# Digital standards and e-health

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***Abstract**:*
E-health refers to subjects as varied as the patient's search for care or the use of information and communications technology for health purposes. It addresses many an issue, such as the ageing of the population and of health-care professionals, the shortage of medical experts, the equality of access to care, prevention work, patients' access to their clinical data and rare diseases. E-health involves exchanging or sharing health data from systems that are the source of data toward systems that will use the data in an environment that inspires confidence. Its development very much depends on how these systems interact. Furthermore, interoperability is a requirement essential to e-health's well-being. What is meant by interoperability? What are the variants of this concept in Europe (model-building at various levels)? Over the past twenty years, approaches based on use cases for facilitating the drafting of technical standards have been worked out for e-health; but their implementation is still problematic. The use of platforms of open tests is now the best way to solve problems related to the rollout of e-health programs.

E-health (or eHealth)[1] — a concept used since the end of the 20th century — covers fields as varied as: the standard channels for coordinated care, collaborative medicine, access to medical knowledge, telemedicine (diagnosis and treatments), assisted decision-making, the analysis of huge volumes of medical data, or the use of information and communications technology (ICT) for health.[2] At the EU level, e-health is intended to provide citizens with access to secure electronic health-care services of quality. Three priorities have been set as part of the program "Digital Transformation of Health and Care in the Digital Single Market":[3]

- *"citizens' secure access to their health data, also across borders"* in Europe;
- *"personalized medicine through a shared European data infrastructure"*; and
- *"citizen empowerment with digital tools for user feedback and person-centered care"*.

Using ICT technology in health opens perspectives for improvements: citizens' health and well-being, the state of the population's health, medical know-how and research (in particular through data analytics applied to big data on medical and economic activities). In concrete terms, e-health refers to exchanging or sharing health data between the systems at the origin of the data toward those that consume them. Its development is subject to at least two important restrictions: on the one hand, the protection of personal data and the ethics of using them; and, on the other hand, the interoperability of these systems. These two restrictions call for a set of rules for settling the problems encountered when implementing e-health.

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[1] This article has been translated from French by Noal Mellott (Omaha Beach, France). The translation into English has, with the editor's approval, completed a few bibliographical references. All websites have been consulted in April 2019.

[2] The French Agency of Health (ASIP Santé) has assignments in matters of e-health: http://esante.gouv.fr/asip-sante. See too the World Health Organization's website: http://www.who.int/ehealth/en/.

[3] https://ec.europa.eu/digital-single-market/en/policies/ehealth

# Standards for interoperability

Interoperability is the "*capability to communicate, execute programs, or transfer data among various functional units in a manner that requires the user to have little or no knowledge of the unique characteristics of those units*".[4] Interoperability represents a growth market and has been a focus of R&D in recent years.

**Figure 1**: Refined model of interoperability (Antilope 2015)
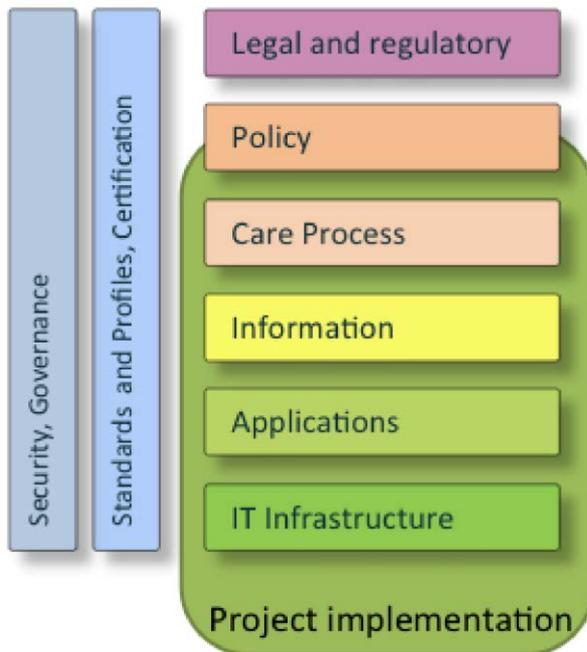


In Europe, a model of interoperability has been built as a series of levels:[5]
● the legal and regulatory level, specifically laws and regulations about exchanging and sharing health data;
● the policy level, where public policies set the organizational rules derived from the previous level and see to the coordination of the work of health-care professionals;
● the level of health-care processes, which describes the sequence of activities;
● the level of health-care data so that the data are "understood" from one end of the process to the other (semantics and syntax);
● the level of applications for exchanges (the transfer of messages and portability of data so that different systems can interpret them); and
● the infrastructure level with its communication protocols.
Let us look more closely at these levels.

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[4] ISO/IEC 2382:2015. Information technology — Vocabulary available at https://www.iso.org/standard/63598.html.

[5] eHealth Network (2015) "Refined European Interoperability Framework", 23 November, 24p. available via https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf See too: Decision (EU) 2015/ 2240 of the European Parliament and of the Council of 25 November 2015 establishing a program on interoperability solutions and common frameworks for European public administrations, businesses and citizens (ISA2 programme) as a means for modernizing the public sector. Available via https://ec.europa.eu/isa2/sites/isa/files/celex_en.pdf.

## *Legislative and regulatory frameworks*

An exhaustive description of the many legal texts that apply to e-health lies outside this article's scope. I shall cite but two examples. First of all, the French Act of 26 January 2016 on the "*modernization of our health system*"[6] states that the discharge letter from the hospital to a patient's doctor, which ensures the continuity of care, has to be dematerialized and stored in a shared medical folder. This act also stipulates the Health Insurance Fund's assignments with regard to the design, implementation and administration of this shared folder; and it calls for a secure system of communication for exchanging information among health professionals. Secondly, the EU directives on patients' rights in crossborder health care and on the protection of personal data foster interoperable, structured formats for ensuring data portability.[7]

## *Description of the coordination of health-care processes and of the work of health-care professionals*

Owing to the variability and extent of coordination implied by levels 2 and 3, there is no strict set of standards. However several methods and codes of good practices have been released and are being used. The intent is to separate the description of the processes of care provided by human actors from its transposition into a management of data flows over the systems involved, systems which include "actors".[8] To reduce complexity, "use cases" serve to describe needs in simple terms so that an end user can understand the description.[9] To help decision-makers formalize their needs, the Antilope Program offers tools for describing use cases from basic processes up to the final scenario, which states how to implement a use case in an interoperability architecture.[10]

## *Data*

This fourth level of interoperability focuses on data. Data lie at the center of several debates about their structure, their availability in systems covering extremely varied needs, and their primary use by health-care professionals (namely, to provide uninterrupted patient care). These professionals expect data to be reliable and interpretable by their system. The structure, consolidation and intelligibility of data (semantics) are the principal issues that arise when exchanging data or controlling their flow.

Semantically, the best known international terminologies are: SNOMED Clincial Terms; Logical Observation Identifiers Names and Codes (LOINC) for laboratory tests and the results; and the International Classification of Diseases and Related Health Problems (ICD10, ICD-10_CM, and soon ICD-11), which several countries, including France, use.[11] However terminologies specific to specialties or organizations are widely used in many countries.

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[6] Act n° 2016-41 of 26 January 2016 is available at
https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000031912641&categorieLien=id.

[7] Directive 2011/24/UE of the European Parliament and the Council of 9 March 2011 on the application of patients' rights in crossborder health care. Available at https://eur-ex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32011L0024.
The General Data Protection Regulation (GDPR): "Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data". Available via:
http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1478961410763&uri=CELEX:32016R0679.

[8] A system "actor" is a function that implements the transactions (based on standards) underlying the exchange or sharing of data.

[9] BOURQUARD K, ORLOVA A & PARISOT C. (2017), "Understanding user needs for interoperability: Defining use cases in eHealth, *Journal of AHIMA*, 88(6), pp. 42-45, available at http://bok.ahima.org/doc?oid=302159.

[10] The Antilope Program for advancing e-health interoperability: https://www.antilope-project.eu/front/index.html.

[11] Respectively: SNOMED CT, https://www.snomed.org; LOINC, https://loinc.org; ICD-10, http://apps.who.int/classifications/icd10/browse/2010/en#; and ICD-11: https://icd.who.int.

A health-care professional's choice of a code is, let us point out, specific the individual patient and context (standard channel of care). Without this context, medical data have very limited worth in the care-giving process. Much work has been done on semantic interoperability, in particular in studies about the descriptions used on the Web (Web semantics): the Web Ontology Language (OWL) and Resource Description Framework (RDF).[12] Other models are being built. Pragmatic, targeted approaches tend to be adopted to facilitate the application of these constantly changing models. By defining a use case corresponding to the user's needs, a set of codes (therefore, by nature limited to the identified needs) can be defined to make implementation easier. Furthermore, there are many secondary uses of data. The value of data is completely different when they are processed in mass, aggregated and reproduced in a more elaborate form for the purpose of statistics, research, epidemiology, knowledge, etc.

In all cases, what is crucial is to have available data of a good quality. This must be achieved in a legal and ethical framework and with the consent of the persons concerned. For this purpose, procedures for anonymizing or pseudonymizing data are used.

## *Applications*

This is the level for implementing information exchanges and sharing.

A relative consensus prevails about the regulations and standards made by international standards organizations. The community of experts and users is important for making standards robust. I might mention: Digital Imaging and Communications In Medicine (DICOM), the Health Level Seven (HL7) standard for exchanges, and HL7 CDA for clinical documents.[13] The drafting of HL7 FHIR[14] on "*fast healthcare interoperability resources*" is drawing to a close. It signals a technological breakthrough compared with the earlier standards since it uses application programming interfaces (APIs) for mobile applications and connections to the Internet. It includes protocols and standards such as RESTful and JSON. For medical devices and equipment, a body of standards exists, such as ISO/IEE 11073 ff. on personal health devices, not to mention other ISO or ITU standards (in particular for electronic security in medicine).

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[12] https://www.w3.org/2001/sw/wiki/OWL

[13] Respectively: DICOM: https://www.dicomstandard.org; versions 2 or 3: HL7: http://www.hl7.org; HL7 CDA release 2: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7.

[14] HL7 FHIR: https://www.hl7.org/fhir/.

**Figure 2**: From a business use case to its implementation in an interoperability architecture (IHE-Europe)
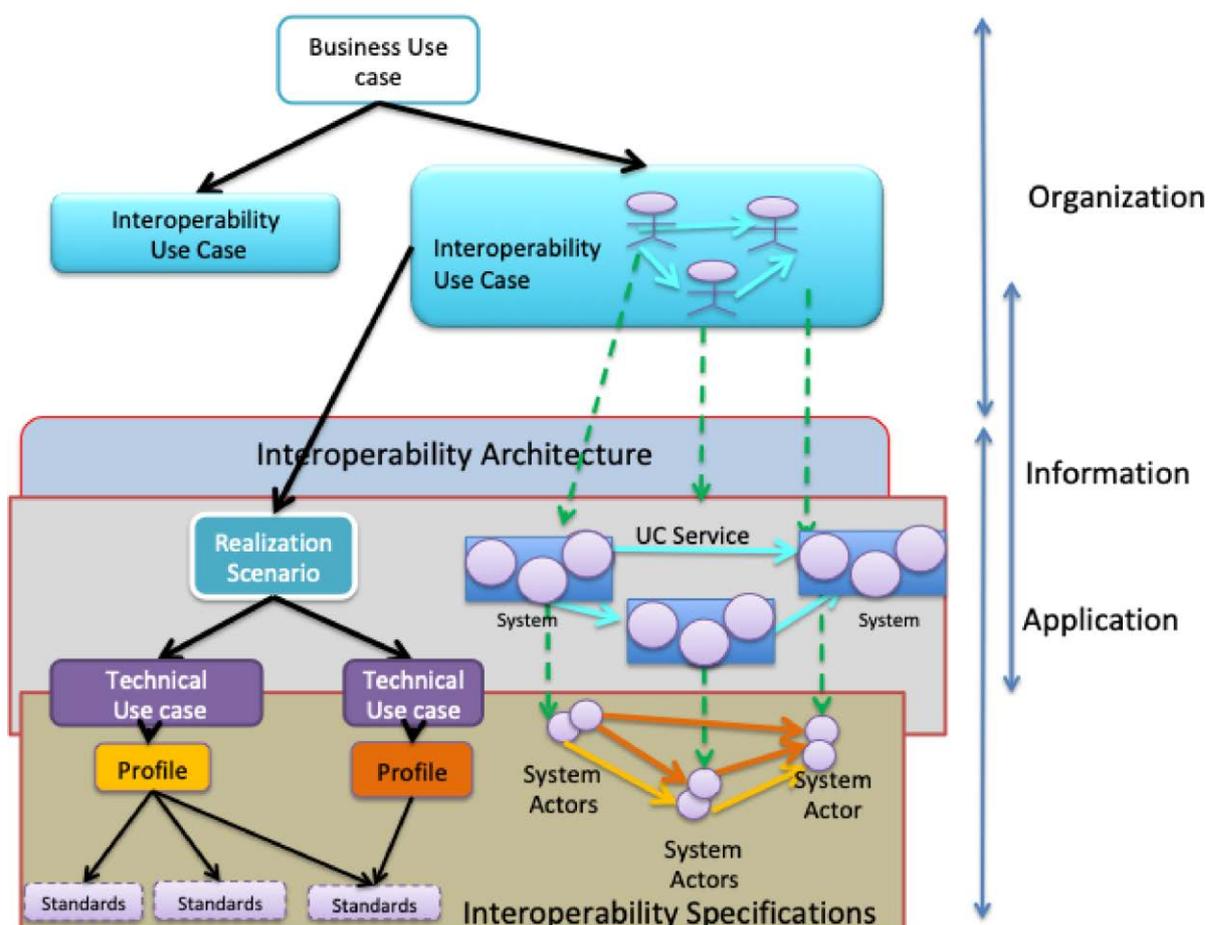


Whereas standards are general enough to respond to all uses, INTEGRATION PROFILES are specifications for use case implementation (Figure 2). Such a profile assembles a set of standards that have to work together to handle use cases (*e.g.*, data series or message formats). Two major consortiums are developing integration profiles in the health field: Integrating the Healthcare Entreprise (IHE) and PCHA/Continua Alliance for connected health devices.

## *Communication protocols and the technical infrastructure*

At this sixth level in support of exchanging and sharing data, formal descriptions are made of the infrastructure and communication protocols; and guidelines and standards, drafted for them. The exchange and sharing of data cannot be achieved without building up confidence to a point that will lead health-care professionals and patients/citizens to adopt and use e-health. This implies managing matters related to the patient's consent, risks, security, the traceability of actions, safe access to clinical data, etc. Regulations, standards and codes of good practices are available on these questions, many of them for fields other than health.

## Standardization in e-health: A driving force

The set of e-health standards has grown considerably over the past twenty years. Digitizing the heavily regulated health sector started in the administration before reaching out into laboratory tests, medical imagery, the pharmacy and services — fields where the first demands for standards on applications inevitably emerged.

The environment is evolving. European states, as well as Europe, have addressed this topic in the effort to cope with new health issues: the ageing of the population, the lack of medical expertise, equal access to care, prevention work, patients' access to their clinical data, the patient's responsibility, standard channels of care, rare diseases, and so forth. Several reports published at the national[15] or European[16] levels have shed light on the need to improve interoperability in the health field. The EU actively supports digitizing crossborder exchanges through programs on the reimbursement of fees and exchanges of clinical information (the eHDSI program: eHealth Digital Service Infrastructure).

As the market expands, technical opportunities abound. Proposals for new standards crop up as a function of technological breakthroughs. They are on the drawing board, but it will take a few years before they take a definitive form. Meanwhile, some standards are genuine successes (*e.g.*, FHIR). With an approach based on use cases, initiatives such as IHE or Continua Alliance associate standards with "profiles" that respond concretely to needs, thus reducing the risk that equipment or applications will turn out to not be interoperable.

## Toward a professionalization of interoperability

Despite the efforts made, new needs have not yet been satisfied. To make available integration profiles for products, a pragmatic approach has to be worked out and tested. Committees of experts have effectively used this approach, which is grounded on five principles:

- identify and describe use cases;
- identify and select standards;
- specify integration profiles;
- develop the tools for testing and run bench tests of the products; and
- bring compliant products to the market.

This approach can fit into a broader process that includes designing new products and testing their uses (by "living labs" for example).

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[15] COMITÉ DES SAGES (2013) *Un projet global pour la stratégie nationale de santé. 19 recommandations du Comité des Sages*, June, 147p. Available via http://solidarites-sante.gouv.fr/IMG/pdf/rapport-cordier-SENSE-sages.pdf.
HAUTE AUTORITÉ DE SANTÉ (2018), *Qualité et sécurité des actes de téléconsultation et de téléexpertise*. *Rapport d'élaboration de la fiche memo* (Saint. Denis: Haute Autorité de Santé) April, 74p. available via
https://webzine.has-sante.fr/portail/upload/docs/application/pdf/2018-04/rapport_delaboration_de_la_fiche_memo_teleconsultation_teleexpertise_avril_2018_2018-04-20_11-04-50_363.pdf.
SIMON P. & ACKER D. (2008), *Rapport: La place de la télémédecine dans l'organisation de soin*, November.

[16] EUROPEAN COMMISSION & EUROPEAN MULTISTAKEHOLDER PLATFORM (2018) *The Rolling Plan for ICT Standardization* (Brussels: European Commission) available at https://ec.europa.eu/digital-single-market/en/news/rolling-plan-ict-standardisation. EUROPEAN COMMISSION (2016) *Blueprint Digital Transformation of Health Care for the Ageing Society*, November, draft version available via http://www.ehealthnews.eu/images/stories/pdf/blueprint_transforming_the_future_of_health_and_care.pdf.
EUROPEAN COMMISSION (2018) "Enabling the digital transformation of health and care in the Digital Single Market: Empowering citizens and building a healthier society", communication of 25 April, 15p. Available at
https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering.

Over the past few years, platforms have sprung up for running tests to check whether systems are capable of exchanging structured data while meeting certain requirements. Integration profiles and standards can be improved by providing a large number of users with test plans, tools and a series of test cases. Contests called "Connectathons" are organized every year in Europe for bringing together developers (who test their products during a limited period, five days at IHE), monitors (who verify the tests) and experts on standards. This sort of event is a genuine bench test for the adoption of standards and for the validation and improvement of specifications on integration. Furthermore, it trains engineers to work in complex environments.

Countries often require product compliance with specifications be certified. This certification might be proprietary (drafted by a single industry or a few manufacturers) or be based on published standards. In recent years, the grids used to assess compliance outline a form of governance and organization for developing and performing assessments of product compliance with standards. The tests are run by accredited laboratories, whose reports are recognized internationally (IHE CAS) or in Europe (EURO-CAS).[17] As such initiatives develop, they will bring about harmonization and forms of exchanges; thus moving us toward a single European market. They also provide a response to the previously mentioned issues of interoperability. Test results, registered in reports, can then be used for the certification often required by national or regional authorities for the sake of confidence. The key question is no longer a standard's worth or purpose but quite clearly its effectiveness for responding to needs once it is implemented.

There are many advantages to using standards of interoperability:
● harmonize a still splintered market (for some products);
● satisfy regulations;
● test products in relation regard to use cases;
● boost the adoption and knowledge of e-health integration profiles and standards;
● improve the quality and structure of clinical data;
● develop and integrate security procedures for exchanging data; and
● reduce the costs of testing.

All these elements are already present to address the issues related to e-health in the coming years. The e-health market will provide new jobs and benefit both patients and health-care professionals, but it cannot be realized if interoperability is not developed and recognized for its worth.

Innovations are in the pipeline, but they have often been developed in bunkers. To produce lasting benefits, it is necessary to improve knowledge about e-health (with a focus on the multilevel model described herein) during postsecondary education. A key to success is the tests carried out by using a joint (national, European and international) set of tools. This can help reduce the time for bringing products to market — products that will become part of a longer value chain and thus increase their own value in the chain.

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[17] ISO/IEC 17025 (2005) "General requirements for the competence of testing and calibration laboratories". The IHE Conformity Assessment Programs: https://www.ihe.net/testing/conformity-assessment/. The eHealth Interoperability Conformity Assessment Scheme for Europe: www.EURO-CAS.eu.