

Contribution of Standards and Profiles to the Interoperability in eHealth

Karima BOURQUARD

IN-SYSTEM, Director Interoperability IHE-Europe

Abstract: This paper provides an overview on the standards that are used in eHealth in order to share and exchange medical data. The development of innovative solutions in eHealth and eAgeing and their adoption is dependent on the sharing of medical data in the health ecosystem. Therefore IT products used to support this ecosystem need to interoperate in a secured and safe manner. The corpus of standards at the international level is quite important but their deployments have proven more complex than expected. The obstacles of the diffusion of the standards are discussed and several possible solutions or recommendations are explored. For instance, the recognition of a set of standards-based integration profiles along with the supportive test tools at the European level gives direction to the suppliers and encourages them to adopt these profiles technical standards in their products. The usage of a European set of profiles by eHealth projects, be it national or regional in scope, will promote the interoperability harmonization among European countries and accelerate the delivery of quality and efficiency in the care processes.

Key words: eHealth standards, interoperability, deployment, health information.

The increasing complexity of the health system, the explosion of medical knowledge as well as the expectation from patients to have access to their medical data, drives the need to improve healthcare services by sharing medical data using the Information and Communication Technologies (ICT).

Giving care to a patient is today no longer the role of a single practitioner but the result of a team across several specialties, locations and time while the patient becomes more and more active in prevention and proactive in maintenance of his own health.

Citizens in Europe increasingly travel and work in another European country and the access to medical data is now becoming a European challenge. The patient mobility directive "aims to facilitate the access to safe and high-quality cross-border healthcare and promotes cooperation on

healthcare between Member States, in full respect of national competencies in organizing and delivering healthcare." ¹.

At the same time, research institutions and public health organizations, have a huge need to access appropriate medical data for biovigilance, epidemiology, medical research on oncology or other specialties.

Active and Healthy Ageing is one of the next societal challenges in Europe which calls for the development of innovative solutions. The deployment of these solutions depends not only on their usability but also on the interoperability of the IT products and devices to be combined to realize them. These solutions will leverage the quality and the efficiency of the care continuum with the integration of the telemedicine, tele-care and ambient assisted living (AAL) tools and other solutions. ²

These many new challenges cannot be met without accessing health information Systems from various organizations. To allow the sharing of medical data, two key elements must be considered, the communication infrastructure and the interoperability of the IT systems and devices interconnected with this communication infrastructure. For the first key element, the following requirements need to be in place:

- The identification of the professionals and patients/citizens who are engaged in care;
- The interoperability between systems among which data is exchanged or shared;
- A secured environment with data protection, who is responsible and who has the right to access to the medical data) for the benefit of the patient/citizen safety.

These requirements being quite broad, this paper will further focus on the second bullet above, the interoperability between systems among which data is exchanged or shared.

¹ Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (Legal basis proposed by the Commission: Article 114 of the TFEU).

² European Innovation Partnership on Active and Healthy Ageing – Synthesis report on the public consultation - DG health and Consumer and DG INFSO – 2011.

■ What is interoperability?

"The ability, facilitated by ICT applications and systems, to exchange, understand and act on citizens/patients and other health-related information and knowledge; among linguistically and culturally disparate health professionals, patients and other actors and organisations; within and across health system jurisdictions in a collaborative manner." (HITCH-D6, 2011)

To operate between them, the systems need to implement standards and protocols at the technical, syntactical and semantic levels. At the organisational level, procedures must be "understandable" by all parties by sharing common approaches.

The standards in eHealth are reaching maturity at the international level with HL7 in eHealth and DICOM³ in imaging. But other standards are also important such as standards defined by W3C (web services recommendations), IEEE (ISO IEEE 11073-X⁴) for devices and OASIS⁵ for security standards (SAML⁶, XACML⁷, ...) and other communication protocols.

International eHealth standards

HL7 (Health Level 7) is an organisation involved in the development of healthcare standards. The most common standards used in healthcare are:

- HL7 version 2.X messaging standards commonly used within healthcare organisations in order to manage workflow such as laboratory, radiology or pharmacy workflows;
- HL7 Reference Information Model (RIM) is an object model representing the HL7 clinical data shared by all domains;
- HL7 Clinical Document (CDA) release 2 leverages the RIM to model clinical records or documents such as discharge summary, Patient

³ <http://medical.nema.org/>

⁴ ISO/IEEE 11073-X: Health Informatics Personal Health Device Communication-Device specialized.

⁵ <http://www.oasis-open.org/>

⁶ Security Services.

⁷ eXtensible Access Control Markup Language.

Summary, ePrescription, ...). The CDA makes documents both machine-readable and human readable. The CDA is fully compliant with the RIM.

All these standards are also ISO standards for most of their versions.

HL7 provides also Arden syntax (language for encoding clinical decision logic), CCOW (clinical Context Object Group) and functional EHR and PHR specifications.

HL7 standards start to be more and more deployed in eHealth domains but have a competitor to some degree with the ISO EN 13606 (see section on European standards) which is also an ISO standard. Solutions to reduce the gaps between the two standards are in progress.

DICOM (Digital Imaging and Communications in Medicine)

The DICOM standard specifies protocol and service classes as well as unique identifier for information objects (UID) in order to transmit medical images and their associated information in a multi vendor environment. "DICOM facilitates the development and expansion of picture archiving and communication systems (PACS) and their interfacing with medical systems." This standard was created by the American College of Radiology (ACR with association of the NEMA (Electrical Manufacturers Association) but is today maintained at the international level with contribution of JIRA (Japan Industries Association of Radiological Systems) and other associations and companies over the world. The scope of the standards is extensive covering several domains such as radiotherapy, nuclear medicine, ophthalmology, ultrasound, digital mammography, surgery, veterinary medicine, pathology, specialties using images in their practises.

HL7 and DICOM coordinates their works for a better harmonization and consistency between standards, for example by contributing to the HL7 RIM in order to add DICOM equivalent data structure that are needed to combine the use of both standards.

Today DICOM is widely adopted worldwide, both by hospitals and Industry.

Other standards

European standards

At the European level, the standards bodies CEN (European Committee for standardization), CENELEC (European Committee for Electrotechnical standardization) and ETSI (European Telecommunications Standards Institute) are now collaborating together in eHealth field. The most involved European standard body in eHealth is the CEN/TC215 committee. During the last ten years, the CEN has developed a corpus of Technical Specifications (TS) and Technical Reports (TR) such as HISA (Healthcare Information System Architecture) and EN 13606 (Electronic Health Communication EHRCOM) and other standards in the field of blood transfusion, medicinal products, patient safety, etc.

To facilitate the use of not only CEN/CENELEC/ETSI standards, the European Commission has completed an evaluation of the standard process in order to adapt the European standardisation system to a more dynamic ICT in health market and societal challenges, especially providing more flexibility to use other standards beyond those of CEN, CENELEC and ETSI. This would include standards issued by recognized fora and consortia such as OASIS, W3C, and IHE.

CDISC (Clinical Data Interchange Consortium)

CDISC develops standards in the field of medical research and related areas of healthcare.

IEEE 11073-X

The IEEE delivered two series of standards dedicated to the Personal Health Device Communication. The first series of 5 specifications are common for all device communication and represents the foundation (ISO, 2004). The second series of specifications are specialized and dedicated to specific devices such as thermometers, pulse oximeters, blood pressure monitors, glucose meters, weighing scales, cardiovascular fitness and activity monitors and strength fitness equipment.

Fora

IHE (Integrating the Healthcare Enterprise)

Standards are not sufficient to assure complete interoperability. Indeed, standards are specified for a large range of usage, thus having to be constrained by use to cases responding to the operational users' needs (DANIEL-LE BOZEC *et al.*, 2006). IHE⁸ (Integrating the Healthcare Enterprise) has defined a complete process in order to specify IHE profiles⁹ responding to the user need and relying on international standards. This process is recognized at the ISO level as a Technical report TR 28380 (ISO, 2008) and based on three main activities:

- definition of use cases by Healthcare Professionals;
- selection of standards at the international level, resulting in the specifications of profiles;
- implementation in the systems and testing of their conformance to the profile specification in a neutral testing and controlled environment called "Connectathon" (connectivity marathon).

Several Connectathons are organised by IHE at the international level: in North America in January, Europe in April, Korea in July, Japan in October, and China in November. Every year, new profiles are tested and feedbacks coming from the industry and the Connectathons contribute to make these specifications robust.

Continua Alliance

In the same philosophy, Continua Alliance¹⁰ defines guidelines based on international standards (such as ISO/IEEE 11073-X) as well as reuses IHE profiles in order to establish connectivity between Personal Health devices and healthcare systems for the benefit of citizens and patients.

Continua Alliance defines a Healthcare connected ecosystem where people with chronic diseases can transmit their vital signs (blood pressure,

⁸ <http://www.ihe.net>

⁹ Profile provides a common language for purchasers and vendors to discuss the integration needs of healthcare sites and the integration capabilities of healthcare IT products. Two types of profiles are identified: integration profiles addressing technical aspects of the interoperability and content profiles addressing the semantic interoperability.

¹⁰ <http://www.continuaalliance.org>

glucose level, weight, ...) seamlessly from home to healthcare professionals and receive information on their condition. Continua Alliance has also defined a certification process that delivers seals to products.

LOINC, SNOMED and other terminologies

To achieve interoperability, terminology and semantics are also key elements that need to be developed. In the laboratory domain, LOINC codes are more and more used in several countries from North America, Europe to Asia. The SNOMED/CT ¹¹ developed by the international fora IHTSDO ¹² based in Denmark, is a multilingual clinical healthcare terminology.

Other terminologies such as ICD-10 ¹³ and UCUM ¹⁴, are also part of the landscape. In this field, clinical use cases driven by healthcare professionals are the best way to define the terminology sub sets in relation with content profiles such as those developed by IHE.

Landscape and impact

In the following Figure, a tentative synthesis presents the landscape of standardisation bodies.

This landscape is not exhaustive and several other organizations are also involved in providing standards of interest in the eHealth domain (WHO-World Health Organisation, GS1 – Global system of Standards, UIT-International Telecommunication Union, ...) and all other related standard or consortium bodies related to telecommunication infrastructures.

This landscape looks very complex and the question of the real added value of such varied standard organisations is asked by end-users in care settings when they feel that these organisations are not answering to their daily problems such as sending a complex order to pharmacist, laboratory or to any other department. Concrete business cases must be taken into consideration in order to select a set of standards or set of part of standards

¹¹ Systematized Nomenclature of Medicine-Clinical Terms.

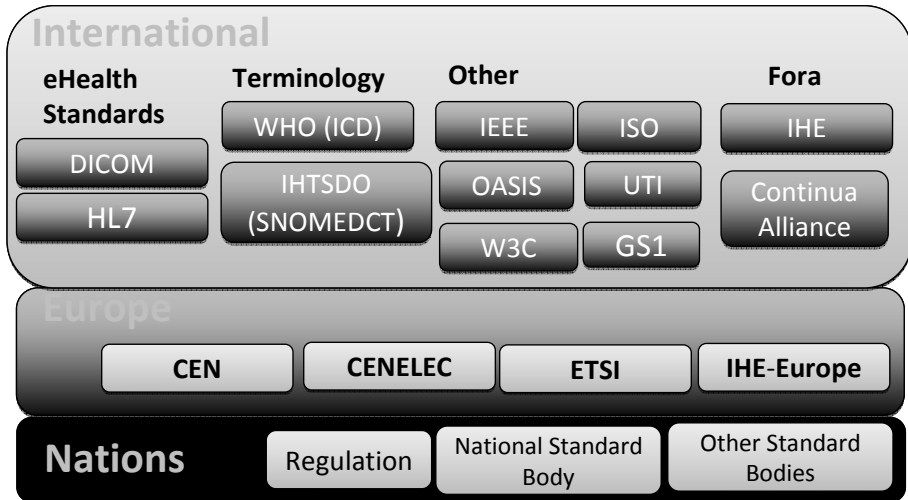
¹² International Health Terminology Standards development Organisation. <http://www.ihtsdo.org>

¹³ International Classification of diseases. <http://www.who.int/classifications/icd/en/>

¹⁴ Unified Codes for Unites of measure. <http://unitsofmeasure.org/>

for building a consistent and coherent "package" called a profile. Standards are generally focused on a specific layer (communication, security, other technical protocols, application, ...) when the use case specification is covered by the sum of all these layers.

Figure 1 - Standard landscape



It is the reason why the tendency is to promote collaborations between standards organisations that have their own specificities and types of members (associations of professionals or professionals, institutions and associations of suppliers or companies). More collaborations between them will better address real needs instead of addressing piece by piece one of the layer or focusing on a part of the use cases.

This new paradigm is the first step for improving standards that will become more and more mature. Their usage, continuous and consensual process of maintenance will increase their robustness and their deployment in the community. The second step focused on the promotion of their adoption by the industry is included in several reports or documents in Europe or at the international level ¹⁵, (GALLAHER *et al.*, 2004).

Deployment of robust standards and profiles which support health interoperability between systems will allow the development of telemedicine when the environment is still changing quickly: ageing population, decrease

¹⁵ Council conclusions on innovation in the medical device sector, Luxembourg, 6 June 2011.

of Healthcare professionals in Europe, cuts in the health budget, ... These new challenges are already there and it is time to concretely deploy experimentations and to learn from them. In the following sections, after a presentation of some deployment as examples, the last section will develop some arguments in order to find levers that will accelerate deployment of standards and profiles in Europe.

■ Deployment of profiles and standards

Today, standards and IHE profiles are deployed in several countries across the world, including Europe in healthcare providers (hospitals) or in regional/national or European programs. In the following examples, key elements that can be used to accelerate standards deployment are highlighted.

National program

In France, the national Electronic Health Record program (DMP) has specified an interoperability framework which relies on several IHE profiles (for example the IHE-XDS (IHE ITI, 2010) profile ¹⁶ used for supporting the interoperability infrastructure). Content profiles based on the HL7 CDA (Clinical Document Architecture) describing the content of medical documents such as patient summaries, laboratory report, pathology report, etc.) are also used. ASIP Santé, the national agency that leads the DMP program has set up a conformance certification of healthcare IT solutions. As of June 2011, about 20 companies are certified for the set of profiles described in the ASIP Santé interoperability framework.

From the beginning in 2004, the project is known as having difficulties to start for several reasons (political, organisation and technical aspects). At the technical level, players have quickly converged on the need for the development of the interoperability framework based on international standards.

¹⁶ The aim of this profile is to offer a web-based service for sharing Electronic Health Records (EHR) among several health organizations.

European project

At the European level, the epSOS project (European Patient Smart Open Services) ¹⁷ develops an interoperability framework for exchanging Patient Summary, ePrescription and eDispensation for a mobile patient. This interoperability framework is also based on IHE profiles and the medical documents are structured as HL7 CDA documents. Implementation by 11 countries, have been tested at an epSOS projectathon in April 2011 (Pisa, Italy), where during one week, medical documents were exchanged in a controlled testing environment. Pilot deployment is planned for fall 2011. This project has recently been extended to 23 countries in Europe and will foster the structuration of the interoperability framework between countries but also within country by percolation. Indeed this project, by defining and building a service infrastructure that demonstrates cross-border interoperability of health records in Europe, has direct impact on the national infrastructure even if not explicitly within direct scope. The project has also embarked on defining common policies (such as patient consent policy, security policy, access right policy, etc.) and governance (governance of the identification of the professionals and patients for example) in order to ensure the legality of such exchanges.

The terminology needed for semantic health information exchange between Nations is also a challenge addressed by the epSOS project: based on a common subset of clinical codes, each Nation maps their own clinical subset codes with the common adopted terminology called pivot.

One of the benefits of such a project is the reuse and extension of existing test tools and a testing platform that allow the diffusion in the nations experience on the usage of the standards and profiles in a concrete way. Because the tools are open and available on line, nations teams use them intensively and give them opportunities to fine tune their solutions.

Hospital Information Systems

The hospital is also a main user of standards: the Hospital Information System is not a monolithic system but is composed of several specific products, for example Patient Management System, EHR System, Laboratory Information System (LIS), Radiology Information System (RIS),

¹⁷ <http://www.epsos.eu/>

Picture Archiving Communication System (PACS), Pharmacy Information System, ... Healthcare workflows need to be managed and data exchanged among all these systems. Integration profiles (IHE workflow profiles) often based on Standards such as HL7, are ready to use and several suppliers have already implemented them in their products. The challenge in this case is to accelerate the transition phase when proprietary standards and international standards and profiles are working together. The trust in the future by vendors who invest of such new standards is balanced by the others who think that they will loose their market. The direct impact of this situation is that end-users today have difficulties to find interests of deploying standards and profiles when they need an integrated and optimized Hospital Information System. The challenge is to find levers to make this transition phase as short as possible.

Discussion

These standards and profiles described in this article have recently matured and in some areas are not yet widely adopted by stakeholders. Several reasons can be listed but five are presented here:

- *Quality Safety issues:* the roles, responsibilities and obligations of suppliers and healthcare providers have to be clarified by simple rules at the national level. One of the ways to define a responsibility scheme, is to develop a clear process of labeling or certification of products that may help to address safety issues. However this is not sufficient, as the exchange/sharing of medical data involves two or more partners not only at technical level, but also at the semantic and organizational levels and all three levels have to be perfectly synchronized and understandable by each partner;
- *Adoption of the international standards in Europe:* the standards will efficiently support the development of innovative solutions and therefore increase the competitiveness of the suppliers and allow them access to a new market outside Europe. In eHealth the most relevant standards are international standards and the regulation in Europe need to be adapted in order to recognize such standards;
- *Semantic interoperability:* it needs to be aligned with the medical processes which, today, are not harmonized across all needed specialties. They are too often customized by the local organizations, local vocabularies or simply by the healthcare practitioners themselves. It is unacceptable to think that these problems will be solved by reducing the diversity of the

medical practices (for example by defining or using one coding system). Translation and transcodification are solutions expected to be used in the short-term to support the process of semantic interoperability;

- *Communication and training:* Access to standards and their implementation need to develop a critical mass of knowledge through Europe by educating technical staff and Engineers but also healthcare professionals. It is a high priority for developing such knowledge in order to be able to define business cases, specify integration profiles and to give feedback to the international standards bodies for the recognition of the European research in this area;

- *Governance:* Health and social care are the competence of the European countries. For the coordination of the deployment a set of common relevant profiles and standards in countries has to be organized.

■ Perspective and future

Societal changes (eInclusion, eAgeing, security, social networking, international cooperation) drive new opportunities: innovative solutions (sensors, network infrastructures, web based services, ...) are the first application of the interoperability framework using common policies and standards leading to a better integration and development of the software solutions responding to new usages.

The European Commission has clearly identified these challenges in several documents (Digital Agenda, Work Program 2011 – ICT, etc.) as well as programs within European Countries which are also developed in order to foster innovation.

The next steps for accelerating the adoption of the standards and profiles, is to launch a labeling or certification process. Based on a testing of a set of profiles, the testing will cover the conformity of the systems to the set of standards that are constrained in the profiles. The interoperability conformance should rely on agreed tests cases applied to systems from a broad range of vendors.

Labeling and certification should be based in the same testing process but for the certification, the laboratory testing or the inspection bodies (audit the suppliers performing self-testing) there need to be accredited bodies (IHE IT Infrastructure, 2010). The certification is also more and more used

for regulation purpose and the debate on the effectiveness of regulation or incentives is still open in eHealth. A preliminary study (HITCH-D4.3, 2011) on labeling/certification scenarios gave a general direction for the deployment of such a labeling/certification processes.

Three alternatives of labeling/ certification were identified:

- Labeling/certification of products by third party: the testing process is performed by a third party according to the specifications and requirements, in the scope of the labeling/certification. This can be seen as an ex-ante control;
- Self-assessment of products with external audit: the testing process is performed directly by the supplier according to the specifications and requirements. The supplier is subject to an external audit performed by an inspection body (accredited or not). This can be seen as a ex-post control;
- Self-assessment of products: the testing process is performed directly by the supplier according to the specifications and requirements.

These alternatives have benefits and limitations that depend on the maturity of the market, the extra costs related to the process, the emergence of new interoperability profiles and the legal framework related to the patient safety and security.

In an emerging and innovative market, third Party Labeling/Certification of products seems to be a reasonable first step approach to develop an initial mass of interoperable products. As the market becomes more stable and mature, self-assessment with external audit should become the natural transition being less cumbersome and more dynamic.

The articulation between the European level and the national level in order to harmonize the testing processes is dependent on a set of common profiles, specifications and requirements. This testing process (at the two levels) must be supported by an Interoperability Quality Management System (interoperability QMS). A first version was developed in the HITCH project (see JOANSEN *et al.*, 2011). The risk of divergence in Europe will be therefore better controlled.

The other way to decrease this danger is to provide to the stakeholders a set of test tools and test cases that will help implementers to improve their products. Based on open source licenses, the test tools should be available on line. Several tools are available today. The most popular used today are based on a testing management platform developed under an open source

license called Gazelle ¹⁸. This platform offers several test tools on line such as validation services of CDA documents (IHE Patient Care Coordination, epSOS medical documents), validation services for HL7 messages or DICOM objects, SAML objects, certificates (in the context of IHE and epSOS project), simulators of actor that simulate the behaviors of the systems according the profile specifications. All these tools can be used directly by suppliers and systems installers. An evaluation of the existing test tools in eHealth is available on the HITCH project website ¹⁹.

The use of a common set of tools contributes strongly to the convergence and development of the interoperability solutions and allows more dynamic knowledge sharing.

These testing tools are well adapted to test the conformity to standards and profiles. The organization of testing sessions where systems from different vendors run workflow tests in a controlled environment will cover the interoperability validation. Every year in each region of the world, such testing events are organized. In Europe, more than a hundred systems run a thousand tests in one week in the testing session called by IHE, connectathon ("marathon of connectivity"). During one week, the validation is under the responsibility of a neutral team of testers called Monitors.

The eHealth ecosystem should include numerous tools that can be considered for developing innovative solutions in Europe. However prerequisites need to be established. The next steps are first to recognize across Europe a consistent set of existing standards and profiles that support the most common use cases (eHealth Interoperability Framework). Next on this foundation, a consensual implementation roadmap needs to be agreed by users and providers of solutions, along with the development of common test plans and test tools forming a robust testing platform under a high level of quality management system. Finally, one should define interrelated labeling or certification scenarios between national, regional (e.g. European) and international level for convergence and mutual consistency.

¹⁸ <http://gazelle.ihe.net/>

¹⁹ <http://hitch-project.eu/testing-tools>

■ Conclusion

Interoperability eHealth is now a concept with increasing maturity and its strategic impact is much better understood by high level management that is focused on the ICT market. The use of international standards and profiles adopted by providers of solutions should be encouraged in the public procurement in the future (see note 14) and then it will foster the investments of suppliers as well as user organizations or public authorities. As a result, it should increase harmonization and quality of the products, thus enhancing patient safety.

The eHealth ecosystem is now ready to accept and to support an effective and coordinated work program on interoperability.

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