Towards Interoperability of EHR Systems: The Case of Italy

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Abstract: The great benefits that Electronic Health Records are able to provide in terms of improvement of the quality of care and reduction of costs have led many international organizations to implement enabling systems. However, the systems designed and realized are very often not able to interoperate each other, due to several reasons, varying from the existence of different local needs to the use of diverse health informatics standards. The lack of interoperability among these systems can result in decreased levels of quality of patient care and waste of financial resources. In Italy, the autonomy about healthcare delivered by the Italian Constitution to each region caused the spread of heterogeneous regional EHR systems, thus not able to interoperate each other. This paper presents the result of an effort made within a convention between the National Research Council of Italy and the Agency for Digital Italy, for the specification of the Italian architecture for the interoperability of regional EHR systems. Such an architecture has been defined according to the requirements provided by Italian Laws recently issued and approved by a National Technical Board.

1 INTRODUCTION

In the last decades, many countries in the world have made significant efforts to develop Electronic Health Record (EHR) systems (Aminpour et al., 2014). The main reasons are: i) improving the quality of care services, and simultaneously ii) reducing health care costs (Black et al., 2011; Shekelle et al., 2006). ISO defines EHR as a "repository of patient data in digital form, stored and exchanged securely, and accessible by multiple authorized users". It contains retrospective, concurrent and prospective information and its primary purpose is to support continuing, efficient and quality integrated health care (ISO/TR 20514, 2015).

Despite such efforts in the realization of EHRs, the systems developed, both at regional and national level, are very often not able to interoperate each other (Ludwick and Doucette, 2009), due to a plethora of reasons. First, each country or regional domain is characterized by its own legal requirements, especially about privacy protection. Second, countries or regions have typically different needs, depending on their dimension, number of citizens, number of healthcare facilities, etc. Finally,

the development of the systems have been started in different periods, adopting or applying diverse standards in different ways (Dogac et al., 2007).

The lack of interoperability among these systems can result in decreased levels of quality of patient care and waste of financial resources. In fact, when a patient benefits from a health service outside her/his health care domain, the health professional that treats the patient is not able to access the patient health information, due to the impossibility of cooperation between the EHR system used by the health professional and the one related to the patient. Therefore, the health professional typically requires the patient to repeat a clinical exam already executed. With respect to interoperability, several levels of interoperability have been defined in literature (Kalra et al., 2007): *technical interoperability*, for which the systems share the communication protocols making possible, e.g., the exchange of bytes between them; *syntactic interoperability*, which aims at making the systems capable of communicating and exchanging data through the sharing of data formats; *semantic interoperability*, whose purpose is to enable systems to exchange data and interpret the information exchanged in the same way; *organizations & services*

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interoperability, where business processes are shared between the systems.

The importance of making EHR systems able to interoperate each other has motivated by the increase of the phenomenon of the patient mobility for reasons of care. For example, we can consider Italy where 570k hospitalizations are made by patients in a region different from that they reside (Istat, 2015).

In Italy, the autonomy about healthcare delivered by the Italian Constitution to each region caused the spread of heterogeneous regional EHR systems. After some national initiatives aimed at proposing a first architectural model at national level, the emanation of Italian norms has allowed defining both i) the national architectural model of reference, and ii) the functional and privacy requirements to be respected by all the Italian regions. In this scenario, this paper presents the Italian architecture designed for the interoperability of EHR systems by a National Technical Board, coordinated by the Agency for Digital Italy (AgID) and the Ministry of Health, with the technical support of the National Research Council of Italy (CNR) and the participation of the Ministry of Economy and Finance and Italian regions.

This paper is organized as follows. Section 2 provides a background on the main standards and projects on e-health data interoperability. Section 3 describes the main features of the national interoperability architecture, highlighting the cross-border business processes. Section 4 presents the technical details about the architecture. Finally, Section 5 concludes the paper with some final remarks and indications for future works.

2 BACKGROUND

2.1 Health Informatics Standards

HL7 is a non-profit organization involved in the development of international health informatics interoperability standards. Version 2 of the standard is currently implemented in numerous health organizations, whereas Version 3 is based on an object-oriented model named Reference Information Model (RIM). From the RIM, it was derived the Clinical Document Architecture (CDA) standard, which specifies the structure and semantics of clinical documents. Currently, HL7 is involved in the definition of a new health interoperability standard, named FHIR, which combines the best features of the previous versions (HL7 [online], 2016).

IHE is an international initiative founded by RSNA and HIMSS with the goal of supporting the integration of health information systems through existing standards. IHE constantly defines integration profiles, which aim to solve problems related to specific use cases. In this context, the profile more relevant in the IT Infrastructure domain is XDS, which has the scope of facilitating the sharing of patient electronic health records across health enterprises (IHE [online], 2016).

2.2 International and National Projects

Canada Health Infoway is an independent, federally-funded, not-for-profit organization with the responsibility of accelerating the adoption of digital health solutions across Canada. Along with the Canadian provinces and territories, Infoway provided a national framework called EHR Blueprint, with the aim of guiding the development of the systems in each different province. The key elements of the framework, built following a Service-Oriented Architecture (SOA) based on the HL7 Version 3 standard, are: gateways, data repositories, registry services, infostructure, access mechanisms (Canada Health Infoway [online], 2016).

U.S. Healtheway (now Sequoia) is a non-profit, public-private partnership that operationally supports the eHealth Exchange project. With production starting in 2007, eHealth Exchange has become a rapidly growing community of public and private organizations, with the aim of facilitating the exchange of health information in a trusted, secure, and scalable manner. The exchange is realized through Web Services conforming to specifications based on IHE integration profiles. Finally, in order to support the health information exchange at local and national level, an open-source software named CONNECT has been developed (The Sequoia Project eHealth Exchange [online], 2016).

In Europe, each country has developed or is developing its national EHR system. The aim of the epSOS project, which involved 25 different European countries, was to realize a large-scale pilot testing the cross-border sharing of two kinds of health documents: patient summary and electronic prescription. To achieve such an objective, a service infrastructure was designed, built, and evaluated. The national EHR systems communicate each other by means of gateways, named National Contact Points (NCPs), by exchanging: i) messages based on IHE specifications, and ii) clinical documents in the HL7 CDA format (epSOS Project [online], 2016).

In Italy, a first prototypal architectural model for the realization of an interoperability secure EHR infrastructure, named InFSE (Ciampi et al., 2012),

was defined and developed within three conjunct projects between the Department of Technological Innovation of the Presidency of the Council of Ministers and CNR. The infrastructure, in absence of a norm, was designed with the aim of enabling interoperability among regional EHR systems. The components of the infrastructure were implemented and used in experimentations that have had the scope of enable the interchange of clinical documents by means of the interoperability of some regional EHR systems. The software components of the InFSE infrastructure were also used within the national IPSE project linked to epSOS, in which 10 Italian regions were involved. The aim of the project was to make regional EHR systems able to interoperate each other for the interchange of patient summaries.

3 NATIONAL EHR ARCHITECTURE

In Italy, the Laws 179/2012 and 98/2013, and the subsequent decree DPCM 178/2015 (Decree 178, 2015), have provided the Italian legal system of a definition of EHR, meant as the set of digital health and social-health data and documents generated from present and past clinical events, about the patient. According to the norms, EHR can be used for three finalities: a) prevention, diagnosis, treatment and rehabilitation; b) study and scientific research in the medical, biomedical and epidemiological field; c) health planning, verification of the quality of care and evaluation of health care.

The regulatory framework has permitted to a National Technical Board to define a set of reference guidelines for the implementation of the EHR systems (Chiaravalloti et al., 2015). Then, a set of technical specifications, which establish the main requirements to be met by the regions, have been defined to guarantee interoperability at different levels: *technical interoperability* is assured by sharing communication protocols among services interfaces; *syntactic interoperability* is reached by the use of common data formats; *semantic interoperability* is guaranteed by adopting both same data formats and coding systems; *organizations & services interoperability* is enabled by the sharing of common cross-border processes.

3.1 Key Principles of EHRs

Each regional EHR system is been developing in accordance with the requirements specified by the norm, guidelines and specifications. The main architectural constraints imposed are the following:

- **Patient Consent:** every patient can take advantage of the functionalities offered by the EHR system of the health care provider region of the patient. To this aim, she/he has to express two types of consent: i) a consent enabling the population of the EHR with her/his clinical documents by the health facilities; ii) a consent enabling the consultation of the EHR by health professionals. Specifically, the patient is allowed choosing the professional roles permitted to access her/his EHR by defining specific privacy policies.
- **Index Metadata Model:** the health care provider region of the patient has the responsibility of mantaining index metadata related to all the documents related to its patients, even if such documents are produced and maintained by health facilities sited outside the region.
- **Proxy-based Interoperability Model:** the system of the health care provider region has to operate as a mediator with the other regional systems in all the cross-border processes in which its patients are involved.
- **First Implementation of EHRs:** even if EHRs can contain a multitude of tipologies of information, the first mandatory kinds of clinical documents to be accessible via EHR are patient summary and laboratory report. Then, in this first phase, only details about the finality of care of the patient are defined.

3.2 Cross-border Processes

In order to enable communication among regional EHR systems, cross-border services have to be implemented according to a SOA paradigm.

Such services have to satisfy a set of national business processes, according to them each region may assume a different role: the health care provider region assumes a role named RDA; the region that stores a document of a patient, whose RDA is represented by another region, takes the role of RCD; the region that provides a health service to a patient whose RDA is another region is named RDE; finally, the region that does not act anymore as the health care provider region assumes the role of RPDA.

The cross-border processes, shown in Figure 1, are based on the assumption that a health professional intends to consult the EHR of a patient whose health care provider region is different from the one in which the health professional operates.
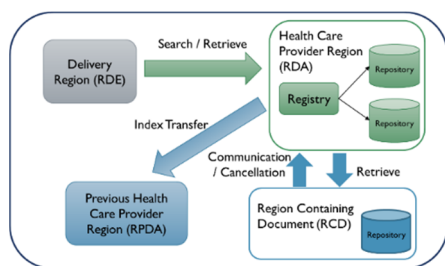
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Figure 1: Roles in the cross-border processes.

All the business processes (described below), before their execution, require to identify preliminarily the patient and the health professional:

- **Searching for Documents:** RDE requires RDA to consult the EHR of the patient. RDA returns the list of documents for which the user has access rights.
- **Retrieving a Document:** RDE, after obtaining the list of documents, requires RDA retrieving a document. RDA returns the document if the user has access rights. Eventually, RDA forwards the request to RCD if the document is available outside.
- **Creating or Updating a Document:** RDE transmits to RDA the list of metadata of a document created/updated for a patient of this one (the document is stored in RDE, which therefore serves as RCD). RDA stores the metadata in its system.
- **Invalidating a Document:** RCD requires RDA to perform a logical deletion of metadata related to a document, due to the invalidation of this one.
- **Transferring of Index**: a new RDA requires RPDA to transfer the index of the EHR (list of all metadata and privacy policies) associated with the patient. RPDA returns the index, which is registered in the new RDA, and then disable it.

In order to achieve semantic interoperability, several standards in different domains exists, e.g. CIDOC-CRM (CIDOC-CRM [online], 2016) in the cultural domain. Due to its specificity, to assure semantic interoperability for the e-health domain, suitable standards have been individuated: HL7 CDA Rel. 2 specifies the structure and semantics of clinical documents, whereas clinical content is represented by using a set of coding systems, like ICD9-CM, LOINC, ATC, and AIC.

3.3 Architecture Components

All the regional EHR systems are based on the registry/repository paradigm. The clinical documents produced by the health facilities are stored in repositories and indexed in a regional registry by means of appropriate metadata.

The mandatory metadata are: document type, document state, document identifier, creation date, author identifier, patient identifier, repository reference.
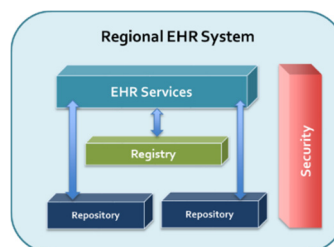

Figure 2: Architecture of a regional EHR system.

The interoperability of the regional EHR systems is based on a nationwide federated model, based on a System-of-Systems approach, where each regional system is realized by taking into account local needs.

In order to make the regional systems able to interoperate each other, each EHR system exposes a set of cross-border services, which preliminarily verify the possession of the rights by the user and provide all the functionalities needed to manage, search, and consult metadata and documents.

The architecture of the distributed system at national level is shown in Figure 3.
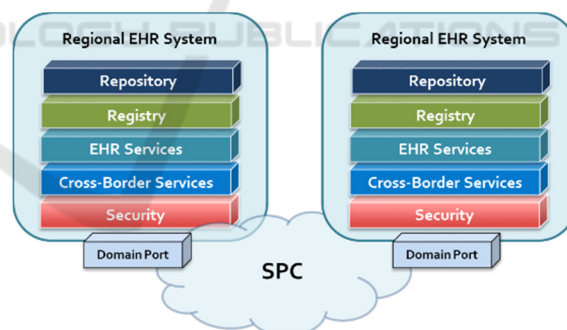

Figure 3: Architecture of the national system.

The security model adopted is based on a Circle of Trust among the regions. Each region is responsible for the claims made in the process of request of the cross-border services provided by the other regions. In addition, all the communications among the regional systems are exchanged through the Public Connectivity System (SPC), the Italian technological infrastructure for exchanging information assets and data between Public Administrations.

Specifically, every cross-border service is linked

to the SPC infrastructure by means of specific software components called Domain Ports.

4 TECHNICAL DETAILS

4.1 Cross-border Services

The cross-border services to be implemented according to the business processes described above have to be able to exchange messages compliant to IHE XDS.b transactions, opportunely localized at Italian level. IHE XDS profile provides specifications for managing the exchange of documents that care delivery organizations have decided to share.

A brief description of the structure defined for the communication with the services is provided below:

- **Document Search:** allows authorized users retrieving the index metadata related to documents satisfying specified search criteria (patient id, date, document type and status). The communication protocol of this service is compliant to the IHE ITI-18 transaction (Registry Stored Query).
- **Document Retrieval:** allows authorized users retrieving a specified document from its id. The communication protocol of this service is compliant to the IHE ITI-43 transaction (Retrieve Document Set).
- **Metadata Communication:** allows authorized users sending index metadata to the health care provider region of the patient to which a created/updated document refers to. The communication protocol of this service is compliant to the IHE ITI-42 transaction (Register Document Set-b).
- **Metadata Cancellation:** allows authorized users requesting logic cancellations of index metadata relating to a document invalidated. The communication protocol of this service is compliant to the IHE ITI-62 transaction (Delete Document Set).
- **Index Transfer:** allows transferring the index of the EHR related to a patient from a regional system to another, after the change of the health care provider region by the patient. The communication protocol of this service is compliant to the IHE ITI-18 transaction (Registry Stored Query).

4.2 Security Aspects

The main security aspects treated concern user identification and access control, in that issues like integrity, confidentiality and auditing are assured by the use of the SPC infrastructure as a secure channel of communication among the Italian Public Administrations.

To this aim, the claims to be transmitted by every region in the SOAP messages exchanged among the cross-border services are attested by digitally signed SAML 2.0 assertions. A brief description of such assertions is reported below:

- **Identification Assertion:** certifies the identification data of a patient and her/his health care provider region; the assertion is issued by a national Identity Provider.
- **Attribute Assertion:** certifies the data relating to the user making the request, the operating environment and the type of activities to perform; the assertion is issued by the region that intends to use a cross-border service offered by another region.
- **Identity Assertion of the RDA:** certifies the identity of the health care provider region of the patient (RDA). This assertion, issued by RDA, is used in case of a request sent by RDE for retrieving a document available in RCD, through RDA, which acts as a proxy. RCD uses this assertion to verify if the request is really sent by RDA.

4.3 National Framework Services

In order to support the cooperation among the EHR systems, a national technical framework providing a set of central services has been realized by CNR in collaboration with AgID.

The services offered by the framework have been identified analyzing the needs indicated by the regions in their project plans for the realization of the EHRs. The purposes of these services vary from managing service endpoints, to enabling the homogeneous presentation of the clinical documents represented according to the XML-based HL7 CDA format by means of national style sheets, to handling the terminologies.

Besides, in order to support the correct development of the cross-border services by the regions, a test environment realizing the business processes described above has been implemented. Such a test environment is able to simulate the behavior of a typical regional EHR system and allows regional domains verifying the correctness of the request messages for the invocation of the cross-border services.

5 CONCLUSIONS

In this paper, the architectural model of reference for the realization of the EHR in Italy was presented. The architectural model was formalized by a National Technical Board in order to meet the organizational, functional, privacy, and technical requirements provided by Italian norms recently emanated. According to such requirements, a patient can choose: i) whether she/he intends to benefit from the EHR provided by her/his health care provider region, and ii) the privacy policies that regulate the access to her/his EHR. In order to support patient mobility, regional EHR systems have to interoperate each other in order to execute five main cross-border processes: searching for documents, retrieving a document, creating or updating a document, invalidating a document, transferring of index. These processes are realized by a set of cross-border services that every regional EHR system has to make available. The services have to be able to analyze SAML assertions transmitted by the requesting regions in order to verify if the user possesses the rights established by the patient in exam. Then, some central services have been realized and shared for supporting the interoperability among the regional EHR systems and the implementation of the cross-border processes. As future work, it is planned to specify further technical details about some relevant aspects, like digital signatures, style sheets, patient identification. Some critical aspects concerning the adoption of cloud computing technologies for EHR services need a deep investigation, in order to both i) individuate appropriate deployment and service models, and ii) assure suitable privacy level agreements. Finally, additional work will concern the extension of the architecture for executing processes able to use the EHR for finalities of research and government, after that a new decree will define the main requirements.

ACKNOWLEDGEMENTS

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