eHealth

Interoperability for eHealth:

facing challenges and overcoming barriers

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TMA-BRIDGE WORKSHOP

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 'infostructure' to make different systems work together.

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*Telemedicine 2010: Visions for a Personal Medical Network, The Telemedicine Alliance, ESA-BR-229, July 2004; http://www.esa.int/telemedicine-alliance
† www.atis.org : website of Alliance for Telecommunications Industry Solutions.

The Need for Standards and Common Infostructures

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.

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* 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:

eHealth Service	Priority for Trans-National Action
Care	Structured and harmonized messages and trans-national Electronic Health Record
Education	Web Community Services
	Reliable Health information webs for the citizen
Administration	Reimbursement
Surveillance	Early Warning Systems (comparable Public Health Data)

Table 1 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 privac**y 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
‡DISCERN, URL: http://www.discern.org.uk, accessed 18 February 2005. The DISCERN project is based in the University of Oxford, Division of Public Health and Primary Health Care, at the Institute of Health Sciences.

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 eAdiministration, 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

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*Especially true of second opinions

†E.g. Kohll judgement, Case C-155/96 of 28.04.98, ECR 1998 p. I-1931; Smits et Peerbooms judgement, Case C-157/99 of 12.07.01, ECR 2001 p. I-05473 ; Vanbraekel judgement, Case C-368/98 of 12.07.01, ECR 2001 p. I-05363.

‡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.

**E.g. Kohll judgement, Case C-155/96 of 28.04.98, ECR 1998 p. I-1931; Smits et Peerbooms judgement, Case C-157/99 of 12.07.01, ECR 2001 p. I-05473 ; Vanbraekel judgement, Case C-368/98 of 12.07.01, ECR 2001 p. I-05363.

††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
‡E.g. Kohll judgement, Case C-155/96 of 28.04.98, ECR 1998 p. I-1931; Smits et Peerbooms judgement, Case C-157/99 of 12.07.01, ECR 2001 p. I-05473 ; Vanbraekel judgement, Case C-368/98 of 12.07.01, ECR 2001 p. I-05363.
§COM(2004) 301, Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union.
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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.

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