. This would make the targeted reference clinical terminology publicly available and free of charge, and support a common approach to linking national classifications, to support cross-border health care.

The eHSFG also recommend the development of tools for mapping between case-mix groups used in Europe, including the underpinning coding systems for diagnoses and procedures. In order to reach an international multilingual reference terminology, they recommend that Member States should:

- Ensure the Europe-wide referencing of and easy access to the content of existing health coding systems based on registration of such systems by the Eurorec Institute.
- Support the international convergence towards a common framework for formal representation, and eventually the development and maintenance of a multilingual clinical reference terminology. This effort should build on existing efforts in formal representations such as GALEN and SNOMED, and be carried out in liaison with the WHO Family of International Classifications.
- Make the targeted reference clinical terminology publicly available free of charge.
- Support a common approach to link national

\* International public goods refer to programmes, policies, and services that benefit countries in more than one region. Global Public Goods for Health, the report of Working Group 2 of the Commission on Macroeconomics and Health, World Health Organization, Geneva, August 2002.



classifications of procedures, to support cross-border reimbursement of health care.

- Provide the basis for benchmarking case-mix-based performance measures.

The ITU-T provides descriptions of clinical data representations, clinical standards and standards for managing multilingual reference terminologies.

The ESA Telemed Programme states that a standardised format for medical data is needed. Fields of application for the Programme are: Interconnectivity, management of trauma, emergencies and disasters, HEWS for environmental risks, eHealth education, homecare, service for the citizens and mobility. XML-based HL7 together with the specification of CDA are identified as the best candidates.

WHO has wide experience in this field and has been contacted by the European Commission to act as custodian of this single-access-point initiative.



### *Strategy 11: Increase awareness of the importance of existing interoperability related standards for eHealth*

*Action 11: Ensure that data-interchange standards are known, understood and implemented in both supplying and procuring organisations*

The European Commission should support, using the appropriate mechanisms, activities for increasing awareness of the importance of existing interoperability-related standards for eHealth. These activities would target different communities:

- Political decision makers, who should be made aware of the impact of common standards for protection of investment, safety and confidentiality of patient data, and quality of service.
- Users, and users-to-be, should have access to health-related ICTs and standardisation issues in their educational pre-, post-graduate, and continuing medical/IT education curricula in order to understand the benefits of interoperability.

These targeted user-groups should be made aware of the importance of existing useful standards related to eHealth interoperability by:

- Demonstrating that cross-border interoperability is possible and useful with existing technologies and standards.
- Undertaking broad information dissemination activities to ensure that useful interoperability standards are known, understood and most importantly used from governmental to local decision level through activities such as: High-level ministerial conferences, Web portals, eHealth and professional conferences, periodical publications, media coverage, regional workshops.
- Supporting the development of eHealth standardisation activities within a coordinated interoperability framework as well as the functionality and practicability of existing standards on simulation on real cases, such as Integrated Healthcare Enterprise connectathons.

### *Steps already taken*

Standards for data transmission have been agreed by International Standardisation bodies (SDOs) and are available extensively at the SDO points of contact, although not easy to interpret and often not free of charge.

The main obstacles to the full updating of these standards are the incompatibility of the multiple standards used in the different clinical institutions/devices and the lack of awareness of these standards by the decision makers in the procurement process.

For the first obstacle, international SDOs and industrial companies are initiating multiple initiatives to improve the coordination of different standards and commercial solutions. The eHealth Standardisation Coordination Group is one example of these coordination efforts.

For the second obstacle, current interoperability groups have been ineffective in raising the level of awareness related to standards among the decision makers and end users.

The EC has asked Member States to identify and outline interoperability standards for health data messages and electronic health records, taking into account best practices and relevant standardisation efforts. The EC projects I2-Health/ERA eHealth include technical interoperability and connectivity issues implicitly as part of the general goals of these projects.

The ITU-T aims as part of its mandate is to consider the requirements for appropriate development paths for health profiles of existing standards from different sources in order to provide functional sets for key health applications and to strengthen the cooperation between the SDOs involved, improving information exchange between organisations and avoiding duplications of effort. The aim is to support activities to increase user awareness of the existing standards, case studies, etc., and establish and maintain a dedicated

website with information on eHealth standards, eHealth case studies, and standardisation activities.

The eHSFG recommends provision of the means needed to create an inventory of those standards that are necessary to meet identified business requirements; to ensure that the appropriate European Standards Organisations are mandated to develop them, in so far as they do not already exist; to establish arrangements for testing interoperability based on these standards, and to ensure that they are, where appropriate, accounted for in conformance testing, quality labelling and certification processes. They recommend making all eHealth standards available free of charge to users in Europe as well as globally, particularly supporting less-resourced developing countries.

The ESA Telemed Programme promotes the use of Open Standard solutions for integration and interoperability of the information and communications systems. It aims to stimulate the adoption of solutions going beyond the regional and national limits, allowing mobility of data, people and services on one side and enabling the achievement of economy of scale on the other. In general, the ESA Telemed Programme will direct the development of demands towards a reasonable direction for better health for all, with optimal use of available resources. The projects will end up as sustainable services and powerful standards-in-use settings that will then allow the industry to produce products to serve the evolving markets around such settings.

### *Benefits to stakeholders*

The creation of a transparent set of standards and pilot applications will support the achievement of the goals of the Lisbon Accord for a Europe dedicated to the realisation of high-technology-based solutions.

The Standardisation Development Organisations will benefit from a stable and efficient framework in which to develop, coordinate, agree and disseminate the relevant standards to the user community.

## 5. CONCLUSIONS



*This report contains concrete recommendations for action within a concise and consistent strategic framework. The recommendations made in this report are based on:*

- A Vision of a citizen-centred interoperable Health service across the EU respecting the civil rights of all its inhabitants
- An analysis of the requirements for interoperability which would support trans-national eHealth within the European Union
- Recommendations for action to improve trans-national eHealth interoperability\*
- An analysis of the initiatives and strategies for eHealth and its implementation at a European level or internationally
- The results of an international workshop held by TMA Bridge to make recommendations on appropriate actions to foster trans-national eHealth in Europe
- Feedback from presentations given by the TMA Bridge team at a number of international conferences on eHealth
- Direct input received from the participating organisations, being ESA, ITU and WHO.

This strategy is supported by a series of recommended actions, which are intended to provide the basis for action by:

- the Council of Ministers in its role of directing the actions of the European Commission towards proposing actions for the implementation of trans-national eHealth services;
- the European Commission in its role as proposing actions necessary for the improved performance of Europe, especially in the fostering of the rapid and effective implementation of eHealth services;
- the Ministers of Health in their role to ensure that their countries are able to provide an effective eHealth-based service to citizens from other European Member States temporarily or permanently resident in their countries;

- the European Parliament in its role to ensure that European citizens receive the proper care and respect where ever they are located in the European Union and ensuring that Europe progresses rapidly along the lines laid down in the Lisbon Accord.

Local, national, and international stakeholders need to act to ensure an enthusiastic uptake of trans-national eHealth services that promote access to, quality and equity in health systems. They need to collect evidence on the benefits derived from actual eHealth services, ensure the digital health divide† does not lead to e-exclusion by creating a gap between those who have access to internet-based health care and those who do not, and perform continuous evaluation and monitoring of progress towards meeting the needs of citizens as proposed in the TM Alliance Vision for 2010.



*ESA/ESTEC, Noordwijk, The Netherlands*

† Improving Health Literacy in the EU: towards a Europe of informed & active health for citizens, I. Kickbusch. <http://www.ilonakickbusch.com>.

## 6. LOOKING AHEAD

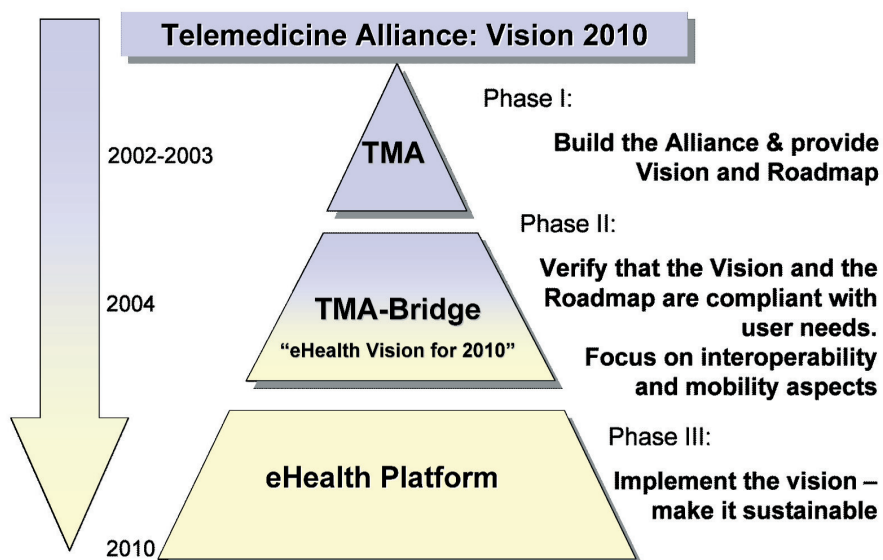


*Realisation of the vision of citizen-centred trans-national eHealth services for all of Europe's citizens requires cooperative and coordinated action from many levels of society. Recommendations have been made that should facilitate the implementation of this vision.*

Whilst eHealth is a part of eSociety, it differs from many of the other elements, that are driven by market forces. eHealth is in its early stages of development and requires more funding and co-ordination between national and regional governments.

Thus, coordinated action, especially on a political level, is prerequisite for success. The new Member States, while entirely revamping their health infrastructures, are moving ahead rapidly and are in search of guidance; the 'old' Member States are certainly lagging behind (because of their already existing, massive and well-developed infrastructures) and certainly not yet adequately providing the guidance being sought.

Figure 4. From a vision to implementation

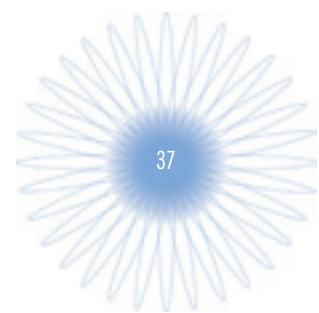






The TM Alliance has fulfilled its goals set out for Phases I and II, as illustrated in the diagram on the facing page. The baton is now passed on to those who wish to take it – but they must take hold together and move forward in one direction, and then there will be success; otherwise there will be chaos and much wasted effort and resources. Just as good teamwork is mandatory for the successful completion of a project, so too with ‘Project eHealth’ only cooperative and coordinated teamwork

between the Member States of Europe can and will yield success. This will not only enable the growth of trans-national European cooperation and foster the growing group of trans-national European citizens, but will also strengthen the hand of European industry and catalyse innovation, thus enabling Europe and Europeans to assume their rightful place, role, and responsibilities incumbent upon them on the World stage.



## APPENDIX

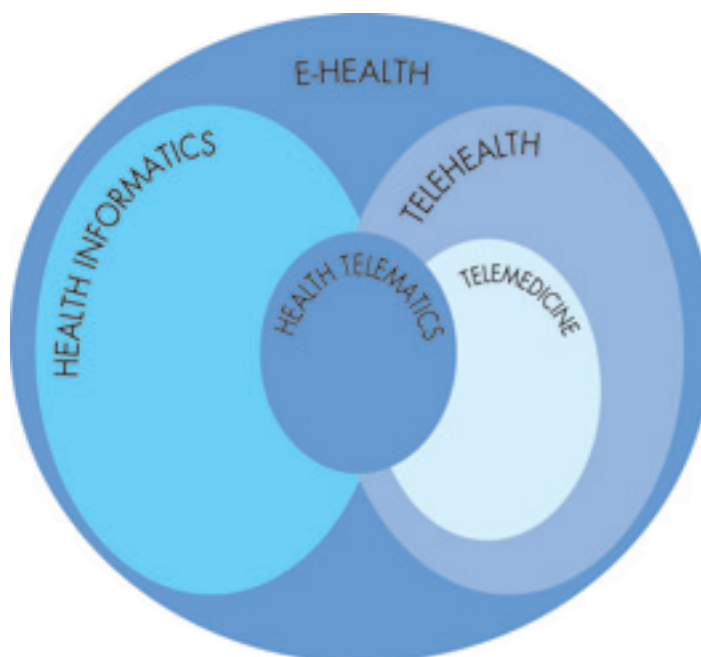


Figure 5.  
The relationship between  
the various terminologies  
associated with eHealth\*

### Definitions

*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.*

*The term 'Interoperability', although mainly used here in the domain of eHealth and Telemedicine, is not limited to these domains.*

*The following definitions of these terms fit well with this document:*

### **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.†

### **Telemedicine:**

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 interests of advancing health and their communities.‡

### **Interoperability:**

In the context of eHealth, interoperability is the way in which reliable data is provided and communicated in a secure, accurate and efficient way. It has to surmount barriers of national policies, culture, language, and systems of medical knowledge representation and use of ICTs.

### **Trans-national Services**

Trans-national services refer here to actions, operations or duties performed to benefit European citizens involving cross-border cooperation of two or more nations or national institutions.

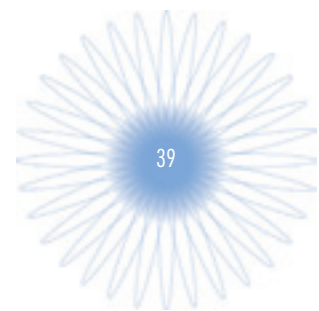
\* Telehealth Melbourne 2000, Fact Sheet 5.

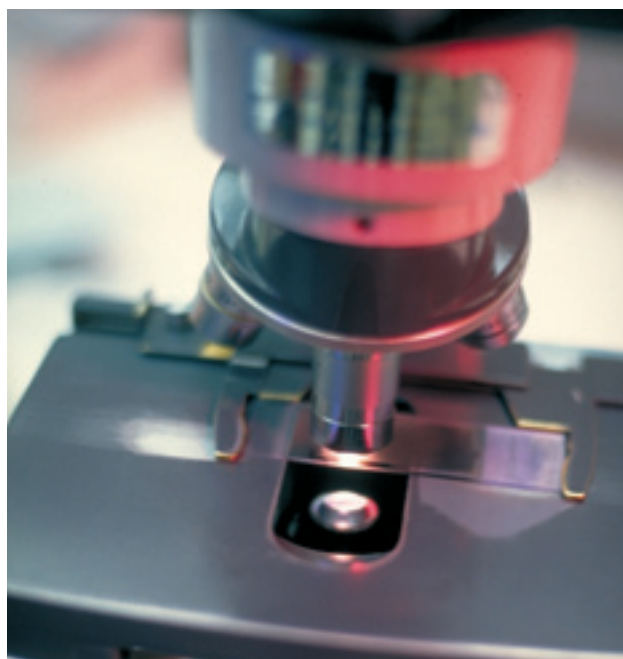
† Ministerial Declaration, eHealth, 22 May 2003.

‡ WHO, 1997.

## Acronyms

CDA	Clinical Document Architecture
CEN	Comité Européen de Normalisation (European Committee for Standardisation)
EC	European Commission
ECJ	European Court of Justice
EEA	European Economic Area
EHR	Electronic Health Record
eHSCG	eHealth Standardisation Coordination Group
eHSFG	eHealth Standardisation Focus Group of CEN/ISSS
eHWG	eHealth Working Group
DRG	Diagnosis Related Groupings
ERA	European Research Area
ESA	European Space Agency
ESTEC	European Space Research and Technology Centre
EU	European Union
GALEN	Generalised Architecture for Languages, Encyclopaedias and Nomenclatures (in Medicine)
GHOS	Global Health Over Satellite
HEWS	Health Early Warning Systems
HL7	Health Level 7
ICD	International Classification of Diseases
ICT	Information and Communication Technology
IHE	Integrating Healthcare Enterprise
IP	Internet Protocol
IST	Information Society Technologies
IT	Information Technology
ITU	International Telecommunication Union
ITU-D	ITU Telecommunication Development Bureau
ITU-T	ITU Standardisation Bureau
PKI	Public Key Infrastructure
SDO	Standard Developing Organisation
SNOMED	Systematised NOMenclature of MEDicine
SSA	Specific Support Action
TM	Telemedicine
TMA	Telemedicine Alliance
WHO	World Health Organization
XML	Extensible Mark-up Language





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*The opinions expressed in this document are those of the authors and do not necessarily reflect the views of the European Commission, European Space Agency, World Health Organization, International Telecommunication Union, their memberships, or their Member States*

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