



Workshop on semantic interoperability prerequisites for efficient e-health systems

Initial considerations

Vers. 6.7, Jan. 31, 2005

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1 Executive Summary

Most countries and international organisations in the world are challenging a new critical point named interoperability between systems and personal information since they have introduced the utilisation of ICT in Healthcare (e-Health). These requirements to use ICT are expected to increase regularly in the future.

The different aspects of interoperability (Electronic Health Records, messages, security, terminology and languages, data types, information models, architectures, archetypes, standards, etc.) are addressed by divergent initiatives aiming at exchanging not only data or information, but also at transferring meaning: in healthcare, such a practice is related to risk. As a consequence, semantic interoperability is becoming a central issue. On the other hand advanced technologies in computer and other disciplines, such as artificial intelligence, allow for much more complex problems solving in routine: this is possible through the use of such tools as ontologies and formal representations, hidden within the computer for terminology, or personal microprocessor cards for security.

In the light of the convergence of views at the global level (WHO and its collaborating centres) and in the European Union communities with respect to the desirable objective, it seems necessary to embark on a process that will prompt the divergent initiatives to be concerned with semantic interoperability in health care settings in a global context.

The first step will be a workshop (WS) to establish a framework to address the various dimensions of semantic interoperability for a limited set of topical sub-domains. An inventory of available and missing tools would be drawn up and strategies recommended to develop on the one hand additional research activities and, on the other hand, for targeted short term benefits implementations.

The WS will discuss technically the steps to be recommended to Member States as a roadmap to achieve the objective of semantic interoperability. The output will be a position paper to be made public in order to elicit mutually supportive action proposals from interested parties from both public and private sector stakeholders.

2 Objective and expected outcome of the workshop

The objectives of the meeting are

- i) to identify the various dimensions and aspects of semantic interoperability, particularly in the context of the overall interoperability (technical, functional, etc) of e-health systems
- ii) to review the state of the art of these aspects, including linguistic and knowledge engineering research
- iii) to identify further research challenges and topics needed to be addressed on national and international level
- iv) to recommend strategies where short-term benefits for target communities may reasonably be expected, with a definition of criteria for assessment;

The expected output should be a report where concrete suggestions for inventory of existing state of the art methods and tools is presented together with recommendations for further research and strategies for improved deployment of existing tools.

The outcome will be an important input both for planning of future research agenda in this field as well as for feeding the existing Action Plan implementation as defined in European Commission Communication on *eHealth - making healthcare better for European citizens: An action plan for a European eHealth Area*.

3 Background

3.1 Semantic Interoperability

Modern ICT capabilities raise huge information exchange expectations. Industry, regulators and other stakeholders have long recognized the need for improved interoperability, i.e. the fact that data produced in one system is readily useable in another system with minimal or, preferably, no human interventions.

Technical and functional interoperability has now matured to provide reliable operational platforms. Content interoperability now emerges as a domain needing attention.

Initial efforts in that area were devoted to data registries, listing the data categories that should be part of any particular data set under consideration. It was then found useful to add metadata that would qualify the type of data that should be allowed in any particular data category. This ranged from specific formats (like date type) to controlled vocabularies (pick lists, where strict compliance was required).

More recently, automatic language processing and intelligent information retrieval emphasized the need for true semantic interoperability, i.e. the guarantee that any particular language in a data set is unambiguous and actually has the same meaning for subsequent user systems. In addition the meaning must be captured in such a manner that it can be both formally described in order to be processable by machines and transformed based on pre-established rules in order to be easily understood by humans.

Furthermore, the perspective of a facilitated exchange of information between different language communities has been stimulated by claims that a language-independent concept representation would act as a reference point that would contain the agreed set of features required to capture any notion unambiguously. From there rule-based derivations could generate the **various language** realisations.

The importance of semantic interoperability has grown in recent years with the emergence of **increasingly interrelated information systems**. First implemented for management and administrative functions, they soon evolved to cover population-based considerations (aggregability for statistical purposes). Nowadays, they focus on clinical patient care requirements, including information retrieval, patient record communication, decision support in clinical care, quality assurance in care practice, and overall resource allocation.

Initial small-scale, domain-specific, mono-purpose highly detailed **clinical terminologies** are now become part of very large integrated systems. In order to increase their relevance, there is a need to map content point-to-point among the various components. Large scale **mapping** exercises are undertaken, supported by increasingly complex rule-based strategies and validated by resource-intensive consensus building by expert communities.

Conversely, large-scale, generic, multipurpose, highly structured classifications are being localized for particular use in different contexts, mostly in the form of national modification of the original instrument. Compatibility with the original source needs to be ascertained, in order to permit integration of new, specific knowledge in successive revisions.

The scientific community increasingly recognizes the need to have the two approaches integrated in a generalized and **evolutionary knowledge representation system** from which all specific applications could be directly but uniformly derived. This is seen as particularly conducive to the **efficient flow of information in multi-country settings and trans-border situations**, to the proper assessment of resource allocation strategies, and to the implementation of a true **citizen-centred** health and medical information system.

3.2 WHO activities

3.2.1 Perspective

At a global level, WHO is taking steps to achieve this high level objective, while remaining focused on concrete, efficient and robust solutions that can be implemented in resource limited settings.

Traditionally vested with constitutional mandate to develop and maintain international classifications and nomenclatures that would serve the needs of the global community of Member States, the Organization and its network of Collaborating Centres for the Family of International Classifications are increasingly aware of the importance, actually the pressing need, to address the issue of a meaningful interaction between clinical terminologies and international classifications. This would expand the scope of the application of its tools, enriching its population-based public health concerns with real-life information gathered at the point of care.

Furthermore, the increasing availability of advanced knowledge formalization tools opens new prospects for more real-time, update and revision processes in the constantly changing world of medical knowledge, and also the flexibility to adapt to individual country needs more quickly and at a more affordable cost, thus bringing world knowledge closer to the people that need it most.

3.2.2 WHO planned activities

Various projects proposals are being debated with the community of WHO Member States to that end. Discussions are under way to assess the **need, feasibility and relevance** of a new ICD revision. Processes ensuring successful implementation are being evaluated in the light a possibility offered by new technologies. Possible **linkages** with major clinical terminology systems are being studied. Various **pilots are being designed** to validate the use of the more robust technologies that have emerged. **Areas for research** are being identified where currently available solutions are defective. Closer monitoring of **possible synergies** between **public and private sector enterprises** are being scrutinized and international cooperation, validation, and regulation (authorization, certification, etc.) scenarios are imagined to render the best possible services to the community of stakeholders. A synthesis of planned activities is provided in the WHO business plan for classification-related activities.

3.3 European Union activities

3.3.1 Perspective

- a) the recently published European Union **e-Health Action Plan** (AP) which - in the context of the *eEurope* strategy - aims at moving towards a European e-Health Area and develops an ambitious programme of activities extending till 2010,
- b) the eTEN project "Interoperability initiative for a European e-health area" (**I2-Health**) to start as of Feb. 01, 2005, and
- c) the European Research Area (FP6 IST) project "Towards the Establishment of a European e-Health Research Area" (**e-Health ERA**) to probably start as of April 01, 2005.
- d) the new EU Framework [Research] Programme 6 (FP6) 4th Information Society Technology (IST) **call for proposals** to support the realisation of the e-Health Action Plan, particularly the item concerning (semantic) interoperability

3.3.2 European Union initiatives

3.3.2.1 European Commission e-Health Action Plan

In the recent "Action Plan for a European e-Health Area" of April 30, 2004, adopted by the European Council as defining EU policy in the e-health area, interoperability plays a central role:¹

"Interoperability of health information systems:

Member States have expressed the need to support actions that cover the development of standards addressing the interoperability of diverse systems and services and to explore in particular the possibilities of open source applications to achieve this objective. In this context, the need for future standards is clearly emphasised so as to solve interoperability concerns in a way which will benefit all stakeholders through the possible adoption of Open Source reference implementations for care services. In addition, an open and more free access to future and existing e-Health standards should be recommended, taking inspiration from models such as the World Wide Web Consortium². The exchange of experience in the use of open standards and open source solutions among health administrations in Member States should be promoted.

Interoperability of electronic health records:

*Achieving a seamless exchange of health information across Europe requires **common structures and ontologies**³ of the information transferred between health information systems.*

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.

Mobility of patients and health professionals:

Within the European Union, patients and health professionals are becoming increasingly mobile. The Communication on patient mobility has made a number of proposals to manage the challenges resulting from this development. Recommendations include improving the exchange of information, and establishing specialised reference centres on health information. The Communication on patient mobility is presented as part of an overall strategy on health care together with the present communication and that on the open method of coordination⁴.

3.3.2.2 eTEN I2-Health project

Currently various EU Member States (MS) are launching initiatives to introduce e-health infrastructures and applications. They are dealing with critical issues of technical, semantic and workflow interoperability almost exclusively at the regional or national level. These developments threaten to hamper the further development of a European and global market in e-health applications and cross-border services.

Building upon the activities in MS, the results of European RTD, and learning from global efforts, the eTEN *I2-Health* project will initiate a process for accelerating the deployment of interoperable e-health infrastructures and applications for global use. It will

- identify interoperability and connectivity issues and priorities, barriers and gaps, and solution approaches,

¹ See Commission of the European Communities - COM (2004) 356: Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: e-Health - making health care better for European citizens: An action plan for a European e-Health Area, Brussels, 2004-04-30.

² <http://www.w3.org/>.

³ An ontology defines the terms used to describe and represent an area of knowledge, and are used by people, databases, and applications that need to share domain information (a domain is a specific subject area, such as health or medicine). See <http://www.w3.org/TR/2002/WD-webont-req-20020307/>.

⁴ The open method of coordination in relation to health care is addressed in the Communication from the Commission COM(2004) Modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the 'open method of coordination'.

- focus on fundamental interoperability issues (like identification of actors, organisations, adequate measures to achieve interoperability, integration tests and certification)
- analyse similarly key topics relating to e-prescription and messaging
- develop a roadmap and concrete projects involving all relevant actors - guided by an open discussion process amongst Member State Health Authorities.

Allowing for patient mobility and cross-border medical care is a key EU policy priority and one focus of the e-Health Action Plan. Identifying needs, gaps and next steps will help to realise concrete solutions to reach these goals. Thus the project will impact on and contribute towards global, patient centred seamless health service processes, equal access for all, and a greater efficiency of health systems. Interoperability will allow more effective health services to be delivered wherever citizens are and wherever they may have come from.

3.3.2.3 e-Health European Research Area (ERA) project

The goal of the e-Health ERA project is to coordinate planning of national innovation-oriented e-health RTD as the basis for a common road-map and joint RTD activities, thereby establishing an effective ERA in this key IST field and important global market. Reducing the serious fragmentation of current planning can be expected to have a strategic impact on regional, national and trans-European e-health infrastructures, improve the quality of medical outcomes and hence the quality of life of citizens where ever they live.

This project emerged from an initiative involving 20+ EU Member State Health Ministries to improve RTD coordination and exploit the potential for European synergy. They wish to avoid barriers to patient and professional mobility in the Union threatening from uncoordinated IST uptake and ensure progress in line with the European e-Health Action Plan. Project work will structure European e-health RTD, build a suitable e-health ERA portal, identify priority topic clusters, locate cooperation opportunities, identify best practice, set consensual benchmarks, propose priorities for action and draw up a coherent Europe-wide road-map and action plan, finally proposing sustainable long-term mechanisms for European coordination. A Steering Committee, to which over 25 Ministries have already committed, will oversee and direct work, adopt priorities and road-map, initiate engagement in joint RTD activities and adopt sustainable mechanisms.

3.4 EU FP6 4th IST call for proposals

To further support overall e-health R&D in general and the e-Health AP in particular, the recent FP6 4th IST call requests proposals for so-called *Specific Support Actions* or *Coordination Actions* with, inter alia, the following focus:⁵

"Roadmaps for research and developments in ICT for health leading to recommendations for actions and to preparatory actions at European level. Proposed roadmaps should take into account not only technological but also financial, legal and research community aspects. The intermediate milestones should constitute results that are applicable and of benefit to health research and clinical practice. International developments and dissemination at the appropriate levels should be included. The following R&D roadmap is called for:

a) *Interoperability of e-Health systems*. Special emphasis should be given to *semantic interoperability, classifications, terminologies* and their limitations as well as a realistic approach and applicability in clinical settings. The use of Open Source model should be considered.

3.5 US Department of Health and Human Services

In its recent Request for Information (RFI) on "the goal of interconnecting clinicians", interoperability is loosely defined as "the ability to exchange patient health information among disparate

⁵ Cf. http://www.cordis.lu/ist/workprogramme/wp0506_en/2_4_11.htm

clinicians and other authorized entities in real time and under stringent security, privacy and other protections"⁶

Later this RFI talks about "interoperability **and** clinical health information exchange".⁷

When talking about *why we need interoperability*, the RFI resorts again to a wide definition of interoperability by stating these objectives:

"Interoperability is

- necessary for compiling the complete experience of a patient's care, ... is accessible to clinicians as the patient moves through various healthcare settings. Interoperability is needed for clinicians to make fact-based decisions so medical errors and redundant tests can be reduced.
- ... also critical to cost-effective and timely data collection for biosurveillance, quality measurement and clinical research."⁸

Here it is distinguished between individual, on the spot clinical decision making and public health and knowledge management issues.

3.6 CEN/ISSS

In its recently published report the *CEN/ISSS eHealth Standardization Focus Group* defines interoperability as "a state which exists between two application entities when, with regard to a specific task, one application entity can accept data from the other and perform that task in an appropriate and satisfactory manner without the need for extra operator intervention."⁹

Furthermore, it notes: "Interoperability is the only sustainable way to help partners acting in various locations, with different expertise, perspectives, statuses and agendas, possibly cultures and languages, and using distinct information systems from different vendors, to collaborate harmoniously to deliver quality health care.

At the very top of an 'interoperability scale' are three levels, each one subdivided: functional, syntactic, and semantic. Full sharing of information requires that the two top levels of interoperability are reached:

1. functional and syntactic interoperability: the ability of two or more systems to exchange information (so that it is human readable by the receiver);
2. **semantic interoperability**: the ability for information shared by systems to be understood at the level of formally defined domain concepts (so that the information is computer processable by the receiving system).

However, semantic interoperability is not an 'all-or-nothing' concept. The degree of semantic interoperability depends on the level of agreement between sender and receiver regarding the terminology, and the content of archetypes and templates to be used. Semantic interoperability is essential for automatic computer processing to underpin real value-added EHR clinical applications such as intelligent decision support, care planning, etc. Indeed, healthcare delivery deals dominantly with information and knowledge management. What is at stake here is not only exchanging data and information but reusing and processing them, i.e. semantic interoperability is the objective."

Depending on the location of the "two application entities" as mentioned by CEN, we may want to further differentiate between intra-organisational interoperability, local/regional/national health

⁶ US Department of Health and Human Services: Development and Adoption of a National Health Information Network (NHIN) - Request for Information, Nov. 09, 2004, p. 2. see <http://www.hhs.gov/healthit/rfi.html>

⁷ Ibid., p. 4, 2nd point

⁸ Ibid., p. 2

⁹ Cf. CEN/ISSS eHealth Standardization Focus Group "Current and future standardization issues in the e-Health domain: Achieving interoperability", draft V8.2, 2004, pp. 35-36

system interoperability, and international/cross-border interoperability, each posing its own set of issues to indeed achieve full interoperability.

4 Delineation of the topical domain

4.1 Dimensions and issues of semantic interoperability

To further delineate the topical domain of the workshop, the following matrix (cf. *Table 2*) may be helpful. On the one hand, semantic standards are needed across any e-health application which is to become an element in an interoperable system. On the other hand, semantic or terminological standards are a key element in the common infrastructure of e-health systems, and they must not only become established and agreed upon as standards, they are also in need of implementation guides, certification of the supporting software systems, have to meet organisational/health system rules and regulations, and should be coordinated and administered at the European and global level, including translation into other languages etc.

TABLE 1: OVERVIEW OF DIMENSIONS AND ISSUES OF SEMANTIC INTEROPERABILITY

Interoperability requirements	Applications requiring interoperability																		
	Health and clinical services					Common infrastructure services				Public health			Admin			R&D			
	EHR / EPR	messages / requests	imaging	workflow	...	Identifica-tion		terminology	Security, PKI	citizen health info	surveillance / epi-demiology	statistics	QA	reimbursement	supplies	HRM	knowledge man-agement	guidelines	..
patient						doctors	institutions												
1. Standards:																			
- Basic																			
- Functional / syn-tax																			
- Semantic	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
- Templates for contents / optimal data sets																			
- Localisation (Integration into national & other contexts)																			
2. Implementa-tion guides & regimens																			
3. Certification																			
4. Organisational rules																			
5. Global coordi-nation																			

4.2 Semantic interoperability: a complex implementation process, with huge added value

To speed up the successful implementation of standards for interoperability, David J. Brailer recently proposed "a three-tier architecture to help standards for health information technology gain acceptance and widespread use":

"I suggest that private-sector standards organizations adopt a three-tier architecture that will accelerate the adoption of health information standards and make interoperability a true foundation for the industry. The tiers would be as follows.

Tier 1: development. The process would be much like it is today: Expert panels and consensus groups determine the detailed attributes of a given standard, test the standard, and advocate for it. Many organizations may compete on standards, and some may collaborate. A variety of overlapping organizations would engage in standard development.

Tier 2: authorization. One single private organization or commission would be vested with the authority by standard-development organizations to determine which standards are to be adopted, when they should be put into use, what the schedule for future standards should be, and what gaps exist in existing standards. This organization essentially ratifies and coordinates the flow of standards into the market and provides a managed mechanism for orderly progress over time.

Tier 3: certification. One or more private organizations would be chartered to perform inspections of specific products that are being sold to determine their compliance with authorized standards. Vendors or buyers could request certification for products at any time during a product's life cycle. Certification should be voluntary, although payers may link pay-for-performance or grant other privileges to certified products. Information about certified products should be publicly available.

Implementing the architecture. The authorization and certification organizations would be best created by voluntary consensus of current standard-development bodies. To succeed, these organizations require broad governance and the buy-in of multiple stakeholders, including consumers, physicians, hospitals, and health plans. The authorizing organization could also perform certification, although this would require mechanisms to ensure that the struggle for economic power created through certification does not harm the credibility or effectiveness of the authorization process.

Such a standard-diffusion architecture would increase the confidence of buyers and sellers of information tools that the correct product is being developed and delivered. It would accelerate the recognition of the profound relevance of standards to people who don't discuss standards for a living. Most importantly, such an approach would foster a thriving health information services industry that can exceed customers' expectations, innovate and invest in new research, and attract private capital to leverage public funds. It would provide a mechanism for new standards, such as those published here about electronic prescribing, to have a clear path from concept to use."¹⁰

4.3 A human user oriented perspective

In a multi-lingual context, particularly when considering cross-border health care, we should go beyond the technical level and include citizens (health professionals, patients, ...) as part of the interoperable system, i.e. we need an interface between the "separate application entity on each side" as defined by CEN and others, and the person (clinician, nurse, patient, ...) who inputs the information into the unit and the one who interprets and acts on the output at the other side. We may be able to capture this by a wider definition of what "semantic interoperability"

¹⁰ David J. Brailer (2004) Translating Ideals For Health Information Technology Into Practice: A three-tier architecture to help standards for health information technology gain acceptance and widespread use. Health Affairs, May 25 2004, <http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.318v1/DC1?ck=nck>

means, i.e. we would have to translate, e.g., concepts and terms as defined and modelled by terminology systems like SNOMED CT not only into the respective national language but also with respect to the medical culture and understanding in a given health system context.

5 Workshop concept

5.1 Participants, location and date

The list of prospective *participants* is attached, subject to their availability.

5.2 Venue

The workshop will be held in Brussels, Av de Beaulieu 31 6/30

5.3 Dates and times

Monday 14 February-Tuesday 15 February 2005. The workshop will be held from 12:00 noon through 6:00 p.m. on Monday 14 February 2005, and again from 9:00 a.m. through 4:00 p.m. at the latest on Tuesday 15 February 2005.

Annex

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