TELEMEDICINE ALLIANCE - A BRIDGE TOWARDS COORDINATED EHEALTH IMPLEMENTATION

EHEALTH INTEROPERABILITY IN EUROPE: CHALLENGES AND INITIATIVES

Interoperability Study Report

Lead Partner for Deliverable: ITU
Start/Duration of project: 1 August 2004 – 31 July 2005
Dissemination Level*: PU (Public)
Deliverable Number: TMA-Bridge_Del-4
Document Number: TMAB-ESA-TN-040
Electronic File Name: TMAB-Del.4-Interop. Study Report_Iss1-Rev0.doc
Issue/ Revision: 2/ 0
Due date of deliverable: M9
Actual Date: 28 July 2005
Number of pages: 115

Project co-funded by the European Commission within the 6th Framework Programme (2002-2006); Priority 2 Information Society Technologies (IST); Specific Support Action (SSA); Project No. IST-507871.

*PU = Public, PP = Restricted to other programme participants, incl. the Commission Services (CS), RE = Restricted to a group specified by the consortium (incl. the CS), CO = Confidential, only for members of the consortium (incl. the CS)
### APPROVAL

| Document Title | TELEMEDICINE ALLIANCE - A Bridge Towards Coordinated eHealth Implementation  
Del. 4: Interoperability Study Report | issue 2 | revision 0 |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Responsible</td>
<td>Alexander Ntoko (Kerstin Ludwig)</td>
<td>date</td>
<td>28 July 2005</td>
</tr>
<tr>
<td>WP Responsible</td>
<td>Alexander Ntoko (Kerstin Ludwig)</td>
<td>date</td>
<td>28 July 2005</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>Clivo Tristram</td>
<td>date</td>
<td>29 July 2005</td>
</tr>
<tr>
<td>Approved by (Coordinator)</td>
<td>Didier Schmitt</td>
<td>date</td>
<td>29 July 2005</td>
</tr>
</tbody>
</table>

### CHANGE LOG FOR ISSUE: 2

<table>
<thead>
<tr>
<th>Reason for new revision/issue</th>
<th>Section</th>
<th>Issue</th>
<th>Revision</th>
<th>Document status</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Review</td>
<td>All</td>
<td>0</td>
<td>3</td>
<td>Draft available for the Technical Review</td>
<td>20-02-2005</td>
</tr>
<tr>
<td>Interoperability Workshop</td>
<td>All</td>
<td>0</td>
<td>4</td>
<td>Advanced draft for Workshop on Interoperability</td>
<td>11-03-2005</td>
</tr>
<tr>
<td>Release to the EC</td>
<td>All</td>
<td>1</td>
<td>0</td>
<td>Validation from WS inputs</td>
<td>29-06-2005</td>
</tr>
<tr>
<td>Update acknowledgements, references, dissemination level for submission to EC</td>
<td>All</td>
<td>2</td>
<td>0</td>
<td>Release to the EC</td>
<td>29-07-2005</td>
</tr>
</tbody>
</table>
ACKNOWLEDGEMENTS

The main authors and contributors to this Interoperability Study Report were:

C. Bescos M. Diop
A. Dunbar M. Garcia-Barbero
J. Kass K. Ludwig
A. Ntoko N. Rossing
A. Runge D. Schmitt
C. Tristram

The authors acknowledge the review and inputs of the participants to the workshop on interoperability organized by the Telemedicine Alliance on 18-19 March 2005 at ESA / ESTEC:

G. Borgulya G. Claeys
K. Donnelly R. Foggie
A. Güell J.C. Healy
G. Klein G. Lorenz
R. Mainz L.E. Nohr
P. Pére O. Purcarea
P. Ross S. Schug
J. Smith V. Traver
L. Van den Broek

Special thanks goes to the support and collaboration of the Director of ITU Telecommunication Standardization Bureau (ITU-T).

Credits should be given to the following individuals contributing to the successful completion of this report:

H.P. Bursig, COCIR S.F. De Campos Neto, ITU-T
G. Dietzel, Consultant A. Güell, CNES
G. Klein, CEN TC-251 D. Padeken, BMGS, Germany
V. Traver, eHSCG

DISCLAIMER

This report has been prepared by the Telemedicine Alliance consortium made up of European Space Agency (ESA), International Telecommunication Union (ITU) and World Health Organization (WHO), as part of the European Community 6th Frame Work Programme.

“EHealth in Europe: Challenges and Initiatives” is part of deliverables of the Telemedicine Alliance – a Bridge towards coordinated eHealth implementation.

Other reports and information on this project can be found at www.esa.int/tma-bridge or www.esa.int/telemedicine-alliance.

The opinions expressed in this study are those of the authors and do not necessarily reflect the views of the International Telecommunication Union, its Member States and Sector Members, the European Space Agency, the World Health Organization or their Member States.
EXECUTIVE SUMMARY - EHEALTH INTEROPERABILITY IN EUROPE: CHALLENGES AND INITIATIVES

The Telemedicine Alliance and TMA-Bridge: a vision and a challenge

The Telemedicine Alliance (TMA), a partnership of the European Space Agency (ESA), International Telecommunication Union (ITU), and World Health Organization (WHO), in its first phase of work, formulated ‘Telemedicine 2010: Visions for a personal medical network’2 for eHealth by 2010: These visions placed the citizen at the center of any transition to eHealth. The research carried out identified many barriers that had to be overcome before this eHealth Vision could be realized; the main obstacle was recognized as lack of interoperability within and between national and regional healthcare systems.

This Interoperability Study Report from the TMA’s second phase of work, the TMA-Bridge, provides background material on achieving interoperability concerning trans-border issues of national eHealth services with emphasis on the citizen. It is targeted to support decision-makers in the European Commission and the European Member States, especially with regard to trans-national eHealth.

Interoperability is not just technical – it is much more

Interoperability must cover the areas of political, organisational, social and technical interoperability each with its own framework to comply with the definition of Alliance for Telecommunications Industry Solutions:

Interoperability is “…the ability of systems, units or forces to provide services to and accept services from other systems, units, or forces and to use the services so exchanged to enable them to operate effectively together…”4.

Where the systems are technical and human, there are different frameworks of interoperability for eHealth: Policy framework, Organizational and Social framework, and Technical framework.

Systems do not have to be the same to communicate with each other

There are, and will continue to be, many different types of both health Information Technology (IT) systems and health delivery systems across Europe. This should not be an impediment to interoperability, since if they are well preconceived with regard to interoperability, then quite different systems can still communicate with each other. Moreover, parallel, but compatible, initiatives and developments will provide a good basis for testing different applications and configurations, allowing successful models to serve as an array of options for systems still under development or those experiencing problems. However, it takes the agreed use of common standards and compatible interfaces to enable different

2 Telemedicine Alliance, 2004a, pp.8-11
3 An adapted version of this report has been issued in brochure format for distribution at the Ministerial Conference, eHealth 2005, in Tromsø (Norway), 23-24 May 2005, and subsequent events. The authors also acknowledge the contribution of G. Klein, to this executive summary.
systems working together. These systems should satisfy the users’ needs considering mobile citizens and patients, healthcare professionals, administrative institutions, governments, etc.

**The need for standards and common infrastructures**

Many standards exist for the required eHealth services. However, there is a lack of understanding on the possibilities to compile and to use them. Moreover, some standards may not adequately represent the users’ needs. Thus, a list of requirements for eHealth services should be compared with the existing standards and users’ needs. Additional eHealth standards need to be developed based on this list of requirements. These standards should avoid duplication of already existing standards.

The recent CEN/ISSS eHealth standardization Focus Group report makes recommendations to the Member States and the Commission on required actions. It is noted that the existing formal European Standardization system with CEN/TC 251 (the committee for health informatics) has not, and cannot, alone develop all the standards needed. The global co-operation of standardization bodies like CEN, DICOM, HL7, IEEE, ISO, ITU and OASIS in collaboration with WHO in the recently formed global eHealth Standardization Co-ordination Group (eHSCG), is welcome as a source of information on all standards required and should be given support to be better able to give advice to the users.

It is, however, recognized that the available standards often require further precision and implementation profiles for specific applications. The necessary work should be done together with industrial companies and users reaching consensus on a global level.

In addition to standards and interoperable products, it is necessary to ensure the development of the following information structures that require national work, but in a co-ordinated common structure with shared resources in Europe:

1. A common conceptual system for clinical facts in records with associated multilingual reference terminologies. SNOMED CT is an available system of health vocabulary software technology that all European Member States should evaluate, and it may be the best candidate to build on. Cooperation with the centre for classification of the World Health Organization is advised in this process. In addition, it is noted that for some fields, multinational terminologies exists outside of this, such as ICD-10 and IUPAC/C-NPU for laboratory tests.

---

5 View of experts at the TMA-Bridge workshop on interoperability, Noordwijk, 18-19 March 2005
7 The eHSCG was endorsed by ITU-T Study Group 16 in May 2003. TMA has observer status. eHealth Standardization Coordination Group, 2004b, available: [http://www.ehscg.org](http://www.ehscg.org)
2. An electronic directory service targeted to eHealth key stakeholders with information on providers, professionals and the services offered should be built, based on federated national directories (which in turn may be based on regional directories). Basic standards and initiatives in some countries exist, but no common action yet. The directory service needs to consider the issue of subsidiarity and of digital signatures. It is recommended to have a defined chain of trust for the information provided and the information provider\(^9\). Clear definitions of the service are required on its management contents, target groups, trust schemes, depth of hierarchy, management rights of supervising institutions, etc. It is useful to create this service either under the Directorate of EC or another dedicated European institution.

3. A European system to verify professional registration of licenses to practice in the different countries that works across borders. A European licensing system fosters comparison and mutual recognition of professionals working in their own country on national cases, on cases abroad as well as professionals working abroad. These accreditations should be part of the information stored in the electronic directories.

**A Holistic Approach should encompass the various Healthcare domains**

The TMA divided the broad arena of eHealth into four domains: Care, Education, Surveillance and Administration\(^10\). For the purposes of this study, priority actions for the citizen were identified for each domain, as shown in Table 1 below:

<table>
<thead>
<tr>
<th>eHealth Service</th>
<th>Priority for Trans-National Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care</td>
<td>➢ Structured and harmonized messages and trans-national Electronic Health Record</td>
</tr>
<tr>
<td>Education</td>
<td>➢ Web Community Services</td>
</tr>
<tr>
<td></td>
<td>➢ Reliable Health information webs for the citizen</td>
</tr>
<tr>
<td>Administration</td>
<td>➢ Reimbursement</td>
</tr>
<tr>
<td>Surveillance</td>
<td>➢ Early Warning Systems (comparable Public Health Data)</td>
</tr>
</tbody>
</table>

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

The TMA’s systematic philosophy involved analysis of each healthcare domain priority along each infrastructure framework. This allowed presenting a complete picture together with external international experts, making it possible to view the interactions between all parts and then to identify the gaps and formulate the requisites to enable the realization of interoperable eHealth across healthcare systems.

---

\(^9\) The issue is to define the point when trust can be established, where the reader and the Government respectively cannot control the directory.

\(^10\) The TMA’s holistic approach is consistent with the WHO’s recently adopted eHealth strategy at its 2005 General Assembly, that 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_wha06/en/index.html
Challenges we are facing on the way to eHealth

ECare

Twenty years of efforts in standardisation of clinical messages and electronic health records have not ensured interoperability either between levels of care (primary to secondary or specialised care) or between regions and countries. Interoperability includes the problem of semantics in a multi-cultural context. The interpretation of the information collected in the Health Record is still far away from being processed automatically. Moreover, the lack of implementation of internationally defined standards on data protection, security and privacy is perceived to be one of the highest issues for eHealth at a national and international level. Up to now, despite implementation of the EU directive on data protection\(^{11}\) and electronic signatures\(^{12}\), there are few guidelines with respect to automatic processing of healthcare data; this has become an annoying roadblock to introduction of eHealth methods, especially regarding cross-border data processing. Issues of liability for patients’ data, will become a growing problem especially for telemedical and trans-national services, where legal guidelines are not well defined or consistent across the EU. There is also the liability for medical action dependent on data received from another person/organisation in both the same country or another.

After more than 10 years of EC IST research programmes\(^{13}\) investing resources in Health Records, some lessons have been learned:

- A well thought-out strategy before starting is critical;
- Break the pattern of large-scale “all-at-once” implementations (start with smaller scale, but upgradeable and expandable implementations, with greater likelihood of success);
- Commitment of the “leaders”, especially those who have to use the systems on a daily basis is essential. If leading stakeholders are not involved or committed, failure is likely;
- Ensure legal and ethical compliance;
- Do not underestimate the need for user acceptance (habits, culture, financial and training investment);
- None of the parties can do it alone! (co-operation / collaboration between the stakeholders);
- Do not reinvent the wheel; seek implemented cases of good practice.


**eEducation**

In the relatively affluent and educated EU region, citizens increasingly wish to take an active role in decisions about their health care. Online consumer health information\(^{14}\) is growing at an unprecedented rate, but users and providers currently have no systematic way of judging its quality. It is becoming accepted and expected that access to good information is a right of the patient and a duty on the health professional, though to know what is “good quality” information is a challenge. Self-help for the citizen and self-training for the professional is relatively easy to obtain via the Internet, and self teaching multi-media applications can become very effective educational tools. Likewise community groups can exchange and share information today as never before – all potentially to the mutual good of all within or across borders. EEducation and eLearning within and across borders has basically the same requirements and objectives, but the legal liability in both cases may differ from country to country. But once again there is no mechanism available to guarantee quality of information or professional oversight of chat-groups to ensure that it does not result in misinformation.

In Europe’s increasingly trans-national atmosphere of expatriate citizens and health providers requiring and offering services across borders, linguistic and cultural problems become increasingly prevalent; the mobile patient and professional needs access to information in a language and cultural flavour that can be easily understood. This adds to the existing problems of semantics and ontologies in healthcare, problems that could potentially be solved via eEducation.

**eSurveillance**

In the context of disasters, disease outbreaks or bio-terrorism attacks, early warning and monitoring systems may help to gather intelligence and detect or even predict diseases early, and communicate and exchange information electronically worldwide. With increased, easy, and fast travel to all corners of the globe, disease can be carried very easily and rapidly over long distances and spread very widely. If interoperable data can be collected and collated quickly, the job of identifying, tracing and dealing with such outbreaks can be carried out more successfully and early enough to minimize damage. The establishment of the European Centre for Disease Control (ECDC) in Sweden, is a major commendable step.

Although some measures are already nationally implemented, one of the main challenges of interoperability is to allow quick cross-border reactions and countermeasures, because warning systems demand rapid and thoughtful responses to be effective. The greater completeness of information and the speed that can be provided by electronic systems with the ability to model disease/threat progression offer critical tools to develop strategic response plans. Their full potential cannot be reached until the following conditions are in place:

- Ontological cross-reference between different disease surveillance systems;
- A unified approach to disease monitoring and data collection;
- The creation of modelling systems parallel in function to weather forecasting systems;
- Appropriate capacity building through training for data researchers, analysts, data providers, etc.

\(^{14}\) The DISCERN project is based in the University of Oxford, Division of Public Health and Primary Health Care, at the Institute of Health Sciences. Discern, available: [http://www.discern.org.uk](http://www.discern.org.uk).
Finally, all these systems should be highly interoperable helping:

- To improve the quality of the data by importing data from meta-databases, namely benefiting largely from health mapping\textsuperscript{15};
- To increase the speed of information sharing, in particular through export of information into other information systems; and thus to improve predictability, prevention, control, and treatment;
- To correlate the data with data collected in other parts of the world.

In order to fulfill such requirements, various ICTs such as satellite telecommunications to transmit data or monitoring satellite for tele-epidemiology are necessary to build efficient eSurveillance systems; but the key is that such measures must be interrelated with each other, targeting common objectives, collecting comparable data, and making this data immediately available for analysis.

For the systems to be effective:

- It is necessary for collaboration to exist between with international organisations, government agencies, healthcare and public health institutions, and authorities for meteorology, geological survey, socio-economic and Earth sciences.
- They require political commitment and a standardized approach of collecting data throughout a network of networks.

**eAdministration**

For the domain of eAdministration, the priority sub-domain of eReimbursement was selected, and is discussed herewith. Trans-national eReimbursement covers the flows associated with funds allocation and payments where they are concerned with care provided to persons outside the provider/country’s insurance system.

The key issues for reimbursement are:

- Non-availability of reimbursement for telemedicine services, either inside or outside a country\textsuperscript{16};
- Lack of agreement on:
  - Medical acts to be reimbursed;
  - Scale of fees and reimbursement percentages;
  - Mechanisms for assuring quality of service;
  - Mechanisms for patients to maintain control over their medical and administrative data, i.e. possession and active declaration of will as the basis for change of data through e.g. PIN;
- Confusion between existing bi-lateral agreements and the recent court decisions\textsuperscript{17} and reinterpretation and clarification\textsuperscript{18} of EEC Regulation 1408/71\textsuperscript{19};

\textsuperscript{15} Health mapping programmes integrate geographic information and related data management for infectious diseases surveillance and control. WHO, 2005e, available: http://www.who.int/csr/mapping/gisandphm/en/

\textsuperscript{16} This is especially true of second opinions.

• Variable levels of knowledge about rights and responsibilities of the purchasers, providers and citizens;
• Lack of appropriate information and communication mechanism between purchaser and provider to ensure:
  o Consistency of interoperable medical ontology between countries;
  o Privacy and confidentiality and agreement on what is medical and administrative data;
  o Speed - rapid transfer of information - authentication and pre-approval;
  o Trace-ability;
• The majority of trans-national reimbursement systems are paper based;
• Difficulty in integrating new ICT systems into business processes by providers;
• There is no standardised approach for the rapid authorisation of medical acts in other countries of the European Union.

The reimbursement of healthcare services between European countries is well established for emergency medical interventions and is covered by the E1XX paper-based system. The recent EU Court of Justice decisions\(^\text{20}\) and EEC Regulation 1408/71\(^\text{21}\) potentially extend this to elective treatments, providing pre-authorisation has been provided and where the visit was expressly for the purpose of receiving treatment\(^\text{22}\). Policy makers will have to introduce new mechanisms to handle pre-authorisation and to ensure that treatment data can be transferred back to nationally or locally held electronic healthcare records.

Increasingly the current paper-based systems will be inadequate for the volume of transactions resulting from treatment of citizens whilst visiting another country or transferred there for medical treatment.

The impacts of these issues are:
• Reimbursement are seen as a major barrier to implementation of eHealth and especially, trans-national eHealth services\(^\text{23}\).
• Legal basis for trans-national reimbursement has improved greatly by recent court decisions\(^\text{24}\) and reinterpretation and clarification\(^\text{25}\) of EEC Regulation 1408/71\(^\text{26}\). (Persons may receive

---

\(^{18}\) Commission of the European Communities (CEC), 2004b, COM(2004) 301

\(^{19}\) This refers to the application of social security schemes to employed persons and their families moving within the Community.


\(^{21}\) This refers to the application of social security schemes to employed persons and their families moving within the Community.

\(^{22}\) CEC, 2005a, available: http://europa.eu.int/comm/employment_social/healthcard/citoyens_en.htm

\(^{23}\) Expert Views – Interviews in: Telemedicine Alliance, 2004b


\(^{25}\) CEC, 2004b, COM(2004) 301
elective treatment in hospitals or by general practitioners whilst travelling or living in other European countries, and get reimbursed.) Although the Regulation is quite clear, national legislation and many practical issues make it very difficult for the citizen who wishes to take advantage of these new rights.

- Reimbursement of telemedical services is similar to specialist services and is normally excluded from the treatment agreements.
- Implementation of effective eAdministration systems for efficient and speedy reimbursement is still a long way off even where reimbursement is allowed.
- Citizens do not know whether the treatment they have received will be reimbursed until after they have paid.

The risks of not moving forward

The TMA has analysed the needs for transnational interoperability and has provided guidelines and recommendations on how to move forward. The question may arise for some policy makers and industrial investors, as to the necessity of moving forward in a Europe-wide coordinated manner concerning transnational interoperability: Achieving agreement and progressing in a co-ordinated manner across 25 Member States is costly, slow, and difficult to achieve.

Stakeholders and policy makers must, however, realize that the cost of inaction is even greater. Where investment is already being made, if preconditions for interoperability are not now taken into account, it may cost very dearly to make the necessary changes in the future. Thus, the rate of implementation should be as fast as possible. Moreover, much potential investment in applications and infrastructure is being held up because industrial parties are unwilling to take the risk of introducing applications that risk becoming out of date and unusable in the future. This is a risk that national Governments may have to take, but with similar costly consequences.

Concluding Recommendations

TMA-Bridge has formulated a number of recommendations, which have been reviewed and are supported by the participants of a recently held workshop on Interoperability to which experts representing the various domains of eHealth were invited. A selection of these recommendations are summarised below concerning European and national policy actions, the issue of standards as well as the issue of security and data protection:

---

20 This refer to the application of social security schemes to employed persons and their families moving within the Community.
European and national policy actions

- Build on the experiences in e-Society, e-Government, e-Commerce, and e-Banking, in particular, and e-Europe, in general, to avoid wherever possible separate development efforts in eHealth.

- A co-ordinated steering of resources and priorities for pan-European interoperability actions including standardization should be established. It is noteworthy that a group of representatives of the health ministries working on eHealth is already established\(^{27}\). Its effort to create a special interoperability platform, which includes experts from industry, standardization and health professionals, is welcomed and important.

- The system for authentication and authorisation of health professionals should be reconsidered. More co-operation between the responsible bodies in the Member States is required and preferably a system where a health professional authorised in one Member State can also provide services over the public network to citizens and providers in other Member States. Alternatively, a special European licensing for some eHealth services such as the evaluation of images should be considered.

- Generate top-level political support by the European Commission by creating a briefing paper for the Council of Ministers, which after adoption would be incorporated into each Member State’s policy objectives.

- Set targets for cost savings through the use of trans-national eHealth services.

- Encourage the adoption of trans-national telemedicine services through policy initiatives backed by action on fee scales.

- Start to introduce a European-wide scheme for accreditation of telemedicine providers implemented by national centres of competence.

- Maintain strong support for the European Health Insurance card as the first step towards improved eHealth especially during the second phase in which some medical data will be added.

- Encourage national health systems, professional bodies and patient groups to introduce a certification mark for approved health-related websites.

- Encourage the speedy development and implementation of European-wide e-surveillance and health warnings by inter-connecting existing national and international systems.

- A European level web portal should be established for monitoring the impact of interoperability actions identifying suitable indicators for measuring the impact, for defining milestones, and for creating guidelines for reporting progress.

- Encourage user involvement and training for effective implementation and use of eHealth services and applications.

---

\(^{27}\) This is the Health Care Authorities (HCA) Working Group of EHTEL in conjunction with I2Health initiated in February 2005.
On the issue of Standards

• Create and implement a standardised electronic method for the transfer of administrative and medical data between countries.

• Encourage the development and adoption of interchange standards between countries to avoid the factorial problem created under individual bilateral agreements.

• Create a European-wide ontology interoperability guide to enable translation of fee scales, medical acts.

• Coordinate the activities and recommendations of the diverse standardization bodies and interoperability initiatives in order to bring forward a clear message for action to the Member States decision makers.

• Ensure that the voices of all stakeholders, especially those who are users of the standards, are heard and their needs incorporated into any recommendations made to increase the possibility of adoption.

• Take into account application of interoperability standards in all domains of eHealth and the needs and requirements of all frameworks, including cultural, organisational, and coordinated policy, as well as technical aspects.

• Make the standards simple, easy to access and obtain, and easy to adopt.

• Encourage the work of the eHealth Standardization Co-ordination Group (eHSCG) to provide a lead.

• Bring to the attention of all parties the recommendations of the CEN/ISSS eHealth Focus Group.

• Bring to the attention of decision makers the activities of trans-national organisations, such as NATO, who are adopting practical solutions for eHealth.

On the issue of Security and Data Protection

• Ensure that data transmitted trans-nationally is done so securely and used only for the designated purpose by the designated person.

• All data transmitted between countries must be subject to the required level of security, e.g. as embodied in the Electronic Signature Directive28, such as it being encrypted and digitally signed.

• All data held, updated or transmitted should be subject to the controls shown to be equivalent to best practice, including, but not limited to traceability, non-revocation, etc.

• A common Public Key Infrastructure (PKI) for certificates based on open, international standards should be used to support the key security services for interoperable services across borders: encryption for confidentiality, authentication and authorisation of users, access control, non-repudiation and data integrity on electronic documents to allow auditability. It is noted that the directory service for basic information on providers also can be used for security certificates, but special bodies and trust agreements must exist in all Member States to issue certificates that are mutually recognized in other countries, EU Member States and non-EU ones29.

---


Table of Contents

EXECUTIVE SUMMARY - EHEALTH INTEROPERABILITY IN EUROPE: CHALLENGES AND INITIATIVES................................................................................................................................................V

PREFACE ...................................................................................................................................................... XVIII

1 OVERVIEW...............................................................................................................................................1

1.1 Introduction ........................................................................................................................................ 1
1.2 Objectives and purpose of the interoperability study ................................................................. 2
1.3 Scope of this document .................................................................................................................. 3
1.4 Methodology .................................................................................................................................. 4

2 TRANS-NATIONAL INTEROPERABILITY ..................................................................................6

2.1 Introduction ...................................................................................................................................... 6
2.2 Transnational services .................................................................................................................. 6
2.3 The notion of interoperability..................................................................................................... 10
2.4 Scope of selected Trans-national services ................................................................................ 12
2.5 General infrastructure of technical eHealth interoperability.................................................... 16

3 ECARE: TRANS-NATIONAL ELECTRONIC HEALTH RECORDS........................................... 20

3.1 Introduction ...................................................................................................................................... 20
3.2 Policy Framework for eCare ........................................................................................................ 22
3.3 Social-Organisational Framework for eCare.............................................................................. 25
3.4 Technical Framework for eCare .................................................................................................. 27
3.5 Initiatives and Solutions for eCare ............................................................................................. 29
3.6 Expanding the models to Europe................................................................................................. 32

4 EDUCATION: WEB COMMUNITY SERVICES AND HEALTH INFORMATION ON THE INTERNET ........................................................................................................................................ 33

4.1 Introduction ...................................................................................................................................... 33
4.2 Policy framework for eEducation ................................................................................................. 34
4.3 Social-Organisational framework for eEducation ..................................................................... 34
4.4 Technical Framework for eEducation ......................................................................................... 37
4.5 Initiatives and Solutions for eEducation..................................................................................... 39
5 ESURVEILLANCE: EARLY WARNING SYSTEMS .............................................................. 44

5.1 Introduction .............................................................................................................. 44
5.2 Policy Framework for eSurveillance ........................................................................... 45
5.3 Social-Organisational Framework for eSurveillance .................................................. 47
5.4 Technical Framework for eSurveillance ................................................................. 50
5.5 Initiatives and tools for eSurveillance ................................................................. 53

6 EADMINISTRATION: EREIMBURSEMENT ................................................................ 55

6.1 Introduction .............................................................................................................. 55
6.2 Policy Framework for eAdministration ...................................................................... 57
6.3 Social-Organisational Framework for eAdministration ............................................ 59
6.4 Technical framework for eAdministration ............................................................. 62
6.5 Initiatives and Solutions for eAdministration ......................................................... 64

7 THE WAY FORWARD .................................................................................................. 68

7.1 eHealth: the next pillar of the Health Market.......................................................... 68
7.2 eHealth services, the holistic approach .................................................................... 68
7.3 Reaching global understanding while respecting regional HC delivery .................. 69
7.4 Implications for all stakeholders ............................................................................. 71
7.5 The need for standards and common ‘infrastructures’ ............................................. 72
7.6 The issue of security and data protection ............................................................... 75
7.7 The risks of not moving forward ............................................................................. 76
7.8 Towards a sensible strategy ...................................................................................... 76

ACRONYMS AND ABBREVIATIONS .............................................................................. 78

BIBLIOGRAPHICAL REFERENCES .............................................................................. 83

ANNEXES ......................................................................................................................... 97

Annex-1: General Infrastructure of Technical eHealth Interoperability
Annex-2: Standards & Supporting Initiatives Related to EHR
Annex-3: Standards List from EHSCG (draft)
Annex-4: Brochure for 2005 Tromsø Conference
Annex-5: Initiatives and Tools for eSurveillance
Annex-6: Personal communication, COCIR
Annex-7: Europe & CIS ICT indicators, 2003
List of Tables

Figure 2-1 Multi-layer structure of interoperability for eHealth 11
Figure 2-2 Illustration of data exchange between users (care information providers and citizens) 11
Figure 3-1 Map of connexion between regions involved in the Baltic eHealth initiative 30
Figure 3-2 IHE methodology 32
Figure 4-1 Internet users 38
Figure 5-1 The four main requirements of effective early warning systems 49
Figure 6-1 The Health triangle 55
Figure 6-2 Planned introduction of the European Health Insurance Card in the EU 65

List of Figures

Figure 2-1 Multi-layer structure of interoperability for eHealth 11
Figure 2-2 Illustration of data exchange between users (care information providers and citizens) 11
Figure 3-1 Map of connexion between regions involved in the Baltic eHealth initiative 30
Figure 3-2 IHE methodology 32
Figure 4-1 Internet users 38
Figure 5-1 The four main requirements of effective early warning systems 49
Figure 6-1 The Health triangle 55
Figure 6-2 Planned introduction of the European Health Insurance Card in the EU 65
PREFACE

This document is the first of two key deliverables of the TMA-Bridge project. The two deliverables, together, provide the key output of the project: Deliverable 4 is the Interoperability Study Report, which provides the key recommendations that are prerequisite for overcoming the barriers for eHealth Interoperability, while Deliverable 5 follows up with a strategic plan with recommendations towards policies that would lead to satisfying the requirements formulated herewith.

Key to the production of this work is a workshop on eHealth interoperability organised by the TMA (18-19 March 2005), where experts reviewed a draft version of this document and provided critique as well as useful inputs, which were incorporated into this version.

In order to keep this document short, reference annexes are provided as separate documents (see list attached at the end of this document).

For the busy reader, an Executive Summary is provided at the beginning. This summary has appeared in an adapted version as a brochure that was first circulated at the recent Tromsø eHealth 2005 Ministerial Conference.
1 OVERVIEW

1.1 Introduction

1.1.1 Context of interoperability study and TMA-Bridge

The Telemedicine Alliance (TMA) project, in its first phase, created a vision for citizen-centred eHealth. Validation by experts indicated that one of the main barriers to its successful implementation was lack of interoperability in the social, cultural, educational, political and technical domains between health systems and services. This interoperability study report analyses the problems of interoperability and recommends actions to resolve them.

1.1.2 General background

‘Europeanisation’, globalisation and an elderly population

The citizens of the European countries are increasingly mobile as their work, holidays, and retirement finds them in a country other than their native one. Their average age is increasing which brings a demand for greater healthcare services. Trans-national healthcare services are increasingly needed to satisfy these demands, whether they are for efficient eAdministration, effective and efficient eCare or supporting health eEducational needs. National healthcare systems, where they are supported by Information and Communication Technologies (ICTs), can provide the basis for meeting these needs both within and external to Europe, if they could interoperate.

Trans-national eHealth projects are increasing both in Europe and other developed countries

In Europe, eHealth projects have been sponsored by the European Commission and national Governments to develop and test concepts of trans-border interoperability. Where these are solely bilateral then there is a danger that these solutions will not be applicable to all, highlighting the need for a European vision in all projects.

This activity has been mirrored in the large number of national eHealth projects within the G7 nations and Australia.

Increasingly the emphasis is turning to the difficult problem of trans-national interoperability. This is required to support the fundamental objectives in the European treaty of allowing citizens to live and work wherever they wish within Europe.

Successful eHealth is more than technical and care

The TM Alliance project (Phase 1) demonstrated that eHealth is more than telecommunications technical and medical care. To be successfully implemented and used it must be treated in an holistic manner. eHealth spans organisational, cultural and social, and policy frameworks and includes eCare in addition to

---

30 Telemedicine Alliance, 2004a, pp.8-11
other domains, such as eEducation, eSurveillance, and eAdministration. The basis for eHealth are ICTs, and it provides opportunities to create new services and solutions that will appear in the future.

**EU action plan and interoperability**

The European (EU) initiatives in the domain of eHealth attempt to address these newly arising needs, as exemplified in COM(2004)301 [...patient mobility and healthcare], COM(2004)304 [...open method of coordination], and COM(2004)356 [...a European eHealth area]. The latter sums it all up:

“Interoperability should enable the integration of heterogeneous systems; allow secure and fast access to comparable public health data and to patient information located in different places over a wide variety of wired and wireless devices.” 31

These show that Europe is aware of the need to seriously address interoperability across all domains of healthcare that can be served by ICTs.

**Interoperability and standardization bodies**

There are many standardization bodies and working groups already set up in Europe and around the world (e.g. CEN, CEN/ISSS, eHSCG, ISO, ITU, etc.). Some are focused mainly on national interests such as ANSI and others mainly on the developed nations. Despite these many activities there has been little action to adopt standards for international interoperability. This will create problems as countries rapidly introduce modern ICT systems in response to cost and other pressures. These solutions are usually inward looking with little thought to cross-border eHealth activities.

### 1.2 Objectives and purpose of the interoperability study

#### 1.2.1 General objectives and purpose of study

The general objective is to raise awareness about the importance of trans-border interoperability and inform stakeholders in eHealth about the issues and solutions.

The purpose is to provide a background document on trans-national interoperability of eHealth services with an emphasis on the citizen. The target audience is decision-makers in the Commission of the European Communities and EU Member States. They will be supported in their actions to implement eHealth between countries in a way which is coherent and interoperable.

The target date for implementing the TM Alliance vision is 2010.

#### 1.2.2 Specific objectives and work description

- Identify and analyse the critical areas for the interoperability of Health Systems across Europe, from the political, organisational, social and technical points of views.
- Define a framework for promotion and assessment of interoperability.

• Prepare an interoperability work-plan, identifying TMA-Bridge consortium role.
• Promote appropriate European and world-wide standardisation initiatives and the eHealth Standardization Coordination Group (eHSCG) amongst service providers, decision makers, and the medical community.
• Create a roadmap and guidelines to bridge the gap between present analyses and objectives identified in the “Vision 2010” including political, organisational, social and technical aspects.

1.3 Scope of this document

1.3.1 General Scope
• To ensure the usefulness and readability of this report the broad domain of eHealth has been exemplified by a selection of best practices;
• The study has been kept to an explanation of requirements, challenges and solutions of eHealth interoperability and its implications of inter-related policies and activities;
• The target audience are the decision-makers of the EC and the 25 Member States who responsible for the wide spectrum of trans-national eHealth interoperability.
• This document is focused on the critical trans-national issues for the mobile citizen. It provides recommendations for the achievable first set of steps towards open coordinated agreements amongst the Member States.

Working towards these goals will lay the foundation and provide the catalyst for later more complete solutions.

1.3.2 Description of chapters

The main chapters are briefly described herewith:

<table>
<thead>
<tr>
<th>Chap.</th>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Overview</td>
<td>Background of Interoperability in eHealth context from TMA Phase-I and in present TMA-Bridge work; objectives, purpose, and scope of this deliverable</td>
</tr>
<tr>
<td>2</td>
<td>Trans-national Interoperability</td>
<td>Definitions of Interoperability in the context of the domains of eHealth and the frameworks of analysis</td>
</tr>
<tr>
<td>3</td>
<td>eCare</td>
<td>Analysis of the interoperability issues of the Electronic Health Record along the frameworks of Policy, Organizational &amp; Social, and Technical; proposed solutions</td>
</tr>
<tr>
<td>4</td>
<td>eEducation</td>
<td>Analysis of interoperability issues of Web Community Services and Reliable Health information webs for the citizen, along the frameworks of Policy, Organizational &amp; Social, and Technical.</td>
</tr>
<tr>
<td>5</td>
<td>eAdministration</td>
<td>Analysis of interoperability issues of the Reimbursement along the frameworks of Policy, Organizational &amp; Social, and Technical.</td>
</tr>
<tr>
<td>6</td>
<td>eSurveillance</td>
<td>Analysis of interoperability issues of the Early Warning Systems along the frameworks of Policy, Organizational &amp; Social, and Technical.</td>
</tr>
<tr>
<td>7</td>
<td>The Way Forward</td>
<td>A synthesis of the results with a view of going forward towards implementation of solutions. Paving the road ahead.</td>
</tr>
</tbody>
</table>

Table 1-1 Domains of eHealth and priority trans-national services
1.4 Methodology

1.4.1 Domains and Frameworks of Analysis

Domains of Healthcare

For the purposes of this study the broad subject of healthcare has been categorized into four domains: Care, Education, Surveillance, and Administration. A specific example has been selected for each domain for analysis. These examples represent a prioritised list proposed by TMA as presented in Table 1-2.

<table>
<thead>
<tr>
<th>eHealth Service</th>
<th>Priority for Trans-National Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>eCare</td>
<td>Trans-national Electronic Health Record</td>
</tr>
<tr>
<td>eEducation</td>
<td>Web Community Services</td>
</tr>
<tr>
<td></td>
<td>Reliable Health information webs for the citizen</td>
</tr>
<tr>
<td></td>
<td>Web information for professionals (outside scope of TMA-Bridge)</td>
</tr>
<tr>
<td>eAdministration</td>
<td>Reimbursement</td>
</tr>
<tr>
<td>eSurveillance</td>
<td>Early Warning Systems (comparable Public Health Data)</td>
</tr>
</tbody>
</table>

Table 1-2 Domains of eHealth and priority trans-national services

Frameworks for Analysis

Following the holistic philosophy of TMA-Bridge, three frameworks of analysis were identified: Policy, Organizational and Social, and Technical. These frameworks are clarified further in Table 1-3.

<table>
<thead>
<tr>
<th>Framework</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy</td>
<td>Guidelines for role of eHealth service in healthcare on local, regional, national, and trans-national levels</td>
</tr>
<tr>
<td></td>
<td>Political agreement for finance and investment</td>
</tr>
<tr>
<td>Organisational &amp; Social</td>
<td>Regulation and legislation</td>
</tr>
<tr>
<td></td>
<td>Obligations</td>
</tr>
<tr>
<td></td>
<td>Liability</td>
</tr>
<tr>
<td></td>
<td>Remuneration</td>
</tr>
<tr>
<td></td>
<td>Equal access (social)</td>
</tr>
<tr>
<td>Technical</td>
<td>Hardware and software connectivity</td>
</tr>
<tr>
<td></td>
<td>Human connectivity with data</td>
</tr>
</tbody>
</table>

Table 1-3 Frameworks of analysis
1.4.2 Description of Methodology

Structure of analysis

- Definitions: development of definitions to provide an unambiguous and consistent ontology of eHealth terminology for this report;
- Dedicated analysis of each domain;
- Analysis of the domains inside their respective frameworks;
- Synthesis of results to provide a logical and integrated approach which can be implemented.

Logical Approach

1. Based on Phase-I: “Challenges and barriers to eHealth interoperability”;
2. Identify “requirements” to meet challenges and overcome barriers;
3. Review existing “Solutions and initiatives of eHealth related interoperability activities” using best practices / case studies;
4. Formulate “recommendations” to close the gaps and lower critical barriers;
5. Create an eHealth strategic plan for Interoperability (WP 5).

Workshop on interoperability (WP 6.1)

- The interoperability study was reviewed at a workshop on interoperability held in March 2005. The workshop was so planned that a draft version of this document was ready for review by the invited experts so that they could:
  - Identify potential solutions to the existing barriers to interoperability;
  - Prioritise the proposed solutions for interoperability for trans-national services having a citizen-centred approach;
  - Review and validate the draft version of this interoperability study;
  - Identify issues that hinder or support development of interoperability in European eHealth;
  - Develop guidelines to improve the different frameworks of the eHealthcare system (policy, organizational and social, technical).

Strategy report and recommendations (WP5)

The results of Work Package 4, Interoperability, will be fed into Work Package 5, which defines a strategy and plan of action for consensus on interoperability standards for eHealth.
2 TRANS-NATIONAL INTEROPERABILITY

2.1 Introduction

The general trend in demographics is affecting the healthcare sector tremendously: Western Europe is currently the area of the world with the highest proportions of elderly people and is projected to remain so for at least the next 50 years\textsuperscript{32}. The migration flows within extensive regions inside the continent and from Southern countries are generating a different map of health needs and technology capabilities. The European Union has removed most of the obstacles for the free mobility of its citizens, who can go to any country they wish to visit or live in for any period of time. Access to high quality health care is a fundamental right for all, but provided in various ways in different member states. The introduction of new technologies made available to the areas and hospitals outside the traditional elite educational centres open up for better prospects of receiving advice and training from experts by establishing virtual specialist teams. Hospitals, specialists and others will be able to offer their services on virtual markets for healthcare services in the EU and beyond.

The recent communications from the European Commission (the eHealth Action Plan and related communications to Mobility of Patients and Method of Open Coordination) highlight how information and communication technologies can be and should be used to deliver better quality health care to citizens across Europe. As far as eHealth is concerned, The "EC Action plan” refers specifically to the use of the electronic health record, the electronic prescriptions, the health insurance cards, etc. with the major objective to contribute to better care for European citizens.

The recent rulings from the European Court of Justice, dealing with patients’ rights to health services abroad in view of the right to free movements of citizens, services goods, have transformed the perception of the rights of patients moving across Europe. The provision of healthcare services abroad are now regulated and the reimbursement procedures have been agreed on.

2.2 Transnational services

The free movement of persons is a fundamental right of the European internal market, and gives citizens of Europe the opportunity to live, work, establish a business, and study in all European Union Member States\textsuperscript{33}. The objective of Community Directives is to eliminate obstacles to the freedom of individual movement, and to all European Citizens the same rights by eliminating discrimination on the basis of nationality.

\textsuperscript{32} Telemedicine Alliance, 2004a, p.12

\textsuperscript{33} A proposal has been made for a Directive on services in the internal market ("Bolkenstein 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. CEC,2004a, COM (2004) 2 final/3
European citizens are mobile. In 2003, more than 400 million tourists travelled around Europe for short term stays both business and pleasure. 320 million of these (roughly four fifths) were Europeans travelling to other European Member States\textsuperscript{34}.

Health systems have to take into account this mobility. They have to provide emergency services for people travelling using an E111, non-emergency services for those staying up to two years using the E12X procedures, and for long or permanent stays where citizens are treated similarly to the state’s own citizens. This citizen mobility also modifies the disease incidence and vectors that are subject of surveillance.

2.2.1 The mobile citizen

The contemporary understanding of mobility includes those citizens, who move from their home countries for short-term tourism, short-term migration and long-term migration.

**Short-term stays:** Tourism (pleasure or business)

“Tourism” is defined as activities of persons travelling to and staying in places outside their usual environment for not more than one consecutive year for leisure, business and other purposes.\textsuperscript{35}

For European Citizens travelling within Europe it can be defined as per the E111 agreements.

It also includes those citizens who specifically travel to another country to receive health care such as joint replacements or cancer care.

**Mid-term stays:** Residents for part of a year (migratory labour, students, retirees)

A *Short Term Migrant* is a person who moves to a country other than his or her usual residence for a period of at least three months but less than a year (12 months) except in cases where the movement to that country is for purposes of recreation, holidays, visits to friends and relatives, business, medical treatment or religious pilgrimage. For purposes of international migration statistics, the country of usual residence of short-term migrants is considered to be the country of destination during the period they spend in it\textsuperscript{36}.

To ensure consistency with the administrative arrangements this is extended in the case of European Citizens to up to two years. This covers those cases where a sovereign state is responsible for the expense of healthcare provision provided to one of its citizens, whether they be retired, working or temporarily resident in another country.

**Long-term stays:** Residents for more than a year (immigrants, foreign labour, students and retirees)

A *long-term international migrant* is a person who moves to a country other than that of his/her usual residence for a period of at least a year (12 months), so that the country of destination effectively becomes his or her new country of usual residence\textsuperscript{37}.

\textsuperscript{34} World Tourism Organization, available: http://www.world-tourism.org/market_research/facts/highlights/Highlights.pdf
\textsuperscript{35} Eurostat and Directorate-General XXIII of the European Commission, 1998, p. 2-3
\textsuperscript{37} Eurostat, 1999
It also includes those citizens who have adopted health insurance and health care arrangements equivalent to the citizens of the country in which they are resident.

Benefits

Mid-term stay or short-term migrants are those citizens who could benefit most from improved access to health systems and health information which cross borders. They often spend a part of each year in more than one member state and therefore would benefit from coordination between health care systems. Additionally, mid-term stay citizens are often retirees who have one or more chronic conditions requiring greater use of the health system and significant interoperability between systems especially in repeat drug prescribing and monitoring procedures.

European citizens wishing to receive high quality healthcare as quickly and as close to home as possible may choose to receive it elsewhere under their rights as EU citizens, as confirmed by the European Court of Justice\textsuperscript{38}.

2.2.2 Needs and demands of patient mobility

Facilitating the mobility of persons and goods is identified in the EU eHealth Action Plan\textsuperscript{39} as one of the eight main challenges for healthcare systems.

The European Commission has communicated in COM(2004) 301, the follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union, that four main areas of activity related to mobility need to be addressed, as follows\textsuperscript{40}:

- “European cooperation to enable better use of resources
- information requirements for patients, professionals and policy-makers
- the European contribution to health objectives;
- and responding to enlargement through investment in health and health infrastructure”.

On a wider scale the World Health Organization, states that “…the growing political instability coupled with the fact that economic growth is stagnating in a considerable number of countries means that uprooting and displacement – be it for political, environmental or economic reasons – will probably continue and become an even greater public health challenge…”\textsuperscript{41} This will provide a challenge for Europe as many will see Europe as an attractive destination and demographic shifts will encourage this inward migration. The challenge will be to avoid discrimination due to language and cultural barriers, legal status and other economic and social barriers.

\textsuperscript{38} CEC, 2004b, COM(2004) 301 final, p.5
\textsuperscript{39} CEC, 2004c, p. 14
\textsuperscript{40} CEC, 2004b, COM(2004) 301 final, p.5
\textsuperscript{41} World Health Organization, 2003b, p.7
**European co-operation**

Individual Member States share the basic social principals of universal access on the basis of need, high-quality health provision, and financial sustainability on the basis of solidarity, the challenge is to make these applicable between states. The enlargement of the European Union will in the short term highlight the differences between countries’ investments and competences in health care and the extend of their eHealth systems.

- Citizens who move need to understand their patient rights, entitlements and duties.
- Citizens might expect health systems in Member States to be coordinated so capacity can be balanced across the Union.
- Freedom of movement of health care professionals between States in response to requirements would assist in smoothing demand peaks.
- Appropriate use of the relevant advances in medical technology to provide better citizen care.

**Information requirements for patients, professionals and policy-makers**

- Citizens who move expect coordination of information so that the right information required for their diagnosis and treatment is available to the right person at the right time. As stated in the EU eHealth action plan\(^\text{42}\), “If interoperable, given patient mobility, electronic health records\(^\text{43}\) will also improve conditions for treatment in other European Union countries.”

- To ensure accurate monitoring and planning, information on the volume and nature of patient flows for tourism, short-term migration and long term migration is required. The Health Council has called on the Commission to create a European Public Health Portal. On 2 June, ministers adopted conclusions on eHealth, patient mobility and heart health. Envisioned to facilitate dissemination of European-wide public health information, this portal should become operational by 2005\(^\text{44}\).

- Citizens demand that their data is protected and the sharing of confidential data between Member States is done in a safe and secure manner, conforming to the national laws and European Directives.

**eHealth and transnational services**

eHealth provides a means by which the needs and demands of citizens who move can be addressed. eHealth offers the underlying tools to support all four recommendations of the EC communication on mobility\(^\text{45}\) through:

---

\(^42\) CEC, 2004c, p. 8

\(^43\) However, countries are in the early stages of national electronic healthcare record implementations.


• European cooperation to enable better use of resources
  o eAdministration for managing and planning (e.g. E1XX, private insurance billing, European electronic health insurance card, support for trans-national laboratory/radiology services). The reimbursement of services provided using eHealth remains a major challenge. Currently, eHealth services are reimbursed in Germany, Greece, Norway and Finland in appropriate cases.
  o eEducation for dissemination of information (e.g. clinical databases, Web communities for professionals).

• Information requirements for patients, professionals and policy-makers
  o eSurveillance for monitoring and coordinating health system (e.g. Europe-wide mortality and morbidity reporting for notifiable diseases).
  o eCare through the electronic patient record to support specialized services (e.g. cancer treatment centres, personal disease management systems for individual patients or patient groups, emergency data set).

• The European contribution to health objectives
  o eCare provision for ensuring fair access, quality, solidarity and fair financing.

• Responding to enlargement through investment in health and health infrastructure
  o eAdministration for managing and planning (e.g. reducing prescription errors).

2.3 The notion of interoperability

Interoperability of eHealth systems and networks is critical in order to be sure that the eHealth technology achieves its objectives for citizens, providers and Member States’ policies. In the context of eHealth, interoperability is the way in which reliable data is provided and communicated in a secure, accurate and way. It has to surmount barriers of culture, language, systems of medical knowledge representation and use of ICTs.

The notion of interoperability is defined, among others, by the Alliance for Telecommunications Industry Solutions as “…the ability of systems, units or forces to provide services to and accept services from other systems, units, or forces and to use the services so exchanged to enable them to operate effectively together…”46. TMA added human beings to this definition as illustrated in Figure 2-1.

---

46 Alliance for Telecommunications Industry Solutions, 2005, available: [www.atis.org](http://www.atis.org)
Figure 2-1 presents the holistic approach of the frameworks identified of interoperability for eHealth, i.e. policy framework, socio-organizational framework, and technical framework of interoperability.

The red arrows demonstrate the possible interactions between the different frameworks representing the same level of importance in this model. The frameworks are not isolated islands, but represent interrelated requirements, challenges, and solutions. Giving an example, reimbursement issues belong both to the organizational and social framework in terms of cross-border health care systems and cultural interactions involved as well as to the policy framework (e.g. legal aspects of reimbursement) and to the technical framework (e.g. standardized reimbursement dataset).

This structure is specific to each area willing to exchange information with other areas and is a mandatory element for successful trans-national data exchange.
Figure 2-2 illustrates the idea of interoperability for eHealth purposes. It represents the exchange of information between health care information providers, e.g. hospital or medical practitioners, and European citizens or patients across country borders, and summarizes all the conditions to be fulfilled provided in the definitions of the different interoperability frameworks.

The difference of shapes in the multi-layers structure of interoperability symbolizes the different patterns of e.g. systems, technologies, culture, language, habits, practices, etc. between countries that want to enable interoperable and compatible electronic exchange of data. To be efficient, the data transmission shall be successfully performed through all the layers of each national system from one user to another (end-to-end).

2.4 Scope of selected Trans-national services

Examples either close to a state of implementation or of high priority were selected to provide a focus to each of the domains as presented in the Table 2-1. Prioritization is made by relevance to the needs of mobile citizens or their suitability to being a test bed for interoperability.

<table>
<thead>
<tr>
<th>eHealth Domains</th>
<th>Priority Trans-national Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care</td>
<td>Trans-national Electronic Health Record</td>
</tr>
<tr>
<td></td>
<td>Transmission of free text patient information</td>
</tr>
<tr>
<td>Education</td>
<td>Web community groups for chronic patients</td>
</tr>
<tr>
<td></td>
<td>Networks of International centres of references for professionals</td>
</tr>
<tr>
<td></td>
<td>Web sites with reliable and easy-to-find Health Information</td>
</tr>
<tr>
<td>Surveillance</td>
<td>Early Warning Systems (comparable Public Health Data)</td>
</tr>
<tr>
<td>Administration</td>
<td>Reimbursement</td>
</tr>
</tbody>
</table>

Table 2-1  Domains of eHealth and priority trans-national services

2.4.1 eCare Provision

eCare is the largest and most recognized area of eHealth. eCare provision consists of the following applications of ICTs to health:
### Management Categories

<table>
<thead>
<tr>
<th>Professional consultation</th>
<th>Means, Tools and Services</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Purpose is to arrive at a diagnosis or an investigative procedure that will provide a diagnosis and prognosis. In some cases this might be followed by treatment;</td>
</tr>
<tr>
<td></td>
<td>Performance of specialist consultation and second opinion;</td>
</tr>
<tr>
<td></td>
<td>On-line professional health groups;</td>
</tr>
<tr>
<td></td>
<td>Patients communicating with health professionals;</td>
</tr>
<tr>
<td></td>
<td>Professionals consulting one another, either because of greater availability of expertise elsewhere or to make use of services either not available locally or less expensive or of greater quality elsewhere.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Assisted intervention</th>
<th>Means, Tools and Services</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Robotic assistance, simulation, etc.;</td>
</tr>
<tr>
<td></td>
<td>Remote monitoring of an intervention with advice (similar to consultation but in real time).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Monitoring</th>
<th>Means, Tools and Services</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Remote monitoring of biological activity;</td>
</tr>
<tr>
<td></td>
<td>Mobile/fixed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Information sharing/ access</th>
<th>Means, Tools and Services</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Personal health assessments;</td>
</tr>
<tr>
<td></td>
<td>Patients accessing personal healthcare information;</td>
</tr>
<tr>
<td></td>
<td>Information sharing between providers to support more efficient and better quality outcomes.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Citizen data and information management</th>
<th>Means, Tools and Services</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Electronic healthcare card;</td>
</tr>
<tr>
<td></td>
<td>Electronic healthcare record;</td>
</tr>
<tr>
<td></td>
<td>Partial data transmission required for a specific intervention;</td>
</tr>
<tr>
<td></td>
<td>The right information at the right time, to the right person.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Organizational management</th>
<th>Means, Tools and Services</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Information for the management of healthcare organizations.</td>
</tr>
</tbody>
</table>

### Electronic Health Records

Trans-national Electronic Health Records relates to:

- Provision of information to a health professional or to the citizen to enable better treatment or management of a specific condition;
- Provide reliable updating of the patient record with data related to the international intervention.
2.4.2 Education

<table>
<thead>
<tr>
<th>Management Categories</th>
<th>Means, Tools and Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional development</td>
<td>Professional development for remote health professionals; Continuous education for healthcare professionals; Access to current literature.</td>
</tr>
<tr>
<td>Prevention</td>
<td>Prevision of preventive health education and services for health enquiries.</td>
</tr>
<tr>
<td>Knowledge generation</td>
<td>Information collection and knowledge creation for research.</td>
</tr>
</tbody>
</table>

Table 2-3 ICT applications of eEducation

Web community Groups for chronic patients

Trans-national web community groups for chronic patients can be defined to include those web community groups, which are:

- For chronic patients having a particular condition;
- For those with education or solidarity as a focus;
- Trans-national in nature.

Web sites with reliable and easy-to-find Health Information

Trans-national web health information websites can be defined to include those which:

- Provide knowledge, information or educational information on specified conditions, diseases or treatments;
- Provide a second opinion for citizens / patients.\(^\text{47}\)

\(^{47}\) This ignores the problem of how to distinguish reliable information from “false, biased or unprofessional” information.
2.4.3 Administration

<table>
<thead>
<tr>
<th>Management Categories</th>
<th>Means, Tools and Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchasing/ billing of products and provider services</td>
<td>Patient and provider health product purchases (ex. Prescriptions, contact lenses/glasses); Coordination of health care financing &amp; reimbursement; Purchasing of trans-national services by a sovereign state for use inside its own borders; Contractual arrangements for treatment of a nation’s citizens in another state.</td>
</tr>
<tr>
<td>Aggregation and reporting</td>
<td>Aggregation and reporting of administrative data including quality, clinical outcomes, performance etc.</td>
</tr>
</tbody>
</table>

Table 2-4 eAdministraton

Trans-national reimbursement

Trans-national reimbursement is an example of eAdministrative issue. Trans-national reimbursement of healthcare services includes two distinct situations:

- The citizen receives health care services in a country other than that of their legal residence.
- The citizen receives health care services in their country of legal residence from a provider who is located in a country other than that of the citizen’s legal residence.

In case 1, reimbursement addresses the following:

- **Policy level**: trans-national agreements (e.g. bi-lateral agreements, EU directives) including who is eligible to receive services, what is covered, how much is paid for the service, quotas, etc.
- **Organizational and Social**: compatibility of description of services (e.g. ICD), language of communication, use of the E1XX (insurance cards and readers).
- **Technical level**: electronic exchange of data about the patient to the provider (eligibility) and about the healthcare service provided to the purchaser (insurance cards and readers).

In case 2, reimbursement addresses the following:

- **Policy level**: trans-national agreements (e.g. bi-lateral agreements, EU Directives) including who is eligible to provide services, what is covered, how much is paid for the service, quotas, etc.
- **Organizational & Social**: compatibility of description of services, language of communication
- **Technical level**: electronic exchange of data about the patient to the provider (eligibility) and about the healthcare service provided to the purchaser.
2.4.4 Surveillance

eSurveillance comprises of public health, epidemiology, research and investigation and emergency response.

<table>
<thead>
<tr>
<th>Management Categories</th>
<th>Means, Tools and Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health</td>
<td>Epidemiology and Prevalence trends; Prevalence, infectious disease control, disaster preparedness.</td>
</tr>
<tr>
<td>Research &amp; investigation</td>
<td>Electronic health information collection, analysis and reporting;</td>
</tr>
<tr>
<td>Emergency response</td>
<td>Natural Catastrophes, War, peace-keeping;</td>
</tr>
</tbody>
</table>

Table 2-5 eSurveillance

Early Warning Systems

Early warning systems demand rapid and thoughtful responses to be effective. In order for a European model of disease and threat progression to offer critical tools to develop strategic response plans, the following tools need to be put in place internationally:

- Ontological cross-reference between different disease surveillance systems to support concerted actions;
- A unified approach to disease monitoring and data collection;
- The creation of modelling systems parallel in function to weather forecasting systems.

2.5 General infrastructure of technical eHealth interoperability

Using advanced ICTs efficiently and effectively for health matters demands not only harmonization of policy and socio-organizational areas, but also the compatibility and interoperability of technical instruments to electronically record, store, transfer and share medical data.

The implementation of eHealth is closely linked to the efforts of bridging the digital divide and to foster equal citizens’ integration into the Information Society through the components of awareness, accessibility and affordability. Several levels of interoperability related to eHealth cover a range from security aspects, to semantic interoperability: security and confidentiality, architecture, data format, standardization, applications, and semantics.

2.5.1 A bridge for the digital divide

Access to healthcare and public health services is an important objective supported by using advanced digital tools and telecommunications. Though other innovations of the ‘e-area’ e.g. eGovernment and eCommerce already integrated ICTs for their purposes, the health sector is rather a latecomer to using ICTs.
Generally, technical eHealth solutions will only be used once stakeholders:

- are fully aware of the importance of integrating advanced ICTs in their daily work,
- have diversified access to an expanded and modern connectivity infrastructure,
- possess the means to obtain affordable services, equipment and training,
- and have sufficient trust in eHealth services and applications to meet levels for confidentiality, security, reliability and to deliver expected benefits.

Interoperability is assessed as a driver for bridging the gap. Rural and underserved areas, inter alia, can benefit from coordinated strategies for interoperable broad-data exchange, standards and common terminologies, and the development of eHealth ICTs. In doing so, the U.S. Departments of Veteran Affairs and Defence recommend e.g., to identify lessons learned of data sharing initiatives; to continue adopting standards with a view on affordable health ICTs development; to design eHealth technologies to serve rural and remote areas; and to foster the development of electronic patient health records. The TMA proposes recommendations in Chapter 7 aimed to facilitate a coordinated approach for implementing transnational interoperable eHealth in Europe.

2.5.2 Secured communications

Security is a prerogative to build trust and confidence in the Information Society and in the use of ICTs. Ensuring the security of information is both a challenge for users and suppliers. Lack of confidence in existing solutions has hindered implementation of Health informatics applications and the effective use of the Internet.

The eEurope 2005 Action Plan recommends action on security by introducing policies for improving networks and information systems, eAuthentication through smart cards, privacy directives, citizens’ rights, international trade, industrial policy, law enforcement, etc. Through the electronic signatures directive and the data protection legislation for electronic communication, the EU aims to reduce security and privacy concerns for a wide range of services and to ensure accurate operations.

The generic security constraints concentrate on the five dimensions of confidentiality, authentication, integrity, non-repudiation, and authorization. In order to create a secure basis for sending confidential medical data between heterogeneous systems across boarders, ICTs must cover certain requirements:

---

48 U.S. Departments of Veteran Affairs and Defense, 2004, pp. 21-22
Security areas | Interpretation
--- | ---
Confidentiality | Data is protected from unauthorized disclosure
Authentication | The identity of users and resources is verified.
Data integrity | Data is protected against unauthorized modification.
Non-repudiation | A party cannot subsequently deny a transaction by proof of ownership, data origin, etc.
Authorisation / access control | Users hold defined rights including the granting of access based on access rights.

Table 2-6 eHealth security

More specifically, eHealth must ensure physical and logical data protection while preserving the use of data from obsolete technologies with a safe way to migrate from analogue to numeric data. EHealth services and applications must also satisfy legal and ethical rules on privacy, data protection, copyrights, contents, etc. In case that a medical case turns into a legal issue, health professionals needs protection.

Since emphasizing on one aspect of security measures can often have a negative impact on other security aspects, the security measures for health information need special tailoring according to the needs of the health care environment. Thus, the involvement of the human being, and third parties such as transfer operators and storage operators, needs to be considered together with hardware and software matters when developing secure applications and providing customer-focused services:

Confidentiality can be obtained by digital signatures and asymmetric encryption such as Public Key Infrastructure (PKI). The challenge for standardization bodies is, however, to find a common denominator satisfying security and legal requirements at the same time.

Authentication is covered by asymmetric PKI, though there is no internationally recognized standard.

Integrity needs to ensure that neither data (text, image, video, voice) nor the medical report has been changed; both documents should be inseparable.

Non-repudiation is possible through e.g. ISO 7498-2 (network security) and ITU X.509 (PKI and Privilege Management Infrastructure to be used e.g. for ePrescription).

Authorisation can be achieved through e.g. X.805 since healthcare information systems need end-to-end security.

---

52 ITU, 2004d, pp.39-42
53 based on Mandil, S., 2001, pp.634 in Beolchi (ed.)
57 International Telecommunication Union (ITU), 2004d, pp.1-24
In addition to the above-mentioned attributes, healthcare information systems need to consider accuracy, validity, quality of medical data as well as the privacy of the individual. A more extensive description of the security infrastructure can be found in Annex-1 of this document.

**Architecture and standards**

Medical data transmission is diverse in nature and requires a framework of different information processing procedures. Data stored, transmitted, etc. covers text, video, image and voice, often requiring large bandwidth and appropriate interfaces. Examples for improving eHealth architecture through multimedia systems are ITU H.323, fibre optics and xDSL access systems, etc. Broadband wireless and/or fixed network infrastructure needs to be promoted. The different technologies such as copper, optics, satellite, mobile, WLAN, Blue tooth, etc. have to be considered in standardization procedures. Though there are already many, potentially competing, standards existing (see annex 3 provided by eHSCG), standardization bodies need to act fast in integrating user requirements and finding a common denominator in terms of ‘meta’ or ‘bridge’ standards for enabling their use across borders.

From a security legal and regulatory perspective, the technical aspects to protect individuals and the free movement of data are supported by the standardization bodies of CEN, CENELEC, IEEE, IEC, ISO, and ITU as well as supranational bodies such as EU, OECD, Council of Europe and UN. Some relevant documents are:

- OECD "Guidelines on the protection of privacy and trans-border flows of personal data";
- OECD "Guidelines for the security of information systems and networks: towards a culture of security";
- Council of Europe "Convention for the protection of individuals with regard to automatic processing of personal data" No. 108;
- EU Parliament and Council of Europe on the protection of individuals with regard to the processing of personal data and on the free movement of such data, Directive 95/46;
- OCHCR "Guidelines for the regulation of computerised personal data files", adopted by the United Nations General Assembly resolution 45/95 of 14 December 1990;
- Health Insurance Portability and Accountability Act (HIPAA).

---

58 ITU, 2003a, pp.12
59 Organisation for Economic Co-operation and Development (OECD), 1980, available: http://www.oecd.org/document/18/0,2340,en_2649_34337_1815186_1_1_1_1,00.html
60 OECD, 2002, pp.28
64 HIPAA is relevant for organizations dealing with other institutions in the U.S. U.S. Department of Health and Human Services, 1998, available: http://aspe.hhs.gov/admnimp/bannerps.htm#security
3 ECARE: TRANS-NATIONAL ELECTRONIC HEALTH RECORDS

3.1 Introduction

Although this chapter focuses on the electronic health record as a key element of eCare it is essential to list the most relevant types of clinically related eServices and information exchange services. The following cases of eCare services have been identified with a cross border aspect:

3.1.1 Information flow across borders

Some of the most important benefits of eCare consist in a rise in the quality of treatment and better utilisation of resources. At the same time, the new communication technology helps remove the barriers that geography can put in the way of patient treatment, i.e. ubiquitous treatment. The necessary specialist knowledge is available where it is needed – without the patient/general medical staff having to be moved to receive the best treatment. Some probable scenarios are described as follows:

- Travelling patients seeking care in another country and in that context, contact is required with the provider in the country of origin using eCare. Request messages for information could be:
  - Basic administrative set as from the EC eHealth Action Plan; 65
  - A minimum clinical data set which may contain diagnoses, allergies, other highly relevant facts;
  - A set of current medication;
  - Lab results;
  - Images from previous examinations;
  - ECG results;
  - EHR data structured for specific chronic conditions;
  - More or less complete EHR.

- Patients seeking elective care in another country:
  - Outpatient (free choice);
  - Hospital (pre-approval may be needed).

- Patients abroad seeking assistance through eCare directly with his home country provider (using telephone or Web). This may lead to actions from the home provider in various forms:
  - Advice;
  - Referral to a local provider (which may need electronically communicated health data with a service request message);
  - A prescription sent to a local pharmacy.

---

• Professional providers sending data or samples derived from a patient to a provider in another country for analysis (possibly including a diagnosis) and electronic reporting back.
• Real time consultations between professionals in different countries using video.
• Patients seeking information about health care providers and their services using “Yellow Pages” in the country where they are, or possibly in other countries before a possible visit for care purposes.

It is evident that less structured ways of communications between countries are already in use, and will be developed in the future, before the finalization of a common understanding of the Electronic Health Record, its architecture, purpose, ownership and location. For interoperability purposes, it is important to agree on some definitions and terms in order to establish the current regional/national platforms that will be able to handle transactions between local health record systems in the future.

3.1.2 The Electronic Health Record (EHR) and its definitions

The continuous life-long multidisciplinary comprehensive digitized health record has been the basis for many research initiatives. To date there is no large-scale implementation of an EHR featuring strong interoperability outside single organizations. The TMA-Bridge Description of Work states that medical record standardization is not achievable within the timeframe of one year. Nevertheless, the smooth communication of medical data/records leading to a kind of safe “medical mail” system is achievable and essential.

It is still necessary to agree on the meaning and scope of the EHR itself. There is as yet no single ISO definition of the EHR. A number of common definitions of the EHR from a variety of different organizations range from very succinct to quite lengthy and encompass a range of somewhat different scopes. This is not surprising since several of these definitions originally referred to the more or less variant names for the EHR including the EHCR (Electronic Health Care Record), EPR (Electronic Patient Record), CPR (Computerized Patient Record), and EMR (Electronic Medical Record). Whilst it is recognized that these terms are sometimes given different shades of meaning in different countries and different health sectors (e.g. the English NHS makes a distinction between the EHR and the EPR), it is intended that the requirements for standardization related to international transactions will generally apply to all of these variants.

The Electronic health record (EHR) is defined functionally as a repository of information regarding the health status of a subject of care in computer processable form, stored and transmitted securely, and accessible by authorized users. It has a commonly agreed logical information model which is independent of EHR systems. Its primary purpose is the support of continuing, efficient and quality integrated health care and it contains information, which is retrospective, concurrent, and prospective.

---

66 Yellow pages are also useful for professionals. They should be federated from national services into European including translation.
67 TMA, 2004c, p.18
69 ISO/TS 18308 ISO TC 215/SC /WG 1
70 ISO/TR 20514 Health informatics – EHR definition scope and context.
For the purpose of this report, the most important aspect from all the models, definitions, and scopes of the Electronic Health Records is their utility for international information exchange\(^{71}\): a pre-standard was published in 1992 by CEN\(^{72}\) and revised in 1997 on Healthcare Information System Architecture, which provides a middleware definition and lays the foundation for:

- Managing complex clinical care;
- Reducing errors and inequalities;
- Reducing duplication and delay;
- Connecting multiple locations of care delivery;
- Delivering evidence-based health care;
- Underpinning population health and research.

In addition, empowerment and involvement of citizens in their health agenda is required, and maybe to reduce healthcare costs.

This report follows the definitions of basic concepts for care process according to CEN TC 251\(^{73}\).

### 3.2 Policy Framework for eCare

#### 3.2.1 Challenges

The main challenges facing the implementation of EHR that are interoperable on a trans-European level are:

- Existing data protection, security and privacy legislation is not perceived adequate for electronic health information transfer;
- Political priorities: cost vs. benefit considerations for the citizen;
- Decision making process;
- Digital divide concerns.

**Data protection, security and privacy:** These concerns are perceived to be one of the highest priorities for eCare at a national level. This was confirmed by 54 experts in eHealth in the course of the Telemedicine Alliance project\(^{74}\).

Liability in connection with standards of care and medical malpractice, responsibility for security and confidentiality of patient-specific information are major legal challenges. Owing to the computerized communications involved in eCare, determining where transactions occurred, which laws apply and which courts have jurisdiction will be challenging.

---


\(^{72}\) CEN/TC 251 prENV 12967-1-1997

\(^{73}\) CEN/TC 251 prEN 13940 Health informatics Concepts to support continuity of care

\(^{74}\) TMA, 2004b, pp.1-93
Although most EU Member States have data protection laws, these laws differ greatly in scope. In order to standardize the rights of the citizen with respect to protection of personal data across the EU member states, in 1995 the EU issued Directive 95/46 with detailed guidelines for the implementation of national laws on data protection in all member states. This directive was later followed by other related directives and regulations, such as Directives 97/66/EC, 2002/58/EC, and EC Regulation No 45/2001.

This common legal basis throughout Europe makes possible the sharing of personal medical information, but does not guarantee it as it has not been implemented identically in each country. There remain a number of obstacles before this goal can be achieved.

**Political priorities:** Political priorities in health systems must always take into account the cost-benefit ratio of introducing new technologies. In the expert views gathered during TMA’s first phase there was no agreement on whether costs would increase or decrease in long term. However, there would be an initial capital investment on ICT infrastructure, there was consensus on the benefits in quality of care, patient empowerment and continuity. These benefits are difficult to assess and in the closely related area of EHRs the costs have been greater than anticipated and the evaluated benefits less.

**Decision making process:** A trans-national cooperation required to provide healthcare professionals with the appropriate quantity and quality of patient information to treat citizens when they are abroad has not been established. Citizens who move need coordination of information so that the right information required for their diagnosis and treatment is available to the right person at the right time. As stated in the EU eHealth action plan, “If interoperable, given patient mobility, electronic health records will also improve conditions for treatment in other European Union countries.”

The End-users are not organized at a European level. Only associations of health professionals like general practitioners, specialists and nurses are represented at a European scale. It is the concern of governments to promote decisions and incentives for involving the industry in the development of standards, and professionals for the mapping of terminologies.

**Digital divide:** There is a disparity in access to digital services between the nations of Europe and between the large towns and countryside. Today this may still affect some professionals and citizens in need of medical services, especially the elderly. However with a continued evolution the problem will diminish in Europe. This may impact the ability to access services and interchange data whilst staying in another country.

---

3.2.2 Requirements

The perception of current data protection, security and privacy legislation as appropriate for the protection of health information must be addressed. The Directive 95/46/EC for the protection of individuals with regard to the processing of personal data and on the free movement of such data\(^{80}\) is appropriate to ensure national EHRs are implemented in such a way that they can be securely accessed, read and updated in other European countries. Nevertheless, it is necessary that guidelines with regard to processing of health data be consistent across the EU\(^{81}\) and can and do differ significantly between the States and even regions. Liability concerns must also be addressed and the issues related to appropriate determination of jurisdiction clarified.

Political priorities for health systems in Europe are normally centered on quality, patient empowerment, and continuity of care; the appropriate technology assessment tools will need to be developed for eHealth to ensure that it meets these priorities. The EU Ministerial Declaration on eHealth of 2003 states that “the ministers recognized that efficient national planning and evaluation of health policy, as well as cost effective delivery of health care, require speedy, accurate and comprehensive exchange of data. Ministers noted that the accessibility to appropriate health information can be enhanced through the use of secure shared eHealth applications, such as those described in the objectives of the eEurope 2005 Action Plan, and agreed in the Council’s Resolution 2 of 18 February 2003 on the implementation of the eEurope 2005 Action Plan\(^{82}\).”

A high level group should identify the priorities for applications and services (but not for the technologies and standards), and then a selected group of experts (industry, SDOs and end-users) should develop the standards and guidelines.

A trans-national agreement on the minimum data set is required. In COM (2004) 301 follow-up to the high-level reflection process on patient mobility and healthcare developments in the European Union states that to ensure the legal infrastructure for the exchange of information should include:

- Authentication of the moving patient/citizen
- Entitlement of the service abroad
- Accreditation of the medical professional abroad
- Accreditation of the information sent: source, receiver, purpose, context, quality and format of the information, privacy.

It will be practically impossible to agree on a minimum data set standardized for all cases of trans-national care. Nevertheless, efforts from European projects have been able to create a reference data set in certain chronic diseases, e.g. diabetes.

\(^{80}\) Directive 95/46/EC. Unfortunately, this harmony is inconsistently applied in the area of healthcare, where subsidiarity allows national sovereign right to determine the most suitable form of healthcare system and the appropriate form for inclusion into national legal systems. The national or regional information or data protection commissioners or health ministries have issued slightly different guidelines. EU Parliament and Council, 1995

\(^{81}\) At present this is not the case since these guidelines remain the prerogative of Member States.

\(^{82}\) CEC, 2003, pp.1
It is suggested that a similar set for up to the most common conditions should be developed.

In a recent communication the EC called for action regarding the issue of interoperability of EHRs:

“By end 2006, Member States, in collaboration with the European Commission, should identify and outline interoperability standards for health data messages and electronic health records, taking into account best practices and relevant standardisation efforts.”

“Achieving a seamless exchange of health information across Europe requires common structures and ontologies of the information transferred between health information systems”

Distributed access to EHRs is now part of many national strategies. It is an item on the agenda of the Health Ministries including: England (NpfIT), France, Norway, Belgium, The Netherlands, Denmark, Spain (Andalusia), Italy, etc. The impact on the global market of the different approaches taken is not certain.

### 3.3 Social-Organisational Framework for eCare

#### 3.3.1 Challenges

At present interoperability in the EU has been achieved through bilateral, trilateral, or multilateral agreements, covering various limited domains of cross-border healthcare services. EHealth requires agreement on simpler, standards-based interfaces to avoid the large number of potential combinations and permutations of limited agreements.

The Member States of Europe have a large diversity of languages, medical semantics, and ontologies, plus a variety of healthcare systems, delivery of health services, and culture. The public, private and hybrid systems do not have an **agreement** on what treatment will be reimbursed. There are also differences in healthcare professional **qualifications** and referral **practices** and gate-keeper roles. All of this leads to the **confusion** of the citizen seeking treatment in another country and creates barriers for interoperability between the health-care systems in Europe.

Achieving interoperability will therefore require not only technical expertise, but also a considerable amount of human understanding to ensure trust and comprehension.

**European transfers: no plan for a procedure**

Trans-border reimbursement procedures are evolving towards the European Health Insurance Card, but in all other aspects of eHealth, including eCare, there are no standardized organisational procedures either for data exchange or professional accreditation.

#### 3.3.2 Requirements

Apart from the political decisions related to authorization, there is a need to organize a service for checking **accreditation of medical professionals** at a European Level or via federated national systems.

---

83 COM (2004) 301, CEC, 2004b, p.17
At a European level, in order to support ePrescriptions and transfer of medication lists across borders, there is a need for a pan-European database on all products marketed in the different countries. The European Medicines Evaluation Agency\textsuperscript{84}, whose main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use should be assigned the task to develop this central repository.

The main requirement on the organisational level is to ensure that the necessary information is available at the point of care in another country. There have been agreements and standards related to the minimum data set to carry via a health card, but this is not the only necessity when a citizen travels. A system to transfer the complete history of the patient in real time does not exist at present. An approach similar to the US Continuity of Care Record\textsuperscript{85} might provide guidelines for implementation.

The Continuity of Care Record, CCR\textsuperscript{86} is a standard specification that has been developed jointly by ASTM International, the Massachusetts Medical Society, the Health Information Management and Systems Society, the American Academy of Family Physicians, the American Academy of Paediatrics, and the American Medical Association. The CCR has been developed in response to the need to organize and make transportable a set of basic patient information consisting of the most relevant and timely facts about a patient’s condition. It is intended to foster and improve continuity of patient care, reduce medical errors, improve patients’ roles in managing their health, and assure at least a minimum standard of secure health information transportability. The idea is in place, but it is still too embryonic to be proven effective.

The needs for an empowered citizen in Europe with regard to the health record are:

- Reduction of errors;
- Mobility;
- Quality of service;
- Continuity of service (flow of information on both directions);
- Cost;
- Controlling the cost for citizens and health providers/governments, but
- Shortening clinically unacceptable waiting time (when other countries offer same but quicker services);
- Privacy;
- Respect to cultural differences.

The citizens are demanding the service of a personal record to be put in place\textsuperscript{87}: Regulation 1408/71 that co-ordinates social security legal schemes has recently been amended to streamline and modernize access to

\textsuperscript{84} EMEA, 2005, available: http://www.emea.eu.int/
\textsuperscript{85} Medical Records Institute, 2005, available: http://www.medrecinst.com/library.asp
\textsuperscript{87} See various European Court of Justice rulings such as Kohll C-158/96 (1998) ECR-1931 and Decker C-120/95 (1998) ECR-1831.
health care across borders, particularly when undue delays occur in the patient’s home Member State. In January 2004, the Commission adopted a proposal for a Directive on services in the internal market (COM(2004)2 final), which lays down a framework for the provision of services in the internal market, including health services, and for their reimbursement by the relevant health insurance institutions when healthcare is provided in another Member State. It should also be noted that, in March 2002, the Commission made a proposal on the recognition of professional qualifications which includes medical professions 88.

Taking the advantage of the re-structuring of the information systems for the adaptation to international reimbursement procedures for insurance and social security systems, exchange of medical information could be considered in the same process.

In order to ensure the citizen-perspective and to foster the market for European products, all the stakeholders involved in the organisation of the healthcare services, should be represented in the decision process to adapt the organisational framework of interoperability.

3.4 Technical Framework for eCare

3.4.1 Challenges

Twenty years of efforts in standardization of medical informatics have not ensured interoperability either between levels of care (primary to secondary or specialized care) or between regions and countries. This is mainly because those standards have not been implemented in the installed healthcare information systems. The situation for industry is changing, as the adoption of standards in commercial products is becoming necessary on a global scale. However, harmonization of de-facto standards and official standards is not always complete.

Interoperability is the main challenge for eCare technical implementation, including the problem of semantics in a multi-cultural context. The interpretation of the information collected in the health record is still far away from being processed automatically.

When sensitive information goes beyond the walls of a doctor’s practice the security risks to the data become less predictable. Even though security technology for eSociety services (eBanking, eGovernment, eEducation, etc.) is mature enough to fulfil legal requirements and earn the trust of the citizens, health information remains a sensitive issue.

For technical interoperability it is certainly not possible to ensure a unique standard for all the use cases. Not one standard will fit all the needs. However, technical solutions are easily exportable. Regional practical examples are good references when following standards and interoperability at a larger scale considering the adaptation of the other frameworks.

3.4.2 Requirements

Standards

At this stage, there are well-documented standardization requirements for health informatics. Tremendous efforts have already been put by CEN, ISO, OpenEHR and industrial groups into initiatives for structuring and modelling the generic architecture of EHRs. Despite these intellectual efforts, there is very little practical information available for commercial developers to ensure interoperability.

With the new generation of standards, any EHR system will have to ensure the compatibility with the CEN EHR communications standard, known as EHRCom, already integrating the inputs from HL7, ISO, OpenEHR and CEN (see Annex 2 - Standards and supporting initiatives related EHR for more details).

Structure and terminology

There is a need for an agreement on a simple structure and terminology. Some structured data can be blank in some countries, as long as all respect the structure, it would be interoperable.

There is currently no other terminology system to compete with SNOMED. However, as proposed by the CEN / ISSS eHealth Standardization Focus Group (EHSFG), the policy level should agree in a terminology in one year's time. The approach of taking advantage of what has already been developed and is already available will save precious time in this endeavour to agree on a common terminology. It is no sense to create a new terminology from scratch. The core SNOMED CT terminology should be used and then mapping is required and available already for some (ICD10, procedures, etc.). SNOMED CT is available in English, Spanish and German, and in progress in Danish. However, there is a concern about the language development for other regions. Moreover, used codes in Europe for concrete terminologies exist as follows:

- Lab results: IUPAC or LOINC;
- Drugs EMEA: European Medicines Evaluation Agency;
- Diagnosis: ICD10 in Europe. ICD9 in US.

With existing standards in use, automatic translators can secure interoperability in most cases. European Projects have proven that exchange is not a problem. Plenty of forms exist, but the reluctance of medical conservative community is becoming a hurdle for the extensive exploitation and evaluation of the technical solutions.

The promotion of use of natural language and the transparency of the technology to the final user are key for the gaining of acceptance and trust.

---

89 CEN/ISSS eHealth Standardisation Focus Group, 2005c, p.13
3.5 Initiatives and Solutions for eCare

After more than 10 years of EC IST research programmes investing resources in Health Records, some lessons have been learned:

- Ensure well thought-out strategy before commencing;
- Break the pattern of large-scale “all-at-once” implementations (start with smaller scale, but upgradeable and expandable implementations, with greater likelihood of success);
- Ensure commitment of the “leaders” (if leading stakeholders are not involved or committed, failure is likely);
- Keep it up... and do not just set it up (the importance of maintaining and sustaining);
- Ensure legal and ethical compliance (otherwise implementation will fail before it gets launched);
- Do not underestimate user acceptance (habits, culture, financial and training investment);
- None of the parties can do it alone! (need cooperation / collaboration between the stakeholders).

There are examples of national or regional implementations of Health records in concrete areas (general practitioners, specialties, and hospitals) that have been successful in the concrete domain, but cannot be easily extrapolated to a general EHR, and much less in the hands of the patient.

Though this is “taking more time than expected”, progress to a solution is being made, some examples of international collaboration should be mentioned.

3.5.1 National initiatives

The impact of the US CCR initiative, the English Npflt, the French plan for introducing the electronic medical record for the citizens and broadly advanced initiatives in new Member States should be closely monitored and the exchange of experiences should be established via a group of national experts, in order to maximize the cross-border interoperability between systems.

3.5.2 Baltic eHealth initiative

The experience gathered in standardized messaging (EDIFACT and XML) between health care professionals in the Nordic Countries (Norway, Sweden and Denmark) is consolidated to initiate extensive collaborative experiences across-border. The Northern Norwegian Health Network in Norway, Sjunet in Sweden, and MedCom in Denmark are reference implementations or regional and national health care networks in Europe, as well as the Andalusian Envisand, the Crete HYGEIA-net and the Finish implementation.

The aim of Baltic eHealth is to reduce rural migration and show that eHealth is an effective means to increase access to healthcare of high quality in rural areas. With the introduction of eHealth services, Baltic eHealth aims to provide more equal treatment in the Baltic Sea region by creating a large trans-

---

national infrastructure for eHealth, the Baltic Sea Healthcare Network\(^91\). The objective of Baltic eHealth is therefore to link already existing healthcare data networks in Denmark, Norway and Sweden plus two regional networks in Estonia and Lithuania, as shown in the Figure 3-1. Two pilot projects of ultrasound and radiology will demonstrate how it can help prevent rural migration. The interregional project began in September 2004 and will terminate in August 2007 and is coordinated by the Danish Centre for Health Telematics.

The project’s core strategic cooperation concept is the trans-national and cross-sector network in which 17 partners from seven nations take part. They include regional governments, offices and authorities, health insurance companies, regional development companies, universities, hospitals and clinics as well as others involved in the health service\(^92\). This network of partners guarantees improved regional development and better health care.

![Figure 3-1 Map of connexion between regions involved in the Baltic eHealth initiative\(^93\)](image)

### 3.5.3 Harmonisation and dissemination of standards

On the technical level, reference implementations of international messaging (previously based on EDIFACT and now based on XLM messaging) across secured networks are proof of concept of the real impact of standardized interfaces without attempting to unify the underlying Medical Historical Archives.

---

\(^91\) Baltic eHealth, 2004a. pp.1-3  
\(^93\) Baltic eHealth, 2004a. p.4
This is supported by harmonization of standards for EHR architectures and models\(^94\) and the coordination of the different initiatives in the publication of the EHRCom (CEN EN13606).

**The EHRcom TaskForce (prEN 13606)**

In December 2001 CEN TC/251 confirmed a new Task Force, known as “EHRcom”\(^95\), to review and revise the 1999 four-part pre-standard ENV 13606 relating to Electronic Healthcare Record Communications. The intention of this work is to propose a revision that could be adopted by CEN as a formal standard (EN) during 2004. The Enquiry Process in CEN has started in October 2004 (prEN13606).

The Task Force was out to base the revision of ENV 13606 on the practical experience that has been gained through commercial systems and demonstrator pilots in the communication of whole or part of patients’ EHRs, mainly in Europe and Australia.

The overall mission statement of the EHR communications standard proposed by the Task Force was to produce a rigorous and durable information architecture for representing the EHR, in order to support the interoperability of systems and components that need to interact with EHR services:

- as discrete systems or as middleware components;
- to access, transfer, add or modify health record entries;
- via electronic messages or distributed objects;
- preserving the original clinical meaning intended by the author;
- reflecting the confidentiality of that data as intended by the author and patient.

**IHE – Integrating Healthcare Enterprise**

The mission of the Integrating the Healthcare Enterprise (IHE) organization\(^96\) is to improve the interoperability among healthcare IT systems for the communication of these health records. IHE is a non-profit organization, started in 1998 and sponsored by professional bodies, representing the healthcare users, and healthcare industry. It provides real-world interoperability solutions based on existing healthcare standards, e.g. HL7, DICOM, CEN, etc., and IT standards such as OASIS and W3C. The professional organizations identify the interoperability priorities; the industry provides the technical framework. IHE follows a pragmatic process that delivers step-by-step solutions every 18 months, which is the period between the start of the development framework and its demonstration in products.

Another unique part of the IHE methodology, represented in figure 3-2, is its annual multi-vendor interoperability testing sessions for healthcare supplier products. These foster an industry-wide support of IHE integration profiles in products. Close to one hundred healthcare vendors worldwide have contributed

\(^{94}\) See TMA-Bridge Del.4, Annex-2: ‘Standards & Supporting Initiatives Related EHR’ for details.

\(^{95}\) OpenEHR, 2004, available: [http://www.openehr.org/standards/t_cen.htm](http://www.openehr.org/standards/t_cen.htm)

\(^{96}\) IHE-Europe, 2005, available: [www.ihe-europe.org](http://www.ihe-europe.org)
to, and demonstrate the delivery of, ready-to-integrate products to benefit healthcare enterprises, small and large. CIOs and clinicians appreciate its positive impact.

3.6 Expanding the models to Europe

The different initiatives are not often referenced as a model for eCare development in Europe. Findings and solutions of one national implementation could be transferred to other European regions and contribute to the modernization of trans-border health provision supported by ICTs. Although targeting regions, most applied solutions present interesting features for eHealth at European level since the European states and regions are facing similar social, political, and economic challenges today and in the future.

Within the framework of initiatives like “eHealth for Regions” such as the Baltic initiative, knowledge and best practice experiences should be exchanged, trans-regional strategies developed and new technologies tested and implemented. The findings and solutions could then be transferred to other European regions and contribute to the modernization of European health systems.

---

97 IHE-Europe, 2005, available: www.ihe-europe.org
4 EEDUCATION: WEB COMMUNITY SERVICES AND HEALTH INFORMATION ON THE INTERNET

4.1 Introduction

The growing pressure on healthcare systems to be more efficient and control costs together with the increasing “democratisation” of healthcare have raised the importance of a better-informed citizen and health care professionals, both striving to improve their knowledge and better manage certain conditions. The fast development of biomedical sciences strengthens the need of maintaining health care professionals updated.

The use of ICTs and the possible use of the web for education presents a unique opportunity. In supporting these desires eEducation allows interactive education and access to reference material at a distance.

eEducation aims at empowering, enabling and engaging citizens and health professionals to gather health related information from relevant web sites. We can consider two different situations when using the web as a platform for eEducation:

- free access to information by citizens and health care professionals;
- more structure and focus, addressing groups specifically.

Interactive eEducation allows for:

- health care professionals:
  - continuing education;
  - acquisition of professional credits\(^98\);
  - peer discussion groups;
  - discussion groups focusing on specific conditions open to citizens;
- citizens / patients
  - access to special certified groups;
  - establishment of citizens / patients groups with common problems.

Key issues

The key issues facing healthcare professionals are ensuring

- the reliability of the information and its provenance;
- protection of the users from malicious influence;
- consistency of advice given with national healthcare policies.

\(^98\) Web services for professionals have a key role – but very contentious and should not be directly addressed in this section of the report.
4.2 Policy framework for eEducation

4.2.1 Challenges

The legislation in many countries do not consider the use of the web as a recognized form of education. Moreover, the quality of the information provided worldwide is not controllable. Thus, Governments need to find a way in which, if they want to use the web as a mean for health care professionals or citizens/patients education, the certified information can be clearly identified.

4.2.2 Requirements

If eEducation is going to be formally recognized there are several requirements to be met:

- existing legislation on distance learning and medical education should be applied and, if distance learning education is not recognized, legislation may have to be development to make eEducation recognised as formal training;
- existing legislation on publication of health related knowledge or medical content should be applied;
- institutions which provide interactive eEducation or reference material should be certified or approved by national authorities;
- clear indication through certification or direct links as to which institutions are certified providers of eEducation or reliable reference material should be clearly marked. In some cases, this includes the incorporation of a national health seal that approved institutions can use on disseminated information. A trusted national health portal is one example of a secure information source for citizens and professionals alike.

The level of governance required for information is less than that required for personalized advice. To obtain advice a patient/citizen would have to submit personal data – and public web sites are not necessarily secure enough for that purpose.

Rather than fine detail in codes, it would be better to agree on high level principles, e.g. right of all EU citizens to access information anywhere in the European Union.

4.3 Social-Organisational framework for eEducation

4.3.1 Challenges

The use of eEducation as a tool for distance learning poses several challenges in the system.

Quality and certification of health information on the Internet

More and more consumers of healthcare demand quality evidence-based information as increasingly they wish to take an active role in decisions about their health care99. Online consumption of health

99 Quality healthcare information requires evidence-based background where existing. If no evidence is available, quality aspects skip to current accepted practices.
information is growing at an unprecedented rate\textsuperscript{100}, but there are not well established systems to allow the users to judge its quality. Access to good information is a right of the patient and a duty of the health professional or the health care institution. Thus, the challenge is to know what is “good quality” information. Two approaches have been suggested to answer this:

Provide a list of assessment criteria, with which the user will be able to distinguish from good to bad information, i.e. the web site provides understandable explanations of diagnosis\textsuperscript{101}, treatment and prognosis with alternatives and explanation of uncertainties and concerns such as likely potential co-morbidities;

Certify the data as being accurate, based on scientific evidence and up to date. This requires an internationally accepted approach to Internet site certification for health data.

Currently, there are some Governments that have established certified web sites that also provide pointers to reliable health information sites for the general public. However, there is no organized general approach for providing either professional or patient education, e.g. recognized patient groups such as the Asthma Association of Great Britain or France need to consider the introduction of such marks. Now, the approach is very parochial both by professional and health interest groups.

Generally, organizations and health associations provide education via public networks or approve and certify educational information or courses for the use by others. Many informative web sites are dealing with particular pathologies (web communities). These sites are, to some extend, self-certifying. There are few competent certifying bodies – Government or health institution ‘brands’ are possibly adequate.

There may be a need for Governments (regional/national or trans-national) to service web communities where the community is small (rare pathologies) or where sites deal with stigmatized conditions.

Training on how to distinguish ‘good’ from ‘bad’ sites could start at school, as children are learning how to use computers at early ages.

Costs

eEducation has the potential to significantly reduce the cost of the training of medical professionals and support citizens and patients information at a low cost. However, there are few approaches resulting in recognized marks. Approval and recognition mechanisms must be included into the education programmes of the professional bodies and the great potential of eEducation must be considered for continuing education and in the job training of professionals.

Similarly, better informed citizens can reduce medical costs by improving their life styles and their treatment by surfing on health related web sites and, consequently, applies the relevant recommendations. If the goal is to enable patients and citizens to be better informed, the quality of the information that the information is relevant and suitable for education and knowledge dissemination is needed.

\textsuperscript{100} DISCERN, available: http://www.discern.org.uk

\textsuperscript{101} Explanations are focused on the intended and identified target group for the web sites.
Interactive self help services can replace many visits to general practitioners and thus reduce the cost of health care. However, these services can also do a great deal of damage if the advice given is inaccurately.

**Adaptation to cultural and individual differences**

Education methods vary widely from country to country in content and in the tools and methodology used. These affect the way groups react to web services and Web Community Groups\(^{102}\). So web communities and education sites for citizens and health care professionals have to be tailored to both language and culture in order to be attractive, accepted and visited by citizens and professionals.

The information and/or advice shall be adapted to the different categories of citizens looking for some information: healthy ‘browsers’, newly diagnosed and chronic sufferers. They may have different expectations, especially about the information degree they are looking for. The level of provenance must increase as users move from healthy to chronic. Thus, there is a clear role for professionals or institutions to signpost to reputable sites.

Although globalisation and the wide use of the Internet are diminishing cultural and language differences, there are still wide barriers to overcome. Translation tools facilitate to a point the language barriers, but most people like to access information and education in their own languages; and the tool is not up to handle medical terminology. Even minorities differences are not necessarily addressed by national authorities making information available in minority languages. Access technologies should also help disabled persons to use the Internet since many adequate offerings are already available.

There remains the problem of cross border flows as nearly all the government and professional bodies are, by nature, single nationality and mainly interested in their own country. Nevertheless, citizens want to have access to the widest information possible. The web sites indicating a higher number of hits are the ones related to illness or new treatments. Patients and patients groups access those sites from all over the world. The “certification” of sites becomes of extremely importance when that sites deal with new drugs and treatments.

**Provision of access to public information**

Public health organizations and associations have to make public information available without restriction to everybody and conform to accessibility rules. They also have a responsibility to ensure that information is reliable and of known provenance.

To guarantee reliability, public health institutions responsible should also be members of schemes offering certification marks for the data provided.

**Cooperation between organization and associations**

Mechanisms for cooperation between international organizations, their respective Member States and non-governmental organizations will not only avoid uncoordinated and isolated actions, but will also increase the level of confidence and trust of citizens in the health information provided and will diminish

---

\(^{102}\) Useful examples are eCommunities on diabetics or cardio-vascular diseases sharing information and experiences.
the cost of developing and making the information available. Languages and recognition thus become the bigger barriers for cooperation.

4.3.2 Requirements

The requirements for eEducation are as follows:

- Quality and certification of health information on the Internet needs to be assessed through common assessment criteria to provide a basis for accuracy, reliability and up-to-date state of data, with the training already starting at school;
- Costs needs to be reduced through continuous accredited education and training of professionals to foster the use of interactive self help services;
- Web communities and education sites for citizens, patients and health care professionals have to be tailored to both language and culture in order to be attractive, accepted and visited by citizens and professionals, considering the needs of minority target groups such as disabled persons;
- Supra-national bodies, national Governments and non-governmental organizations should coordinate their actions to enhance the users' confidentiality in the information provided.

4.4 Technical Framework for eEducation

The rapidly increasing use of all aspects of the web is evidence enough for linking geographically dispersed information sources and information based tools, which provide a unifying platform for information sharing. Properly structured ICTs have a central role in educational processes, disseminating knowledge and information, in particular since the enlargement and the linking of EU regional networks can provide some synergies. New technology innovations and free Internet access are recognized as providing potential benefits to all.

4.4.1 Barriers for health eEducation services

Accessibility to information

Even though there is widespread Internet access in Europe, its availability and usage for all is not yet realized. Often, people with disabilities or living in remote locations have the least access to the Internet since there is no adequate ICT literacy or no sufficient ICT infrastructure provided. Though data is available on European Internet users, main telephone lines and mobile subscribers (Figure 4-4), comparative “…indicators on the percentage of health staff using computers and using the Internet would be useful…” This means that Governments need to take corrective actions in covering their jurisdictional surface with appropriate ICTs. eGovernment is the driving force behind providing greater

---

103 COM (2002) 263 final. CEC, 2002a, p.8
104 see annex-7, ITU, ICT indicators, 2003
105 ITU, 2003d, p.59
web access, and this extends to eHealth and eEducation: usability and accessibility are rights of patients and should be afforded top priority.

![Internet Users (p.100)](image)

**Figure 4-1  Internet users**

### Web community sites

Interest groups wishing to create web communities often do not have access to the skills needed to effectively create them, i.e. developing and using collaborative software needs active support in the early stages.

### Trust and security

As mentioned above, the trustworthiness and security of medical sites is one of the key issues. The risk of spreading non-accurate information and causing a worst-case scenario of damage of trust in the population is quite high. From the technical side, citizens are more likely to be attracted to secured web sites. It is of great concern to the European security infrastructure that the data supplied via public networks considers integrity, privacy and confidentiality of individual health information, even if shared in communities.

### Connections and software

Wherever terrestrial networks are available, optical fiber, dedicated telephone lines, and xDSL data transmission technologies come into effect. Wireless access to local networks is possible through microwave multipoint distribution system and satellite networks, but not all of Europe has been equipped significantly.

Developing web sites requires adequate software and design skills. Many relevant software to generate, operate and access web communities and eEducation sites is proprietary, i.e. it forces interested individuals either to buy the technology required or to search for open source software.

---

106 ITU, Europe and CIS ICT indicators, 2003 (see Interoperability Study Report, annex-7)
Yet some technology issues remain on linking data and the introduction of semantic web technologies, which offer only a partial solution to some of the problems.

### 4.4.2 Requirements of virtual health communities

Before the potential of eEducation can be realized, the following issues need to be resolved:

- Clarification of the new relationships between the Citizens/patients and the Professionals in electronic communities, from a national and European perspective;
- Identification of open or restricted access for specific target groups, when developing an on-line education programme, including knowledge management, targeted promotion of services, support/maintenance systems and security of data storage;
- When the web is used for personalised advise and education of patients, provision of moderation for Health Web Communities containing sensitive information;
- Collection of methods for measuring the satisfaction of users against their expectations and assessment criteria for the quality of service and ease-of-use for web-based systems (provision of tools for sharing documents, discussions, news, search function, etc.);
- Benchmarking of existing proven practices mechanisms to provide the eCitizen with trust, visibility, accessibility (portals, telecentres), limited bureaucracy, responsiveness, transparency, accountability, security (PKI etc.), updated information, neutrality, and accuracy of information by using the currently available technical infrastructure;
- Source of funding to cover technology provision, which needs to guarantee:
  - a satisfying responsiveness to user needs and user capabilities;
  - content structure and quality;
  - scalability;
  - compatibility between hardware and software solutions allowing to use the existing bandwidth and computing capacity available to users;
  - adequate middleware services using meta-level protocols for controlling the structure of the web community;
  - compliance tests to ensure that the functionality of the system is ensured if new technology is implemented.

### 4.5 Initiatives and solutions for eEducation

Initiatives to increase interoperability for the use of ICTs for eEducation mainly focus on social-organizational and technical solutions as detailed below. National Health Authorities are encouraged to show political commitment for the development through web publishers and the use of ICTs in education of citizens and professionals for health as a way to support quality of health care and diminish cost by reaching a higher number of citizens and health care professionals.

The current different national initiatives provide evidence for the benefits of eEducation through time saving research for health related information, trust building and team work within a community,
networking across borders, efficient ways to communicate with a large audience, increase of the image of information providers as well as increased transparency of services.

4.5.1 Health on the Net initiative

The Health on the Net Foundation focuses on patients and individuals, medical professions, and web publishers\(^\text{107}\). This non-governmental organization created the Code of Conduct (HONcode) to help standardize the reliability and credibility of medical and health information available on the World-Wide Web. The HONcode defines a set of rules to:

- hold Web site developers to basic ethical standards in the presentation of information;
- help make sure readers always know the source and the purpose of the data they are reading.

It is not an award system, nor does it intend to rate the quality of the information provided by a Web site. HON is recognized by the EU as a reliable health information provider due to its accredited information.

4.5.2 Personalized Information Platform for life and health Services (PIPS)

The PIPS project is part of the 6\(^\text{th}\) Framework Programme of the EC with the aim to generate valuable information -in-time, for citizens, authorities, healthcare professionals and providers through the latest ICTs\(^\text{108}\). The concept is to foster a two-sense knowledge exchange between actors, based on personalized services of preventive and predictive medicine, assuring the global sustainability of the system.

4.5.3 MedCIRCLE

MedCIRCLE is a collaboration of trusted European health subject gateways, medical associations, accreditation, certification, or rating services with the common goal to describe, explain or evaluate websites for Internet rating, certification, labeling and evaluation of health information\(^\text{109}\). For carrying out their assessments, members use a free of charge standardized vocabulary/metadata language based on PICS/RDF/XML. A prototype toolbar, programmed as Visual C++ and ActiveX DLL, offers browser helper application, reputation management, feedback for users, collaborative filtering, etc. Publishers using this tool need programming experience in COM/COM+/OLE, Win32 API, and Java/Servlet to produce standardized websites and access to subject gateways.

4.5.4 Internet Healthcare Coalition

Since 1997, the Internet Healthcare Coalition has been working to provide clear guidance for evaluating online sources (more than 20,000 Web sites dedicated to nearly every conceivable health subject) of health information - from product- or disease-related sites developed by regulated manufacturers, to peer-

---


reviewed electronic publications, to patient support and discussion groups. The coalition's goal is to
develop well-informed Internet healthcare consumers, professionals, educators, marketers and media\textsuperscript{110}.

4.5.5 DISCERN project

The aim of the British DISCERN project was to develop an instrument to enable consumers and
information providers to judge the quality of written consumer health information on treatment choices. DISCERN was also developed as a set of quality guidelines for authors.

The DISCERN instrument consists of 15 questions plus an overall quality rating. Each of the questions represents a separate quality criterion and is accompanied by hints to guide the user. The overall quality rating at the end of the instrument is an intuitive summary of answers to all the questions, and can be used to select and reject information or to highlight its weaknesses. DISCERN is also a potentially useful tool for the Internet. A new project to develop an online version of DISCERN has the objective to ensure that DISCERN is appropriate and accessible to all users and providers of online consumer health information on treatment choices\textsuperscript{111}.

4.5.6 NHS Direct Online and NeLH

In the UK, the National Health Service provides, inter alia, NHS Direct Online, a citizen-centred on-line health information websites offering healthcare advice, directory and medical dictionary services, with access to a 24/7 nurse help line. Both services are widely accepted, with 500,000 visitors in January 2003\textsuperscript{112}, and calls to NHS Direct record monthly rates of around 97 per cent\textsuperscript{113}. In order to support communications between NHS Direct Online and specialist libraries, the NeLH plans for the eCommunity to develop an additional 'room' open to patients\textsuperscript{114}.

4.5.7 Vårdguiden

The Stockholm county deploys a health information portal in the Swedish language only. The gateway offers information about healthcare services, helpdesk, etc. Patients and public health personnel have log in passwords to ensure confidentiality of further questions\textsuperscript{115}. In 2002, 55,000 users per month access the website, which already resulted in corresponding time-savings of EUR 1.25 million per year\textsuperscript{116}.

4.5.8 Sundhed and MedCom

The infrastructure of the Danish national Health Portal connects public health authorities, professionals and citizens. Particularly, citizens are encouraged to gather reliable advice on health medical treatment

\begin{footnotes}
\item\textsuperscript{110} Internet Healthcare Coalition, 2003, available: http://www.ihealthcoalition.org/index.html
\item\textsuperscript{111} DISCERN, available: http://www.discern.org.uk
\item\textsuperscript{112} Silber, D., 2003, p. 6
\item\textsuperscript{113} Politics, 2005, available: http://www.politics.co.uk/issues/nhs-direct-$2413582.htm
\item\textsuperscript{114} NHS, 2004, available: http://libraries.nelh.nhs.uk/cardiovascular/library/NeLH_SL_Handbookv1.1.doc#NHSDO
\item\textsuperscript{115} Vårdguiden, 2005, available: http://www.vardguiden.se/
\item\textsuperscript{116} Silber, D., 2003, p. 6
\end{footnotes}
and disease prevention. The gateway is strongly linked to MedCom, the national healthcare data and information network in Denmark. XML communication via VPN ensures secure data transmission; open standard for EDI-mail ensures compatibility and interoperability between IP-based networks and old VANS networks.

4.5.9 GEANT and GRIDs

To establish a high-capacity and high-speed communications network for all researchers in Europe (GÉANT) and specific high performance Grids and test-beds (GRIDs).

The GÉANT project is a collaboration between 26 National Research and Education Networks representing 30 countries across Europe, the European Commission, and DANTE. Its principal purpose has been to develop the GÉANT network - a multi-gigabit pan-European data communications network, reserved specifically for research and education use. The project also covers a number of other activities relating to research networking. These include network testing, development of new technologies and support for some research projects with specific networking requirements.

4.5.10 Doctors working in prison: human rights and ethical dilemmas

The World Medical Association has established a first course for doctors practicing in prisons. The Internet course presents relevant topics in ethics and human rights that are important to doctors and other health personnel working in prisons. The course is free of charge; users can enter and get an overview as unregistered users or they can register to obtain a diploma at the end.

4.5.11 Specific web communities

More than 20,000 health related web sites present diversified information such as issues on cancer, cardio-vascular diseases, diabetes, influenza, etc. Web communities can also include research initiatives such as T1Dbase, a public website and database that supports a specific diabetes research community. Otherwise, eCommunity sites have chatting possibilities, library links, web portal, eCommunity links, etc. or can be as simple as emailing about a disease triggered by a tummy tuck.

4.5.12 Dynamics in Wiki’s: Access for all?!

A special example for dynamical web community groups of another kind represent so called wikis. A wiki is a simple online database, based on a server software with which any user easily can edit web pages through any web browser. The ease of use facilitates eCommunities, through which anybody can exchange ideas. Since the access is free and open, data once written on the Internet is not confidential at

---

120 Smink, L et al., 2005, available: http://nar.oupjournals.org/cgi/content/full/33/suppl_1/D544
121 Web Communities Serve as Early Warning for Disease Outbreaks. Weblogs, 2005, available: http://telemedicine.weblogsinc.com/entry/1234000880023268/
all and so is the contents. Wikis, though a good tool for individual exchange of special interest groups, do not have accredited or certified information on their websites. On the contrary, the information can even be erroneous.

4.5.13 Standards and semantics

Since health information on the Internet is such a wide field, standards are crucial to ensure interoperability and compatibility between the different systems. Here, providers need to consider the capabilities of ICT access and literacy since the availability of the contents in an appropriate language provided has tremendous impact on the diffusion of Internet services.
5 ESURVEILLANCE: EARLY WARNING SYSTEMS

5.1 Introduction

In the context of disease outbreaks or bio-terrorism attacks, early warning systems may help to gather intelligence and detect or even predict diseases early, and communicate and exchange information electronically worldwide. If some measures are already nationally implemented, one of the main challenges interoperability is to allow quick cross-border reactions and risk countermeasures.

Fundamental elements of e-Surveillance include\textsuperscript{122}:

- Public health by the reporting of notifiable infectious diseases;
- Rapid epidemiological analysis of electronic data collected on the field or retrieved from various sources, including health, clinical, socio-economic information as well as environmental and weather data, etc.;
- Electronic statistical analysis of these data and reporting through meta-databases;
- Modelling of anticipated impacts of disease incidence;
- Management of health consequences of natural and man-made disasters and wars;

These systems serve the following important functions:

- Alerting rapidly people locally thanks to pre-defined thresholds, to prevent as quickly as possible the spread of the disease locally;
- Alerting governments and international organisations to a healthcare risk so that they can take action first at the national level and then as necessary in order to coordinate actions across more than one country;
- Identifying the prevalence of defined diseases as part of the understanding of their impact and transmission factors;
- Identifying threats to a population so that advice can be given and action taken by governments and responsible authorities. Good examples are the Influenza, SRAS, small pox, etc.

Early warning systems demand rapid and thoughtful responses to be effective. The greater completeness of information and the speed that can be provided by electronic systems with the ability to model disease/threat progression offer critical tools to develop strategic response plans. Their full potential cannot be reached until the following circumstances are put in place:

- Political commitment;
- Ontological cross-reference between different disease surveillance systems;

\textsuperscript{122} Telemedicine Alliance, 2004a, p.10.
• A unified approach to disease monitoring and data collection;
• The creation of modelling systems parallel in function to weather forecasting systems;
• Appropriate capacity building through training for data researchers, analysts, data providers, etc..

Finally, all these systems should be highly interoperable, helping to:

• improve the quality of the data by importing data from meta-databases, namely benefiting largely from health mappings;
• increase the speed of information sharing, in particular through export of information into other information systems; and thus to improve predictability, prevention, control, and treatment;
• improve predictability, prevention, control and treatment;
• use the data to train specialists, e.g. on epidemiological investigation and intervention;
• correlate the data with data collected in other parts of the world.

In order to fulfil such requirements, various ICTs such as satellite telecommunications to transmit data or monitoring satellite for tele-epidemiology tools are necessary to build efficient eSurveillance systems interrelated with each other and targeting these objectives.

5.2 Policy Framework for eSurveillance

At the beginning of the 21st century, the world is still confronted with the emergence of new or newly recognized pathogens (e.g., Nipah, Ebola, Marburg); the recurrence of well-characterized outbreak-prone diseases (e.g., cholera, dengue, influenza, measles, meningitis, shigellosis, yellow fever); and the accidental or deliberate release of biological agents (e.g., BSE, nvCJD, anthrax).

Whereas longstanding, traditional approaches to contain outbreaks were defensive (“brick wall”), trying to secure borders from the entry of emerging infectious diseases, innovative approaches have been established consisting of early warning surveillance systems, epidemic preparedness plans, stockpiles of essential materials and communication and information sharing through networks, providing information for action.

5.2.1 Challenges

The challenges posed by epidemic-prone infectious diseases are:

• how to contain the international spread of outbreaks,
• how to assist countries at risk from being overwhelmed by outbreaks;
• how to coordinate and focus global resources as no one institution has all the capacity.

The main challenges facing early warning systems are:

• Spread of diseases due to higher individual mobility (most traditional methods of containment are no longer applicable);
• Lack of collaboration between Member States in exchanging basic disease data;
• Disjointed communication, information and knowledge transfer at all levels - local, regional, national, international;
• Lack of national preparedness plans, very important to educate the public avoiding panics to quickly and efficiently react to the threat;
• Lack of pool of experts to travel rapidly;
• Communicable diseases continuously evolve over time and are resources intensive. For surveillance systems to be efficient, they need to develop at the same speed or even faster than the diseases;
• The need for continuous evolution of warning systems and response plans to ensure defences evolve and adapt with diseases (Flu and bio-terrorism);
• Lack of means in terms of personnel, equipment or education for verification of outbreaks and for confirming the initial report of outbreak information;
• Lack of resources to minimize the negative consequences of reporting outbreaks;
• Need to educate the medias regarding for example communications guidelines on timely press releases in the case of outbreaks;
• Lack of sufficient incorporation of the non-governmental sector (e.g. academia) plays a pivotal role in some countries for the identification of epidemics of international importance;
• Means to control inappropriate responses by members of the international community to national events, which have been blown out of proportion by domestic politics and media. A few cases of an unusual disease in a developed country can overshadow the occurrence of large numbers of cases in endemic areas. Often, the magnitude of the response to an unusual disease far exceeds the reaction to ongoing occurrences of the same illness in endemic areas, e.g. fear of SARS as opposed to the media coverage regarding the common flu.

5.2.2 Requirements

Since communicable diseases and biological attacks do not stop at jurisdictional borders, consensus on a national and international scale is crucial to foster interoperability endeavours in eSurveillance, such as:

• European and national surveillance systems, networks and response plans;
• Revised International Health Regulations to prevent, protect against, control, and provide public health responses to the international spread of disease;
• European and international institutions to increase the level of education for public health professionals, epidemiologists, physicians, veterinaries, pharmacists, etc.

A roadmap on the mobility of citizens in Europe without administrative barriers is currently being set up by the EU Council. The ministers of EU Member States have already properly apprehended this issue and the roadmap is to be released.
Finally, commitment of both the political and technical actors at the European level seems mandatory to define a general framework of action:

- Political commitment with official representatives of the Member States taking the appropriate decisions, and strong political backing-up from the European parliament. Due to of the strong competitiveness in this area, actions should be taken now. Member States should also inform their regional planners;
- Technical commitment from the industry, where sufficient and significant proven market is a prerequisite. Support from the industry is still lacking, and makes the actual discussion on interoperability an academic and useless exercise.

Timescale is critical because the related market is highly competitive; by not acting quickly, one takes the risk of losing the advantage for the European industry.

5.3 Social-Organisational Framework for eSurveillance

5.3.1 Challenges

Communicable diseases such as tuberculosis, measles and influenza represent serious risks to human health, contributing to about one third of all deaths occurring globally. They do not respect national frontiers and can spread rapidly if actions are not taken to combat them. New diseases such as HIV/AIDS and avian flues emerge and many others develop drug-resistant forms.

Pan-epidemics such as the ‘Spanish flu’ killed over 40 million people in 1918-1919. Today, the most attention has been allocated to human infection by avian influenza viruses\(^\text{123}\) and severe acute respiratory syndrome (SARS)\(^\text{124}\): These diseases are opportunistic to increased migration and global traveling for mutation and rapidly spreading pan- and epidemics.

The challenges for early warning and surveillance systems are to gather appropriate data through thorough investigation, data aggregated via standardized protocols into databases, and quick dissemination of information. This is key within and outside of national borders without being hindered by bureaucratic barriers. The coherent flow of information between local, regional, national, and international data collection facilities allows to improve the monitoring and coordinating of health systems across Europe. Thus, comparable and rapidly disseminated public health data support overcoming organizational issues between countries.

Referring to cultural differences and access to information at a social level, institutions disseminating information based on early warning systems face the fear or even mass hysteria of citizens towards communicable diseases with high mortality rates. During the SARS epidemic, ICTs supported early detection and internationally rapid information exchange. Some of the technologies brought forward


\(^{124}\) “…More than 8,000 persons with probable SARS have been diagnosed; 812 patients have died…”. Kamps, B. & C. Hoffmann (ed.), 2003, available: http://www.sarsreference.com/sarsreference.pdf
during the SARS epidemic may have been more directed towards reassuring people that "something is being done," i.e., fighting an "epidemic of fear." To understand "fear epidemiology" is important because early warning systems monitoring data from a large number of people “…may not be able to discriminate between a true biological epidemic and an epidemic of fear…”\textsuperscript{125}. Critical evaluation of early warning systems thus should integrate the lessons learned from past experiences. Moreover, this need is reinforced by the confusion for the amount and complexity of actors involved by this epidemic. Such diseases generate also profound economic impact, affecting tourism, education and employment, through the victims of the epidemic such as tourists, pupils or workers. Due to missed and cancelled business opportunities in the field of health care, tourism, trade, etc. as a consequence of SARS, Toronto experienced considerable economic loss: early warning systems should have the ability to limit economic issues generated by disasters. Last, but not least, the level of risk to consider can vary depending on the situation. There seems to be an obvious level already catered for by WHO which is the ‘international communicable dangerous diseases level’ such as for SARS, HIV/AIDS. But there are also lower level conditions such as flu, and other communicable diseases that can affect people on a daily base and more frequently than other major disasters. Therefore, in order to face such challenges with the final objective to help controlling, slowing down or even stopping spread of diseases or any threat for the health or well-being of citizens, early warning and surveillance systems have to reach various requirements.

5.3.2 Requirements for eSurveillance

At social and organizational level, early warning systems shall fulfil some basic requirements. Among its requirements, e-Surveillance\textsuperscript{126} should especially:

- monitor and coordinate health system, increasing therefore the potential eHealth to facilitate the mobility of European citizens across the world;
- improve information systems for decision making and early response in emergency situations, increasing therefore the potential of eHealth to generate a significant impact on health system stewardship.

According to the international strategy for disaster reduction established by the United Nations, “a complete and effective early warning system comprises a chain of four elements, spanning a knowledge of the risks faced through to preparedness to act on early warning. Failure in any one part can mean failure of the whole system”\textsuperscript{127}.

\textsuperscript{125} Eysenbach, G., 2003, available: http://www.jmir.org/2003/2/e14/
\textsuperscript{126} Dario, C. et al, 2004
Elements 1, 3 and 4 can be influenced at social and organizational level:

- **Prior knowledge of the risks faced by communities**: organizations shall be aware of the potential risks of diseases able to spread and move across a country in order to anticipate reactions and develop countermeasures. For instance, organizations could try to use currently available technical solutions like databases to increase the knowledge about such diseases.

- **Dissemination of understandable warnings to those at risk**: managing and disseminating information among the health professionals and to the citizens is a crucial aspect, but the information shall be useful, understandable by and distributed to everybody (no information discrimination). This implies several systems: for instance the Internet, although widely available, is not accessible by all in Europe. The data must also be reliable and updated as often as possible.

- Organizations should also guarantee the **social impact of the delivered warnings**: they have to be sure that the content of the messages they want to transmit can be correctly delivered to the citizens: for instance, the information should be clear enough to be understood by a majority, but should avoid the introduction of fear, which could generate panic movements. Thus this implies a management of information at organizational level.

- **Knowledge and preparedness to act**: Such a management of information should also allow a better coordination of health related actions. Efficiency for early warning systems implies the set-up of defined and agreed procedures for organizations involved in eHealth in place to allow quick response. These procedures should integrate different mechanisms of hazards detection and dissemination of the alarms across country borders (worldwide and not only European countries). Periodic testing and reviewing of data as well as the identification of lessons learned from previous outbreaks should be stored in accessible databases for effective knowledge management. Therefore, all these requirements for early warning and monitoring systems require a level of political support, laws and regulations and institutional responsibility.

---

The implementation needs national policies to develop and encourage the use of early warning systems across borders. Specific responsibilities throughout the chain need to be agreed and implemented together with the necessary manuals, procedures and tested operational procedures.

5.4 Technical Framework for eSurveillance

5.4.1 Technical challenges for health related early warning systems

Early warning systems are critical to protect the global village and to foster sustainable health prevention and development regarding the needs of local communities. Combating the human vulnerability to diseases and disasters is the objective of using ICT in eSurveillance systems.

Every event of public health risk requires a different response and a decision on a political basis. This also includes the collection, analysis and dissemination of data on a sub national, national, European and global scale. Even if real-time surveillance systems exist in countries, it is not taken for granted that the information will be distributed immediately, or at all, to others due to political or economic reasons.

Epidemiological analysts face, furthermore, barriers of appropriate data collection from countries that do not possess suitable collection methods including, e.g. health mapping tools. Accurate and reliable data are not permanently available from public health institutions and governments to reflect the status quo of the situation in urban, rural and remote regions, so that adequate data gathering to cover situational change is not ensured. This also refers to applying the appropriate technology to collect data of known and yet unknown diseases.

Human and animal epidemics are closely tied to environmental factors. The spread of contagious diseases such as cholera, malaria, etc. is often due to local or global ecological changes, population mobility, housing surroundings, etc. Techniques such as tele-epidemiology to gather data on epidemics from various environmental sources exist, but are mostly used in developing countries. Furthermore, eSurveillance stakeholders, i.e. civil protection experts, clinicians, epidemiologists, microbiologists, public health institutions and health-oriented citizens, are not satisfactorily aware of the existing eSurveillance tools such as the potentiality of satellite monitoring to obtain and use precise data.

The recent human tragedies triggered by earthquakes, floods and tsunamis affect peoples worldwide. Communication links are often disrupted and relief workers do not get access to data about the number of injuries or deaths, about their location and about the medical aid necessary. Even in emergency situations, trans-border use of telecommunication equipment and knowledgeable human resources is often impeded by regulatory barriers such as resources being delayed in importing and deploying telecommunication equipment without prior consent of local authorities. Until now, there are no sufficient

---

130 Del Mar Lleo, M., 2004
global regulatory frameworks to address disaster reduction features under the licensing management of operators\textsuperscript{137}.

From a specific technical perspective, there is the challenge to overcome security issues that result in a lack of confidence from the user side. This can be tackled through the use of PKI and technologies that address pertinent issues related to authentication, integrity, non-repudiation, and authorization as discussed in Chapter 2.5. Though the data sent is not related to individual personalized confidential data, but rather to aggregated information, they are nevertheless prone to criminal attacks if not guaranteed appropriately through dedicated networks. To effectively use the existent infrastructure for eSurveillance is another issue. Though access to broadband is available in most parts of Europe, not everybody can benefit from it. The example of France shows that the country still has 15\% of public hospitals without broadband internet connectivity\textsuperscript{132}.

- Finally, the main technical barriers\textsuperscript{133} identified are:
  - Lack of data and lack of access to data (data on paper, data on “private” archives, etc.);
  - Lack of communication infrastructures, standardisation, and networks coordination;
  - Lack of biological models and climate models able to accurately project changes in disease transmission patterns and in extreme meteorological events;
  - Lack of an integrative and multidisciplinary approach;
  - Technology is unfamiliar and unproven in an operational environment.

5.4.2 Requirements for technical interoperability of early warning systems

In order to properly use eSurveillance, it is critical that up-to-date, reliable, accurate data is available for data analysis. Early warning systems can foster existing disease prevention and disaster control systems to identify rescue areas in arising health events and emergencies. The political commitment from either side of the border and across regions to exchange data is important for preventing the spread of infectious diseases. It is thus crucial that governments, local institutions, scientists, technicians, educators, public health professionals, citizens and travellers have access to eSurveillance data collecting bodies.

Centres of networks should thus include public health, defence, food agencies, veterinarian health, and communication competencies. Consequently, immediate reports on disease outbreaks should trigger timely response strategies\textsuperscript{134}.

The observations within early warning systems require the implementation of an environmental database mapping the risks arising from air-, vector- and water-borne diseases as well as extreme meteorological events. Effective and accurate information flow is ensured if the parties concerned have a common understanding of ontology and terminology. The data exchanged between governments, network centres,

\textsuperscript{131} ITU, 2005c, p.5
\textsuperscript{133} Del Mar Lleo, M., 2004
\textsuperscript{134} United Nations- IDNDR Secretariat, 1997, pp.2-5
emergency room physicians, etc. should reflect the current national and regional situation and requires a certain set of standards. Any change observed of the situation should be rapidly disseminated to the appropriate experts and institutions concerned. However, some experts emphasize to make the information available for anyone anywhere at any time\textsuperscript{135}. The latter option would, consequently, involve the \textit{adequate education of the media} concerning the contents of messages to the general public.

<table>
<thead>
<tr>
<th>The message to the public should also contain guidelines for behaviour.</th>
</tr>
</thead>
<tbody>
<tr>
<td>For performing surveillance systems being in place and people being aware of the appropriate use of technology, early warning systems require \textit{integrative data systems} detecting changing trends and subsequently the rapid transmission of the alert signal to adequate stakeholders. Such systems need e.g. tele-epidemiology and sentinel networks, which analyse environmental factors in relation to human and animal epidemics. The Department of Veterans Affairs covers this issue with “…the need for surveillance systems to be sensitive enough to address small number issues and broad enough to track emerging infections…”\textsuperscript{136}.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Besides recognizing the importance of monitoring the environment through high technology, e.g. satellites, the alerts are closely related to the information diffusion through timely radio and television broadcasting as well as through printing media.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disseminating information that emphasizes the vulnerability of mankind through media always affects the political and economical scene. Since existing national \textit{regulations} dealing with the import and use of telecommunication resources trans-nationally are not automatically waived in emergencies and disasters, regulators need to push operators to include specific disaster conditions in their \textit{licensing} procedures\textsuperscript{137}. Both in case of ‘regular’ environmental changes and of \textit{disasters, security} issues need to be addressed. Adequate data protection and confidentiality of information transmitting participants should include secure socket layer (SSL) technology, verification of access rights and redundant back-up of data.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>The maximum technically feasible should be made to ensure data protection. The question of data privacy should then be under the citizens’ responsibility: once aware of the risks the citizens should have the opportunity to decide about the risks they are ready to accept.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key technical features need to include real-time \textit{ICTs} with flexible, ease-of-use, multilingual user interfaces, indicator search, immediate access to, alert of and analysis tools of most recent data, multicasting and integration with other applications. Generally, high traffic data transmission demands high mobility, robustness of communications systems in both permanent monitoring and emergencies, with an even faster deployment for temporary events. Less sophisticated warning systems of ‘regular’ citizens include access to basic voice, fax and internet connectivity\textsuperscript{138}.</td>
</tr>
</tbody>
</table>

\textsuperscript{135} Del Mar Lleo, M., 2004
\textsuperscript{136} United States of America – Department of Veterans Affairs, 2004, p.6
\textsuperscript{137} ITU, 2005c, p.5
\textsuperscript{138} During the Tsunami of December 2004, the population of a whole Indian coast village was rescued through a simple telephone call from the East.
Not only for urban, but also for underserved areas the use of broadband should be a common tool.

With reference to the above mentioned technical barriers, modes of communications should contain terrestrial telecommunications, broadcast television and radio, videoconferencing, video and other data via networks, voice, and satellites. Authorized emergency communications should include priority treatment of signalling through networks such as Next Generation Networks based on IP. A priori, all existing communications tools should be appropriately used in case of emergency.

Applications should not only concentrate on diagnosis-based systems, which often have delays in information dissemination, but include web-based syndrome surveillance systems as part of emergency room management software.

5.5 Initiatives and tools for eSurveillance

An extensive description on initiatives and tools for eSurveillance is given in Annex 5. It covers the political back-up in the European Union related to surveillance, early warning and bio-terrorism. The European Centre for Disease Prevention and Control plays an important role in pushing European surveillance.

The global co-operation via networks on communicable diseases relates to international health regulations, global outbreak alert and response network, global public health intelligence network, centers for disease prevention and control, and free database access of WHO collaboration centers.

Due to the recent threat of avian influenza, background information on the virus is provided separately. Disasters and emergencies occurred during the last years so that efficient use of ICTs is crucial. The Tampere Convention came into effect, calling States, inter alia, to facilitate the immediate provision of telecommunication assistance in a catastrophe and to cover the installation and the operation of reliable, flexible communication services. Available information related to the provision of emergency telecommunications during relief operations can be found on websites such as Reliefweb or ITU, ITU-T Recommendations E.106, and ITU-T Study Group 13 Question 3/13, inter alia, cover emergency related issues.

The technical side furthermore covers platforms, applications and standards for disaster relief operations and use of ICTs.

---

139 Carlberg, K. et al., 2002
141 Reliefweb, available: http://www.reliefweb.int/telecoms/tampere
142 Reliefweb, available: http://www.reliefweb.int/telecoms
143 International Telecommunication Union, 2005b, available: http://www.itu.int/itudoc/itu-d/publicat/86892.html
To conclude, early warning and monitoring systems in the eSurveillance domain are critical for preventing and controlling as much as possible the spread of communicable and non-communicable diseases. It is necessary to collaborate with international organisations, government agencies, healthcare and public health institutions, and authorities for meteorology, geological survey, socio-economic and Earth sciences. Effective eSurveillance can detect and control health threats, concentrate on the key resources and investigating trends as well as support policy decision-making through the provision of accurate health information. For the systems to be effective, they require political commitment and a standardized approach of collecting data throughout several networks with a common understanding of ontologies. Further modelling systems relying on environmental data can increase the effectiveness of both the local and regional surveillance, international networks and networks of networks. Certainly, the maximal usage of electronically maintained surveillance systems depends on accurate ICT applications and appropriately trained personnel that collects, manages, and analyses the data for timely, accurate reporting and information dissemination.
6 EADMINISTRATION: EREIMBURSEMENT

6.1 Introduction

For the domain of eAdministration, the priority sub-domain of eReimbursement was selected, and is discussed herewith. The main actors in reimbursement of healthcare services are represented in the triangle below:

![The Health triangle diagram](Image)

The health triangle represents the provision and finance of health care. It shows resources being transferred to patients when care is delivered and financial resources pass from the citizen to the “insurer” and from the insurer to the provider against an agreed provision.

Trans-national eReimbursement covers the flows associated with funds allocation and payments where they are concerned with care provided to persons outside the provider/country’s insurance system. Allocation includes the agreements for the basket of services, the price of services, and the quality of services. The key issues for reimbursement are:

- Non-availability of reimbursement for telemedicine services, either inside or outside a country\(^{147}\);
- Lack of agreement on:
  - Medical acts to be reimbursed;
  - Scale of fees and reimbursement percentages;
  - Mechanisms for assuring quality of service;
  - Mechanisms for patients to maintain control over their medical and administrative data, i.e. possession and active declaration of will as the basis for change of data through e.g. PIN.

---

\(^{146}\) Reinhardt, U.E., 1990

\(^{147}\) This is especially true of second opinions.
• Confusion between existing bi-lateral agreements and the recent court decisions\(^{148}\) and reinterpretation and clarification\(^{149}\) of EEC Regulation 1408/71\(^{150}\);

• Variable levels of knowledge about rights and responsibilities of the purchasers, providers and patients;

• Lack of appropriate information and communication mechanism between purchaser and provider to ensure
  o Consistency of interoperable medical ontology between countries;
  o Privacy and confidentiality and agreement on what is medical and administrative data;
  o Speed- rapid transfer of information - authentication & pre-approval;
  o Trace-ability.

• The majority of trans-national reimbursement systems are paper based;

• Difficulty in integrating new ICT systems into business processes by providers

• There is no standardised approach for the rapid authorisation of medical acts in other countries of the European Union.

The reimbursement of healthcare services between European countries is well established for emergency medical interventions and is covered by the E1XX paper based system. The recent court decision\(^{151}\) and EEC Regulation 1408/71\(^{152}\) potentially extend this to elective treatments, providing pre-authorisation has been where the visit was expressly for the purpose of receiving treatment\(^{153}\).

Policy makers will have to introduce new mechanisms to handle pre-authorisation and to ensure that treatment data can be transferred back to nationally or locally held electronic healthcare records.

Increasingly the current paper-based systems will be inadequate for the volume of transactions resulting from treatment of citizens whilst visiting another country or transferred there for medical treatment.

---


\(^{149}\) COM(2004) 301, Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union.

\(^{150}\) On the application of social security schemes to employed persons and their families moving within the Community.


\(^{152}\) On the application of social security schemes to employed persons and their families moving within the Community.

The impacts of these issues are:

- Experts see Reimbursement as a major barrier to implementation of eHealth and especially, trans-national eHealth services\textsuperscript{154}.

- Legal basis for trans-national reimbursement has improved greatly by recent court decisions\textsuperscript{155} and reinterpretation and clarification\textsuperscript{156} of EEC Regulation 1408/71\textsuperscript{157} (Persons may receive elective treatment in hospitals or by general practitioners whilst travelling or living in other European countries, and get reimbursed). Although the Regulation is quite clear, national legislation and many practical issues make it very difficult for the citizen who wishes to take advantage of these new rights.

- Reimbursement of Telemedical services is similar to specialist services and is normally excluded from the treatment agreements.

- Implementation of effective eAdministration systems for efficient and speedy reimbursement is still a long way off even where reimbursement is allowed.

- Citizens do not know whether the treatment they have received will be reimbursed until after they have paid.

The domain of eAdministration is analysed below using the Policy, Social-Organisational, and Technical Frameworks.

6.2 Policy Framework for eAdministration

6.2.1 Challenges

There remains a considerable amount of work to be done for EU Member States to harmonize their internal regulations covering cross-border eAdministration of healthcare until they reflect the current set of EU directives\textsuperscript{158}, and rulings of the European courts. The status with regard to eHealth is even more confused.

In most trans-national cases, agreements for specialist treatment are bilateral\textsuperscript{159}, meaning that criteria vary between country pairs. Thus, citizens cannot be certain as to their eligibility for treatment or reimbursement, outside emergency treatment. These separate agreements lead to confusion for all

\textsuperscript{154} Telemedicine Alliance, 2004b


\textsuperscript{156} COM(2004) 301, CEC, 2004b

\textsuperscript{157} On the application of social security schemes to employed persons and their families moving within the Community.

\textsuperscript{158} “...Online health services. By end 2005, Commission and Member States will ensure that online health services are provided to citizens (e.g. information on healthy living and illness prevention, electronic health records, teleconsultation, e-reimbursement)....”. COM (2002) 263, CEC, 2002a

\textsuperscript{159} They are specifically excluded from the pan-European agreements on medical care.
stakeholders including policy makers, travellers, residents and administration staff responsible for putting reimbursement into practice and also leads to duplicated systems.

Moreover, there are differing regulations for data protection in each country and no universally accepted guidelines for administration of eHealth services and their reimbursement that guarantees the privacy of personal data, across and between all healthcare systems in the EU (and potentially, beyond).

6.2.2 Requirements

There are several pre-requisites to ensure successful eReimbursement:

- Coordinate legislation on the use of electronic media for financing and reimbursement systems.
- Establish the mechanisms for treatments requiring pre-authorisation.
- Ensure that each citizen and provider has access to information regarding a citizen’s entitlement to care and the procedures for payment and reimbursement at the point that it is needed, usually when treatment is being requested. The current information is often unknown or difficult to find.

The European Health Care is being introduced in paper form prior to being replaced by electronic means from 2008. This still requires an EU citizen to carry two pieces of identity, the other being an identity card or passport changing to a digital format with biometric data included. The question has to be posed, why it would be not sufficient to have a single identity card which, coupled with a professional identity card, would uniquely identify the patient, provider and together with entered information, the medical act undertaken, with immediate information to the patient as to the entitlement to re-imbursement?

This latter approach would also serve to reduce the fraudulent use of cross-border healthcare services. In order to ensure efficient reimbursement the EU is investigating the introduction of a common system to identify patients based on best practice.

6.2.3 Case 1- Reimbursement of medical services in a country other than that of legal residence

The situation with reimbursement has been clarified with recent court decisions regarding rights for treatment in other Member States and reinterpretation and clarification of EEC Regulation 1408/71. Persons may receive both emergency and elective treatment in hospitals or by general practitioners whilst travelling or living in other European countries, and get reimbursed provided that the service is reimbursable in the citizen’s country of origin and not of a specialist nature. The implementation of these decisions at grass roots level may still be variable.

162 On the application of social security schemes to employed persons and their families moving within the Community.
6.2.4 Case 2- Reimbursement of Telemedicine Services

Few eHealth services are reimbursed internal to country and none between countries. It may be that they are treated as other specialist services and, therefore, only be available under bilateral agreements. This means that new regulations regarding reimbursement of Telemedicine services have to be created before these services can become a reality.

6.2.5 Data Privacy in eAdministration

The EU has adopted directives (EC Directive 95/46) for harmonizing data protection laws in the EU, but there remain many grey areas in the domain of healthcare, and Member State legislation is not consistent. Guidelines for use, disclosure, and processing of health-related personal data vary widely across the EU, where such guidelines exist. Transfer of administrative data which can contain personal data plus the code for the service received, needs to be protected as even knowledge of where a patient was treated is potential important. Until data protection legislation is completely harmonized, trans-border flows remain problematic.

6.3 Social-Organisational Framework for eAdministration

6.3.1 Challenges

The Social and Organizational challenges are considered here in a few broad groups:

- Reimbursement for ‘telemedical’ services;
- Reimbursement for services away from ‘home-base’;
- Awareness of the citizen and health service provider of the legal and practical bases for reimbursement of the above services;
- Implementation of eHealth ICT infrastructure for efficiently effecting reimbursement;
- Ensuring that eAdministration of reimbursement can be effected across organisations/institutions, regions, countries of the EU, and globally;
- Guaranteeing Data Privacy, confidentiality and security in eAdministration.

Reimbursement for ‘telemedical’ services

A major barrier, and hence challenge, to implementation of trans-border eHealth is that telemedical services, whether of diagnostic or second-opinion nature, are not covered by a specific service fee in most healthcare systems. Therefore, with the exception of some phone calls between consultants, it is difficult to determine how these services could be provided. If citizens are to be allowed to consult experts in other countries then structures\(^{163}\) will have to be put in place to ensure that they can be reimbursed. It

\(^{163}\) These will have to include a fee scale, agreements on legal liability, reimbursement and data privacy and confidentiality.
should be noted that examples, such as teleradiology, are usually the result of special agreements between institutions, even trans-nationally.

Reimbursement for services away from ‘home-base’

European States are attempting to control the expenditure on healthcare to ensure efficiency and effective treatment for their citizens. Many who do this through “gate-keeping services of GPs to secondary healthcare”, will wish to keep this in place even if the patient is treated in another country. The increasing mobility of European citizens is straining this model especially as the control systems are paper based and therefore slow.

The danger is that many patients, especially chronic care patients could receive inappropriate care or care which contradicts national policies whilst staying in another country. Alternatively the care they receive is too late because of the delays in authorization. In both cases patients could find themselves in the position of either not being able to see a specialist (because of home referral rules) or else of not being reimbursed (because of local reimbursement conditions).

Some Telemedical services are, by their very nature, provided away from ‘home base’ and thus fall into this difficult category. Unless this non-eHealth reimbursement barrier is first lowered many Telemedical services do not have hope of being realized.

An example to illustrate the issue could be:

- A citizen is temporarily resident in another EU country (A) for a period of six months. The citizen is suffering from a condition that requires a radiological examination. This condition is thought by the citizen to be a recurrence of a previous condition, for which he has been treated in another EU country (B), which is not his country of origin.
- The radiological examination is made in country A and the patient wishes the local doctor to speak to the original radiologist to verify any conclusions drawn and the course of action proposed.
- To do this the administration system has to ensure that treatment received in country A can be reimbursed and that the consultation made to the Radiologist in the country B is also reimbursed even though it might appear as a consultation charge on the treatment in country A. The legal system has to allow the transfer of the data between the two clinicians and define the legal liability issues in the remote consultation.

For eHealth services (including telemedicine) to become a reality, an organisational framework backed by either bilateral or European-wide legislation will have to be introduced.

Identification and Accreditation of Services

Mobile citizens, especially those often in other EU countries than their own, are greatly in need of information regarding accreditation of services and identification of health providers providing them. Access to such information could well be part of the holistic eAdministration domain of eHealth. In practice this can often be left to the provider who will not provide treatment unless there is a clear route to reimbursement.
Respecting the subsidiary rules, **accreditation** must be under the control of local governments, who will also have introduced advice for visitors on which services are reimbursable. This however has to be available in a language which the visitor can understand for it to be useful.

**Pre-authorisation of medical procedures**

The E1XX system allows for emergency and chronic care, but does not include access to specialized services. It also allows for treatment whilst visiting, but does not allow citizens to travel to another country for the purpose of being treated\(^\text{164}\). Control over expenditure by insurance companies or governments must not be reduced and they will require **pre-authorisation** for certain elective procedures for those citizens having an extended stay in a country. Without eAdministration procedures in place, this authorization could arrive too late and result in more expensive emergency treatment that has been performed later.

**Implementation of ICTs for efficient reimbursement and cost savings**

Governments and healthcare stakeholders investing in eHealth ICT infrastructure do so focused on their own countries. The lack of emphasizing trans-border interoperability increases the possibility of incompatible systems, which increase **costs** and lose the European industry the **opportunity** to develop effective systems, which are globally competitive. This focus also means that expertise from other countries, which could be provided using eHealth techniques, are not considered due to the difficulties of cross border administration issues.

Internal to their own countries many governments are engaged in **harmonizing** their internal systems to increase healthcare delivery efficiency and reduce waste due to fraud, error or duplications.

Standards of practice need to be developed which are European wide to support the creation of efficient trans-national authorization of treatment and reimbursement operating within standardized timescales.

### 6.3.2 Requirements

The basic legal infrastructure for trans-national reimbursement is in place\(^\text{165}\). The problem is that it is inefficient and can deprive the citizen of their **rights** granted under the law. The following points need to be addressed to ensure effective reimbursement for all citizens in Europe.

- Creation and **publication of rules** on trans-national treatment and reimbursement throughout the EU, coupled to their availability, in all European languages, when required.
- Citizens must not be deprived of services in another country that they could obtain in their own one. They may also be able to **obtain treatments** that they could not obtain in their own country, though there is no requirement for this to be reimbursed.

\(^{164}\) Where this happens it is a result of a bilateral agreement between countries or a commercial arrangement entered into between an insurance company and a provider in another country.

\(^{165}\) COM(2004) 301; see comments on Reg.1408/71 and on form E111, p.2-3
There must be **transparency** of reimbursement so that it is clear to the patient when he/she will be reimbursed, what he has to pay out of his own pocket and when he needs pre-authorization for e.g. reimbursement of more expensive treatment.

**Coordination of ontologies** and service items is a prerequisite to facilitate reimbursement and in order that the patient can know whether the treatment he is receiving is considered as such and is reimbursed in the country of origin.

**Employment of ICTs** at all steps of the administrative process is prerequisite for effecting quick reimbursement, and ensuring transparency.

**Extending reimbursement** of traditional treatment to telemedical treatment in a coordinated manner across the EU, so that

- telemedical treatment will be reimbursed;
- there is transparency of what exactly is reimbursed for each country’s citizens;
- awareness and education for all stakeholders in the chain of services, from citizen, to health provider and insurer, is prerequisite for successful application of eAdministration technologies.

Having a coordinated European organisational structure for eAdministration process with **interoperable standards** in place so that third countries will make their systems interoperable with the potentially large EU market facilitating a more open and higher quality market for healthcare treatment especially eHealth.

A timescale for the implementation of an electronic replacement for the E11X and E12X cards together with **agreements for the transfer of medical data** for emergency and continuing treatment in another European country.

### 6.4 Technical framework for eAdministration

#### 6.4.1 Challenges

Internally to each country there already exist regional or national communication networks, or there are implementation plans, to transfer administrative and healthcare data as part of each country’s efforts to control healthcare expenditure. In the case of trans-border flows, data is transmitted by **paper** and the delays run into many months and, in some cases, years.

The consideration of transferring the data electronically is usually an afterthought following the political decision. The lack of universally accepted communications **networks** or data interchange **standards** create an environment in which technical implementation of eAdministration is critically impaired.

**Human-computer interactions**

The key issues include limited **accessibility, usability** and **functionality** of **affordable** software or web-based services as well as the patients’ and the providers’ **resistance to change** from paper-based formats to electronic submissions. The latter is illustrated e.g. on claims for injectables where the paper...
forms were mostly not standardised and the correct NDC codes were entered in the correct place\textsuperscript{166}. This problem was also identified by CEN/ISSS eHSFG in January 2004 when it was not possible to analyse eHealth applications due to the missing basis for reimbursement\textsuperscript{167}. Thus, stakeholders' needs and functional requirements have to be identified and coordinated across Europe based on Europe-wide standards.

**Impact on service delivery**

The incompatibility of electronic-based claims systems across Europe results in claims processing complexity and errors\textsuperscript{168}.

The first steps are being taken with the proposed EU health insurance card replacing forms E1XX travellers.

### 6.4.2 Technical requirements and potential solutions

The key technical issues to be addressed are:

- Simplification and **modernization** of administrative procedures under security requirements;
- Cross-reference **ontology** to ensure unambiguous translation of eAdministration terms;
- Standardised **datasets** for both reimbursement and authorisation of medical acts with enough flexibility for upgrading;
- Unique **identification** of citizens and their entitlement to healthcare;
- Unique identification and certification of providers and their authorisation to conduct certain procedures;
- An agreed **coding schema** for a tariff of accepted eHealth procedures and charges (bilaterally);
- European wide agreed **data protection definitions** applied to eAdministration;
- European-wide approach on **specification of interfaces** between architecture and primary systems, workstations, networks, servers, directory tools;
- An agreed set of standards for transmitting administrative data which is **secure**, reliable and meets all the standards defined for administrative data and can be interfaced with existing and planned administration systems\textsuperscript{169}.

In order to foster this process, COM (2004)356\textsuperscript{170} requested the European Member States to develop a roadmap by end 2005 addressing, *inter alia*, the issue of eAdministration.


\textsuperscript{167} CEN/ISSS eHealth Standardization Focus Group, 2004a, [http://www.centc251.org/FocusGroup/FocusN-Documents/eHealth_14Guidance.doc](http://www.centc251.org/FocusGroup/FocusN-Documents/eHealth_14Guidance.doc)


The administration of billing systems for eHealth is no different in principle to other trans-national eAdministration procedures and can be based on eAdministration in banking and industry and could use existing OASIS and UN-EC/CEFACT for ebXML and traditional Electronic Data Interchange (EDI) as electronic business standardization technologies\textsuperscript{171,172}. However\textsuperscript{173} at present there is a considerable debate as to whether this provides adequate security, as certain countries claim that the security requirement for healthcare is greater than for banking transactions. There is also an unwillingness by some countries’ representatives to accept solutions already in use in other countries, e.g. the use of the same card reader in France for reading the “Carte Vitale” and the Bank Card.

The CEN/ISSS eHealth Standardization Focus Group identifies priorities for the application of ICTs to health from 2005 to 2010, identifies relevant standards and existing gaps, missing standards for reimbursement and sustained use, etc.\textsuperscript{174}.

The International Telecommunication Union, ITU-T, is currently developing a Roadmap for Telemedicine to identify the gaps of open global eHealth standards. \textit{Inter alia}, financial healthcare transactions mentioned are enrolment and leaving a health plan, health plan premium payments, eligibility check and credit authorisation, billing and payment for covered services, healthcare claim status query, healthcare payment and remittance advice\textsuperscript{175}. A list of “best and real practices in Telemedicine where recognized standards are applied” analyses current initiatives, results and draws conclusions\textsuperscript{176}.

To summarize, in order to achieve interoperability of internal and external eHealth systems and processes across borders, European Member States need to find a consensus on an eHealth architectural framework which is then built using international standards.

6.5 Initiatives and Solutions for eAdministration

There have been many initiatives and they have demonstrated the potential for eAdministration, but the goal of an integrated administrative and healthcare system remains some way from a successful conclusion until all the components of policy, organisation, and technology are made interoperable.

\textsuperscript{173} Notes of eAdministration workgroup at Interoperability Workshop held March 18-19th 2005; ESA, Noordwijk, The Netherlands.
\textsuperscript{174} CEN/ISSS, 2004a, available: http://www.centc251.org/FocusGroup/FocusN-Documents/eHealth\_14Guidance.doc
\textsuperscript{175} ITU, 2005d, pp. 1-5
\textsuperscript{176} eHSCG, 2004b
6.5.1 The European Health Insurance Card

The European Health Insurance Card (EHIC) is being introduced in all EU Member States between 1\textsuperscript{st} June 2004 and 31\textsuperscript{st} December 2005, depending on transition arrangements. It replaces the E111 and E111B for tourists, the E110 for international lorry drivers, E128 for students and people working in other states, and E119 by people registered unemployed seeking work outside their own country. The objective is to speed up reimbursement processes between different countries, reduce costs and reduce fraud of current procedures. It is proof that people are insured, with reference to a standardized clinical and administrative set of data. This card allows access to health services by European Citizens\textsuperscript{177} as if they were citizens there and if they have to pay then it is supposed to enable immediate reimbursement.

In the first instance it will be used visually, but later it may be used to store and provide access to medical and insurance data. This is a long-term initiative from a political, organizational and technical angle. At a political level, there is a need for consensus on the requirements regarding content and structure of the European Health Insurance Card, accompanied by supporting standards from the standardization bodies.

6.5.2 Trans-border flows

The Baltic countries and certain German regions have undertaken a number of trials leading the way towards cross-border telemedicine services. These either make use of existing networks or create new ones, but with the same intention of providing access to the best advice possible to ensure that treatment is well founded and avoids errors.

\textsuperscript{177} The term ‘European Citizen’ here refers to all citizens living in Europe (not only passport holders of the EU Member States).
CITTIS Project

In the CITTIS Project\footnote{CITTIS, 2005, available: www.cittis.com}, telemedicine services are shared between four hospitals on either side of the Danish-German border. In providing this service it was decided to use English as a common language and an agreed mix of international and local standards. Heavy emphasis was placed on the conformance to local laws and regulations.

Baltic Network

Ten partners in Denmark, Norway, Sweden, Estonia and Lithuania have joined together to provide eHealth services in the Baltic Network\footnote{Baltic eHealth, 2004b, available: www.Baltic-eHealth.org}. This allows small rural hospitals to make use of the facilities of large hospitals regardless of their country. Thus, assistance can be provided at the critical early diagnostic stages using radiological and ultra-sound equipment, without moving the patient.

The network makes use of existing networks.

GIE SESAME-Vitale, Netlink, Netc@rds, Transcards

- SESAME-Vitale\footnote{GIE SESAM-Vitale, 2005a, available : http://www.sesam-vitale.fr/divers/pdf/projets_internationaux_en_br.pdf} uses new ICTs, such as smart cards, mainly in France for electronic claims. There is also close collaboration with Germany. Carte Vitale 2 contains an upgrade with more storage capabilities\footnote{Bédère, P., 1999, available : http://www.sesam-vitale.fr/netlink/cts99.pdf} and a picture of the owner with the intention of reducing fraudulent use.

- Netlink incorporates two cards, one for patient, one for clinician, with different access rights to data. Digital signatures ensure confidentiality, integrity, etc.\footnote{GIE SESAM-Vitale, 2005b, available : http://www.sesam-vitale.fr/programme/programme_eng.asp}

- Netc@rds (also incorporating Sesame-Vitale technology) is part of the eTen programme of the EC, including France, Germany, Austria, Italy, Greece, Finland, Czech Republic, Slovakia, Slovenia\footnote{Netcards, 2005, available : http://www.netcards-project.com/index.php}.

- Transcards is part of the "INTERREG III" programme and involves 2 countries, France and Germany. It also uses Sesame-Vitale technology\footnote{GIE SESAM-Vitale, 2005c, available : http://www.sesam-vitale.fr/transcards/tcd_accueil_eng.htm}.

6.5.3 NATO standardisation agreement for development and implementation of medical information systems

The NATO standardization agreement paves the way towards exchanging information between different country's medical information systems so that NATO personnel can be treated in the country where they
are treated and their medical data returned to the normal responsible authority. The standards apply to patient care and support, health services administration, and planning and evaluating health services\textsuperscript{185}.

### 6.5.4 Looking after Tourists – the Meditrav Project

The Meditrav Project\textsuperscript{186} covering 24 months was set up to create a test environment for caring for chronic health patients when they are travelling abroad. It included designs not only to provide the care for patients, but also automated administrative processes with the key being the smart card. The project did not go on to produce a viable product but provided valuable learning. It demonstrated the complexity of attempting to provide an integrated administration and medical care system when only the technical aspects are considered.

### 6.5.5 National Programmes

One of the examples of recent national initiatives is that of the German government, outlined below.

**Bit4Health**

This deals with eAdministration and eCare. The aim is to develop an electronic health card which provides connectivity between healthcare providers and servers, basic standards for the operating systems and applications for the electronic health card\textsuperscript{187}.

\textsuperscript{185} Lam, D.M. et al., 2004, pp. 459-465


\textsuperscript{187} Deutsches Institut für Medizinische Dokumentation und Information, 2004, available: [http://www.dimdi.de/de/eHealth/karte/basisinformation/umsetzung/index_38295.htm](http://www.dimdi.de/de/eHealth/karte/basisinformation/umsetzung/index_38295.htm)
7 THE WAY FORWARD

7.1 eHealth: the next pillar of the Health Market

The current activities in the eHealth domain worldwide and the speed of developing new technologies for global trade and information exchange in a knowledge-based and mobile society serve as the basis for coherently implementing trans-national health services across the European Union. Fostering interoperability from a holistic policy, and taking into account socio-organisational and technical angles, is a critical component to strengthen the European market of Health Services. The focus is on providing trans-national eHealth services with the objective to reduce costs in the healthcare and public health sectors, to empower the citizen, and to improve accessibility, efficiency and quality of service using ICTs.

‘The way forward’ concludes the analysis of the critical areas of interoperability of the health systems across Europe and proposes recommendations to bridge the gap between the current status quo and the objectives identified by TMA-Bridge to implement the core components of eHealth by 2010\(^\text{188, 189}\).

7.2 eHealth services, the holistic approach

In order to ensure a holistic approach, the TMA divided the broad arena of eHealth into four domains: Care, Education, Surveillance, and Administration. Furthermore, for the purposes of this study, priority applications were identified for each eHealth service domain, namely:

<table>
<thead>
<tr>
<th>Service Domain</th>
<th>Priority Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care</td>
<td>Structured and harmonized messages and transnational Electronic Health Record;</td>
</tr>
<tr>
<td>Education</td>
<td>Web community services; reliable health information webs for the citizen;</td>
</tr>
<tr>
<td>Administration</td>
<td>Reimbursement;</td>
</tr>
<tr>
<td>Surveillance</td>
<td>Early warning systems (comparable public health data).</td>
</tr>
</tbody>
</table>

The analyses of these four domains of eHealth were carried out for each of the three infrastructure frameworks: Policy, Socio-organisational, and Technical. This allowed to paint a complete picture with a view of the interactions between all parts, to identify the gaps and to formulate the requirements towards a coordinated implementation of eHealth in European healthcare systems.

\(^{188}\) Telemedicine Alliance Bridge, 2004, pp.8-11

\(^{189}\) The conclusions of Chapter 7 are based on the previous analysis of each eHealth domain from a holistic angle by the Telemedicine Alliance. The draft document was discussed and validated by the 29 participants of the workshop on interoperability, organised by the Telemedicine Alliance at ESTEC 18-19 March 2005. Further details of this workshop are provided in Deliverable 6.1 of the second stage of Telemedicine Alliance, i.e. the report on the workshop on interoperability (Telemedicine Alliance, 2005).
Though the citizen and patient respectively is one of the stakeholders\textsuperscript{190}, initiatives and activities in eCare, eSurveillance and eAdministration rather emphasize the roles and interests of the healthcare professionals and providers. The priorities identified for eEducation are different in that focus is on rapidly exchange of information for consumers to move towards healthier lifestyles, which is a domain traditionally outside the boundaries of Health Services. The integration of all domains of eHealth multiplies the potential benefits for the citizens.

\section*{7.3 Reaching global understanding while respecting regional HC delivery}

EHealth services, \textit{per se}, have been identified as eServices and eApplications in the field of eCare, eEducation, eSurveillance, and eAdministration. The efforts in several developing and developed countries on implementing eHealth differ according to their \textit{needs}, missions, strategies, procedures, time scales, \textit{readiness} and results. Countries rarely have the same denominator as starting point, though leveraging potentials of the Internet and public networks as a \textit{low-cost channel} for the delivery of eHealth applications is recognized as a tool to better regional, in the long-run even global, access to health services.

In order to benefit from ICTs for health matters, the \textit{commitment} from national governments, private sector, public health sector, media, and civil society is strongly required. The ultimate goals for achieving a global Information Society and bridging the digital divide, supported by eHealth, oblige decision-making forces to drive for raising \textit{awareness}, \textit{accessibility} and \textit{affordability} of the services. Though there are different roads to eHealth, a good basis for end-users to accept change in their behaviour is that the key stakeholders should clearly express their needs, requirements and expectations, upon which industry can adapt their products, supported by standardization bodies.

The outcomes should consider both the \textit{mobile citizens} and their treatment in their own country, as well as their treatment in another country. It is necessary that the national and international actions initiated or maintained by the EU Member States fit with the latter’s responsibility for their own \textit{healthcare systems} and supporting IT systems.

It is important that the World Health Organization has, at its recent General Assembly (Geneva, 16-25 May 2005), adopted an \textit{eHealth strategy} urging Member States to pursue the potential benefits and to provide the necessary infrastructure, connectivity and interoperability needed, according to the situation of the region or country. This strategy is therefore highly relevant for the EU objectives and for its collaboration on eHealth with less favoured countries\textsuperscript{191}.

Considering the current socio-economic environment of the health sector, globalisation and mobility of citizens, facilitating access to eApplications and services on health related matters, improving network access and reducing costs of communications will clearly have an impact on the eHealth arena. The time is more than ripe for consorted and coordinated action.

\textbf{We need to act now.}

\textsuperscript{190} The vision of the TMA considers the citizen as the central stakeholder (Telemedicine Alliance, 2004, p. 36).

The TMA recommends the following:

- A co-ordinated steering of resources and priorities for pan-European interoperability actions including standardization should be established. It is noteworthy that a group of representatives of the health ministries working on eHealth is already established\(^{192}\). Its effort to create a special interoperability platform, which includes experts from industry, standardization and health professionals, is welcomed and important.

- The professional qualifications needed for eHealth are recognised throughout Europe and that professionals can provide services in all countries. This implies that more co-operation between the responsible bodies in the Member States is required and preferably a system, where a health professional authorised in one Member State can also provide services over the public network to citizens and providers in other Member States. Alternatively, a special European licensing for some eHealth services such as the reading of medical images should be considered. The recently adopted new Directive\(^ {193}\) for the recognition of professional qualifications across the EU is lauded by the TMA\(^ {194}\). However, it does not specifically support trans-national telemedical services\(^ {195}\) which would require the Directive to be extended.

- Targets are set by Member States for cost savings through the use of trans-national eHealth services.

- The adoption of trans-national tele-medicine services is encouraged through policy initiatives backed by action on fee scales.

- An European-wide scheme for accreditation of tele-medicine providers is implemented by national centres of competence.

- The introduction of the European Health Insurance card is an important first step towards improved transnational eHealth. Steps will need to be taken to ensure that an electronic version can be introduced with the minimal delay. It should include an emergency dataset and must be interoperable with card readers and associated software in all Member States.

- Member States build on the experiences in eSociety, eGovernment, eCommerce, and eBanking, in particular, and eEurope, in general, to avoid wherever possible separate development efforts in eHealth.

- Governments or professional bodies should include links to reputable healthcare web sites.

---

192 Health Care Authorities (HCA) Working Group of EHTEL in conjunction with i2-Health (initiated Feb. 2005)


194 The need for licensing and accreditation of healthcare professionals and services for cross-border medical practice to be easily recognisable across borders, whether the service is provided personally or via Telecare or Telediagnosis was underlined in the TMA Phase-I Final Report.

195 What this Directive does not explicitly say is that a doctor can be resident in one country and offer services in another; it also does not specifically stipulate that a doctor in one country can admit patients to a hospital in another. Moreover, licensing for some eHealth services, such as the reading of medical images should be considered. This Directive is therefore is not yet the open door to a market for trans-national telemedicine.
• Encourage the rapid development and implementation of European-wide eSurveillance and health warnings by building on the work of the European Centre for Disease Prevention and Control and creating the foundations for interoperability between national and international health surveillance systems in Europe.

• A European level web portal should be established for monitoring the impact of interoperability actions identifying suitable indicators for measuring the impact, for defining milestones, and for creating guidelines for reporting progress.

• The user should be involved and should receive training for effective implementation and use of eHealth services and applications. This is an interactive process starting with a pilot group of practitioners of the healthcare and public health sector, citizens and patients with rather intense training regarding the systems implemented. In parallel, the public needs training on issues, processes, benefits to enhance behavioural change. After successful training and systems implementation, the pilot groups would serve as multiplicators, which would speed up training and reduce its cost.

7.4 Implications for all stakeholders

7.4.1 Benefits for all stakeholders

In order to reap the benefits of interoperability some barriers need to be overcome: One is the psychological barrier to the introduction to ICTs still to be found amongst health care personnel. Nevertheless, it should be clear that interoperability provides benefits for all stakeholders. It can:

• Broaden market for healthcare solutions and products;
• Open up the choice for the consumers and professionals;
• Enhance the care of mobile citizens and professionals;
• Enable comparable analyses (for monitoring quality indicators, costs, procedures…).

7.4.2 Healthcare institutions

Each country is responsible for its own healthcare system and the supporting IT systems. Healthcare and public health institutions need to exchange data across country boundaries. From a technical interoperability perspective, there is no difference between hospitals located within one country or in several countries. It is, however, critical to define a compatible interface so that the information transferred from end-point to end-point is understood and guaranteed.

7.4.3 Industry

The importance of having the active participation of all key stakeholders cannot be overestimated. If the end-users are not involved in defining their requirements, which the industry needs to meet with their products, then it is less likely that standards proposed by 3rd party organizations will have effective impact. The adoption of these standards requires actions by institutions such as Hospitals and various...
professional bodies. Though the industry could be a driver for interoperable standards, the requirements from the users and purchasers need to fit with the standard purchasing policies that exist for all systems with international interfaces. Therefore the most effective approach is for requirements and standards to be prepared in a partnership of purchasers and providers. Purchasers incorporate their needs into their purchasing requirements and the industry incorporates requirements and policies into their product specifications. The resulting standards are preferable to proprietary solutions as they foster compatibility and interoperability between different systems. Where systems are acquired which do not conform, barriers to interoperability are created.

To create a Europe wide market for systems and create the basis for eHealth requires the creation and adoption of international standards for interoperability, promoted and supported industry, healthcare institutions and governments.

7.4.4 Citizens

The prospects for achieving real citizen-centred eHealth (with the recent legal decisions on healthcare treatment outside the country of the patient’s origin, and the resulting legal implications for the Member States), look good – on paper – for the mobile citizen. However, the practical implementation of operational frameworks to satisfy these legal requirements lags far behind. It is clear that bilateral and cross-border agreements meet the immediate needs but do not provide long-term solutions and become complex without solutions for interoperability on a pan-European scale.196

With increased access to the Internet, citizens can receive health related information for quality of care and prevention on a 24/7 scale. However, the quality of the information provided escape regulatory activities. In order to provide adequate quality of service to an ‘empowered citizen’, certification bodies are necessary, but impractical. Correct translation in foreign languages, definition of common ontologies and links from Governments or professional bodies to reputable health-related web sites ensure that European citizens have equal access to quality health information.

7.5 The need for standards and common ‘infostructures’

Many standards exist for the required eHealth services. However, there is a lack of understanding on the possibilities to compile and to use them. The recent CEN/ISSS eHealth Standardisation Focus Group report delivers recommendations to the Member States and the Commission on required actions. It is noted that the existing formal European Standardization system with CEN/TC 251, the committee for Health informatics, has not, and cannot, alone develop all the standards needed. The global co-operation of standardisation bodies and fora like CEN, DICOM, HL7, IEEE, ISO, ITU and OASIS in collaboration with WHO, in the recently formed global eHealth Standardization Co-ordination Group (eHSCG)197, is

196 Experience in other sectors of society (e.g. WTO) has shown that the sum of many bilateral agreements amongst a block of nations has little overall impact; but that binding agreements amongst that block of nations as a whole have a major impact.

197 The eHSCG was endorsed by ITU-T Study Group 16 in May 2003. TMA has observer status. EHSCG, 2004a, available: http://www.ehscg.org
welcome as a source of information on all standards required and should be given support to be better able to give advice to the users.

It is, however, recognised that the available standards often require further precision and implementation profiles for specific applications that often also require a series of standards. This should be done together with industrial companies and users with cooperation and collaboration on a global level.

In addition to standards and interoperable products, it is necessary to ensure the development of the following information structures that require national work, but in a co-ordinated common structure with shared resources in Europe.

- A common concept system for clinical facts in records with associated multilingual reference terminologies. SNOMED CT is an available system that all Member States should evaluate, and it may be the best candidate to build on. Co-operation with WHO centre for classification is advised in this process. In addition, it is noted that for some fields, multinational terminologies exists outside of this, such as ICD-10 and IUPAC/C-NPU for laboratory tests.

- A electronic directory service targeted to eHealth key stakeholders with information on providers, professionals and the services offered should be built, based on federated national directories, which in turn may be based on regional directories. Basic standards and initiatives in some countries exist, but no common action yet. The directory needs to consider the issue of subsidiarity and of digital signatures. It is recommended to have a defined chain of trust for the information provided and the information provider\textsuperscript{198}. Clear definitions of the service are required on its management of contents, target groups, trust schemes, depth of hierarchy, management rights of supervising institutions, etc. It is useful to create this service either under the Directorate of EC or another dedicated European institution.

- A European system to verify professional registration of licenses to practice in the different countries, that functions across borders. A European licensing system fosters mutual recognition of professionals working in their own country on national cases, on cases abroad as well as professionals working abroad. These accreditations should be part of the information stood in the electronic directories.

\textbf{On the issue of standards}

- Create and implement a standardised method for the transfer of administrative and medical data between countries.

- Encourage the development and adoption of interchangeable standards between countries to avoid the factorial problem created under individual bilateral agreements

- Create a European-wide ontology interoperability guide to enable translation of fee scales, medical acts by a neutral interoperability body.

\textsuperscript{198} The issue is to define the point when trust can be established, where the reader and the Government respectively cannot control the directory.
• Coordinate the activities and recommendations of the diverse standardization bodies and interoperability initiatives in order to bring forward a clear message for action to the Member States’ decision makers.

• Ensure that the voices of all stakeholders, especially those who are users of the standards, are heard and their needs incorporated into any recommendations made to increase the possibility of adoption.

• Take into account application of interoperability standards in all domains of eHealth and the needs and requirements of all frameworks, including cultural, organisational, and coordinated policy, as well as technical aspects.

• Make the standards simple, easy to access and obtain, and easy to adopt.

• Encourage the work of the eHealth Standardization Co-ordination Group (eHSCG) to provide a lead (see below).

• Bring to the attention of all parties the recommendations of the CEN/ISSS eHealth Focus Group (see below).

• Bring to the attention of decision makers the activities of trans-national organisations, such as NATO, who are adopting practical solutions for eHealth (see below).

The eHealth Standardization Co-ordination Group (eHSCG)

Establishment of the eHealth Standardization Co-ordination Group (eHSCG) was proposed by the workshop on “Standardization in eHealth” (Geneva, 23-25 May 2003) by representatives of several standardization bodies and WHO, and endorsed by ITU-T SG16 in May 2003. A formal invitation to join was sent from ITU to WHO, ISO/TC 215, CEN/TC 251, IEEE/11073, IEC/TC62, DICOM and HL7 and sought nomination of representatives; most responded positively, and others have since joined. The eHSCG is, in principle open to all key players in the arena of standardization.

This initiative demonstrates the positive will of most standardization bodies to collaborate for the best interest of industry and users. The overall objective is to promote stronger co-ordination amongst the key players in the eHealth Standardization arena and to promote specific eHealth standards and support eHealth specifications. The eHSCG is performing informal consultation and co-ordination on a voluntary basis and its recommendations are purely advisory. In particular they do not supersede any official and legal co-ordination procedures in place at national and international level -therefore the practical impact of this group is still to be proved.

---

199 All except IEC responded and have participated in the planning phase. Subsequently OASIS formally joined the group.

200 Other key players may also join as observers, as has the TM Alliance.
CEN ISSS eHealth Focus Group

The CEN/ISSS eHealth Focus Group was formed to prepare an overview public report\textsuperscript{201} on current and future standardization issues on the eHealth Domain. The document, finalized and ready for public comment, promotes the establishment of a permanent platform that will report to the High Level Group on Health Services and Medical Care, in agreement with Member States and the Commission.

The TMA supports the recommendations made in this report, and the activities of this group, especially the need expressed for a Europe-wide view on the requirements for standardisation and its implementation in specific domains, in collaboration with standards organisations, based on input from relevant stakeholders communities.

NATO

NATO, also, needs common standards to allow treatment for their armed forces where-ever they might need it. This is currently difficult. NATO have created STANAG – Standardisation Agreement (Subject: Standards for Development and Implementation of Medical Information Management & C3 Systems)- to set standards to provide practical and easily implementable solutions. This allows military patients to be treated in civilian facilities. NATO includes countries within the EU and having close relations with it. This approach provides a model for civilians.

7.6 The issue of security and data protection

The importance of ensuring security and data protection along the road to eHealth implementation must be underlined. Notwithstanding, it is acknowledged that this is sometimes used as an excuse for inaction. The key elements for data protection are underlined, such as:

- Ensure that transmitted trans-nationally data is done so securely and used only for the designated purpose by the designated person.
- All data transmitted between countries must be subject to the level of protection embodied in the various data protection directives.
- All data held, updated or transmitted should be subject to the controls shown to be equivalent to best practice, including, but not limited to traceability, non-revocation, etc.
- A common Public Key Infrastructure (PKI) based on open, international standards should be used to support the key security services for interoperable services across borders: encryption for confidentiality, authentication and authorisation of users, access control, non-repudiation and data integrity on electronic documents allow auditability. The mutual recognition by different countries of trusted third parties and different national infrastructures\textsuperscript{202} requires the same approach like the one established for the national European identification cards: A policy level agreement based on a legal, regulatory framework serves as the basis to recognize the specific national

\textsuperscript{201} CEN/ISSS eHealth Standardization Focus Group, 2005c

infrastructures. A mobile citizen being treated in a country other than its origin and being in the need to exchange its data consequently has to follow the defined procedures. These international actions require appropriate coordination. Standards-based open, international PKI can facilitate the interoperability of systems and different trusted third parties once the legal framework is put in place.

- The Electronic signature directive 1999/93/EC considers PKI and the implementation strategy to be the responsibility of national Governments. It can be either regulators or other institutions, which are responsible for accreditation of legal and market aspects, that agree on certification of trusted third parties. Today, there is no example of mutual recognition of PKI and digital signature in terms of the Electronic signature directive.

Nevertheless, it must be noted that the requirements of the EU Directives on data protection suffer from national differences in the domain of medical data (since healthcare has been a national prerogative): Such differences should be resolved if they constitute a barrier to interoperability.

7.7 The risks of not moving forward

The TMA has analysed the needs for interoperability and has provided guidelines and recommendations on how to move forward. The question may arise for some policy makers and industrial investors, as to the necessity of moving forward in a Europe-wide coordinated manner: Achieving agreement and progressing in a coordinated manner across 25 Member States is costly, slow, and difficult to achieve.

Stakeholders and policy makers must however, realize, that the cost of inaction is even greater. Where investment is already being made, if preconditions for interoperability are not now taken into account, it may cost very dearly to make the necessary changes in the future. Moreover, much potential investment in applications and infrastructure is being held up because, industrial parties are unwilling to take the risk of introducing applications that risk becoming out of date and unusable in the future. This is a risk that national governments may have to take, but with similar costly consequences.

It is therefore of utmost urgency and incumbent on all affected stakeholders to get together and agree on basic guidelines and interoperability standards that can be used as the infrastructure for building upon: The costs of inaction, or action that is too slow and too little, are far higher than timely investment.

7.8 Towards a sensible strategy

This document contains a set of recommendations, which, if followed, not only face the challenges, but, should overcome the barriers to interoperability for eHealth, and lead to sensible implementation of eHealth in Europe. However, as with all proposed recommendations, there is a gulf between proposing recommendations for dealing with interoperability issues and finding the formula for strategic policies and tactical approach and vehicles for translating these recommendations into reality. The TMA has

203 The definition of these procedures goes beyond the scope of this document.
recognized this need and has therefore analysed the underlying issues of such a strategy, how it fits in with the EC issued Action Plans, and the needs of the Member States and stakeholders. These analyses, together with a set of strategic recommendations, are provided in Deliverable 5 of TMA-Bridge: “Strategic Plan”.
## ACRONYMS AND ABBREVIATIONS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS</td>
<td>Acquired ImmunoDeficiency Syndrome</td>
</tr>
<tr>
<td>API</td>
<td>Application Program Interface,</td>
</tr>
<tr>
<td>ASTM</td>
<td>American Society for Testing and Materials</td>
</tr>
<tr>
<td>ATIS</td>
<td>Alliance for Telecommunications Industry</td>
</tr>
<tr>
<td>BMGS</td>
<td>Federal Ministry of Health and Social Security, Germany</td>
</tr>
<tr>
<td>BSE</td>
<td>Bovine Spongiform Encephalopathy / Mad Cow Disease</td>
</tr>
<tr>
<td>CCR</td>
<td>Continuity Care Record</td>
</tr>
<tr>
<td>CEFACT</td>
<td>Centre for Trade Facilitation and Electronic Business</td>
</tr>
<tr>
<td>CEN</td>
<td>Comité Européen de Normalisation (European Committee of Standardization)</td>
</tr>
<tr>
<td>CEN/ISSS</td>
<td>CEN/Information Society Standardisation System</td>
</tr>
<tr>
<td>CEN/TC251</td>
<td>CEN - Technical Committee 251 for Medical Informatics</td>
</tr>
<tr>
<td>CENELEC</td>
<td>Comité Européen de Normalisation Electrotechnique - (European Committee for Electrotechnical Standardization)</td>
</tr>
<tr>
<td>CNES</td>
<td>Centre National d’Etudes Spatiales</td>
</tr>
<tr>
<td>COCIR</td>
<td>European Coordination Committee of the Radiological and Electromedical Industries</td>
</tr>
<tr>
<td>COM</td>
<td>Communication from the EC</td>
</tr>
<tr>
<td>CPR</td>
<td>Computerized Patient Record</td>
</tr>
<tr>
<td>CS</td>
<td>Commission Services</td>
</tr>
<tr>
<td>DANTE</td>
<td>Delivery of Advanced Network Technology to Europe</td>
</tr>
<tr>
<td>Del</td>
<td>Deliverable</td>
</tr>
<tr>
<td>DICOM</td>
<td>Digital Imaging and Communications in Medicine</td>
</tr>
<tr>
<td>DLL</td>
<td>Dynamic Link Library</td>
</tr>
<tr>
<td>eBES</td>
<td>e-Business</td>
</tr>
<tr>
<td>ebXML</td>
<td>electronic business Extensible Markup Language</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>ECDC</td>
<td>European Centre for Disease Control</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
</tr>
</tbody>
</table>
EDI
Electronic Data Interchange

EDIFACT
Electronic Data Interchange For Administration, Commerce and Transport

EEC
European Economic Community

EHCR
Electronic Health Care Record

EHIC
European Insurance Card

EHR
Electronic Health Record

EHRcom
Electronic Health Record Communication

eHSCG
eHealth Standardization Coordination Group

eHSFG
eHealth Standardization Focus Group of CEN/ISSS

EMEA
European Medicines Evaluation Agency

EMR
Electronic Medical Record

EN
European Norm

ENV
Standard draft

EPR
Electronic Patient Record

ESA
European Space Agency

ESRIN
European Space Research Institute

ESTEC
European Space Research and Technology Centre

ETHEL
European Health Telematics Association

EU
European Union

EWRS
Early Warning and Response System

EWS
Early Warning Systems

FAQ
Frequently Asked Questions

G7
Group 7

GEANT
Gigabit Research Network

GP
General Practitioner

H/W
Hardware

HC
Healthcare

HCA
Health Care Authorities

HIV
Human Immunodeficiency Virus

HL7
Health Level 7
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>HON</td>
<td>Health On the Net</td>
</tr>
<tr>
<td>ICD</td>
<td>International Classification of Diseases</td>
</tr>
<tr>
<td>ICT</td>
<td>Information and Communication Technology</td>
</tr>
<tr>
<td>IDNDR</td>
<td>International Decade for Natural Disaster Reduction</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electrotechnical Committee</td>
</tr>
<tr>
<td>IEEE</td>
<td>Institute of Electrical and Electronic Engineers</td>
</tr>
<tr>
<td>IHE</td>
<td>Integrating Healthcare Enterprise</td>
</tr>
<tr>
<td>IP</td>
<td>Internet protocol</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization of Standardization</td>
</tr>
<tr>
<td>ISO/TC 215</td>
<td>ISO - Technical Committee 215 on Health Informatics</td>
</tr>
<tr>
<td>Iss</td>
<td>Issue</td>
</tr>
<tr>
<td>IST</td>
<td>Information Society Technologies</td>
</tr>
<tr>
<td>IT</td>
<td>Information Technology</td>
</tr>
<tr>
<td>ITU</td>
<td>International Telecommunication Union</td>
</tr>
<tr>
<td>ITU-D</td>
<td>ITU Telecommunication Development Bureau</td>
</tr>
<tr>
<td>ITU-T</td>
<td>ITU Standardization Bureau</td>
</tr>
<tr>
<td>IUPAC</td>
<td>International Union of Pure and Applied Chemistry</td>
</tr>
<tr>
<td>LOINC</td>
<td>Logical Observation Identifiers Names and Codes</td>
</tr>
<tr>
<td>MS</td>
<td>Member States</td>
</tr>
<tr>
<td>NATO</td>
<td>North Atlantic Treaty Organization</td>
</tr>
<tr>
<td>NDC</td>
<td>National Drug Code</td>
</tr>
<tr>
<td>NeLH</td>
<td>National Electronic Library for Health</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>NpfIT</td>
<td>National Plan for IT</td>
</tr>
<tr>
<td>nvCJD</td>
<td>New variant Creutzfeldt-Jakob-Disease</td>
</tr>
<tr>
<td>OASIS</td>
<td>Organization for the Advancement of Structured Information Standards</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>PICS</td>
<td>Platform for Internet Content</td>
</tr>
<tr>
<td>PIN</td>
<td>Personal Identification Number</td>
</tr>
<tr>
<td>PIPS</td>
<td>Personalized Information Platform for life and health Services</td>
</tr>
</tbody>
</table>
PKI   Public Key Infrastructure
PP    Restricted to other Programme Participants
prEN  Standard draft sent for CEN ballot (pre-Standard)
PU    Public
R&D   Research and Development
RDF   Resource Description Framework
RE    Restricted
Rev   Revision
S/W   Software
SARS  Severe Acute Respiratory Syndrome
SDO   Standard Developing Organisation
SNOMED Systematized NOmenclature of MEDicine
SNOMED CT SNOMED Clinical Terms
SSA   Specific Support Action
SSL   Secure Socket Layer
STANAG Standardization Agreement
T1D   Type 1 Diabetes
TM    Telemedicine
TMA   Telemedicine Alliance
TMAB  TMA-Bridge
UI    User Interface
UN    United Nations
URL   Uniform Resource Locator
US    United States
USA   United States of America
VANS  Value Added Network
vCJD  Variant Creutzfeldt-Jakob disease
VPN   Virtual Private Network
W3C   World Wide Web Consortium
WHO   World Health Organization
<table>
<thead>
<tr>
<th>WP</th>
<th>Work Package</th>
</tr>
</thead>
<tbody>
<tr>
<td>WS</td>
<td>Workshop</td>
</tr>
<tr>
<td>xDSL</td>
<td>x-Digital Subscriber Lines</td>
</tr>
<tr>
<td>XML</td>
<td>Extensible Mark-up Language</td>
</tr>
</tbody>
</table>
BIBLIOGRAPHICAL REFERENCES


CITTIS. Borderless Healthcare Communication - Collaboration in telemedicine between Danish and German health service., URL: http://www.cittis.com, accessed 26 January 2005


EUROPEAN SPACE AGENCY (2002). Modus operandi: how satellites track a mass killer. URL: http://www.esa.int/export/esaCP/ESATR5TYWC_Improving_0.html, accessed 3 February 2005


GEANT. The GÉANT project. URL: http://www.geant.net/server/show/nav.007008, accessed 12 April 2005


HEALTH EARLY ALARM RECOGNITION AND TELEMONITORING SYSTEM. The project. URL: http://heartsproject.datamat.it/hearts, accessed 6 January 2005


HEALTHCARELINK, Healthcarelink. URL: http://www.healthcarelink.md, accessed 11 January 2005


MEMO CONSORTIUM. DICTATE project – a voice mediated system for structured entry of medical data. URL: http://www.med-mobile.org, accessed 20 January 2005

NEMA, DICOM. URL: http://medical.nema.org, accessed 15 November 2004

NETCARDS. Trans-European access to health services for mobile citizens. URL: http://www.netcards-project.com/index.php, accessed 14 May 2005


REGENSTRIEF INSTITUTE. Logical Observation Identifiers Names and Codes. URL: http://www.loinc.org, accessed 20 January 2005


RELIEFWEB, Emergency telecommunications. URL: http://www.reliefweb.int/telecoms/tampere, accessed 6 January 2005


UNITED NATIONS (1990). Guidelines for the Regulation of Computerised Personal Data Files, New York: UN


VARDGUIDEN, Vårdguiden. URL: http://www.vardguiden.se/, accessed 9 January 2005


WEBLOGS, Web communities serve as early warning for disease outbreaks. Telemedicine Insider. URL: http://telemedicine.weblogsinc.com/entry/1234000880023268/, accessed on February 02, 2005


ANNEXES

List of annexes to this document, which are provided as separate documents.

Annex-1: General Infrastructure of Technical eHealth Interoperability
Annex-2: Standards and Supporting Initiatives Related to EHR
Annex-3: Standards List from EHSCG (draft)
Annex-4: Brochure for 2005 Tromsø Conference
Annex-5: Initiatives and Tools for eSurveillance
Annex-6: Personal communication, COCIR
Annex-7: Europe and CIS, ICT Indicators, 2003
TELEMEDICINE ALLIANCE - A BRIDGE TOWARDS COORDINATED eHEALTH IMPLEMENTATION

eHEALTH INTEROPERABILITY IN EUROPE: CHALLENGES AND INITIATIVES

Interoperability Study Report - Annex 1: General infrastructure of technical eHealth interoperability

Lead Partner for Deliverable: ITU
Start/Duration of project: 1 August 2004 – 31 July 2005
Dissemination Level*: PU (Public)
Deliverable Number: TMA-Bridge_Del-4
Document Number: TMAB-ESA-TN-041
Electronic File Name: TMAB-Del.4-Interoperability Study Report_Annex1_Iss1-Rev1.doc
Issue/Revision: 1/1
Due date of deliverable: M9
Actual Date: 1 July 2005
Number of pages: 13

Project co-funded by the European Commission within the 6th Framework Programme (2002-2006); Priority 2 Information Society Technologies (IST); Specific Support Action (SSA); Project No. IST-507871.

1 PU = Public, PP = Restricted to other programme participants, incl. the Commission Services (CS), RE = Restricted to a group specified by the consortium (incl. the CS), CO = Confidential, only for members of the consortium (incl. the CS)
Telemedicine Alliance

European Space Agency, European Space Research & Technology Centre (ESTEC),
Noordwijk, The Netherlands

World Health Organization - European Office for Integrated Health Care Services,
Barcelona, Spain

International Telecommunication Union: Telecommunication Development Bureau
(ITU-D), Geneva, Switzerland

The Interoperability Study Report has been prepared by the Telemedicine Alliance consortium made up of European Space Agency (ESA), International Telecommunication Union (ITU) and World Health Organization (WHO), as part of the European Community 6th Frame Work Programme.

The authors would like to thank ITU-T and the Director of ITU-T for their valuable support.

"EHealth in Europe: Challenges and Initiatives" is part of deliverables of the Telemedicine Alliance – a Bridge towards coordinated eHealth implementation.

Other reports and information on this project can be found at www.esa.int/tma-bridge or www.esa.int/telemedicine-alliance.

The opinions expressed in the Interoperability Study Report and its annexes are those of the authors and do not necessarily reflect the views of the International Telecommunication Union, its membership, the European Space Agency, the World Health Organization or their Member States.
Table of Contents

ANNEX-1: GENERAL INFRASTRUCTURE OF TECHNICAL EHEALTH INTEROPERABILITY

1.1 Security......................................................................................................................................... 1
1.2 Architecture................................................................................................................................... 5
1.3 Data structure ............................................................................................................................... 6
1.4 Standardisation............................................................................................................................. 6
1.5 Applications .................................................................................................................................. 7
1.6 Semantics ..................................................................................................................................... 8
1.7 Guidelines..................................................................................................................................... 9

List of Tables and Figures

Table 1 eHealth security dimensions ................................................................................................. 2
Figure 2 eSecurity for the health sector ............................................................................................... 3
ANNEX-1: GENERAL INFRASTRUCTURE OF TECHNICAL EHEALTH INTEROPERABILITY

The interoperability of eHealth does not only consider policy and socio-organizational domains, but its technical perspective has also an impact on the efficient exchange of medical data. Several levels of interoperability related to eHealth cover a range from security aspects, to semantic interoperability: security and confidentiality, architecture, data format, standardization, applications, and semantics. This annex highlights the basic requirements to ensure eHealth interoperability from a technical perspective. It is thus necessary that the different stakeholders exchanging relevant data can actually communicate reliably and securely with each other via compatible networks.

1.1 Security

Ensuring the security of information is both a challenge for users and suppliers. Lack of information, lack of standardization, mistrust regarding security measures and resistance to change from the user side can hinder an increased implementation of Health informatics applications and effective use of the Internet. Lacking the confidence to choose the product with the best cost-benefit ratio and lacking knowledge of being able to update eHealth technology over time according to their particular needs, healthcare professionals are hesitant to invest in non-standardized technology.

The eEurope 2005 action plan addresses such security concerns, among others, through policies such as improving networks and information systems, eAuthentication through smart cards, etc., taking into consideration a holistic approach of various policies on privacy, citizens’ rights, international trade, industrial policy, law enforcement, etc. Through the electronic signatures directive and the data protection legislation for electronic communication, the EU aims to decrease security and privacy concerns for a wide range of services and to ensure accurate operations.

Besides applying the legal considerations, suppliers need to customize their products according to their clients’ needs. The main eHealth security threats can be summarized as follows:

- Unauthorized access to and modification of (confidential) information;
- Wrong identification of the source/origin of medical information transmitted via the Internet;
- Non-repudiation of eHealth transactions through authorized medical personnel and/or institutions (e.g. for remote diagnostics and medical advice);
- Level of security of sensitive health information transmitted between connected collaborating medical institutions (e.g. in e-health networks).

These generic security constraints concentrate on the five internationally-agreed consensus on the dimensions of confidentiality, authentication, integrity, non-repudiation, and authorisation, as presented in the ‘Open Systems Security Architecture’ of ITU-T Recommendation X.800. In order to create a secure basis for sending confidential medical data between heterogeneous systems across borders, ICTs must cover certain requirements:

<table>
<thead>
<tr>
<th>Security dimensions</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidentiality</td>
<td>Data is protected from authorized disclosure.</td>
</tr>
<tr>
<td>Authentication</td>
<td>The identity of users and resources is verified.</td>
</tr>
<tr>
<td>Data integrity</td>
<td>Data is protected against unauthorized modification.</td>
</tr>
<tr>
<td>Non-repudiation</td>
<td>A party cannot subsequently deny a transaction by proof of ownership, data origin, etc.</td>
</tr>
<tr>
<td>Autorisation / access control</td>
<td>Users hold defined rights including the granting of access based on access rights.</td>
</tr>
</tbody>
</table>

Table 1 eHealth security dimensions

Since X.800 does not cover implementation specification, conformance assessment of any implementation or additional security measures that may be needed to support the OSI security features, X.805 provides the ‘Security Architecture for Systems Providing End-to-End Communications’, which builds on the concepts of X.800 and the Security Frameworks of X.810 – X.816. X.805 refers to both the five areas of confidentiality, authentication, data integrity, non-repudiation, and access control, and additionally integrates the dimensions of communication security, availability, and privacy. Communication security ensures the flow of information only between authorized end-points. Availability guarantees that there is no denial of access authorized, which is particularly important throughout emergency and disaster recovery activities. Privacy security deals with protecting information that can be derived from the observation of networks such as users’ visits of IP addresses and their geographic location.

Ensuring the security of both the infrastructure itself and the confidential medical information that runs through it is critical for successful implementation of interoperable systems. Security concerns in the unique health sector, with its document-intensive operations, thus drive the demand for access control.

---

6 based on Mandil, S., 2001, pp. 634 in L. Beolchi (ed.)
7 International Telecommunication Union, 2004d, pp. 39-42
8 International Telecommunication Union, 2004d, pp. 1-6
and security solutions. A modern medical and public health setting should enable various medical professionals, healthcare specialists and citizens residing in different locations to access medical data in a secure and standardized way, without putting at risk sensitive information. This is even more important whether digital signature laws are not consistent across the EU, and never mind beyond it. Among the common eSecurity technologies, Public Key Infrastructure (PKI) covers the concerns of authentication, confidentiality, integrity and non-repudiation (see figure 1).

**1.1.1 Data confidentiality**

PKI addresses the security and trust concerns of eHealth services in public networks through qualified digital signatures and asymmetric encryption. Encryption is used to make messages indecipherable except by those who have an authorized decryption key through single-key encryption or public/private key encryption. In case of no personal exchange of keys, electronic certificates are issued by a trusted third party (certification authority) to ensure that the specific public key /asymmetric cryptography belongs to a specific person or organisation\(^9\).

**1.1.2 Authentication**

PKI can be used to suitably authenticate users to a network by checking their credentials against information stored in directories. One solution adapted by most security solution providers is, e.g. ITU-T Recommendation X.509, which creates a framework for establishing digital identities through certification\(^10\).

National initiatives, e.g. Australia, Canada, and Sweden, as well as standardisation bodies such as ISO and CEN developed specifications based on PKI systems. However, the professional community does not

---

\(^9\) International Telecommunication Union, 2004d, pp. 1-15

fully accept a community-wide PKI system\textsuperscript{11} as a cryptographically secure mechanism, but prefers specialized end-to-end authentication according to local needs\textsuperscript{12}.

With reference to telemedicine, biometrics may provide security authentication for medical data through the verification on physiological and behavioural measures. Nevertheless, there is yet the uncertainty of the level of adequate security. In cooperation with ISO/IEC, IEEE, IETF and other bodies such as OIML and BIPM, ITU-T Recommendation X.1081 as a ‘Framework for the Specification of Security and Safety Aspects of Telebiometrics’ needs to be enhanced by the end of the 2005-2008 study period for telecommunication based on cryptographic technology\textsuperscript{13}. One example for implementing telebiometrics through a ‘card and finger’ authentication of a digital identification system is provided by a private Brazilian company for a Brazil-wide network\textsuperscript{14}\textsuperscript{15}.

1.1.3 Data integrity

Related to authentication and confidentiality, data integrity is ensured using message digest mechanisms. The digital keys used for documents enable the comparison of the digital key per se with the accompanying document. This procedure ensures that the document has not been changed since it was created.

1.1.4 Non-repudiation

Closely related to authentication, the provision of non-repudiation is ensured through digital signature and digital certification attributes. As mentioned for authentication issues X.509’s PKI and Privilege Management Infrastructure provides basic solutions for auditing and authorisation mechanisms. X.509 was used in eHealth applications for secure access to a hospital diabetes system via Internet and for ePrescription\textsuperscript{16}. X.509 is rather a framework and does not address audit trails to document the actions related to data changes made either as a correction or due to new information. ISO 7498-2 provides a standard on network security to ensure compliance with requirements of declared information.

1.1.5 Authorisation

Authorisation and access control are amongst the basic security measures since the potential for abusing medical data should be eliminated. Access control security protects against unauthorized use of network resources such as stored information, information flows, services and applications. Healthcare information

\textsuperscript{13} International Telecommunication Union, 2004c, available: http://www.itu.int/ITU-T/studygroups/com17/sq17-q8.html
\textsuperscript{14} CAD-S Informática, available: http://www.cads-informatica.com.br/finger.htm
\textsuperscript{16} International Telecommunication Union, 2003c, available: http://www.itu.int/ITU-T/worksem/e-health/abstracts/abs-s5-02.html
systems security mechanisms underlie an architecture of end-to-end network security provided. X.805 matches the open systems security architecture of X.800 and the security frameworks of X.810 – X.816. The X.805 architecture can be applied to those networks where end-to-end security is a concern independently of the network’s underlying technology.

Secure socket layer (SSL) and Virtual Private Networks are other essential security means, which need to be supplemented by other mechanisms such as encrypted file storage and secure data access control, PKI and administrative actions, e.g. joint patient and professional cards.

1.2 Architecture

Medical data transmission is diverse in nature and requires a framework of different information processing procedures. According to IEEE 1471-2000, an architecture for interoperability in eHealth includes “… the fundamental organization of a system embodied in its components, their relationships to each other, and to the environment, and the principles guiding its design and evolution…” 17 18. Basically, end-users deal with four types of eHealth records transmitted, text, audio, still image, and video, and request ubiquitous performance of appropriate technical facilities. Health informatics needs to enable both, portability through appropriate interfaces, as well as interoperability. In order to interconnect different eHealth related networks nationally and internationally via Internet, Internet Protocols 19 (IP) such as IPv4 and IPv6 carries eHealth data and delivers considerable improvements to multicast videoconference-type applications.

Requirements for eHealth interoperability architecture include the distribution of medical station components, internal communication buses, device buses, user interfaces, patient record communications, heterogeneous underlining communications infrastructures, videoconferencing, etc. Other options of architecture include Healthcare Information System Architecture (HISA ENV 12967), Clinical Document Architecture (CDA, developed by HL7), Sun’s Platform independent Framework for eHealth and Open Scalable Architecture for Multimedia Telemedicine Applications (SAMTA) 20.

Besides using an encrypted intranet, companies build their own virtual private network (VPN) using the public network, generally on the Internet, to interconnect geographically distributed facilities. The advantage is to satisfy the needs of remote areas.

Since many eHealth services may rely on Internet access, compatibility between network architectures is crucial. For example, Internet includes ARP/RARP, IP, TCP, and software applications, the OSI seven layer model of ISO refers to physical, link, network, transport, session, presentation and application level, whereas the IEEE architecture is composed of a physical, medium and high level.

In order to be able to use Health Informatics and eHealth services, end users need to have access to hardware. Appropriate communication hardware for terrestrial links (ADSL, ISDN, Modem, etc. for today, VDSL and optical fiber access for future trends) and for wireless connectivity via e.g. UMTS and satellite transmission is a substantial ingredient for this dynamic environment. Furthermore, hardware need to satisfy the requirements for representing multi-media data, in particular high resolution images.

The widespread availability of affordable and ubiquitous broadband access will be a powerful stimulus and enabling factor for the beneficial exploitation of the potential of eEurope. It will allow for new multi-media, multi-platform services, faster data retrieval, and greater ease of “anytime, anywhere” access for users. However, broadband services must be established within a competitive environment which allows for on-going innovation in services and pricing structures and the development of accessible consumer service prices\(^\text{21}\).

### 1.3 Data structure

Since the different stakeholders have various backgrounds and needs, the originator of eHealth data needs to ensure that the message will be received free of errors and understood for the sake of economies of learning as well as to reduce errors in diagnosis and treatment. This can be done through standardized ontological correlated structures. The CEN/ISSS eHealth Standardization Focus Group identifies three broad types of standards for data elements: patient demographics, hospital administration, and health insurance proceedings\(^\text{22}\). Taking into account legal and ethical aspects, regulators need to find a consensus on a local, national, regional (European) and global scale. From a technical viewpoint, strictly specified formats are crucial for transmitting the medical information based on text, databases, pictures, audio and video. This refers to a decision on using broad or limited bandwidth, whether to compress e.g. digital images or not while being stored or transmitted and what system should be used to avoid and correct human and communications errors.

### 1.4 Standardisation

Technical security solutions must satisfy the legal confidentiality requirements that differ from country to country. The U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA) defines strict

---

\(^{21}\) EuroISPA EEIG, available: http://www.euroispa.org/docs/eEurope_final.pdf

\(^{22}\) European Standardization Committee/Information Society Standardization System ISSS eHealth Standardization Focus Group, 2005b, available: http://www.centc251.org/FocusGroup/eHealthStandardizationReport-Part2-Final\%20version\%202005-03-01.pdf
security standards for the protection of security aspects of electronic health data and thus may also affect many European eHealth businesses. A group of 13 major health-IT organizations, such as HL7, HIMSS, American Medical Informatics Association, etc., recently critiqued the HIPAA approach and called for industry-driven, non-proprietary consensus standards solutions\textsuperscript{23}. Covering basic principles of secure health information, the American Society for Testing and Materials offers a listings of guides, specifications and standard practices for Healthcare informatics\textsuperscript{24}.

In the European arena, the Directives on privacy can be used as guiding principles for standardization. ISO/TC 215 Working Group 4 proposed international standards for national bodies to develop and implement data protection principles\textsuperscript{25}. Other European standardization bodies such as CEN/TC 251 and joint initiatives of ISO/IEC published standards on high-level security policy (EN 14484) and security management in health care (ISO/IEC 17799) respectively; most standards explicitly focus on the various health informatics areas, e.g. security for healthcare communication, public key encryption, etc. Both the CEN/ISSS eHealth Standardization Focus Group\textsuperscript{26} and the eHealth Standardization Coordination Group\textsuperscript{27} provide a collection of prioritised applications of technical and non-technical areas of eHealth. ITU-T has recently established a work item on standardization of a multimedia framework for eHealth applications\textsuperscript{28}.

On a European level, more collaboration through recognition and implementation of standards would foster economies of scale for the users.

### 1.5 Applications

Each participant in the healthcare spectrum, i.e. healthcare professionals and providers, support service providers, insurance companies, employers, home users, patients, citizens, etc. need computer system configurations with databases, applications and web servers, being able to be updated according to the functionality required.

EHealth applications compile very specific requirements according to the different user needs. The most vital technical aspects of Health Informatics being accepted\textsuperscript{29} are user friendliness, reliability, error tolerance, security and privacy, service availability, quality of service, and quality of workflow realization.

\textsuperscript{23} Versel, N.(ed.), 2005, available: http://tmlr.net/jump/?c=11715&a=296&m=2833&p=0&t=164
\textsuperscript{26} European Standardization Committee/Information Society Standardization System ISSS eHealth Standardization Focus Group, 2005b, availability: http://www.centric251.org/FocusGroup/eHealthStandardizationReport-Part2-Final%20version%202005-03-01.pdf
\textsuperscript{27} eHSCG promotes stronger coordination amongst the key players in the eHealth standardization domain. Its key members are CEN/TC 251, DICOM, HL7, IEEE 1073, ISO/TC 215, ITU-T, and WHO. In: E-Health Standardization Coordination Group, 2004a, available: http://people.itu.int/~campos/proto/ehscg/modusoperandi.htm
\textsuperscript{29} Cimino, J.J., 1997, pp. 279-284
Current initiatives from eHSCG are, among others, to prepare a roadmap for Telemedicine, which will also refer to the adequate software, user interface, middleware, operating systems, etc.\(^{30}\).

One of the roadmap elements, user interfaces (UI) are especially important when working across country boundaries since those interfaces are designed according the user requirements from a concrete context, language and cultural background. The communication initiated by the user via devices such as terminal, laptop, tablet PC and PDA is bi-directional in real time and requires a certain set of common contents. The benefits of standardized UI of clinical systems include the reduction of errors and of providing new training to professionals if a new system is implemented\(^{31}\).

Open source technology considers semantic interoperability issues since its vision is greater adherence of standards. Open source software may be a useful and more affordable tool for home users in the eHealth domain\(^{32}\), but would be in competition to the industry.

### 1.6 Semantics

In order to ensure a uniform way of different parties understanding each other, common semantics\(^{33}\), ontology\(^{34}\) and terminology need to be implemented. It is not only crucial that the language spoken and written by the human sender of data is understood, but that computers are able to recognize machine processing to assist us in our daily activities. Interfaces between the various layers must be ubiquitous and use semantically correct syntax for transmitting clinical data between different countries and languages. The report of CEN/ISSS eHealth Focus Group addressed semantics in relation to diseases, operations, clinical terms, medical products and ambulatory care\(^{35}\). ISO/TC 215 has on-going work related to semantic interoperability\(^{36}\). Moreover, research is being carried out by EC and WHO on semantic interoperability strategies for the next five years\(^{37}\). Amongst the 40-50 projects within the 6th Frame Work Programme of the EC, funded projects such as DICTATe currently deal with standards for integrating...

---

\(^{30}\) International Telecommunication Union, 2005d, pp. 1-5


\(^{33}\) Semantics “…studies the meaning and the development of meaning in words and signs…”. Through semantic-based knowledge systems, ongoing research intends to achieve semantic interoperability between multimedia web resources and services. In: Beolchi, L. (ed.) & S. Facchinetti, 2003, p. 1003

\(^{34}\) Ontologies are knowledge bodies representing a shared conceptualisation of a particular application area.

\(^{35}\) European Standardization Committee/Information Society Standardization System ISSS eHealth Standardization Focus Group , 2005b, available: [http://www.certc251.org/FocusGroup/eHealthStandardizationReport-Part2-Final%20version%202005-03-01.pdf](http://www.certc251.org/FocusGroup/eHealthStandardizationReport-Part2-Final%20version%202005-03-01.pdf)


medical semantics into speech recognition between mobile applications across Europe. One example of ontologies used for identifying laboratory and clinical observations before sharing this knowledge across boundaries are Logical Observation Identifiers, Names and Codes (LOINC).

In order to find consensus on a comprehensive policy and strategy for semantic interoperability in a dynamic environment of developing ICTs and changing policy requirements, qualified and internationally accepted bodies should take the lead to ensure semantic compliance to stimulate eHealth solutions across Europe. One example of an requirement is an unambiguous and accurate representation of one ontology into the other. It is crucial that the translation between different cultures (languages, medical protocols, localisation issues, etc.) is done appropriately since each jurisdiction is responsible for its own healthcare. International bodies can contribute by developing meta-models so that ontologies used in each country have consistent structures, even if they are differently represented or populated.

1.7 Guidelines

In addition to the above mentioned attributes, healthcare information systems need to consider accuracy, validity and quality of medical data.

From a political perspective, the technical aspects to protect individuals and the free movement of data are supported by the standardization bodies of CEN, CENELEC, IEEE, IEC, ISO, ITU and supranational bodies such as EU, OECD, Council of Europe and the UN, which endorsed the guidelines and recommendations as follows:

- OECD "Guidelines on the protection of privacy and trans-border flows of personal data"
- OECD "Guidelines for the security of information systems and networks: towards a culture of security"
- EU Parliament and Council of Europe, Directive 95/46/EC on the protection of individuals with regard to automatic processing of personal data and on the free movement of such data;
- Council of Europe “Recommendation R(97)5 on the protection of medical data”;
- OCHCR "Guidelines for the regulation of computerised personal data files", adopted by the General Assembly resolution 45/95 of 14 December 1990;
- Health Insurance Portability Act (HIPAA)

39 Regenstrief Institute, available: http://www.loinc.org
40 Organisation for Economic Co-operation and Development, 1980, available: http://www.oecd.org/document/18/0,2340,en_2649_34337_1815186_1_1_1_1,00.html
41 Organisation for Economic Co-operation and Development, 2002, pp.28
To conclude, the Health sector is omnipresent. It is hierarchically interacting across local, national, regional and international frontiers and across sectors such as public health, specialized and general surgery, emergencies/disasters, informatics, medical supplies, etc. Using standardised PKI for health is thus a necessity for secure data interchange. With relevant standardized policies, technical interoperability of diverse infrastructures and adoption of right technology standards, we have the basis for supporting an integrated environment for health transactions on a European, even global level.

40 HIPAA is relevant for organizations dealing with other institutions in the U.S. U.S. Department of Health and Human Services, 1998, available: http://aspe.hhs.gov/admnsimp/bannerps.htm#security
TELEMEDICINE ALLIANCE - A BRIDGE TOWARDS COORDINATED EHEALTH IMPLEMENTATION

EHALTH INTEROPERABILITY IN EUROPE: CHALLENGES AND INITIATIVES

Interoperability Study Report - Annex 2: Standards and supporting initiatives related to EHR

Lead Partner for Deliverable: ITU
Start/Duration of project: 1 August 2004 – 31 July 2005
Dissemination Level: PU (Public)
Deliverable Number: TMA-Bridge_Del-4
Document Number: TMAB-ESA-TN-042
Electronic File Name: TMAB-Del.4-Interoperability Study Report_Annex2_Iss2-Rev0.doc
Issue/ Revision: 2/ 0
Due date of deliverable: M9
Actual Date: 19 July 2005
Number of pages: 18

Project co-funded by the European Commission within the 6th Framework Programme (2002-2006); Priority 2 Information Society Technologies (IST); Specific Support Action (SSA); Project No. IST-507871.

1 PU = Public, PP = Restricted to other programme participants, incl. the Commission Services (CS), RE = Restricted to a group specified by the consortium (incl. the CS), CO = Confidential, only for members of the consortium (incl. the CS)
Telemedicine Alliance

European Space Agency, European Space Research & Technology Centre (ESTEC), Noordwijk, The Netherlands

World Health Organization - European Office for Integrated Health Care Services, Barcelona, Spain

International Telecommunication Union: Telecommunication Development Bureau (ITU-D), Geneva, Switzerland

The Interoperability Study Report has been prepared by the Telemedicine Alliance consortium made up of European Space Agency (ESA), International Telecommunication Union (ITU) and World Health Organization (WHO), as part of the European Community 6th Frame Work Programme.

“EHealth in Europe: Challenges and Initiatives” is part of deliverables of the Telemedicine Alliance – a Bridge towards coordinated eHealth implementation.

Other reports and information on this project can be found at www.esa.int/tma-bridge or www.esa.int/telemedicine-alliance.

The opinions expressed in the Interoperability Study Report and its annexes are those of the authors and do not necessarily reflect the views of the International Telecommunication Union, its membership, the European Space Agency, the World Health Organization or their Member States.
Table of Contents

1 STANDARDS AND SUPPORTING INITIATIVES RELATED TO EHR ..................1
  1.1 GEHR: Good European Health Record ..........................................................1
  1.2 OpenEHR Foundation ......................................................................................1
  1.3 EuroRec ...........................................................................................................2
  1.4 CEN ....................................................................................................................3
  1.5 ISO .....................................................................................................................6
  1.6 HL7 .....................................................................................................................8
  1.7 IHE (Integrating the Healthcare Enterprise) ......................................................10
  1.8 ASTM .................................................................................................................10
  1.9 Other standards: ...............................................................................................11

2 CONDENSED TABLE OF STANDARDS DEALING WITH ELECTRONIC HEALTH RECORDS ..........................................................................................................................12

3 SEMANTICS, CODING SCHEMES AND VOCABULARIES ..........................13
  3.1 SNOMED CT .....................................................................................................13

List of Figures

Figure 2-1 Network of ProRec centres ................................................................2
Table 2-1 Condensed table of standards dealing with Electronic Health Records ....12
Table 3-1 Condensed table of standards dealing with classifications, coding schemes and vocabularies ................................................................................................................15
1 STANDARDS AND SUPPORTING INITIATIVES RELATED TO EHR

1.1 GEHR: Good European Health Record

The GEHR project was an EU 3rd Framework project (Advanced Informatics in Medicine project 2014), and ran from 1992 - 1995. There were 21 participating organisations from eight countries. The main achievements of the GEHR project were:

- requirements for Clinical Comprehensiveness of the EHR, which have since fed into many other projects, including ISO 18308;
- an Architecture Model: a structured object-oriented model of the EHR, which contained basic data types, versioning semantics, and the multi-level structuring now accepted in CEN and HL7.

There are initiatives outside Europe in cooperation with GEHR (Australia).

1.2 OpenEHR Foundation

OpenEHR is a non-profit organisation jointly formed in 2000 by UCL (UK) and Ocean Informatics (AUS) uniting an international community working towards the realisation of electronic health records, which are based on experiences from GEHR and:

- clinically comprehensive and ethico-legally sound;
- interoperable and standards-based;
- implemented as open-source components
to support seamless and high quality patient care.

OpenEHR promotes open-source (Reference models, Archetype models, Design Principles).

Activities: Architecture of EHR (EHR core services level, Knowledge services level, clinical application services level), reference implementations, academic demonstrators. They are actively involved in CEN and HL7 groups.

---

2 Centre for health informatics and multiprofessional education, 2005, available: http://www.chime.ucl.ac.uk/work-areas/ehrs/GEHR
1.3 EuroRec

The European Institute for Health Records (EuroRec)\(^4\) was founded as an umbrella organisation for the National ProRec centres at their initiative (WIDENET) and with the FP 5 support of the EU.

- A non-for-profit organisation;
- Founded in 2002 by the (then) national, but EU supported, ProRec centres in Belgium, Spain, France, and Bulgaria with the firm belief that
- the effective co-operation between all interested parties including users, professionals, authorities, industry, standardisation bodies and others at a European level and through a process of managed convergence towards European EHRs would benefit from the set-up of an appropriate structure based on existing organisations that could promote that mission;
- The number of National ProRec centres were expanded during FP4, and each became:
  - A registered non-for-profit organisation;
  - Established at the national level, and were
    - gathering in a balanced way
      1. solution providers
      2. users, and
  - Developing contacts with all other stakeholders (public authorities, etc.).

\(^4\) EuroRec, 2005, available: http://www.eurorec.org
Two useful and promising activities in preparation:

- Registration of coding systems used in health care;
- Quality Labelling of EHR systems.

EuroRec organises one international conference per year.

### 1.4 CEN

Since 1990 CEN has regarded the Electronic Healthcare Record as one of the most important areas for the establishment of European standards, especially in WG1 (Healthcare Information Modelling and Medical Records). It has so far published two generations of EHR standard, in 1995 and 1999.

**EHCRA (ENV 12265)**

ENV 12265 Electronic Healthcare Record Architecture (1995) was a foundation standard defining the basic principles upon which electronic healthcare records should be based\(^5\).

The scope of ENV 12265 states was to define the basic architectural principles for representing the content and structure of electronic healthcare records.

This European pre-standard provides the foundation for a standard reference architecture for the interchange of electronic healthcare records (in whole or part) between electronic healthcare record systems.

This European pre-standard, in conjunction with succeeding standards:

- enables the content and context of healthcare information of any sort to be recognisable and understandable when displaced from its origin;
- provides the means for referring to healthcare domain information models or syntaxes and for describing how instances of information represented in this way are organised in a healthcare record; and
- provides data structure principles for use by developers in implementing the ethical and legal measures required by national or international regulatory bodies.

This European pre-standard does not apply to the representation of record information within an electronic healthcare system; nevertheless suppliers who wish to exchange records that conform to its

---

\(^5\) [http://www.chime.ucl.ac.uk/work-areas/ehrs/EHCR-SupA/Architecture/index.htm](http://www.chime.ucl.ac.uk/work-areas/ehrs/EHCR-SupA/Architecture/index.htm)
provisions may find it convenient to use it as a reference architecture for the storage, processing, and display of electronic healthcare records in the electronic healthcare record system.

**ENV13606**

A four-part successor standard for **Electronic Healthcare Record Communication, ENV 13606**, was published in 1999.

- Part 1, the Extended Architecture, built on ENV 12265 and defined additional components for describing the structures and semantics in EHCRRs conforming to a range of requirements to allow the content of a healthcare record to be constructed, used, shared and maintained.

- Part 2, the Domain Termlist, defined a set of terminological measures to support various degrees of interoperability of the EHCRs created on different systems or by different teams on the same system.

- Part 3, the Distribution Rules, specified a set of data objects that represent the rules for defining access privileges to part or whole EHCRs, and the means by which security policies and attributes can be defined and implemented.

- Part 4 defined a set of messages to enable the communication of part or whole EHCRs in response to a request message or a need to update a mirror repository of a patient’s EHCR.

Since 1999 several demonstrator projects and a few suppliers have elected to use ENV 13606 in an adapted form as their means of EHR interoperability between systems and enterprises. Regrettably the adaptations made to ENV 13606 have been rather *ad hoc*.

**HISA (ENV 12967)**

The 1999 CEN ‘**Standard Architecture for Healthcare Information Systems**’ (ENV 12967, commonly known as “HISA”) seeks to enable the development of modular open systems to support healthcare.

The HISA standard builds on the extensive work of RICHE, NUCLEUS, EDITH and HANSA in this field. The architecture of any generic healthcare information system is described as a federation of heterogeneous applications, interacting and co-operating through a middleware layer of common services. It specifies the structure of the data maintained and retrieved by each service, without prescribing its internal structure. Both applications and the middleware rely on a set of technological facilities (a bitways layer) to enable the physical connection and interaction of various modules.

Two main classes of common services are identified:

- **Healthcare-related Common Services** (HCS) meeting the particular requirements and activities of users in the healthcare business domain. These relate to the subject of care, activities, resources, authorisation, health characteristics, concepts.
• **Generic Common Services** (GCS) which may be common to any information system in any business domain.

This standard is presently being revised by CEN, and is expected to be published as a full standard (**EN 12967**) in 2005.

**The EHRcom TaskForce (prEN 13606)**

In December 2001 CEN TC/251 confirmed a new Task Force, known as "**EHRcom**"\(^6\), to review and revise the 1999 four-part pre-standard ENV 13606 relating to Electronic Healthcare Record Communications. The intention of this work is to propose a revision that could be adopted by CEN as a formal standard (EN) during 2004. The Enquiry Process in CEN has started in October 2004 (prEN13606).

The Task Force was out to base the revision of ENV 13606 on the practical experience that has been gained through commercial systems and demonstrator pilots in the communication of whole or part of patients’ EHRs, mainly in Europe and Australia.

The overall mission statement of the EHR communications standard proposed by the Task Force was to produce a rigorous and durable information architecture for representing the EHR, in order to support the interoperability of systems and components that need to interact with EHR services:

- as discrete systems or as middleware components;
- to access, transfer, add or modify health record entries;
- via electronic messages or distributed objects;
- preserving the original clinical meaning intended by the author;
- reflecting the confidentiality of that data as intended by the author and patient.

Parts of preEN13606\(^7\):

Part 1: Reference Model
- comprehensive, generic EHR model drawing on 12 years of R&D and 2 previous CEN standards;
- mapped to HL7 RIM and CDA;

Part 2: Archetype Interchange Specification
- adopting the openEHR archetype approach;
TMA-Bridge

TELEMEDICINE ALLIANCE - A Bridge Towards Coordinated eHealth Implementation

Del.4: Interoperability Study Report - Annex-2: Standards & Supporting Initiatives Related to EHR

- compatible with HL7 Template specification;

Part 3: Reference Archetypes and Term Lists
- initial archetypes for Europe, and repository specification;
- micro-vocabularies for the Part 1 model;

Part 4: Security Features
- measures to support access control, consent and auditability of EHR communications;

Part 5: Exchange Models
- messages and service interfaces to enable EHR and archetype communication.

Reference implementations:
- Karolinska Institute, Sweden
- University College London
- Universidad Politecnica de Valencia

CEN ISSS eHealth Report

The recent report from the CEN ISSS Focus Group on eHealth (V 8.2 available for discussion) stresses the importance of Electronic Health Records and the related standardisation initiative.

One of the identified key strategic aims is “improving access to clinical record” and therefore critical applications for achieving this aims have been highlighted:

- Electronic Health/patient records including health record architecture;
- Electronic Transfer of prescriptions;
- Electronic Health data messages […].

This report condenses a literature overview of eHealth related standards and standardisation initiatives.

1.5 ISO

The International Standardisation Organisation within the technical committee 215 has developed some standards related to EHR. Two working groups are leading the task: TC 215/WG 1 Health records and modelling coordination and WG 2 Messaging and communication.

---

8 Refer to pages 54-56 Part1, and executive summary of V8.2
ISO TS 18308 (EHR Requirements)

The purpose of ISO/TS 18308:2004\(^9\) was to assemble and collate a set of clinical and technical requirements for an electronic health record architecture (EHRA) that supports using, sharing, and exchanging electronic health records across different health sectors, different countries, and different models of healthcare delivery. It gives requirements for the architecture but not the specifications of the architecture itself.

The EHR architecture requirements framework is divided in\(^10\):

- **STR1**: Structure
- **PRO2**: Process
- **COM3**: Communication
- **PRS4**: Privacy and Security
- **MEL5**: Medico-Legal
- **ETH6**: Ethical
- **EVO8**: Evolution

Reference Implementation:

- The first known compliance test against the 18308 requirements has been done for the openEHR Reference Model.

**ISO/DTR 20514 – EHR Definition, Scope and Context**

This project began in August 2001 and is due for completion by mid-2004 [Ballot status]. Its target deliverable is an ISO Technical Report which\(^11\):

- describes a pragmatic classification of electronic health records;
- provides simple definitions for the main categories of EHR; and
- provides supporting descriptions of the characteristics of electronic health records and EHR systems.

Previous attempts to develop a definition for the Electronic Health Record (EHR) have foundered due to the difficulty of encapsulating all of the many and varied facets of the EHR in a single comprehensive definition\(^12\).

---


\(^10\) ISO/TS 18308 ISO TC 215/SC /WG 1 Date: 2003-04-23

\(^11\) Partnership for Health Information Standards Newsletter/Update, Issue 20 – Summer 2004
The approach taken in this Technical Report is to make a clear distinction between the content of the EHR and its form or structure. This is achieved by first defining the EHR in terms of its structure (i.e. as a container). This definition (to be called the "basic-generic EHR") is intentionally concise and generic to ensure the broadest applicability to the widest range of existing and future users of EHRs and EHR systems. Such a definition must also be able to support legislative and access control requirements that apply to all ‘forms’ of EHR.

The basic-generic EHR definition is supplemented by a more detailed and specialised definition to cover two of the most essential characteristics of the EHR not covered by the basic-generic definition. These are the ability to share patient health information between authorised users of the EHR and the primary role of the EHR in supporting continuing, efficient and quality integrated health care. There are of course many other important characteristics of the EHR dependent on the scope and context of care, which will not be explicitly expressed in a single supplementary definition. It would be possible to develop a whole series of formal definitions to capture all of the nuances of different care contexts. However, the approach taken in this Technical Report is to keep the number of formal definitions of EHR types to an essential minimum and to demonstrate the inclusiveness of these definitions through explanatory text and examples.

The principle definition of the EHR, which is a specialisation of the basic-generic EHR definition, is called the Integrated Care EHR (ICEHR). The ICEHR is based on a standardised or commonly agreed logical information model which supports semantic interoperability. The openEHR Reference Model and the CEN 13606 Reference Model are examples of models which fit this definition.

1.6 HL7

Health Level 7\(^\text{13}\) develops specifications mainly for application-level messaging between health information systems, but also in other areas such as clinical documents and decision support. Its "version 2.x" messaging standards are in wide use in US and around the world, typically between information systems inside the same hospital, and between hospitals and external laboratories.

Since 1997, Health Level 7 (HL7) has been developing a new set of standards, collectively known as "version 3", or "v3". These are still aimed primarily at defining application messages, but are based on formal models, including the "reference information model", or "RIM". Message content schemas are derived by a restriction process which starts from the Reference Information Model (RIM), and continues through domain information models (DIMs), restricted message information models (RMIMs), common message element types (CMETs), finally ending with hierarchical message definitions (HMDs) and generated message schemas in XML.


\(^{13}\) Health Level Seven, 2005, available: http://www.hl7.org/
**HL7 RIM**

The Reference Information Model is a high-level model to govern the definition of future HL7 v3 messages - evolving since 1999. It contains both generic classes and (legacy) specific classes derived from HL7 v2 messages. It spans the requirements of purchaser/provider messages, hospital sub-system communications, clinical observations, act/workflow management and knowledge representation. It is increasingly adopted internationally as an industry standard.

The RIM itself is too general to be just a model for the EHR - but it can be “applied” to the EHR. The classes represented in v3 are: entities, roles, relationships, participations, acts, and acts-relationships.

**HL7 Clinical Document Architecture**

HL7 CDA provides standards for the exchange, management and integration of data that supports clinical patient care and the management, delivery, evaluation of healthcare service and management of electronic health records.

CDA is a generic model for the communication of clinical documents, very similar to the "Composition" class in the CEN 13606 specification and the "Transaction" class in openEHR. It was originally intended as a standardised way of communicating clinical notes, but the CDA user community tend to use it more as a persistence specification. It is regarded by some as the HL7 equivalent of a record architecture. CDA release 2.0 defines the structural organisation of fine-grained information inside a document.

It is divided in:

- Level 1 CDA focuses on the content of narrative documents: high-level context (parties, roles, dates and time, places) and structural organisation of headings
- Level 2 CDA (draft standard) models the fine-grained observations and instructions within each heading through a set of RIM Act classes
- A template-based methodology is proposed for Level 3, to define specific kinds of documents, observations or instructions

There is a active cooperation between CEN TC251, ISO TC215, OpenEHR and HL7 initiatives towards harmonisation.
1.7 IHE (Integrating the Healthcare Enterprise)

Integrating the Healthcare Enterprise is an international association of vendors, coming from radiology, imaging systems, whose aims are to:

- Improve the quality and cost of healthcare by removing the interoperability barriers (Integration cost = 20% of IT budget);
- Provide an open interoperability framework, based on existing standards;
- Enable cross-vendor environment (best-of-breed);
- Leverage the interoperability solutions in multiple domains (radiology, cardiology, clinical lab, enterprise).

The approach (very practical with an agreed 20 month cycle for a profile):

- Solve real-world integration problems;
- Close co-operation between users and vendors;
- Users prioritise the problems; vendors define the technical solutions;
- Common technical framework, based on established standards (e.g. DICOM, HL7, ...);
- Regular validation sessions (connectathon)
  - 2004 Edition: 50 vendors, 100+ systems
  - Demonstrate the implementations at yearly public demo’s (USA, Europe, Japan)
- Document implementation in Integration Statements.

IHE gathers the major vendors in medical industry (Philips, GE, Agfa, etc.).

**IHE XDS**

IHE has developed a new Integration Profile for Longitudinal EHR called XDS (based on ebXML, EHRCom, HL7 CDA, DICOM SR, HL7 2.3.1., SQL and internet standards). This new profile will be tested in the next connectathon, and should be kept track of.

1.8 ASTM

American Society for Testing and Materials (ASTM) is a voluntary standards development organization in the world-a trusted source for technical standards for materials, products, systems, and services.

---

15 G. Claeys Agfa Healthcare R&D, Technology Manager Co-chair IHE Europe/ Hans Peter Bursig, secretary general COCIR
CCR: Continuity of Care Record

The Continuity of Care Record, CCR[^16], is a standard specification that has been developed jointly by ASTM International, the Massachusetts Medical Society, the Health Information Management and Systems Society, the American Academy of Family Physicians, the American Academy of Pediatrics, and the American Medical Association. The CCR has been developed in response to the need to organize and make transportable a set of basic patient information consisting of the most relevant and timely facts about a patient's condition. It is intended to foster and improve continuity of patient care, reduce medical errors, improve patients' roles in managing their health, and assure at least a minimum standard of secure health information transportability.

1.9 Other standards:

DICOM Structured Reporting

Evolving standard for the communication of the results of investigations to the originating clinical teams. It includes a high-level information model comprising a document header, nested context sections (headings) with a (small) set of defined containment relationships, observations are basic name-value pairs and several data types for values, each with a simple data structure.

Implementation experience is limited. There is currently an active integration work in progress with HL7 (especially CDA).

## 2 CONDENSED TABLE OF STANDARDS DEALING WITH ELECTRONIC HEALTH RECORDS

<table>
<thead>
<tr>
<th>Standard Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENV 13606-1:1999</td>
<td>Health Informatics - Electronic healthcare record communication - Part 1: Extended architecture</td>
</tr>
<tr>
<td>ENV 13606-2:2000</td>
<td>Health Informatics - Electronic healthcare record communication - Part 2: Domain Term List</td>
</tr>
<tr>
<td>ENV 13606-3:2000</td>
<td>Health Informatics - Electronic healthcare record communication - Part 3: Distribution rules</td>
</tr>
<tr>
<td>ENV 13606-4:1999</td>
<td>Health Informatics - Electronic healthcare record communication - Part 4: Messages for the exchange of information</td>
</tr>
<tr>
<td>CEN Report: Electronic Healthcare Record Communication – Domain Model</td>
<td></td>
</tr>
<tr>
<td>ISO/TS 18308:2004</td>
<td>Health Informatics — Requirements for an electronic health record architecture</td>
</tr>
<tr>
<td>ISO TR 20514:2004</td>
<td>Health Informatics — Electronic Health Record Definition, Scope, and Context</td>
</tr>
<tr>
<td>HL7 CDA</td>
<td>The Clinical Document Architecture – Release 1</td>
</tr>
<tr>
<td>prEN 13606-1:2004</td>
<td>Health Informatics — Electronic Health Care Record Communication — Part 1: Extended Health Care Record Architecture</td>
</tr>
<tr>
<td>prEN 13606-2:2004</td>
<td>Health Informatics — Electronic Health Care Record Communication — Part 2: Domain Term List</td>
</tr>
<tr>
<td>prEN 13606-3:2004</td>
<td>Health Informatics — Electronic Health Care Record Communication — Part 3: Distribution Rules</td>
</tr>
<tr>
<td>prEN 13606-4:2004</td>
<td>Health Informatics — Electronic Health Care Record Communication — Part 4: Messages for the exchange of information</td>
</tr>
<tr>
<td>prEN 13606-5:2004</td>
<td>Health Informatics — Electronic Health Care Record Communication — Part 5: Messages for the exchange of information</td>
</tr>
<tr>
<td>prEN 13606-6:2004</td>
<td>Health Informatics — Electronic Health Care Record Communication — Part 6: Messages for the exchange of information</td>
</tr>
<tr>
<td>ASTM 1394</td>
<td>Clinical Laboratory Instruments to Computers</td>
</tr>
<tr>
<td>ASTM E1467</td>
<td>Standard Specification for Transferring Digital Neurophysiological Data Between Independent Computer Systems</td>
</tr>
<tr>
<td>ASTM E1384</td>
<td>Standard Guide for Content and Structure of the Electronic Health Record</td>
</tr>
</tbody>
</table>

Table 2-1 Condensed table of standards dealing with Electronic Health Records\(^{17}\)

---

\(^{17}\) CEN/ISSS eHealth Standardisation Focus Group, 2005b, p.67
3 SEMANTICS, CODING SCHEMES AND VOCABULARIES

The area of semantics and terminology is one of the key aspects of transnational information sharing to:

- Reduce medication-related errors;
- Formalise medical and procedural knowledge;
- Present and assess on the quality of information and processes;
- Promote Evidence based knowledge dissemination.

In recommendation 13 of the CEN ISSS/EHSFG report\(^\text{18}\), the need of an international multilingual reference terminology is highlighted, mentioning efforts in formal representation as GALEN, FMA, SNOMED, and WHO.

3.1 SNOMED CT

SNOMED Clinical Terms (SNOMED CT)\(^\text{19}\) is a dynamic, scientifically validated clinical health care terminology and infrastructure that makes health care knowledge more usable and accessible. The SNOMED CT Core terminology provides a common language that enables a consistent way of capturing, sharing and aggregating health data across specialties and sites of care. Among the applications for SNOMED CT are electronic medical records, ICU monitoring, clinical decision support, medical research studies, clinical trials, computerized physician order entry, disease surveillance, image indexing and consumer health information services.

The SNOMED CT Core terminology contains over 364,400 health care concepts with unique meanings and formal logic-based definitions organized into hierarchies. As of January 2005, the fully populated table with unique descriptions for each concept contains more than 984,000 descriptions. Approximately 1.45 million semantic relationships exist to enable reliability and consistency of data retrieval. It is available in English and Spanish language editions. It is in use in USA, and NHS (England).

\(^{18}\) CEN/ISSS eHSFG, 2005a, p. 11
There is a compiled list of international standards in a report by Ray Rogers\textsuperscript{20}, now updated for the CEN ISSS/EHFG report with the initiatives related to classifications, coding schemes and vocabularies:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>prEN 1068:2004</td>
<td>Health Informatics - Registration of coding schemes</td>
</tr>
<tr>
<td>ENV 1614:1995</td>
<td>Health Informatics - Structure for nomenclature, classification and coding of properties in clinical laboratory sciences</td>
</tr>
<tr>
<td>EN 1828:2002</td>
<td>Health Informatics - Categorial structures for surgical procedures</td>
</tr>
<tr>
<td>ISO DIS 10241:1992</td>
<td>International Terminology Standards - Preparation and Layout (currently under revision)</td>
</tr>
<tr>
<td>prEN 12264:2004</td>
<td>Medical Informatics — Categorial Structures of System of Concepts — Model for the Representation of Semantics</td>
</tr>
<tr>
<td>ENV 14032</td>
<td>Health Informatics - System of concepts to support nursing</td>
</tr>
<tr>
<td>CEN/TS 14463:2002</td>
<td>Health Informatics - A syntax to represent the content of medical classification systems (ClaiML)</td>
</tr>
<tr>
<td>ENV WD</td>
<td>Health Informatics - Clinical knowledge resources – Metadata</td>
</tr>
<tr>
<td>ENV WD</td>
<td>Health Informatics - Categorial structure for anatomy</td>
</tr>
<tr>
<td>CTS WD</td>
<td>Health Informatics - Categorial structure for documentation of patient findings and problems</td>
</tr>
<tr>
<td>CTS WD</td>
<td>CEN Report: Health Informatics - Categorial structure for representation of conditions in classifications, coding systems and clinical terminologies</td>
</tr>
<tr>
<td>ENV NWI</td>
<td>Health Informatics - Categorial structure for a concept system for imaging procedures</td>
</tr>
<tr>
<td>ENV NWI</td>
<td>Health Informatics - System of semantic links in medicine</td>
</tr>
<tr>
<td>ISO WD 17115</td>
<td>Vocabulary of terminological systems</td>
</tr>
<tr>
<td>ISO/TS 17117:2002</td>
<td>Health Informatics - Controlled health terminology – Structure and high level indicators</td>
</tr>
<tr>
<td>ISO 18104:2003</td>
<td>Health Informatics - Integration of a reference terminology model for nursing</td>
</tr>
<tr>
<td>ISO PWI</td>
<td>Health Informatics - Terminology expressions in clinical data</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Organization</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO PWI</td>
<td>Distribution formats for terminology</td>
</tr>
<tr>
<td>ISO PWI</td>
<td>ISO PWI Semantics of terminology</td>
</tr>
<tr>
<td>CAP - College of American Pathologists</td>
<td>SNOMED RT - SNOMED Reference Terminology</td>
</tr>
<tr>
<td>CAP - College of American Pathologists</td>
<td>SNOMED Clinical Terms</td>
</tr>
<tr>
<td>Regenstrief Institute</td>
<td>LOINC - Logical Observation Identifiers Names and Codes (primarily pathology)</td>
</tr>
<tr>
<td>WHO</td>
<td>ICD 10 International Classification of Diseases - 10th Revision</td>
</tr>
<tr>
<td>WHO</td>
<td>ICF International Classification of Functioning, Disability and Health</td>
</tr>
<tr>
<td>WHO</td>
<td>International Non-proprietary Drug Names</td>
</tr>
<tr>
<td>WHO</td>
<td>WHO ATC - Anatomical, Therapeutic, Chemical classification</td>
</tr>
<tr>
<td>WHO</td>
<td>ICMP – International Classification of Medical Procedures</td>
</tr>
<tr>
<td>International Council of Nurses</td>
<td>ICNP – International Classification of Nursing Practice</td>
</tr>
<tr>
<td>American Psychiatric Association</td>
<td>DSM-IV – Diagnostic and Statistical Manual of Mental Disorders</td>
</tr>
<tr>
<td>WONCA / WHO-FIC</td>
<td>ICPC-2 International Classification of Primary Care – 2nd revision</td>
</tr>
</tbody>
</table>

Table 3-1  Condensed table of standards dealing with classifications, coding schemes and vocabularies
TMA BRIDGE

TELEMEDICINE ALLIANCE - A BRIDGE TOWARDS COORDINATED eHEALTH IMPLEMENTATION

eHEALTH INTEROPERABILITY IN EUROPE: CHALLENGES AND INITIATIVES

Interoperability Study Report - Annex 3: Standards list of eHSCG

Lead Partner for Deliverable: ITU
Start/Duration of project: 1 August 2004 – 31 July 2005
Dissemination Level*: PU (Public)
Deliverable Number: TMA-Bridge_Del-4
Document Number: TMAB-ESA-TN-042
Electronic File Name: TMAB-Del.4-Interoperability Study Report_Annex3_Iss2-Rev0.doc
Issue/ Revision: 2/ 0
Due date of deliverable: M9
Actual Date: 12 July 2005
Number of pages: 27

Project co-funded by the European Commission within the 6th Framework Programme (2002-2006); Priority 2 Information Society Technologies (IST); Specific Support Action (SSA); Project No. IST-507871.

† PU = Public, PP = Restricted to other programme participants, incl. the Commission Services (CS), RE = Restricted to a group specified by the consortium (incl. the CS), CO = Confidential, only for members of the consortium (incl. the CS)
The Interoperability Study Report has been prepared by the Telemedicine Alliance consortium made up of European Space Agency (ESA), International Telecommunication Union (ITU) and World Health Organization (WHO), as part of the European Community 6th Frame Work Programme.

The authors would like to acknowledge the cooperation of Mr Vicente Traver, ITU-T, and eHealth Standardization Coordination Group for their assistance with this valuable contribution.

“EHealth in Europe: Challenges and Initiatives” is part of deliverables of the Telemedicine Alliance – a Bridge towards coordinated eHealth implementation.

Other reports and information on this project can be found at www.esa.int/tma-bridge or www.esa.int/telemedicine-alliance.

The opinions expressed in the Interoperability Study Report and its annexes are those of the authors and do not necessarily reflect the views of the International Telecommunication Union, its membership, the European Space Agency, the World Health Organization or their Member States.
Table of Contents

1  STANDARDS LIST .................................................................................................................. 1

2  SUPPORT STANDARDS LIST .......................................................................................... 23
1 STANDARDS LIST

This compilation collects the most important standards in all technical and non-technical areas of e-health as collected by the eHealth Standardisation Coordination Group (eHSCG)\(^2\). The document is distinguished into two sections – the ‘table-of-contents’, and a more detailed description. Each description is bookmarked, and tied to the table-of-contents entry.

Here follows a brief explanation of the fields associated to each standard:

**Url**: gives an URL where the standard is available, for free if possible.

**Category**: field shows the medical environment in which the standard is used.

**Others**: other interesting and latest information.

**Relevance**: in a range from 0 to 100, the relevance is a subjective parameter which designates the importance of the standard in relation to e-Health.

Other fields, like *name, brief name, organization, description or used in* need no further explanation.

<table>
<thead>
<tr>
<th>Organization</th>
<th>Brief Name</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>AENOR</td>
<td>UNE-CR 13694</td>
<td>Safety and Security Related Software Quality Standards for Healthcare (SSQS)</td>
</tr>
<tr>
<td>ANSI</td>
<td>HL7v2.XML</td>
<td>HL7 Version 2.5</td>
</tr>
<tr>
<td>ASTM</td>
<td>E2212-02(^a)</td>
<td>Standard Practice for Healthcare Certificate Policy</td>
</tr>
<tr>
<td>ASTM</td>
<td>e1467</td>
<td>Specification for transferring neurophysiologic data between independent computer systems</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>Organization</th>
<th>Brief Name</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASTM</td>
<td>E1239-00</td>
<td>Standard guide for description of reservation/registration-admission, discharge, transfer systems for Electronic Health Record (EHR) systems</td>
</tr>
<tr>
<td>ASTM</td>
<td>E1384-02*</td>
<td>Standard guide for content and structure of the Electronic Health Record (EHR)</td>
</tr>
<tr>
<td>ASTM</td>
<td>E1744-98</td>
<td>Standard guide for view of emergency medical care in the computerized-based patient record</td>
</tr>
<tr>
<td>ASTM</td>
<td>E1715-01</td>
<td>An object-oriented model for registration, admitting, discharge, and transfer functions in computer-based patient record systems</td>
</tr>
<tr>
<td>ASTM</td>
<td>E1714-00</td>
<td>Standard guide for properties of a Universal Healthcare Identifier</td>
</tr>
<tr>
<td>ASTM</td>
<td>E1902-02</td>
<td>Specification for management of the confidentiality and security of dictation, transcription, and transcribed health records</td>
</tr>
<tr>
<td>ASTM</td>
<td>E2211-02</td>
<td>Specification for relationship between a person and a supplier of an electronic personal health record</td>
</tr>
<tr>
<td>ASTM</td>
<td>E2185-02</td>
<td>Standard specification for clinical XML DTDs in healthcare</td>
</tr>
<tr>
<td>ASTM</td>
<td>E2085-00a</td>
<td>Standard guide on security framework for healthcare information</td>
</tr>
<tr>
<td>ASTM</td>
<td>E2117-00</td>
<td>Standard guide for identification and establishment of a quality assurance program for medical transcription</td>
</tr>
<tr>
<td>ASTM</td>
<td>E1986-98</td>
<td>Standard guide for information access privileges to health information</td>
</tr>
<tr>
<td>ASTM</td>
<td>E1987-98</td>
<td>Standard guide for individual rights regarding health information</td>
</tr>
<tr>
<td>ASTM</td>
<td>E2084-00</td>
<td>Standard Specification for Authentication of Healthcare Information Using Digital Signatures</td>
</tr>
<tr>
<td>Organization</td>
<td>Brief Name</td>
<td>Name</td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
<td>------</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV13734</td>
<td>VITAL</td>
</tr>
<tr>
<td>CEN</td>
<td>EN12052</td>
<td>MEDICOM</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV1064</td>
<td>Computer-assisted electrocardiography</td>
</tr>
<tr>
<td>CEN</td>
<td>CR14300</td>
<td>Interoperability of healthcare multimedia report systems</td>
</tr>
<tr>
<td>CEN</td>
<td>CR12069</td>
<td>Profiles for medical image interchange</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV12388</td>
<td>Algorithm for Digital Signature Services in Health Care</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV13608</td>
<td>Security for healthcare communication</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV12251</td>
<td>Management and security of authentication by passwords</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV13939</td>
<td>Medical Data Interchange: HIS/RIS-PACS and HIS/RIS</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV13735</td>
<td>Interoperability of patient connected medical devices</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV13607</td>
<td>Messages for the exchange of information on medicine prescriptions</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV13606</td>
<td>Electronic healthcare record communication</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV12967</td>
<td>Healthcare Information System Architecture (HISA)</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV12612</td>
<td>Messages for the exchange of healthcare administrative information</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV12537</td>
<td>Registration of information objects used for EDI in healthcare</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV12443</td>
<td>Healthcare Information Framework (HIF)</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV12018</td>
<td>Identification, administrative, and common clinical data structure for ICDs</td>
</tr>
<tr>
<td>CEN</td>
<td>env 12017</td>
<td>Medical Informatics Vocabulary (MI Voc)</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV1613</td>
<td>Messages for exchange of laboratory information</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV12264</td>
<td>Categorical structures of systems of concepts - Model for representation of semantics</td>
</tr>
<tr>
<td>Organization</td>
<td>Brief Name</td>
<td>Name</td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
<td>------</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV12381</td>
<td>Time Standards for Healthcare Specific Problems</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV12538</td>
<td>Messages for Patient Referral and Discharge</td>
</tr>
<tr>
<td>CEN</td>
<td>ENV12539</td>
<td>Request and Report Messages for Diagnostic Services Departments</td>
</tr>
<tr>
<td>FDA</td>
<td></td>
<td>63 FR 64998</td>
</tr>
<tr>
<td>HL7</td>
<td>CCOWV1.5</td>
<td>Clinical Context Object Workgroup Version 1.5</td>
</tr>
<tr>
<td>IEEE</td>
<td>IEEE 1073.5.x</td>
<td>Point-of-care medical device communication</td>
</tr>
<tr>
<td>IEEE</td>
<td>IEEE 1073.2.1.2</td>
<td>Point-of-care medical device communication – Application Profiles – MIB Elements</td>
</tr>
<tr>
<td>IEEE</td>
<td>IEEE 1073.3.2</td>
<td>Medical Device Communications – Transport Profile – IrDA Based – Cable Connected</td>
</tr>
<tr>
<td>ISO</td>
<td>DTR16056</td>
<td>Interoperability of Telehealth Systems and Networks</td>
</tr>
<tr>
<td>ISO</td>
<td>ISO9241</td>
<td>Ergonomics requirements for office work with visual display terminals</td>
</tr>
<tr>
<td>ISO</td>
<td>ISO18812</td>
<td>Clinical analyser interfaces to laboratory information systems</td>
</tr>
<tr>
<td>ISO</td>
<td>ISO11073-20301</td>
<td>Point-of-care medical device communication – Application profile – Optional package, remote control</td>
</tr>
<tr>
<td>ISO</td>
<td>ISO/TR 18307</td>
<td>Interoperability and compatibility in messaging and communication standards -- Key characteristics</td>
</tr>
<tr>
<td>JAHIS</td>
<td></td>
<td>MDS A 0001 - 0017</td>
</tr>
<tr>
<td>NEMA</td>
<td>DICOM 3.0 2004</td>
<td>Digital Imaging and Communications in Medicine</td>
</tr>
<tr>
<td>Regenstrief Institute</td>
<td>LOINC</td>
<td>Logical Observation Identifiers Names and Codes</td>
</tr>
<tr>
<td>Name</td>
<td>Digital Imaging and Communications in Medicine</td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Brief name</td>
<td>DICOM</td>
<td></td>
</tr>
<tr>
<td>Organization</td>
<td>NEMA</td>
<td></td>
</tr>
<tr>
<td>Descriptions</td>
<td>DICOM (Digital Imaging and Communications in Medicine) defines the coding of medical images, the protocols of interchange between both sides and a security policy to hide information from third people.</td>
<td></td>
</tr>
<tr>
<td>Used in</td>
<td>Computer tomography, image archives, telediagnostic, EEG, ECG</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Imaging</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>DICOM 3.0 has added waveform support to allow EEG and ECG interchanges. Website of Reference: <a href="http://www.dclunie.com">http://www.dclunie.com</a></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>VITAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 13734</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Descriptions</td>
<td>VITAL specifies a common representation of vital signs information. It is non-device dependent.</td>
</tr>
<tr>
<td>Used in</td>
<td>Medical device communication</td>
</tr>
<tr>
<td>Category</td>
<td>User Interfaces</td>
</tr>
<tr>
<td>Others</td>
<td>It was specially created for real time services.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>MEDICOM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>EN 12052</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Url</td>
<td><a href="http://www.cenorm.be/catweb/11.100.htm">http://www.cenorm.be/catweb/11.100.htm</a></td>
</tr>
<tr>
<td>Descriptions</td>
<td>This standard is the European contribution to the well-known DICOM.</td>
</tr>
<tr>
<td>Used in</td>
<td>Imaging communication (see DICOM)</td>
</tr>
<tr>
<td>Category</td>
<td>Imaging</td>
</tr>
<tr>
<td>Others</td>
<td>EN 12052 supersedes the former ENV 12052, ENV12623 and ENV12922-1.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Computer-assisted electrocardiography</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 1064</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Url</td>
<td><a href="http://www.cenorm.be/catweb/11.040.50.htm">http://www.cenorm.be/catweb/11.040.50.htm</a></td>
</tr>
<tr>
<td>Descriptions</td>
<td>This standard has been taken up worldwide, not only by European countries</td>
</tr>
</tbody>
</table>

Name: TMA-Bridge

Telemedicine Alliance - A Bridge Towards Coordinated eHealth Implementation

Del.4: Interoperability Study Report - Annex-3: Standards List from EHSCG (draft)
### TMA-Bridge

#### Del.4: Interoperability Study Report - Annex-3: Standards List from EHSCG (draft)

<table>
<thead>
<tr>
<th>Used_in</th>
<th>ECG Machines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Medical Device Communications</td>
</tr>
<tr>
<td>Name</td>
<td>Interoperability of healthcare multimedia report systems</td>
</tr>
<tr>
<td>Brief name</td>
<td>CR 14300</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Provides interoperability of healthcare multimedia report systems</td>
</tr>
</tbody>
</table>

#### Name: HL7 Version 2.5

<table>
<thead>
<tr>
<th>Used_in</th>
<th>Medical information Exchange</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>Messages</td>
</tr>
<tr>
<td>Others</td>
<td>Better support for imaging has been introduced in version 2.5 compared with the previous one.</td>
</tr>
<tr>
<td>Name</td>
<td>HL7 Version 2.5</td>
</tr>
<tr>
<td>Brief name</td>
<td>HL7 v2.XML</td>
</tr>
<tr>
<td>Organization</td>
<td>ANSI</td>
</tr>
<tr>
<td>Url</td>
<td><a href="https://www.hl7.org/library/bookstore/">https://www.hl7.org/library/bookstore/</a></td>
</tr>
<tr>
<td>Descriptions</td>
<td>Old HL7 standards were focused on medical information exchange. With the addition of XML support, multimedia capabilities are now reliable</td>
</tr>
</tbody>
</table>

#### Name: Profiles for medical image interchange

<table>
<thead>
<tr>
<th>Used_in</th>
<th>Imaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>Others</td>
<td>CR 12069 is not a mandatory standard, it is a report.</td>
</tr>
<tr>
<td>Name</td>
<td>Profiles for medical image interchange</td>
</tr>
<tr>
<td>Brief name</td>
<td>CR 12069</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Provides the set of profiles for a given user scenario. Defines greyscale, colour, volumetric and time sequences.</td>
</tr>
<tr>
<td>Name</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
</tr>
<tr>
<td>Algorithm for Digital Signature Services in Health Care</td>
<td>Defines the algorithm used for digital signatures in medicine information exchange.</td>
</tr>
<tr>
<td>Safety and Security Related Software Quality Standards for Healthcare (SSQS)</td>
<td>Proposes several quality norms related to security and protection in e-Health software.</td>
</tr>
<tr>
<td>Security for healthcare communication</td>
<td>Defines concepts for secure systems. Besides that, secure data objects and secure data channels are addressed.</td>
</tr>
<tr>
<td>Management and security of authentication by passwords</td>
<td>It addresses the management and security of authentication by passwords.</td>
</tr>
</tbody>
</table>
**TMA-Bridge**

**Category Security**
**Others Sometimes is mandatory to fulfil legal issues.**

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard Practice for Healthcare Certificate Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E2212-02ª</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Adresses the policy for digital certificates that support the authentication, authorization, confidentiality, integrity, and nonrepudiation requirements of persons and organizations that electronically create or transact health information.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Security</td>
</tr>
<tr>
<td>Others</td>
<td>There are 3 types of certificate: one for computerized entities, one for individual person and the last one for clinical individuals.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard Specification for Healthcare Document Formats</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E2184-02</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Defines requirements for the headings, arrangement, and appearance of sections and subsections when used within healthcare documents.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Standards Methodology</td>
</tr>
<tr>
<td>Others</td>
<td>Use of this specification in conjunction with XML DTDs and the EHR (Electronic Health Records) would further enhance efficiency in time and cost.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard Specification for Transferring Digital Waveform Data Between Independent Computer Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E1713-95</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>This standard defines transferring digital waveform data between independent computer systems.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Messages</td>
</tr>
<tr>
<td>Others</td>
<td>It is also an ANSI approved standard. This standard is currently withdrawn!!</td>
</tr>
<tr>
<td>Name</td>
<td>Standard Guide for Properties of Electronic Health Records and Record Systems</td>
</tr>
<tr>
<td>------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Brief name</td>
<td>E1762-95 (2003)</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Description</td>
<td>The standard defines a document structure for use by electronic signature mechanisms and the characteristics of the electronic signature itself.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Security</td>
</tr>
<tr>
<td>Others</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Interoperability of Telehealth Systems and Networks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>DTR 16056</td>
</tr>
<tr>
<td>Organization</td>
<td>ISO</td>
</tr>
<tr>
<td>Description</td>
<td>Addresses the interoperability of telehealth systems and networks.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Infrastructure architecture</td>
</tr>
<tr>
<td>Others</td>
<td>Part 2 of the standard is related to real-time e-Health systems.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Ergonomics requirements for office work with visual display terminals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ISO 9241</td>
</tr>
<tr>
<td>Organization</td>
<td>ISO</td>
</tr>
<tr>
<td>Description</td>
<td>Ergonomics requirements for office work with visual display terminals.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Visual display terminals</td>
</tr>
<tr>
<td>Category</td>
<td>User interfaces</td>
</tr>
<tr>
<td>Others</td>
<td>Its main purpose is to set up a user-friendly environment for general applications (including e-Health)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Medical Data Interchange: HIS/RIS-PACS and HIS/RIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 13939</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Description</td>
<td>Describes the interchange of sanitary data. HIS/RIS-PACS and HIS/RIS.</td>
</tr>
<tr>
<td>Name</td>
<td>Description</td>
</tr>
<tr>
<td>--------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>63 FR 64998</td>
<td>Proposes a classification for five types of medical image management devices.</td>
</tr>
<tr>
<td>Name</td>
<td>Description</td>
</tr>
<tr>
<td>Medical record, image, text - information exchange</td>
<td>It is related to the information exchange between different medical providers.</td>
</tr>
<tr>
<td>MDS A 0001 - 0017</td>
<td>Standard for electronic filing of medical images with security, compatibility and reproducibility.</td>
</tr>
<tr>
<td>Name</td>
<td>Specification for transferring neurophysiologic data between independent computer systems</td>
</tr>
<tr>
<td>------</td>
<td>--------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Brief name</td>
<td>E1467</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Defines how vital signals such as EEG should be stored.</td>
</tr>
<tr>
<td>Used_in</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>Others</td>
<td>It has not been used in favour of VITAL.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Interoperability of patient connected medical devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 13735</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Descriptions</td>
<td>The standard sets up the basis of interoperability among patient connected devices taking account of VITAL standard to achieve device and signal interoperability.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Medical devices</td>
</tr>
<tr>
<td>Category</td>
<td>Medical Device Communication</td>
</tr>
<tr>
<td>Others</td>
<td>This standard and VITAL standard are designed to work together. Each one specifies a level of interoperability.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Messages for the exchange of information on medicine prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 13607</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Url</td>
<td><a href="http://www.medis.or.jp/2_kaihatu/iso/iso_tc215_wg5/data/part7_f_en13607.pdf">http://www.medis.or.jp/2_kaihatu/iso/iso_tc215_wg5/data/part7_f_en13607.pdf</a></td>
</tr>
<tr>
<td>Descriptions</td>
<td>Specifies a message, called prescription dispensing report message, containing information about prescription items that is sent from the dispensing agent to any other party that is legally permitted to receive such message.</td>
</tr>
<tr>
<td>Used_in</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Messages</td>
</tr>
<tr>
<td>Others</td>
<td>Also available at: <a href="http://www.cenorm.be/catweb/35.240.80.htm">http://www.cenorm.be/catweb/35.240.80.htm</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Electronic healthcare record communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 13606</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
</tbody>
</table>
### TMA-Bridge

**TELEMEDICINE ALLIANCE - A Bridge Towards Coordinated eHealth Implementation**

**Del.4: Interoperability Study Report - Annex-3: Standards List from EHSCG (draft)**

<table>
<thead>
<tr>
<th>Descriptions</th>
<th>Purposes a scheme to define a healthcare record in order the information is recognizable and understandable in different applications.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Used_in</td>
<td>EHR Products</td>
</tr>
<tr>
<td>Category</td>
<td>Knowledge management</td>
</tr>
<tr>
<td>Others</td>
<td>It is divided in four parts.</td>
</tr>
<tr>
<td></td>
<td>Part 1: Extended architecture</td>
</tr>
<tr>
<td></td>
<td>Part 2: Domain term list</td>
</tr>
<tr>
<td></td>
<td>Part 3: Distribution rules</td>
</tr>
<tr>
<td></td>
<td>Part 4: Messages for the exchange of information</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Healthcare Information System Architecture (HISA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 12967</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Describes the Healthcare Information System Architecture (HISA), which is a description of the middleware layer used in healthcare.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Implementations in Denmark</td>
</tr>
<tr>
<td>Category</td>
<td>Infrastructure Architecture</td>
</tr>
<tr>
<td>Others</td>
<td>It is described with diagrams.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Messages for the exchange of healthcare administrative information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 12612</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Specifies messages for the exchange of healthcare administrative information to provide safe, efficient and effective healthcare delivery within hospitals and in primary care.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Messages</td>
</tr>
<tr>
<td>Category</td>
<td>The messages do not cover the reimbursement nor the admission, discharge and transfer processes themselves, but make such processes much easier because of the overall availability of registration and identification data.</td>
</tr>
<tr>
<td>Name</td>
<td>Registration of information objects used for EDI in healthcare</td>
</tr>
<tr>
<td>------</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>Brief name</td>
<td>ENV 12537</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Url</td>
<td><a href="http://www.cenorm.be/catweb/35.240.70.htm">http://www.cenorm.be/catweb/35.240.70.htm</a></td>
</tr>
<tr>
<td>Descriptions</td>
<td>Defines the registration of information objects used for EDI in healthcare for the purpose of information interchange related to healthcare.</td>
</tr>
<tr>
<td>Used_in</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Terminology</td>
</tr>
</tbody>
</table>
| Others | It has two parts.  
Part 1: The Register  
Part 2: Procedures for the registration of information objects used for electronic data interchange (EDI) in healthcare |

<table>
<thead>
<tr>
<th>Name</th>
<th>Healthcare Information Framework (HIF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 12443</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Creates a basic framework to guide healthcare informatics developers. It is a first step in standardising the architectures that will support the latest approaches to the delivery of computer systems such as are required to provide the global information</td>
</tr>
<tr>
<td>Used_in</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Infrastructure Architecture</td>
</tr>
<tr>
<td>Others</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Identification, administrative, and common clinical data structure for ICDs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 12018</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Descriptions</td>
<td>This standard proposes a standardised framework for data structures used with respect to Intermittently Connected Devices (ICDs).</td>
</tr>
<tr>
<td>Used_in</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Infrastructure architecture</td>
</tr>
</tbody>
</table>
| Others | An ICD is a device that stores and transmits person related data in such a fashion that the originator of the information may not receive confirmation of receipt by the recipient.  
Overview info available at: http://www.ramit.be/scripts/imiawg16/1standard |
<table>
<thead>
<tr>
<th>Name</th>
<th>Medical Informatics Vocabulary (MIVoc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 12017</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Defines the Medical Informatics Vocabulary, which is a foundation for the development of a vocabulary of terms used in Medical Informatics.</td>
</tr>
<tr>
<td>Used in</td>
<td>Terminology</td>
</tr>
<tr>
<td>Others</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Messages for exchange of laboratory information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 1613</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Provides a complete implementable specification of the laboratory messages by implementation guidelines to supplement the message definitions. It also provides comprehensive data and structured tables.</td>
</tr>
<tr>
<td>Used in</td>
<td>Messages</td>
</tr>
<tr>
<td>Others</td>
<td>These coding schemes are commonly used to provide precise and unambiguous representation of the data</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Point-of-care medical device communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>IEEE 1073.5.x</td>
</tr>
<tr>
<td>Organization</td>
<td>IEEE</td>
</tr>
<tr>
<td>Url</td>
<td></td>
</tr>
<tr>
<td>Descriptions</td>
<td>Efforts are underway to add standards for enabling internetworking of medical devices across a LAN/WAN.</td>
</tr>
<tr>
<td>Used in</td>
<td>Medical Device Communication</td>
</tr>
<tr>
<td>Others</td>
<td>It is not a standard, it is a serie of standards that will be published soon. More info available at: <a href="http://www.ieee1073.org/standards/standards-at-a-glance/standardsataglance.html">http://www.ieee1073.org/standards/standards-at-a-glance/standardsataglance.html</a></td>
</tr>
<tr>
<td>Name</td>
<td>Point-of-care medical device communication – Application profile – Optional package, remote control</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Brief name</td>
<td>ISO 11073-20301</td>
</tr>
<tr>
<td>Organization</td>
<td>ISO</td>
</tr>
<tr>
<td>Url</td>
<td></td>
</tr>
<tr>
<td>Descriptions</td>
<td>Describes an optional application profile optional packages for remote control.</td>
</tr>
<tr>
<td>Used in</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Medical Device Communication</td>
</tr>
<tr>
<td>Others</td>
<td>Some functions are similar or complement the european standard ENV13735.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Point-of-care medical device communication – Application Profiles – MIB Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>IEEE 1073.2.1.2</td>
</tr>
<tr>
<td>Organization</td>
<td>IEEE</td>
</tr>
<tr>
<td>Url</td>
<td></td>
</tr>
<tr>
<td>Descriptions</td>
<td>MIB Element definitions from the revised DIM standard</td>
</tr>
<tr>
<td>Used in</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Medical Device Communication</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Medical Device Communications – Transport Profile – IrDA Based – Cable Connected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>IEEE 1073.3.2</td>
</tr>
<tr>
<td>Organization</td>
<td>IEEE</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Describes the IrDA-based, RS-232, cable connected transport between devices connectivity. It also set up the basis for firmware upgrades for medical devices.</td>
</tr>
<tr>
<td>Used in</td>
<td>Medical devices</td>
</tr>
<tr>
<td>Category</td>
<td>Medical Device Communication</td>
</tr>
<tr>
<td>Others</td>
<td>This new transport profile offers a key advantage in fostering implementation and adoption of the IEEE 1073 Medical Information Bus Standards. More info at: <a href="http://www.ieee1073.org/standards/11073-30200/11073-30200.html">http://www.ieee1073.org/standards/11073-30200/11073-30200.html</a></td>
</tr>
</tbody>
</table>
### Name
Categorical structures of systems of concepts - Model for representation of semantics

### Brief name
ENV 12264

### Organization
CEN

### Url

### Descriptions
The standard provides the vocabulary and the guidelines to describe the categorial structure of a concept system: the structure consists in practice of a list of involved categories with reference to the available authoritative sources for detailed value.

### Used_in
Category: Terminology

### Others
Medical Informatics deals with a great number of large, overlapping coding systems that are facing each other and conflicting in the coming Integrated Healthcare Information Environment. This standard tries to solve these conflicts.

---

### Name
Time Standards for Healthcare Specific Problems

### Brief name
ENV 12381

### Organization
CEN

### Url

### Descriptions
Provides a set of basic entities, with precisely defined properties and interrelationships among them, that is sufficient to allow an unambiguous representation of time-related expressions.

### Used_in
Category: Terminology

### Others

---

### Name
Messages for Patient Referral and Discharge

### Brief name
ENV 12538

### Organization
CEN

### Url
http://www.cenorm.be/catweb/35.240.70.htm

### Descriptions
It refers to referral and discharge but also covers the request for specialist services and the reports by the specialist service provider, including clinic letters and discharge summaries.

### Used_in
Category: Messages

### Others
Graphical or image information that forms part of a request for or report of a specialist healthcare service is excluded.
<table>
<thead>
<tr>
<th>Name</th>
<th>Request and Report Messages for Diagnostic Services Departments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ENV 12539</td>
</tr>
<tr>
<td>Organization</td>
<td>CEN</td>
</tr>
<tr>
<td>Descriptions</td>
<td>It provides the description of the scope of the messages and its functionality and implementation guidelines for different scenarios.</td>
</tr>
<tr>
<td>Used_in</td>
<td>X-rays, CAT, NMR, ultrasound scans, ECGs, lung-function tests, anatomic pathology and nuclear medicine</td>
</tr>
<tr>
<td>Category</td>
<td>Messages</td>
</tr>
<tr>
<td>Others</td>
<td>The scope is limited to character-based messages, therefore is not related to multimedia.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard guide for description of reservation/registration-admission, discharge, transfer systems for Electronic Health Record (EHR) systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E1239-00</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>This guide identifies the minimum information capabilities needed by an ambulatory care system or a resident facility R-ADT system.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>Category</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>Others</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard guide for content and structure of the Electronic Health Record (EHR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E1384-02ª</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>This guide covers all types of healthcare services, including those given in acute care hospitals, nursing homes, skilled nursing facilities, home healthcare, and specialty care environments as well as ambulatory care.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>Category</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>Others</td>
<td>They apply both to short term contacts (for example, emergency rooms and emergency medical service units) and long term contacts (primary care physicians with long term patients).</td>
</tr>
<tr>
<td>Name</td>
<td>Standard guide for view of emergency medical care in the computerized-based patient record</td>
</tr>
<tr>
<td>------</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Brief name</td>
<td>E1744-98</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Url</td>
<td><a href="http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E1744.htm?E+mystore">http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E1744.htm?E+mystore</a></td>
</tr>
<tr>
<td>Descriptions</td>
<td>It addresses the identification of the information that is necessary to document emergency medical care in a computerized patient record that is part of a paperless patient record system.</td>
</tr>
<tr>
<td>Used_in</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>Others</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>An object-oriented model for registration, admitting, discharge, and transfer functions in computer-based patient record systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E1715-01</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Url</td>
<td><a href="http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E1715.htm?E+mystore">http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E1715.htm?E+mystore</a></td>
</tr>
<tr>
<td>Descriptions</td>
<td>Details the objects that make up the reservation, registration, admitting, discharge, and transfer functional domain of the computer-based record of care.</td>
</tr>
<tr>
<td>Used_in</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>Others</td>
<td>It is intended to amplify guide E1239 with an object-oriented focus.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard guide for properties of a Universal Healthcare Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E1714-00</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Url</td>
<td><a href="http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E1714.htm?E+mystore">http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E1714.htm?E+mystore</a></td>
</tr>
<tr>
<td>Descriptions</td>
<td>This guide covers a set of requirements outlining the properties of a national system creating a universal health care identifier (UHID).</td>
</tr>
<tr>
<td>Used_in</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>Others</td>
<td>Use of the UHID is expected to be limited to the population of the United States.</td>
</tr>
<tr>
<td>Name</td>
<td>Specification for management of the confidentiality and security of dictation, transcription, and transcribed health records</td>
</tr>
<tr>
<td>------</td>
<td>------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Brief name</td>
<td>E1902-02</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>It describes certain steps that shall be taken by those involved in the processes of dictation and transcription of healthcare documentation.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Security</td>
</tr>
<tr>
<td>Others</td>
<td>It also seeks to identify certain dictation and transcription practices that may increase the risks of infringing on privacy and violating security of healthcare documentation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard specification for clinical XML DTDs in healthcare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E2185-02</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Url</td>
<td><a href="http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E2182.htm?E+mystore">http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E2182.htm?E+mystore</a></td>
</tr>
<tr>
<td>Descriptions</td>
<td>This guide provides a compendium of information for the use of E2183 XML DTDs within healthcare. This guide describes design considerations, the architecture of the DTDs, and implementing systems using the E2183 DTDs.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Standards Methodology</td>
</tr>
<tr>
<td>Others</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard guide on security framework for healthcare information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E2085-00a</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Url</td>
<td><a href="http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E2085.htm?E+mystore">http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E2085.htm?E+mystore</a></td>
</tr>
<tr>
<td>Descriptions</td>
<td>Describes a framework for the protection of healthcare information. It addresses both storage and transmission of information.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Security</td>
</tr>
<tr>
<td>Others</td>
<td>It makes use of well-known security algorithms such as SHA-1, triple-DES and others.</td>
</tr>
<tr>
<td>Name</td>
<td>Standard guide for information access privileges to health information</td>
</tr>
<tr>
<td>------</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>Brief name</td>
<td>E1986-98</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>This guide covers the process of granting and maintaining access privileges to health information. It directly addresses the maintenance of confidentiality of personal, provider, and organizational data in the healthcare domain.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Security</td>
</tr>
<tr>
<td>Others</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard guide for individual rights regarding health information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E1987-98</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>This guide outlines the rights of individuals, both patients and providers, regarding health information and recommends procedures for the exercise of those rights.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Knowledge management and Security</td>
</tr>
<tr>
<td>Others</td>
<td>This guide is intended to amplify Guide E1869.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard Specification for Authentication of Healthcare Information Using Digital Signatures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E2084-00</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>This specification covers the use of digital signatures to provide authentication of healthcare information, as described in Guide E 1762. It describes how the components of a digital signature system meet the requirements specified in Guide E 1762.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Security</td>
</tr>
<tr>
<td>Others</td>
<td>This includes specification of allowable signature and hash algorithms, management of public and private keys, and specific formats for keys, certificates, and signed healthcare documents.</td>
</tr>
<tr>
<td>Name</td>
<td>Interoperability and compatibility in messaging and communication standards -- Key characteristics</td>
</tr>
<tr>
<td>------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Brief name</td>
<td>ISO/TR 18307</td>
</tr>
<tr>
<td>Organization</td>
<td>ISO</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Describes a set of key characteristics to achieve interoperability and compatibility in trusted health information interchange between communicant application systems.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Messages</td>
</tr>
<tr>
<td>Category</td>
<td>Messages</td>
</tr>
<tr>
<td>Others</td>
<td>The key characteristics describe inter-application interoperability needs of the healthcare community, in particular the subject of care, the healthcare professional/caregiver, the healthcare provider organization, its business units and the integrated data</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Logical Observation Identifiers Names and Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>LOINC</td>
</tr>
<tr>
<td>Organization</td>
<td>Regenstrief Institute</td>
</tr>
<tr>
<td>Descriptions</td>
<td>The purpose of the LOINC database is to facilitate the exchange and pooling of results, such as blood hemoglobin, serum potassium, or vital signs, for clinical care, outcomes management, and research.</td>
</tr>
<tr>
<td>Used_in</td>
<td>US healthcare framework</td>
</tr>
<tr>
<td>Category</td>
<td>Terminology</td>
</tr>
<tr>
<td>Others</td>
<td>The Regenstrief Institute provides mapping utility called the Regenstrief LOINC Mapping Assistant (RELMA) to facilitate searches through the LOINC database.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Clinical Context Object Workgroup Version 1.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>CCOW V1.5</td>
</tr>
<tr>
<td>Organization</td>
<td>HL7</td>
</tr>
<tr>
<td>Url</td>
<td><a href="http://www.hl7.org/special/Committees/ccow_sigvi.htm">http://www.hl7.org/special/Committees/ccow_sigvi.htm</a></td>
</tr>
<tr>
<td>Descriptions</td>
<td>CCOW V1.0 defined the overall technology-neutral context management architecture (CMA), a core set of data definitions, rules for application user interfaces, and the translation of the CMA to Microsoft’s COM/ActiveX technology.</td>
</tr>
<tr>
<td>Used_in</td>
<td>User Interfaces</td>
</tr>
<tr>
<td>Category</td>
<td>User Interfaces</td>
</tr>
<tr>
<td>Others</td>
<td>This version also support technology mapping to SOAP.</td>
</tr>
<tr>
<td>Name</td>
<td>Clinical analyser interfaces to laboratory information systems</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>Brief name</td>
<td>ISO 18812</td>
</tr>
<tr>
<td>Organization</td>
<td>ISO</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Specifies general messages for electronic information exchange between analytical instruments and laboratory information systems within a clinical laboratory.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Messages and Medical Device Communication</td>
</tr>
<tr>
<td>Others</td>
<td>Covers the specification of messages used by communicating parties and the syntax in which they are communicated. It does not cover the transport mechanisms used for the message interchange.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Specification for relationship between a person and a supplier of an electronic personal health record</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E2211-02</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>This specification covers the relationship between a consumer, organization or custodian and a managing organization (such as a web site or other organization).</td>
</tr>
<tr>
<td>Used_in</td>
<td>User Interfaces</td>
</tr>
<tr>
<td>Others</td>
<td>This specification will not address personal health records (PCHR) that are created and managed by patients on paper records.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard guide for identification and establishment of a quality assurance program for medical transcription</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E2117-00</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>It establishes a quality assurance program for dictation, medical transcription, and related processes. Quality assurance is necessary to ensure the accuracy of healthcare documentation.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Standards Methodology</td>
</tr>
<tr>
<td>Others</td>
<td>This guide establishes essential and desirable elements for quality healthcare documentation, but it is not purported to be an exhaustive list.</td>
</tr>
</tbody>
</table>
2 SUPPORT STANDARDS LIST

The following list by eHSCG collects standards that give support to a great number of telemedicine applications. Although they are not uniquely applied on e-health matters, their functionality can be greatly exploited on the development of telemedicine systems.

<table>
<thead>
<tr>
<th>Name</th>
<th>Specification for transferring digital voice data between independent digital dictation systems and workstations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E2185-01</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Url</td>
<td><a href="http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E2185.htm?E=mystore">http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E2185.htm?E=mystore</a></td>
</tr>
<tr>
<td>Descriptions</td>
<td>Describes the format and content of digitally recorded voice data files. The object is to enable transfer between independent digital dictation systems regardless of manufacturer.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Category Digital voice transferring</td>
</tr>
<tr>
<td>Others</td>
<td></td>
</tr>
<tr>
<td>Relevance</td>
<td>80</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard guide for user authentication and authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>E1985-98</td>
</tr>
<tr>
<td>Organization</td>
<td>ASTM</td>
</tr>
<tr>
<td>Descriptions</td>
<td>This guide addresses the technical specifications for how to perform user authentication and authorization. The actual definition of who can access what is based on organizational policy.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Category Security</td>
</tr>
<tr>
<td>Others</td>
<td>These actions may include access to healthcare information documents, as well as, specific operations on those documents.</td>
</tr>
<tr>
<td>Relevance</td>
<td>80</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>Name</th>
<th>H.323 Packet-based multimedia communications systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>H.323 System</td>
</tr>
<tr>
<td>Organization</td>
<td>ITU-T</td>
</tr>
<tr>
<td>Used_in</td>
<td>Videoconferencing, VoIP</td>
</tr>
<tr>
<td>Category</td>
<td>Videoconferencing</td>
</tr>
<tr>
<td>Others</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Public key infrastructure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief name</td>
<td>ISO 17090</td>
</tr>
<tr>
<td>Organization</td>
<td>ISO</td>
</tr>
<tr>
<td>Descriptions</td>
<td>Defines the basic concepts of a healthcare public key infrastructure (PKI) and provides a scheme of interoperability requirements to establish a PKI enabled secure communication of health information.</td>
</tr>
<tr>
<td>Used_in</td>
<td>Electronic identification, security of Public Administration</td>
</tr>
<tr>
<td>Category</td>
<td>Security</td>
</tr>
<tr>
<td>Others</td>
<td>It has three parts.</td>
</tr>
<tr>
<td></td>
<td>Part 2: Certificate profile.</td>
</tr>
<tr>
<td></td>
<td>Part 3: Policy management of certification authority.</td>
</tr>
<tr>
<td></td>
<td>First Part working draft is freely available at:</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.medis.or.jp/iso/wg4doclist/wg4-n78_pkipart1v4.pdf">http://www.medis.or.jp/iso/wg4doclist/wg4-n78_pkipart1v4.pdf</a></td>
</tr>
<tr>
<td>Relevance</td>
<td>90</td>
</tr>
</tbody>
</table>
TELEMEDICINE ALLIANCE - A BRIDGE TOWARDS COORDINATED eHEALTH IMPLEMENTATION

eHEALTH INTEROPERABILITY IN EUROPE: CHALLENGES AND INITIATIVES


Lead Partner for Deliverable: ITU
Start/Duration of project: 1 August 2004 – 31 July 2005
Dissemination Level¹: PU (Public)
Deliverable Number: TMA-Bridge_Del-4 - Annex 4
Document Number: TMAB-ESA-TN-044
Electronic File Name: TMAB-Del4-Interoperability Study Report_Annex4-front page_Iss2-Rev0_Jul20 05.doc
Issue/ Revision: 2/0
Due date of deliverable: M9
Actual Date: 29 July 2005
Number of pages: 14

¹ PU = Public, PP = Restricted to other programme participants, incl. the Commission Services (CS), RE = Restricted to a group specified by the consortium (incl. the CS), CO = Confidential, only for members of the consortium (incl. the CS)

Project co-funded by the European Commission within the 6th Framework Programme (2002-2006); Priority 2 Information Society Technologies (IST); Specific Support Action (SSA); Project No. IST-507871.
Telemedicine Alliance

European Space Agency, European Space Research & Technology Centre (ESTEC),
Noordwijk, The Netherlands

World Health Organization - WHO Regional Office for Europe, Barcelona, Spain

International Telecommunication Union: Telecommunication Development Bureau
(ITU-D), Geneva, Switzerland

The Interoperability Study Report has been prepared by the Telemedicine Alliance consortium
made up of European Space Agency (ESA), International Telecommunication Union (ITU) and
World Health Organization (WHO), as part of the European Community 6th Frame Work
Programme.

The authors acknowledge the review and inputs of the participants to a workshop on
interoperability organized by the TMA on 18-19 March 2005, with especial thanks to G. Klein of
CEN. The authors also appreciate the support of the Director of the Telecommunication
Standardization Bureau, ITU-T.

“EHealth in Europe: Challenges and Initiatives” is part of deliverables of the Telemedicine Alliance
– a Bridge towards coordinated eHealth implementation.

Other reports and information on this project can be found at www.esa.int/tma-bridge or
www.esa.int/telemedicine-alliance.

The opinions expressed in the Interoperability Study Report and its annexes are those of the
authors and do not necessarily reflect the views of the International Telecommunication Union, its
membership, the European Space Agency, the World Health Organization or their Member States.
eHealth

Interoperability for eHealth: facing challenges and overcoming barriers

eesa

World Health Organization

ITU

European Commission
EHEALTH INTEROPERABILITY IN EUROPE: CHALLENGES AND INITIATIVES

The Telemedicine Alliance and TMA-Bridge: A Vision and a Challenge

This is the second condensed report from the TM Alliance. This Alliance is a partnership of the ESA, WHO, and ITU, which in its 1st phase of work, formulated a Vision* for eHealth by 2010: This vision placed the citizen at the centre of any transition to eHealth so that in the future ICT would be harnessed to make healthcare IT more citizen-centred. During the work on this Vision it was clear that there were many barriers that had to be overcome before it could be realized; the main obstacle was identified as lack of interoperability within and between national and regional healthcare systems.

This summary report, from the TMA’s 2nd phase of work, the TMA-Bridge, provides background material on achieving interoperability within and between national eHealth services with emphasis on the citizen. It is targeted to support decision-makers in the European Commission and the EU national Member States.

Interoperability is not just technical – it is much more

Interoperability must cover the areas of political, organisational, social and technical interoperability to comply with the definition of ATIS - Alliance for Telecommunications Industry Solutions:

Interoperability is "the ability of systems, units or forces to provide services to and accept services from other systems, units, or forces and to use the services so exchanged to enable them to operate effectively together"†.

Where the systems are technical and human, there are different frameworks of interoperability for eHealth: Policy framework, Organizational & Social framework, and Technical framework.

Systems do not have to be the same to communicate with each other

There are, and will continue to be, many different types of health systems across Europe. This should not be an impediment to interoperability, because, if they are well preconceived with regard to interoperability, then quite different systems can still communicate with each other. Moreover, parallel, but compatible, initiatives and developments will provide a good basis for testing different applications and configurations, allowing successful models to serve as an array of options for systems still under development or those experiencing problems. However, it takes the agreed use of common standards and a common ‘infrastructure’ to make different systems work together.

† www.atis.org; website of Alliance for Telecommunications Industry Solutions.
The Need for Standards and Common Infrastructures

Many standards exist for the required services but in some areas it is important that standardization can continue to develop. The recent CEN/ISSS eHealth standardization Focus Group report makes recommendations to the Member States and the Commission on required actions. It is noted that the existing formal European Standardization system with CEN/TC 251 (the committee for Health informatics) has not, and cannot, alone develop all the standards needed. The global co-operation of standardisation bodies like CEN, DICOM, HL7, IEEE, ISO, ITU and OASIS in collaboration with WHO, in the recently formed global eHealth Standardization Co-ordination Group (eHSCG)*, is welcome as a source of information on all standards required and should be given support to be better able to give advice to the users.

It is, however, recognised that the available standards often require further precision and implementation profiles for specific applications that often also require a series of standards. This should be done together with industrial companies and users with cooperation and collaboration on a global level.

In addition to standards and interoperable products, it is necessary to ensure the development of the following information structures that require national work, but in a co-ordinated common structure with shared resources in Europe.

- A common concept system for clinical facts in records with associated multilingual reference terminologies. SNOMED CT is an available system that all Member States should evaluate, and it may be the best candidate to build on. Co-operation with WHO centre for classification is advised in this process. In addition, it is noted that for some fields, multinational terminologies exists outside of this, such as ICD-10 and IUPAC/C-NPU for laboratory tests.
- A directory service with information on providers, professionals and the services offered should be built, based on federated national directories (which in turn may be based on regional directories). Basic standards and initiatives in some countries exist, but no common action yet.
- A European system to verify professional registration of licenses to practice in the different countries that works across borders.

* The eHSCG was endorsed by ITU-T Study Group 16 in May 2003 (TMA is an observer); see http://www.ehscg.org
A Holistic Approach should encompass the various Healthcare domains

The TMA divided the broad arena of eHealth into four domains: Care, Education, Surveillance and Administration. Furthermore, for the purposes of this study, priority actions were identified for each domain, as shown in Table 1 below:

<table>
<thead>
<tr>
<th>eHealth Service</th>
<th>Priority for Trans-National Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care</td>
<td>Structured and harmonized messages and trans-national Electronic Health Record</td>
</tr>
<tr>
<td></td>
<td>Web Community Services</td>
</tr>
<tr>
<td></td>
<td>Reliable Health information webs for the citizen</td>
</tr>
<tr>
<td>Administration</td>
<td>Reimbursement</td>
</tr>
<tr>
<td>Surveillance</td>
<td>Early Warning Systems (comparable Public Health Data)</td>
</tr>
</tbody>
</table>

*Table 1 Domain of eHealth & Priority trans-national services*

The TMA’s systematic philosophy involved analysis of each healthcare domain priority along each infrastructure framework. This allowed the painting of a complete picture together with external international experts, making it possible to view the interactions between all parts and then to identify the gaps and formulate the requisites to enable the realization of interoperable eHealth across healthcare systems. The conclusions reached during this process are presented as follows:

**Challenges we are facing on the way to eHealth**

**eCare**

Twenty years of efforts in standardisation of clinical messages and electronic health records have not ensured interoperability either between levels of care (primary to secondary or specialised care) or between regions and countries. Interoperability includes the problem of semantics in a multi-cultural context. The interpretation of the information collected in the Health Record is still far away from being processed automatically. Moreover, Data protection, security and privacy are perceived to be one of the highest risks for eHealth at a national level. Up to now, despite implementation of the EU directive on data protection*, there are few guidelines with respect to automatic processing of healthcare data; this has become an annoying roadblock to introduction of eHealth methods, especially regarding cross-border data processing. Issues of liability for patients’ data, will become a growing problem especially for telemedical and trans-national services, where legal guidelines are not well defined or consistent across the EU.

---

*Directive 95-46, and follow-up directives.
†I. Yakovidis, “20 Years of eHealth R&D Context”, EUROREC 2004
After more than 10 years of EC IST research programmes† investing resources in Health Records, some lessons have been learned:

- Ensure well thought-out strategy before commencing;
- Break the pattern of large-scale “all-at-once” implementations (start with smaller scale, but upgradeable and expandable implementations, with greater likelihood of success);
- Ensure commitment of the “leaders” especially those who have to use the systems on a daily basis (if leading stakeholders are not involved or committed, failure is likely);
- Ensure legal and ethical compliance;
- Do not underestimate user acceptance (habits, culture, financial and training investment);
- None of the parties can do it alone! (co-operation / collaboration between the stakeholders);
- Do not reinvent the wheel; seek implemented cases of good practice.

**eEducation**

In the relatively affluent and educated EU region, citizens increasingly wish to take an active role in decisions about their health care. Online consumer health information‡ is growing at an unprecedented rate, but users and providers currently have no systematic way of judging its quality. Although it is becoming accepted and expected that access to good information is a right of the patient and a duty on the health professional, to know what is “good quality” information is a challenge. Self-help for the citizen and self-training for the professional is relatively easy to obtain via the Internet, and self teaching multi-media applications can become very effective pedagogic tools to achieve such self-education. Likewise community groups can exchange and share information today as never before – all potentially to the mutual good of all. But once again there is no mechanism available to guarantee quality of information or professional overseeing of a chat-group to ensure that the processes is not one of misinformation.

In Europe’s increasingly trans-national atmosphere of expat citizens and health providers requiring and offering services across borders, linguistic and cultural problems become increasingly prevalent; the mobile patient and professional needs access to information in a language and cultural flavour that can be easily understood. This adds to the existing problems of semantics and ontologies in healthcare, problems that could potentially be solved via eEducation.

**eSurveillance**

In the context of disasters, disease outbreaks or bio-terrorism attacks, early warning and monitoring systems may help to gather intelligence and detect or even predict diseases early, and communicate and exchange
information electronically worldwide. With increased, easy, and fast travel to all corners of the globe, disease can be carried very easily and rapidly over long distances and spread very widely. If interoperable data can be collected and collated quickly, the job of identifying, tracing and dealing with such outbreaks can be carried out more successfully and early enough to minimize damage.

Although some measures are already nationally implemented, one of the main challenges of interoperability is to allow quick cross-border reactions and countermeasures. Early warning systems demand rapid and thoughtful responses to be effective. The greater completeness of information and the speed that can be provided by electronic systems with the ability to model disease/threat progression offer critical tools to develop strategic response plans. Their full potential cannot be reached until the following conditions are in place:

- Ontological cross-reference between different disease surveillance systems;
- A unified approach to disease monitoring and data collection;
- The creation of modeling systems parallel in function to weather forecasting systems;
- Appropriate capacity building through training for data researchers, analysts, data providers, etc.

Finally, all these systems should be highly interoperable helping:

- To improve the quality of the data by importing data from meta-databases, namely benefiting largely from health mappings;
- To increase the speed of information sharing, in particular through export of information into other information systems; and thus to improve predictability, prevention, control, and treatment;
- To use the data to train specialists, e.g. on epidemiological investigation and intervention;
- To correlate the data with data collected in other parts of the world.

In order to fulfil such requirements, various ICTs such as satellite telecommunications to transmit data or monitoring satellite for tele-epidemiology are necessary to build efficient eSurveillance systems; but the key is that such measures must be interrelated with each other, targeting common objectives, collecting comparable data, and making this data immediately available for analysis.

For the systems to be effective:

- It is necessary to collaborate with international organisations, government agencies, healthcare and public health institutions, and authorities for meteorology, geological survey, socio-economic and Earth sciences.
• They require political commitment and a standardized approach of collecting data throughout a network of networks with a common understanding of ontologies.

**eAdministration**

For the domain of eAdministration, the priority sub-domain of eReimbursement was selected, and is discussed herewith. Trans-national eReimbursement covers the flows associated with funds allocation and payments where they are concerned with care provided to persons outside the provider/country’s insurance system.

The key issues for reimbursement are:

• Non-availability of reimbursement for telemedicine services, either inside or outside a country*;
• Lack of agreement on:
  - Medical acts to be reimbursed;
  - Scale of fees and reimbursement percentages;
  - Mechanisms for assuring quality of service;
  - Mechanisms for patients to maintain control over their medical and administrative data, i.e. possession and active declaration of will as the basis for change of data through e.g. PIN;
• Confusion between existing bi-lateral agreements and the recent court decisions† and reinterpretation and clarification‡ of EEC Regulation 1408/71§;
• Variable levels of knowledge about rights and responsibilities of the purchasers, providers and patients;
• Lack of appropriate information and communication mechanism between purchaser and provider to ensure
  - Consistency of interoperable medical ontology between countries;
  - Privacy and confidentiality and agreement on what is medical and administrative data;
  - Speed- rapid transfer of information - authentication and pre-approval;
  - Trace-ability;
• The majority of trans-national reimbursement systems are paper based;
• Difficulty in integrating new ICT systems into business processes by providers;
• There is no standardised approach for the rapid authorisation of medical acts in other countries of the European Union.

The reimbursement of healthcare services between European countries is well established for emergency medical interventions and is covered by the E1XX paper-based system. The recent EU Court of Justice decisions** and EEC Regulation 1408/71 ††potentially extend this to elective

---

*Especially true of second opinions
‡COM(2004) 301, Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union.
§On the application of social security schemes to employed persons and their families moving within the Community.
††On the application of social security schemes to employed persons and their families moving within the Community.
treatments, providing pre-authorisation has been where the visit was expressly for the purpose of receiving treatment*. Policy makers will have to introduce new mechanisms to handle pre-authorisation and to ensure that treatment data can be transferred back to nationally or locally held electronic healthcare records.

Increasingly the current paper-based systems will be inadequate for the volume of transactions resulting from treatment of citizens whilst visiting another country or transferred there for medical treatment.

The impacts of these issues are:

• Experts see reimbursement as a major barrier to implementation of eHealth and especially, trans-national eHealth services†.
• Legal basis for trans-national reimbursement has improved greatly by recent court decisions‡ and reinterpretation and clarification§ of EEC Regulation 1408/71**. (Persons may receive elective treatment in hospitals or by general practitioners whilst travelling or living in other European countries, and get reimbursed.) Although the Regulation is quite clear, national legislation and many practical issues make it very difficult for the citizen who wishes to take advantage of these new rights.
• Reimbursement of Telemedical services is similar to specialist services and is normally excluded from the treatment agreements.
• Implementation of effective eAdministration systems for efficient and speedy reimbursement is still a long way off even where reimbursement is allowed.
• Citizens do not know whether the treatment they have received will be reimbursed until after they have paid.

*See the FAQ at http://europa.eu.int/comm/employment_social/healthcard/citoyens_en.htm
†TM Alliance, Del.12, 2004
**On the application of social security schemes to employed persons and their families moving within the Community.
Concluding Recommendations

TMA-Bridge has formulated a number of recommendations, which have been reviewed and are supported by the participants of a recently held workshop on Interoperability* to which experts representing the various domains of eHealth were invited; a selection of these recommendations are summarised below:

**European and National Policy Actions**

- A co-ordinated steering of resources and priorities for pan-European interoperability actions including standardization should be established. It is noteworthy that a group of representatives of the health ministries working on eHealth is already established†. Its effort to create a special interoperability platform, which includes experts from industry, standardization and health professionals, is welcomed and important.
- The system for authorisation of health professionals should be reconsidered. More co-operation between the responsible bodies in the Member States is required and preferably a system where a health professional authorised in one Member State can also provide services over the public network to citizens and providers in other Member States. Alternatively, a special European licensing for some eHealth services such as the evaluation of images should be considered.
- Generate top-level political support by the European Commission by creating a briefing paper for the Council of Ministers, which after adoption would be incorporated into each Member State’s policy objectives.
- Set targets for cost savings through the use of trans-national eHealth services
- Encourage the adoption of trans-national tele-medicine services through policy initiatives backed by action on fee scales
- Start to introduce a European-wide scheme for accreditation of tele-medicine providers implemented by national centres of competence
- Maintain strong support for the European Health Insurance card as the first step towards improved eHealth especially during the second phase in which some medical data will be added
- Build on the experiences in e-Society, e-Government, e-Commerce, and e-Banking, in particular, and e-Europe, in general, to avoid wherever possible separate development efforts in eHealth
- Encourage national health systems, professional bodies and patient groups to introduce a certification mark for approved health-related web sites

*TMA-Bridge Interoperability Workshop. ESA – Noordwijk, the Netherlands, 18-19 March 2005.
†Health Care Authorities (HCA) Working Group of EHTEL in conjunction with I2Health (initiated Feb. 2005)
• Encourage the speedy development and implementation of European-wide e-surveillance and health warnings by connecting to existing national and international systems.

• Establish a European level web portal for monitoring the impact of interoperability actions.

Encourage user involvement and training for effective implementation and use of eHealth services and applications.

On the issue of Standards

• Create and implement a standardised method for the transfer of administrative and medical data between countries.

• Encourage the development and adoption of interchange standards between countries to avoid the factorial problem created under individual bilateral agreements.

• Create a European-wide ontology interoperability guide to enable translation of fee scales, medical acts.

• Coordinate the activities and recommendations of the diverse standardization bodies and interoperability initiatives in order to bring forward a clear message for action to the Member States decision makers.

• Ensure that the voices of all stakeholders, especially those who are users of the standards, are heard and their needs incorporated into any recommendations made to increase the possibility of adoption.

• Take into account application of interoperability standards in all domains of eHealth and the needs and requirements of all frameworks, including cultural, organisational, and coordinated policy, as well as technical aspects.

• Make the standards simple, easy to access and obtain, and easy to adopt.

• Encourage the work of the eHealth Standardization Co-ordination Group (eHSCG) to provide a lead.

• Bring to the attention of all parties the recommendations of the CEN/ISSS eHealth Focus Group.

• Bring to the attention of decision makers the activities of trans-national organisations, such as NATO, who are adopting practical solutions for eHealth.
### On the issue of Security & Data Protection

- Ensure that trans-nationally transmitted data is transmitted securely and used only for the designated purpose by the designated person.
- All data transmitted between countries must be subject to the level of protection embodied in the various data protection directives.
- All data held, updated or transmitted should be subject to the controls shown to be equivalent to best practice, including, but not limited to traceability, non-revocation, etc.
- A common Public Key Infrastructure (PKI) for certificates should be used to support the key security services for interoperable services across borders:
  - Encryption for confidentiality, Authentication of users and Digital Signatures on electronic documents to allow auditability. Note that the directory service for basic information on providers also can be used for security certificates, but special bodies and trust agreements must exist in all Member States to issue certificates.

---

This document is a summary of Deliverable 4: “EHealth in Europe: Challenges and Initiatives”, being a part of the TMA-Bridge project: “Telemedicine Alliance – a Bridge towards coordinated eHealth implementation”.

The opinions expressed in this document are those of the authors and do not necessarily reflect the views of the European Space Agency, World Health Organization, International Telecommunication Union, their memberships, or their Member States.
Coordinator contact details
To learn more about the Telemedicine Alliance and its work, please contact: European Space Agency

Dr. Didier Schmitt
ESA, Head Life Science Unit
European Space Agency
ESTEC-HME-GA
PO Box 299, NL-2201 AG Noordwijk, The Netherlands

Phone: +31 71 565 4888, Fax: +31 71 565 3661
Mobile: +31 6 22 77 91 90
E-mail: didier.schmitt@esa.int
Telemedicine Alliance Website:
http://www.esa.int/telemedicine-alliance
http://www.esa.int/tma-bridge

Acknowledgements

The main authors and contributors to this work were:
C. Bescos, M. Diop,
A. Dunbar, M. Garcia-Barbero,
J. Kass, K. Ludwig,
A. Ntoko, N. Rossing,
A. Runge, D. Schmitt,
C. Tristram.

Editor: J. Kass

The authors acknowledge the review and inputs of the participants to a workshop on Interoperability organized by the TMA on 18-19 March 2005, with especial thanks to G. Klein of CEN.

Telemedicine Alliance

European Space Agency, European Space Research & Technology Centre (ESTEC), Noordwijk, The Netherlands

World Health Organization - WHO Regional Office for Europe, Barcelona, Spain

International Telecommunication Union: Telecommunication Development Bureau (ITU-D), Geneva, Switzerland

"Project co-funded by the European Commission within the 6th Framework Programme (2002-2006), Priority 2 Information Society Technologies (IST), Specific Support Action (SSA), Project No. IST-2004-507871."
Interoperability Study Report - Annex 5: Initiatives and tools for eSurveillance
Telemedicine Alliance

European Space Agency, European Space Research & Technology Centre (ESTEC),
Noordwijk, The Netherlands

World Health Organization - European Office for Integrated Health Care Services,
Barcelona, Spain

International Telecommunication Union: Telecommunication Development Bureau
(ITU-D), Geneva, Switzerland

The Interoperability Study Report has been prepared by the Telemedicine Alliance consortium made up of European Space Agency (ESA), International Telecommunication Union (ITU) and World Health Organization (WHO), as part of the European Community 6th Frame Work Programme.

"EHealth in Europe: Challenges and Initiatives" is part of deliverables of the Telemedicine Alliance – a Bridge towards coordinated eHealth implementation.

Other reports and information on this project can be found at [www.esa.int/tma-bridge](http://www.esa.int/tma-bridge) or [www.esa.int/telemedicine-alliance](http://www.esa.int/telemedicine-alliance).

The opinions expressed in the Interoperability Study Report and its annexes are those of the authors and do not necessarily reflect the views of the International Telecommunication Union, its membership, the European Space Agency, the World Health Organization or their Member States.
# Table of Contents

1.1 Political back-up in the European Union ......................................................... 4  
1.2 Global co-operation via networks on communicable diseases .............................. 6  
1.3 Disaster and emergency ................................................................................... 8  
1.4 ICTs for early warning systems ......................................................................... 9  
1.5 Examples of tele-epidemiology projects benefiting from space monitoring systems ....... 11
For fear of possible breakout of communicable diseases, biological and chemical attacks, both Governments and public health authorities continuously take measures to establish early warning and response systems that are well equipped with state-of-the-art technology. Using the existing national e-Surveillance technologies, regional and global outbreak alert and response networks connect human and technical resources to rapidly identify, confirm and respond to outbreaks of international importance.2

1.1 Political back-up in the European Union

In responding to the various issues to successfully combat new trends of diseases including new infectious diseases and drug-resistant viruses, the EU network on communicable diseases (CDN) started work in 1999.3 It is built on work done with Member States and consists of two pillars, i.e. surveillance and early warning.

**Surveillance**

Commission Decision 2000/96/EC specifies the list of communicable diseases to be placed progressively under EU-wide surveillance and the criteria for their selection.4 The main task of the network is to monitor and track developments. Within CDN disease-specific networks have been created to focus on, *inter alia*, basic, influenza, sexually transmitted diseases, and tuberculosis surveillance, etc.5

**Early warning**

The second pillar of the CDN is an early warning and response system (EWRS) to alert public health authorities in Member States and the Commission on outbreaks with greater than national dimensions, so that a co-ordinated EU action may be required.

Commission Decision 2000/57/EC clarifies that all events, which could lead to outbreaks of EU-wide significance should be reported under the EWRS irrespective of whether or not a disease-specific network at EU level has been set up. Depending on the specific situation, the Commission and Member States agree on the appropriate action to be taken individually or together.6

This EWRS is a ICT system linking the designated authorities in Member States and the Commission. It allows the immediate exchange of views on risk assessment and management crucial for timely public

---

health action. Already proven to be a useful tool during a number of incidents, the EWRS dealt with e.g. legionnaire’s disease in Belgium and paratyphoid fever in Turkey.

**Bio-terrorism**

The terrorist attacks in the USA on 11 September 2001 and, more specifically, the subsequent ‘anthrax’ scare, brought to the world’s attention the threat of deliberate attacks through the use of biological, chemical or nuclear agents. In the US, the Patriot Act deals with antiterrorism\(^7\). The EU has taken a proactive stance on the issue and reviewed existing systems of protection to minimize the health threats to its citizens. Notable protective measures needed are to co-ordinate public health emergency planning throughout the EU, to prepare and to make available the appropriate treatments. Thus, EC authorities developed a programme to establish a health expert consultation mechanism, strategies on availability and stocks of serums, vaccines and antibiotics as well as a European network of experts for evaluating managing and communicating risks\(^8\).

The Directorate-General for Health and Consumer Protection is currently creating a network and a rapid alert system to add to the scope of the existing EU-wide CDN, put in place in 1999, to detect and oversee any outbreak of infectious diseases. Notably the strength of the early warning and rapid response capacity of these systems will be increased to ensure a timely, coordinated and effective reaction to a terrorist attack of a biological, chemical or a nuclear nature. To coordinate activities between Member States and to carry out the technical work for the set-up of the necessary security mechanisms as defined in the programme, on 01 May 2002 a 'Task Force on Bio-terrorism' was established. It will consist both of EC officials and national experts from different Member States\(^9\).

**Eurosurveillance**

Since 1995, Eurosurveillance offers a free of charge weekly, monthly and quarterly peer-reviewed information portal on communicable disease surveillance and control for the European arena. Its aim is, inter alia, to disseminate relevant information and raise awareness on infectious diseases, to promote the “Network Approach” (Decision 2119/98/EC) of the EC\(^10\), and to maintain appropriate capacity building\(^11\).

**European Centre for Disease Prevention and Control (ECDC)**

The European Centre for Disease Prevention and Control launched at the end of May 2005 has been taken over the type of actions of Eurosurveillance mentioned above. With the partnerships and expertise of European national public health authorities, the independent EU agency supports the strengthening of early warning and surveillance systems across Europe via a networking approach\(^12\). The ECDC in

---

\(^7\) Senate of the United States, 2001, available: [http://www.epic.org/privacy/terrorism/hr3162.html](http://www.epic.org/privacy/terrorism/hr3162.html)


\(^9\) Tegnell, A. et al., 2003, available: [http://www.cdc.gov/ncidod/EID/vol9no10/03-0368.htm](http://www.cdc.gov/ncidod/EID/vol9no10/03-0368.htm)


\(^12\) European Centre for Disease Prevention and Control, 2005, available: [http://www.ecdc.eu.int/index.html](http://www.ecdc.eu.int/index.html)
Stockholm not only identifies, evaluates and communicates data of infectious diseases, but would intervene on its own in case of unknown communicable diseases until “…the source of the outbreak is known and then in cooperation with the relevant competent authorities at national or Community level as appropriate…”\(^3\).

**Training facilities**

At the national centres for surveillance and control of communicable diseases, public health professionals can participate in the “E Programme for Intervention Epidemiology Training”, funded by the European Commission and participating institutes\(^4\). Similar to the aims of Eurosurveillance and of ECDC, the focus is on strengthening capacity and networking to defend the public against current and emergent diseases.

### 1.2 Global co-operation via networks on communicable diseases

In the international context, the EC has been closely co-operating with the “G7+” states\(^5\) and WHO in an effort to ensure an optimal and co-ordinated level of global preparedness and response to the potential threats to public health\(^6\). Both international regulations and networks represent political and organisational efforts to combat dangerous health events. Examples of available tools are mentioned below.

**IHR - a mechanism for international reporting**

Though there is a lack of means to minimize the negative consequences of reporting outbreaks, international initiatives such as the International Health Regulations (IHR), as endorsed in 1969 at the World Health Assembly, will deal with events that pose real international health threats and support countries in mitigating adverse political and economic consequences\(^7\). In order to respond to the challenge of increasing travel and trade in a globalizing world and the still existing threat of outbreaks of emerging and re-emerging diseases, the IHR are currently under revision. The new regulations include operational concepts such as notification, verification and response processes regarding outbreaks, maintenance of national core capacity for early warning and response and rapid international risk assessment and assistance.

**The global outbreak alert and response network (GOARN)**

GOARN is a collaboration of existing scientific and UN institutions and networks that pool human and technical resources for the rapid identification, confirmation and response to outbreaks of international importance. GOARN contributes towards global health security by combating the international spread of infectious diseases.

---


\(^5\) ‘G7+’ states include Canada, France, Germany, Italy, Japan, Mexico, UK, and USA.

\(^6\) Eurosurveillance, 2005, available: http://www.eurosurveillance.org/about/about-02.asp

outbreaks; ensuring that appropriate technical assistance reaches affected states rapidly; and contributing
to long-term epidemic preparedness and capacity building\(^ {18}\). Its operations actively gather epidemic
intelligence information from different sources, process and analyse the data before subsequently share it
through a weekly outbreak verification list with over 900 institutions and professionals in the field of public
health. Simultaneously, a verification process deals with reported outbreaks since the alert might either
rely on rumour or might be real. Upon confirmation, information is widely distributed through the WHO
website and the Weekly Epidemiological Record.

**The global public health intelligence network (GPHIN)**

One of the early warning tools is the secure Internet-based multilingual GPHIN, which searches media
sources globally\(^ {19}\). Though its methodologies represent a pool of informal sources that might rely on
rumors and, thus, of information requiring verification, the ratio of more than 60% of initial outbreak reports
from non-official sources bears some potential for further integration in e-Surveillance. Specifically
focused on Europe, a centralized information system for infectious diseases collects, analyses and
presents data on infectious diseases\(^ {20}\).

**The Pacific Public Health Surveillance Network (PPHSN)**

As specific example from the pacific region, 22 pacific islands departments, Ministries of public health and
allied partner agencies, networks and institutions represent the core members of PPHSN. The network
aims to harmonize surveillance data and to development surveillance systems in its region. Furthermore,
it provides training in field epidemiology and public health surveillance, extends its electronic
communication network and disseminates timely, accurate and relevant information\(^ {21}\).

**Centres for disease prevention and control (CDC) alert systems**

CDC alert systems include both US domestic and international networks. Pulsenet, developed by CDC
and the Association of Public Health Laboratories, is a national molecular sub-typing network using DNA
fingerprinting to identify food borne outbreaks in a timely manner. CDC is also developing Epi-X, a 24/7
data network prototype for tracking outbreak investigations that are underway. Epi-Aid provides outbreak
assistance nationally and internationally and both in non-infectious and infectious outbreaks\(^ {22}\).

**Free database access via FluNet**

Tracking influenza, a collaboration of networks of national centres, WHO collaborating centres and
laboratories, operational in 83 countries and using standard case definitions and laboratory diagnostic,
tests uses FluNet. This database includes standardized data entry and data output as well as summarizes

\(^ {18}\) World Health Organization, 2005a, available: http://www.who.int/csr/outbreaknetwork

\(^ {19}\) World Health Organization, 2005c, available: http://www.who.int/csr/alertresponse/epidemicintelligence/en

\(^ {20}\) World Health Organization, 2003a, available: http://data.euro.who.int/CISID


\(^ {22}\) Centers for Disease Control and Prevention, 2005, available: http://www.cdc.gov/
data on the extent of epidemiological influenza activity and on virological results by geographical location over different time periods. All FluNet's output data are available on the web without access restriction. Public users can get information e.g. on vaccination calendars.

All against influenza ('bird fevers')

If the health event of influenza transmitted from animals to humans occurs and emerges as pandemic as described in chapter 5.3.1, the human societies will be seriously affected. Although responding to the situation can be achieved through averting an influenza pandemic by controlling the present human outbreaks and by preventing further spread, it can also be done through conducting the research needed for better preparedness and response, including GIS and climate-based health modelling studies in the human and domestic poultry population.

The usefulness of space tele-detection has been quite well established already. Arboviral epidemics, which are highly dependent on one or more arthropod species, are well correlated with the dynamic of the respective vector populations, which is in turn very much linked to rainfall conditions. For Japanese encephalitis (JE) viruses, which can infect human through an arthropod, the prevalence levels in the latter depend on the circulation of the virus in the bird populations. Because avian influenza viruses and viruses from the JE complex in the East and West Nile (WN) viruses in the west of the old world share a common dependence on birds and show a seasonality probably due to weather and earth based phenomena, the same bird population the seasonal pattern of the circulation of influenza and JE/WN viruses in correlation with the collection of remote sensing data should be studied.

1.3 Disaster and emergency

Currently prone to several disasters and emergencies, the international scene addresses the issues on a global level. The WSIS Plan of Action specifically refers to the need of establishing monitoring systems and to use ICTs to forecast and monitor the impact of natural and manmade disasters. On 8 January 2005, the Tampere Convention came into effect, calling States, *inter alia*, to facilitate the immediate provision of telecommunication assistance in a catastrophe and to cover the installation and the operation of reliable, flexible communication services. Available information related to the provision of emergency telecommunications during relief operations can be found on websites such as Reliefweb or ITU.

---

23 Reliefweb, 2005, available: http://www.reliefweb.int/telecoms/tampere
25 International Telecommunication Union, 2005b, URL: http://www.itu.int/itudoc/itu-d/publicat/86892.html
1.4 ICTs for early warning systems

Secure transmission of disaster concerns, health events, geographical and meteorological data is a key issue in all eHealth components. Features to protect data and participants rely on SSL technology as used in the financial industry, authorization, integrity, authentication, and non-repudiation.

Platforms and structure of information

Generally, national ICT infrastructure for early warning systems uses common platforms such as SQL servers, sunrise popular databases, etc., but without taking into account European-wide regulations. Though hospitals record patient data on a daily basis, the organization of data requires to be structured according to the users’ needs. Aggregated data from a European perspective consequently needs to consider the different inputs, which are generally automated per hospital. It would eventually be possible to skip this issue if news agencies use the data on their daily updated web sites accordingly.

Regarding application service provider-based emergency room software, information can be gathered through a certain Web browser based on databases housed on industry servers. Thus, this U.S. developed solution is rather industry-focused than relying on governance of a public health institution.

Applications

Applications in early warning systems have several characteristics. Since the late 1990s, public networks, desktop mapping software, and customized programming tools support the collection of data across borders. Since many users prefer to receive information through a mapping formats, database management and mapping systems, e.g. the HealthMapper for epidemiological surveillance, present customized public health applications at national, regional and global level. This public health mapping programme uses geographic information systems (GIS) compiled of different types of data structure (vector or raster), data compression techniques and data storage, hardware and user interfaces. Health related GIS provide information analysis platforms related to human settlements, surrounding health services and the natural environment. Based on data collected from CDCs and WHO, private companies use free of charge, but patented technology to provide charts, graphs and maps.

Spatial data used in GIS have aerial photography, maps, and satellite imagery. Via satellite, gaps of terrestrial communications in remote and underserved areas can be filled. States, epidemiological experts, citizens, etc. obtain additional provision concerning early warning alerts of communicable diseases, meteorological risk events and manmade disasters. Satellites are also used by tele-epidemiological concepts of the Centre National d’Etudes Spatiales (CNES) to track and monitor disease outbreaks.

---

infectious diseases\textsuperscript{29} \textsuperscript{30} \textsuperscript{31}. However, using satellite in eSurveillance is a complementary approach to terrestrial telecommunications.

**Standards**

European policies such as the eEurope 2005 Action Plan aims on integrating national approaches into European-wide solutions. Standardization is thus crucial for compatible e-Surveillance systems. Though data is structured and stored differently in each country, initiatives from hospitals to report in a standardized format and lay-out should be possible if an appropriate consensus is found between Member States.

CDCs’ national electronic disease surveillance system (NEDSS) uses an approach including standards for security, health informatics, data, information architecture and technology for ensuring compatibility with the health care system\textsuperscript{32}.

Fostering the effective information flow certainly requires common understanding of terminologies. The users of early warning systems might have different knowledge about the diagnosis of communicable diseases. To increase the comparability of the data from the different EU Member States an important Commission decision was taken on 19 March 2002. This decision 2002/253/EC lays down case definitions for reporting communicable diseases to the Community network\textsuperscript{33}. The objective of recommended surveillance standards\textsuperscript{34} related to semantics is to ensure that every GP has the same knowledge when diagnosing e.g. SARS to avoid that an eminent case of flu triggers a SARS alert.

For disaster relief operations, ITU-T Recommendation E.106 provides functional requirements, access, features and operational management of the International Emergency Preference Scheme, which allows user access to international telephone service while this service is restricted due to damage, fault or a combination of both\textsuperscript{35}. Concerning assured emergency/disaster communications, ITU-T Study Group 9 works on Recommendations specifying “Preferential Telecommunications over IPCablecom networks”, which cover authentication and priority in IPCablecom networks\textsuperscript{36}. Throughout the study period of 2005-2008, ITU-T Study Group 13 Question 3/13 deals with an “implementation framework related to provision of emergency communications in NGNs”, which meets the requirements of RecommendationY.1271\textsuperscript{37}.

To conclude, early warning and monitoring systems in the eSurveillance domain are critical for preventing and controlling as much as possible the spread of communicable and non-communicable diseases. It is necessary to collaborate with international organisations, government agencies, healthcare and public

\textsuperscript{29} Jenaoptronik, 2004, available:http://www.epidemio.info
\textsuperscript{30} European Space Agency, available: http://dup.esrin.esa.it/index.asp
\textsuperscript{31} European Space Agency, 2002, available: http://www.esa.int/export/esaCP/ESATR5VTYWC_Improving_0.html.
\textsuperscript{35} International Telecommunication Union, 2003b, pp. 1-3
\textsuperscript{36} International Telecommunication Union, 2004a, p. 2
health institutions, and authorities for meteorology, geological survey, socio-economic and Earth sciences. Effective eSurveillance can detect and control health threats, concentrate on the key resources and investigating trends as well as support policy decision-making through the provision of accurate health information. For the systems to be effective, they require political commitment and a standardized approach of collecting data throughout several networks with a common understanding of ontologies. Further modelling systems relying on environmental data can increase the effectiveness of both the local and regional surveillance, international networks and networks of networks. Certainly, the maximal usage of electronically maintained surveillance systems depends on accurate ICT applications and appropriately trained personnel that collects, manages, and analyses the data for timely, accurate reporting and information dissemination.

1.5 Examples of tele-epidemiology projects benefiting from space monitoring systems

Tele-epidemiology consists in studying human and animal epidemics, the spread of which is closely tied to environmental factors. By combining vegetation index data from optical satellites, meteorological data (winds and cloud masses) from Meteorological satellites, and other Earth observation data (wave height, ocean temperature and colour) with clinical data from humans and animals (clinical cases and biomedical diagnostics) and hydrology data (number and distribution of lakes, water levels in rivers and reservoirs), we can construct predictive mathematical models. A number of such approaches have been tested in the last three years. In Senegal, Rift Valley fever epidemics are being monitored using a predictive model based on the rate at which water holes dry out after the rainy season, which affects the number of virus-carrying eggs. This project has achieved good results, encouraging the Senegalese government to provide funding, with support from MEDES38, to extend the approach to all risk zones in which the population and cattle are exposed.

In French Guiana, a tele-epidemiology network was set up in mid-2003 to monitor hemorrhagic dengue fever. This network is being operated jointly by the Pasteur Institute, France’s IRD development research institute, MEDES and the Lyon School of Veterinary Science to study areas where the disease-carrying mosquito is thought to breed. Here again, combining satellite data and epidemiological data is helping to make prevention more effective.

As part of the French Ministry of Research’s Earth-Space Network, a pilot sentinel network has been deployed in Niger and Burkina-Faso to monitor infectious diseases whose spread is tied to environmental factors. For example, parameters such as dust clouds and wind appear to play a crucial role in triggering and spreading meningococcal meningitis. Lastly, a consortium formed by French agronomy research institute INRA, Médias-France and IRD, and funded by the Ministry of the Environment, is monitoring cholera epidemics around the Mediterranean basin. This project is using mathematical models to assess the risk of a resurgence of the disease, which is linked to numbers of cholera-spreading zooplankton.

TELEMEDICINE ALLIANCE - A BRIDGE TOWARDS COORDINATED EHEALTH IMPLEMENTATION

EHEALTH INTEROPERABILITY IN EUROPE: CHALLENGES AND INITIATIVES

Interoperability Study Report - Annex 6: Personal communication, COCIR

Lead Partner for Deliverable: ITU
Start/Duration of project: 1 August 2004 – 31 July 2005
Dissemination Level¹: PU (Public)
Deliverable Number: TMA-Bridge_Del-4
Document Number: TMAB-ESA-TN-042
Electronic File Name: TMAB-Del.4-Interoperability Study Report_Anex6_Iss2-Rev0.doc
Issue/ Revision: 2/ 0
Due date of deliverable: M9
Actual Date: 12 July 2005
Number of pages: 5

¹ PU = Public, PP = Restricted to other programme participants, incl. the Commission Services (CS), RE = Restricted to a group specified by the consortium (incl. the CS), CO = Confidential, only for members of the consortium (incl. the CS)

Project co-funded by the European Commission within the 6th Framework Programme (2002-2006); Priority 2 Information Society Technologies (IST); Specific Support Action (SSA); Project No. IST-507871.
Telemedicine Alliance

European Space Agency, European Space Research & Technology Centre (ESTEC), Noordwijk, The Netherlands

World Health Organization - European Office for Integrated Health Care Services, Barcelona, Spain

International Telecommunication Union: Telecommunication Development Bureau (ITU-D), Geneva, Switzerland

The Interoperability Study Report has been prepared by the Telemedicine Alliance consortium made up of European Space Agency (ESA), International Telecommunication Union (ITU) and World Health Organization (WHO), as part of the European Community 6th Frame Work Programme.

The authors appreciate the support extended by Mr Hans-Peter Bursig of the European Coordination Committee of the Radiological and Electromedical Industry.

"EHealth in Europe: Challenges and Initiatives" is part of deliverables of the Telemedicine Alliance – a Bridge towards coordinated eHealth implementation.

Other reports and information on this project can be found at www.esa.int/tma-bridge or www.esa.int/telemedicine-alliance.

The opinions expressed in the Interoperability Study Report and its annexes are those of the authors and do not necessarily reflect the views of the International Telecommunication Union, its membership, the European Space Agency, the World Health Organization or their Member States.
PERSONAL COMMUNICATION, COCIR

The draft of recommendations mentioned below refers to a working draft of a set of guidelines and recommendations respectively as provided by ITU-D. These recommendations contributed to the proposed recommendations of Telemedicine Alliance as presented in Chapter 7, The Way Forward, of the Interoperability Study Report.

-----Original Message-----
From: Bursig, Hans-Peter
Sent: 17 May 2005 07:37
To: Ludwig, Kerstin
Subject: AW: "The Way Forward", Interoperability Study of TMA Bridge
Importance: High

Dear Mrs. Ludwig,

I apologise for not replying earlier. Unfortunately, I have been unable to react before my absence. I understand that the report is not yet ready and the text is not yet final.

The report addresses a number of parallel issues, ranging from the use of ICT in healthcare (what I understand is labelled "eCare" in the report) to other more general issues. I will only be able to react to the eCare area. On all the other issues, I am not really competent, but the general issues addressed do make sense to me. Facilitating access to eApplications, improving network access and reducing the cost of communication will clearly have an impact in the eHealth area.

With regard to eCare, I would like to stress the point of a bottom-up approach with the strong involvement of medical users as followed by IHE and promoted in the EHIP proposal submitted by COCIR. The idea is that medical users will best know where the problems and hindrances are for the use of ICT in healthcare. Using this knowledge will enable industry and standardisation bodies to provide useful solutions. This will generate immediate improvements for medical professionals and patients. This in turn will initiate a circle of positive experience and further demands for improvement.

Although this is a process of small steps at a time, it seems to be the best approach given the complexity of the issues at hand. Your text does for example propose the linking of national "early warning systems", a system to collect epidemiological data (as well as access to this data) and requests manufacturers to include established data collection tools in their products. This surely does make sense as a long-term goal for a citizen centered eHealth policy. However, I find this approach terribly difficult to implement.

Most hospitals, unless they participate in research or clinical trials, may not be in a position to move data electronically even inside the hospital between different departments. This is the shortcoming that IHE is addressing. A basic communication of this kind needs to be available before any further approaches to cross-border communication can be taken. Positive experience with ICT in healthcare (as generated by the implementation of IHE solutions) will also make healthcare providers as well as patients more willing to engage in more complex applications, such a cross-border communications or epidemiological data collection.

I would therefore recommend that a "problem oriented" rather than a "mission oriented" approach should be proposed as a first step in an implementation process for eHealth applications. Users of ICT in healthcare should be presented with a longer term goal, i.e. the cross-border exchange of health data, but
be asked to indentify individual short term problems on the way towards this goal. This could, for example, be the need to establish interoperability between different departemental information systems within a hospital or between healthcare institutions. It could also be the need to agree on a structured data set for specific clinical information. This involvement of learned users does require limited funding, but no huge research projects.

A mechanism should then be in place to address the issues identified by the users and develop a practicable solution in a timeframe between 12 to 18 months. This mechanism will require a dependable and sufficient funding. An important lesson from the IHE experience is that experts from the medical area as well as industry are more than willing to participate in such an exercise, but need an organisational structure to facilitate their cooperation.

Both elements of this process are being addressed in the EHIP proposal submitted by COCIR. The same proposal has been made in the report of the CEN/ISSS Focus Group eHealth. In doing so, I believe that two things can be assumed as given:

1) The medical equipment manufacturers have endorsed the idea of an open standards environment, where even proprietary solutions need to be interoperable.

2) The report from the CEN/ISSS eHealth Focus Group has confirmed that we do not lack standards in order to make eHealth applications happen. The technology and the standards are there. What is necessary is to put these standards appropriately into use. A process that has been given the name of "interoperability".

Following this approach will also allow EU Member States to implement individual approaches, depending on their national requirements. You are also addressing this issue in your summary. Member States should agree on the longer term goals for the above process (the "mission orientation"), but could then follow different ways to the implementation (the "problem orientation"). For example, one country may choose to start with the introduction of a card-based PKI, while another may first address the data collection and storage within healthcare institutions.

I do hope that you will find these remarks helpful. If the time for the finalisation of the text still permits, I am available for further discussions by phone.

Best regards

Hans-Peter Bursig

COCIR Secretariat General

Stresemannallee 19  D-60596 Frankfurt am Main

web: www.cocir.org

*****************************************************************************
Dear Mr. Bursig,

As discussed last week, please find attached the working draft of guidelines and recommendations respectively of the chapter "The Way Forward" of our Interoperability Study currently under review.

The overall objective is to build a bridge towards a coordinated implementation of eHealth in Europe. The study is focused on citizen-centred, transnational eHealth services (eCare, eEducation, eSurveillance, and eAdministration) considering a holistic approach of three frameworks, i.e. using a policy, socio-organisational and technical perspective, and thus analyzing interoperability barriers, requirements and solutions. Certainly, we will send you the final version of the document.

Thank you very much for offering your feedback on this document, in particular regarding the first ten (10) pages. Please feel free to add and to change any guidelines on how to overcome interoperability issues as appropriate.

We very much appreciate your support and looking forward to hearing from you.

Best regards,

Kerstin LUDWIG
TELEMEDICINE ALLIANCE - A BRIDGE TOWARDS COORDINATED EHEALTH IMPLEMENTATION

EHEALTH INTEROPERABILITY IN EUROPE: CHALLENGES AND INITIATIVES


Lead Partner for Deliverable: ITU
Start/Duration of project: 1 August 2004 – 31 July 2005
Dissemination Level*: PU (Public)
Deliverable Number: TMA-Bridge_Del-4
Document Number: TMAB-ESA-TN-041
Electronic File Name: TMAB-Del.4-Interoperability Study Report_Annex7_Iss2-Rev0.doc
Issue/ Revision: 2/0
Due date of deliverable: M9
Actual Date: 01 July 2005
Number of pages: 3

Project co-funded by the European Commission within the 6th Framework Programme (2002-2006); Priority 2 Information Society Technologies (IST); Specific Support Action (SSA); Project No. IST-507871

* PU = Public, PP = Restricted to other programme participants, incl. the Commission Services (CS), RE = Restricted to a group specified by the consortium (incl. the CS), CO = Confidential, only for members of the consortium (incl. the CS)
The Interoperability Study Report has been prepared by the Telemedicine Alliance consortium made up of European Space Agency (ESA), International Telecommunication Union (ITU) and World Health Organization (WHO), as part of the European Community 6th Frame Work Programme.

“EHealth in Europe: Challenges and Initiatives” is part of deliverables of the Telemedicine Alliance – a Bridge towards coordinated eHealth implementation.

Other reports and information on this project can be found at www.esa.int/tma-bridge or www.esa.int/telemedicine-alliance.

The opinions expressed in the Interoperability Study Report and its annexes are those of the authors and do not necessarily reflect the views of the International Telecommunication Union, its membership, the European Space Agency, the World Health Organization or their Member States.
<table>
<thead>
<tr>
<th>Country</th>
<th>Main telephone lines</th>
<th>Mobile subscribers</th>
<th>Internet users</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2003</td>
<td>000s</td>
<td>p.100</td>
</tr>
<tr>
<td>Estonia</td>
<td>1'351.0</td>
<td>461.0</td>
<td>34.12</td>
</tr>
<tr>
<td>Latvia</td>
<td>2'319.2</td>
<td>661.9</td>
<td>28.54</td>
</tr>
<tr>
<td>Lithuania</td>
<td>3'445.7</td>
<td>824.2</td>
<td>23.92</td>
</tr>
<tr>
<td><strong>Baltic States</strong></td>
<td><strong>7'115.9</strong></td>
<td><strong>1'947.1</strong></td>
<td><strong>27.36</strong></td>
</tr>
<tr>
<td>Albania</td>
<td>3'072.8</td>
<td>255.0</td>
<td>8.30</td>
</tr>
<tr>
<td>Bosnia</td>
<td>3'832.1</td>
<td>938.0</td>
<td>24.48</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>7'506.6</td>
<td>2'858.1</td>
<td>38.05</td>
</tr>
<tr>
<td>Croatia</td>
<td>4'374.0</td>
<td>1'700.0</td>
<td>38.87</td>
</tr>
<tr>
<td>Cyprus</td>
<td>741.6</td>
<td>424.1</td>
<td>57.19</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>10'664.6</td>
<td>3'626.3</td>
<td>36.03</td>
</tr>
<tr>
<td>Hungary</td>
<td>10'334.2</td>
<td>3'602.9</td>
<td>34.86</td>
</tr>
<tr>
<td>Malta</td>
<td>400.0</td>
<td>208.3</td>
<td>52.07</td>
</tr>
<tr>
<td>Poland</td>
<td>38'359.0</td>
<td>11'862.2</td>
<td>30.74</td>
</tr>
<tr>
<td>Romania</td>
<td>21'733.6</td>
<td>4'333.4</td>
<td>19.94</td>
</tr>
<tr>
<td>Slovakia</td>
<td>10'760.1</td>
<td>2'611.7</td>
<td>24.27</td>
</tr>
<tr>
<td>Slovenia</td>
<td>5'377.0</td>
<td>1'294.7</td>
<td>24.08</td>
</tr>
<tr>
<td>Estonia</td>
<td>1'351.0</td>
<td>461.0</td>
<td>34.12</td>
</tr>
<tr>
<td>Latvia</td>
<td>2'319.2</td>
<td>661.9</td>
<td>28.54</td>
</tr>
<tr>
<td>Lithuania</td>
<td>3'445.7</td>
<td>824.2</td>
<td>23.92</td>
</tr>
<tr>
<td><strong>Europe &amp; CIS</strong></td>
<td><strong>870'665.7</strong></td>
<td><strong>334'679.0</strong></td>
<td><strong>38.44</strong></td>
</tr>
</tbody>
</table>

Note: For data comparability and coverage, see the technical notes.

Figures in italics are estimates or refer to years other than those specified.

Source: ITU.