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for the Italian Interoperability Infrastructure of EHR Systems

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The Metadata Information Model for the Italian Interoperability Infrastructure of EHR Systems

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Abstract

A key problem in healthcare informatics is the lack of interoperability among the information systems of different healthcare facilities. This problem hampers the possibility of collecting all the clinical documents of a patient in order to establish his/her Electronic Health Record (EHR). In Italy, this is mainly due to the fact that the implementation of EHR systems has been carried out individually by each regional administration. To address this problem, the Italian Ministry for Public Administration and Innovation and the National Research Council of Italy have undertaken an initiative intended to define a federated interoperability infrastructure that aims at favoring the interconnection of the regional EHR systems. The software infrastructure, called InFSE, lies on a metadata information model shared by the different local EHR systems. This model allows i) the indexing, in regional registries, of patient clinical documents stored in repositories distributed at healthcare facilities according to a shared formalism, and ii) the management of federations of EHR systems. This paper presents the metadata information model for InFSE, obtained by specializing the OASIS ebXML Registry Information Model information model with concepts belonging to standards and initiatives for healthcare domains, such as HL7 RIM Version 3 and IHE XDS profile.

Keywords: information model, electronic health record, infrastructure, metadata, interoperability.

1. Introduction

An EHR is defined by Iakovidis as “digitally stored health care information about an individual’s lifetime with the purpose of supporting continuity of care, education and research, and ensuring confidentiality at all times” [1]. It allows all authorized citizens and health professionals to access the healthcare information within their scope, in any healthcare information system they are stored and with respect to the protection of privacy.

However, the EHR is not a single system, but it is a collection of distributed systems that cooperate with each other in order to share patient healthcare information [2].

In Italy, the implementation of EHR systems has been delegated to the regional administrations. Almost all of these systems are based on the *registry/repository* paradigm, according to which digital clinical documents are i) archived in repositories sited at healthcare facilities, and ii) indexed in a registry, located at a regional node, by storing appropriate metadata.

Nevertheless, each regional government has launched various local initiatives to implement the EHR systems, and this has led to the development of systems with different architectural models and technologies. In addition, the progress of these initiatives is rather patchy.

This development in a haphazard fashion, besides being an objective difference in ensuring to Italian citizens an equal opportunity of access to EHR, poses *interoperability* problems of the solutions already developed by individual regions.

A key problem is represented by the diversity of information models used for the memorization of metadata in the registries of the regional EHR platforms. As a matter of fact, it is not possible to obtain the totality of clinical documents of a patient stored at various regional domains.

The problem of EHR interoperability is rather complex and is subject to different initiatives. In recent years, various healthcare standards have evolved [3], and are still under development, with the goal of ensuring interoperability among heterogeneous healthcare information systems. For example, CEN TC 251 prEN13606 [4] and openEHR [5] are intended to define EHR system architectures to promote the exchange of clinical documents, whereas HL7 RIM Version 3 [6] aims at defining the structure of the content clinical.

Nevertheless, the history of healthcare interoperability of the last three decades has shown that healthcare standards are

not sufficient alone to ensure interoperability. Indeed, they tend to include many if not all possible situations, thus suffering from various ambiguities and offering many choices that hamper interoperability [7].

To address these issues, the “Integrating the Healthcare Enterprise” (IHE) initiative [8] has specified the “Cross-Enterprise Document Sharing” (XDS) profile [9]. The goal of IHE XDS is to facilitate the sharing of clinical documents within an *affinity domain* (a group of healthcare facilities that intend to work together) by storing documents in an ebXML registry/repository architecture. However, IHE XDS is not concerned with semantic aspects, but instead it specifies a set of metadata for document discovery [10].

The InFSE (Technological Infrastructure of Electronic Health Record) project, in collaboration by the Department for Digitization of Public Administration and Technological Innovation of the Presidency of the Council of Ministers and the Information and Communication Technology Department of the National Research Council of Italy, has had the goal to develop a set of reference guidelines for the Italian domain, which define the architectural model of an infrastructure to support interoperability of regional EHR solutions. These guidelines have been approved by the Standing Board of the Electronic Health of Regions and Autonomous Provinces (TSE) [11]. The production of an open source suite of software components compliant with the InFSE architectural model is being implemented as part of a new project, called OpenInFSE [12].

The heart of the InFSE architectural model is represented by a common metadata information model, on which is based a service-oriented architecture (SOA) aiming at federating the regional EHR systems. In order to allow the integration with legacy systems, the metadata of the information model can be mapped with those used in the local systems. Using a shared information model enables regional EHR systems to represent the semantics of clinical document information in the same manner, allowing authorized users to obtain the location of the desired documents even if they are stored in extra-regional domains.

This paper describes the metadata information model of InFSE, which is based on the OASIS ebXML Registry Information Model (eBRIM) standard for the registry metadata management. In particular, the information model specializes the eBRIM model with concepts belonging to the HL7 RIM Version 3 and with metadata used in the IHE XDS profile.

The rest of the paper is organized as follows. Section 2 provides some background information on the eBRIM model and the software architecture of the InFSE infrastructure. Section 3 presents the metadata information model of InFSE, detailing the source model and its eBRIM specialization. Section 4 describes an experimentation concerning the interconnection of some regional EHR systems according to the InFSE information model. Finally, Section 5 concludes the paper.

2. Background

2.1. ebXML Registry Information Model

ebXML (electronic business eXtensible Markup Language) [13] is a set of specifications created by OASIS (Organization for the Advancement of Structured Information Standards) [14] and UN/CEFACT (United Nations Center for Trade Facilitation and Electronic Business) [15] and approved as ISO 15000 standard, with the aim of providing an XML-based shared infrastructure for electronic commerce.

In particular, OASIS ebXML RegRep specifications [16] are a concrete standard about the key components for *document-oriented* architectures, i.e. registry and repository. The specifications provide guidelines for a generic system of storage and define the services to make the preservation, classification, and management of memorized information. Specifically, an ebXML registry/repository is able to store any type of electronic content, whose instances are known as *RepositoryItems*. In addition, an ebXML registry/repository is capable of storing standardized metadata that can be stored to describe the *RepositoryItems* and whose instances are said *RegistryObjects*.

The ebXML metadata information model, said eBRIM, consists of a series of classes derived from *RegistryObject*, whose instances are called objects, and associations among them. Since the eBRIM model is very general, the designers of software applications are typically engaged in the “specialization” of the model for the needs of their domain: this involves the definition of semantics and data structures of the objects to represent, in order to “profile” the information model for the specific purposes.

The main modules of the eBRIM model are the following:

- *Core*: this module encompasses the most commonly used classes. Among these, *ExtrinsicObjects* are the main classes which describe the *RepositoryItems*, the *ExternalIdentifier* classes provide additional information to a *RegistryObject* on identifiers, the instances of the *RegistryPackage* classes allow to group objects of *RegistryObject* type, and the *Slot* classes allow to add arbitrary attributes to the classes.
- *Association*: this module defines the types of association between the objects in a registry/repository.
- *Classification*: this module describes the classifications of the objects defined in the *ClassificationScheme* classes, which represent taxonomies. The items of such taxonomies can be internal or external to the registry/repository.
- *Provenance*: this module contains the classes that allow to describe the parties responsible for managing objects, such as the *Person* and *User* classes.
- *Service*: the classes of this module, like *Service* and *ServiceBinding*, support the registration of service descriptions.
- *Event*: this module contains the classes that allow the registry/repository to support the event notification mechanism.
- *Cooperating Registries*: this module allows to manage the cooperation between multiple registries/repositories through the creation of federations, represented by *HasFederationMember* associations between an object of the *Federation* class and multiple objects of the *Registry* classes.

2.2. Software architecture of InFSE

This paragraph briefly describes the software architecture of the InFSE infrastructure, which is located in a multi-level service-oriented architecture, as shown in Figure 1.

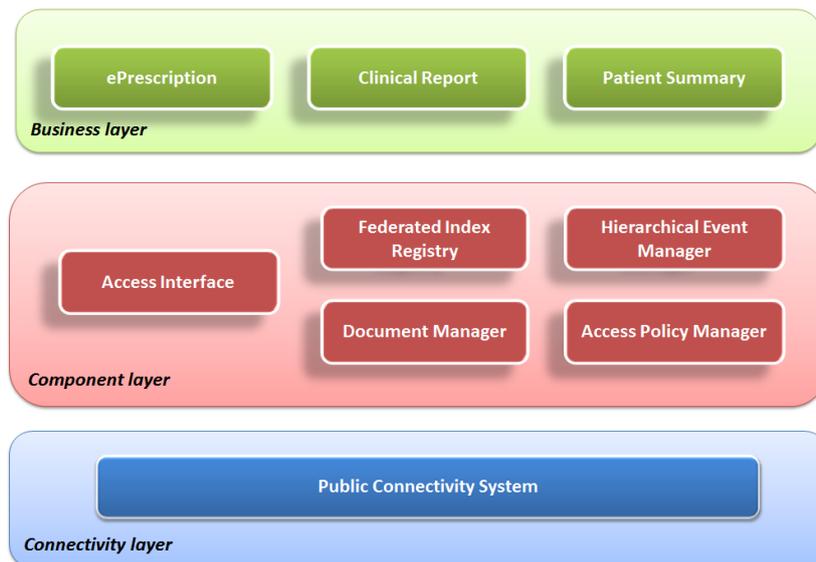


Figure 1. Software architecture of InFSE

The lower level of the architecture, called *Connectivity layer*, is represented by the Public Connectivity System (SPC) [17], a technology infrastructure defined by DigitPA (National Centre for IT in Public Administrations) for the application cooperation between the Italian Public Administrations. The intermediate level, named *Component layer*, includes the infrastructural components of InFSE, which are deployed at the regional nodes and the local nodes represented by the healthcare facilities. Finally, the top layer, called *Business layer*, defines the application services, such as ePrescription, consultation of clinical reports, Patient Summary [18], etc.

As shown in Figure 1, the *Component layer* consists of the following software components:

- *Access Interface*: this component acts as the interface to the infrastructure and is deployed at the regional nodes and, optionally, the local nodes. It receives requests from authorized users and similar components from the other regional domains and forwards them to other infrastructure components of InFSE.

- *Federated Index Registry*: this component represents the core of the infrastructure. It is a distributed software component based on the federation of registries of the regional platforms. The objective of this component is to enable the searching for and the locating of clinical documents archived at the various clinical repositories accessible from the infrastructure. To this aim, it consults a set of metadata stored in the registry deployed at the regional nodes and structured according to the information model described in this paper.
- *Document Manager*: this component is deployed at the repositories of the healthcare facilities. It allows to store and retrieve documents created by an authorized user at each occurrence of a clinical event of a patient.
- *Hierarchical Event Manager*: this component performs the routing and the notification of clinical events to all interested users through a federation of event brokers, by adopting a hierarchical classification of events based on the publish/subscribe paradigm [19].
- *Access Policy Manager*: this component is responsible for general security aspects. It allows, after that the user authentication and identification phases are performed, to authorize access requests to documents and metadata related to a given patient through the assessment of role-based access policies.

3. Information model of InFSE

3.1. General considerations

The most common operations in a system based on the registry/repository paradigm are the information search and retrieval [20]. Therefore, the efficiency of these operations in a federation context is essential and lies in the degree of definition and structuring of metadata in the registry.

Specifically, there are two main possible approaches:

1. registry that contains very few metadata, for example just the “pointing” to the documentary unit and a very small set of related information (e.g. patient identifier, organization, etc.); in this approach, the registry has a semantic structure that is generally referred to as “flat”;
2. registry that contains, in addition to the pointing, more application information on the document, that is a more or less detailed summary; in this approach, the registry needs more metadata at the time of “publication”, by which it describes in greater detail the content of the document, allowing the implementation of more efficient user services (e.g. search for the CBC trend in the clinical reports).

Evidently, the first approach enables to avoid complex publications on the registry. On the other hand, it allows to obtain a high number of specific information only by the application document.

The second approach, by contrast, permits to avoid a discovery of the entire clinical documentation of the patient to reconstruct a particular clinical “episode”, as it facilitates the search for relevant documents, even if the publications of metadata are more laborious.

3.2. Source model

This section describes the specific domain, referred to as *source model*, to map with the concepts of the eBRIM model.

The InFSE source model adopts an intermediate approach to those previously described and is based on an advanced structure with respect to the one defined “flat”. Indeed, the model forecasts the storage in a registry of information corresponding to the main concepts of the HL7 Clinical Document Architecture (CDA) Rel. 2 domain, a standard for structuring clinical documents based on the XML language.

In addition, in order to ensure interoperability with the infrastructures based on the IHE XDS profile, the source model covers the most important concepts of the information model of the XDS.b version of this profile.

Finally, besides to the metadata relating to the indexing of clinical documents, the source model also includes the information necessary for managing registry federations.

the registry only certain information; additional information can be extrapolated later from the header of the documents already stored in the repositories;

- it is possible to adapt the semantics of clinical documents in the different EHR systems because they always have a coded header: for instance, if a reporting event produces an unstructured PDF file, this can be added, as it is, in the body section of an XML HL7 CDA Rel. 2 document, while in the header section can be memorized the metadata (e.g. document type, author, patient, etc.). If the reporting event, vice versa, produces already a form of structure (such as an XML file), the conversion to the HL7 CDA Rel. 2 format is easier. The result is to have two comparable information objects in the semantic aspect, although they were originally completely different.

3.2.2. Concepts of the IHE XDS domain

The concepts of the IHE XDS.b profile covered in the InFSE source model are derived from the IHE IT Infrastructure Technical Framework Volume 3 (ITI TF-3) section [23] and include:

- *XDSDocumentEntry*: represents the document and corresponds to the *ClinicalDocument* concept of the HL7 CDA R-MIM domain;
- *XDSSubmissionSet*: groups all documents related to the same patient in a submission request;
- *XDSFolder*: groups multiple documents that are logically related for several reasons.

3.3. ebRIM specialization on the source model concepts

This paragraph describes the information model of InFSE obtained specializing the concepts of the ebRIM model on the ones of the source model.

The diagram that shows the specializations for the indexing of clinical documents is shown in Figure 3. The model is reported as a class diagram according to the UML formalism, where the specialized ebRIM classes are indicated with stereotypes.

The classes of the diagram can be grouped into three sets, described in the next sub-paragraphs, that represent the following types of information:

- the clinical document and its classifications;
- the different participants involved in the clinical event that caused the creation of the document;
- the objects that allow to correlate multiple clinical documents.

Item	ebRIM concept	Description
id	URN	Identifier of the object within the registry
name	InternationalString	Title of the document
size	Integer	Size of the document (from the IHE XDS domain)
hash	InternationalString	Hash key of the document (from the IHE XDS domain)
effectiveTime	Slot	Time of generation of the document
availabilityTime	Slot	Time of publication of the document in the EHR (from the HL7 RCMR domain)
setId	Slot	Identifier of the revised document
versionNumber	Slot	Version of the document
regionalServiceEndpoint	Slot	Reference to the <i>Access Interface</i> component of a specific region
repositoryServiceEndpoint	Slot	Reference to a specific repository within a region
statusCode	Classification	State of the document (from the HL7 RCMR domain)
code	Classification	Type of the document represented according to the LOINC classification system [24]
templateId	Classification	Identifier of the template used for the document
confidentialityCode	Classification	Level of confidentiality compliant to the HL7 RIM Version 3 model
reasonCode	Classification	Reason that caused the update of the document (from the HL7 RCMR domain)
languageCode	Classification	Language in which the document is written
storageCode	Classification	State of document storage (from the HL7 RCMR domain)
serviceEventCode	Classification	Service performed which led to the creation of the document
completionCode	Classification	State of completion of the document (from the HL7 RCMR domain)
uniqueId	ExternalIdentifier	Identifier of the document

Table 1. Items related to the *ClinicalDocument* object

3.3.2. Representation of the participants to a clinical event

The participants to the clinical event that led to the creation of the document can be represented in the following ways:

- the patient is represented by a *patientId* object of *ExternalIdentifier* type;
- the author and the legal representative are represented by a canonical relationship *Association* between a *Person* object and the *ClinicalDocument* object; in addition, also the specialized field can be specified (through the *personSpeciality* object derived from the *authorSpeciality* concept of the IHE XDS profile);
- the organization that owns the document is represented by a canonical relationship *Association* between the *ClinicalDocument* object and an *Organization* object; the role the organization plays can be specified in the *healthcareFacilityCode* object;
- other types of participants can be expressed using the *AssociatedEntity* concept.

Specifically, the human participants are identified by the identification code of the citizens used in Italy, said *codice fiscale*, consisting in 16 alphanumeric characters. It is important to note that, in order to protect the privacy of the citizens, an anonymized version of such codes is stored in the registry .

Moreover, given the federated nature of the InFSE infrastructure, a higher number of general “roles” which participate to the clinical event can be included in the *AssociatedEntity* concept.

This concept, in association with *ClinicalDocument*, *Person*, and *Organization* concepts, is able to represent all the roles included in the RoleClassAssociative domain of the HL7 RoleClass table [25], containing the role codes in a hierarchical form. For example, the role of level 8 *emergency contact* can be represented by the *ECON* code.

3.3.3. Representation of sets of clinical documents

The documents represented by the *ClinicalDocument* objects can be grouped using the *XDSFolder* and *XDSSubmissionSet* concepts, derived from the IHE ITI TF-3 model. The instances of such concepts are a specialization of the ebRIM *RegistryPackage* concept, linked to the *ClinicalDocument* objects through *HasMember* associations. They are characterized by a *uniqueID* identifier, the type of clinical activity *folderCode* or *submissionCode*, the patient identifier *patientId*, and the time of the event submission *lastUpdateTime* or *submissionTime*. In addition, the *XDSSubmissionSet* object contemplates the *sourceId* attribute containing the sender identifier and is in association with the *Person* and *Organization* objects.

3.3.4. Representation of a federation of registries

Figure 4 shows the portion of the InFSE information model inherent to the management of registry federations, which has to be replicated on every EHR system belonging to the federation.

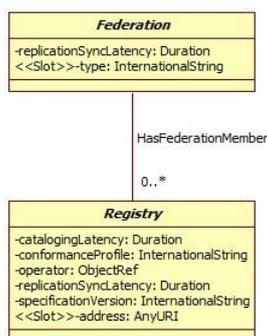


Figure 4. InFSE information model for registry federation management

The InFSE model manages a federation of registries in a manner compliant with the OASIS ebXML RegRep specifications, as described in paragraph 2.1. All the registry of the federation are represented by objects of *Registry* type, each of which has a *Slot* attribute, named *address*, that contains the reference to the *Federated Index Registry* component able to interact with the registry of a specific EHR system.

In general, there are three mechanisms for federating registries with each other:

- *Subscription/notification*: according to this mechanism, which can be based on the publish/subscribe paradigm, each registry notifies relevant information to the registries that are subscribed to particular concepts. For example, a registry of a regional domain can be notified from the registries of other regional domains about information related to the patients resident in that region, facilitating thus the search paths for the construction of the EHR.
- *Static federation*: this federation technique interconnects registries by federating a priori a number of them, so that each query performed on each registry is propagated to the others. In particular, the *address* attribute of the *Registry* object allows each *Federated Index Registry* component to submit a received query to all the other similar components.
- *Dynamic federation*: this technique consists first to redound certain information between the registries according to a specific metric, for example based on the analysis of the number and types of transactions. Secondly, after a certain time, the most convenient federation is determined on the basis of the performance data access.

4. Interconnection of the regional EHR systems

As part of the OpenInFSE project, an experimental interoperability infrastructure based on the InFSE information model has been implemented. This infrastructure is aimed at interconnecting the EHR systems of some regions. The experimentation consists in enabling regional EHR systems to exchange clinical documents related to some patients, available at the various healthcare facilities.

In particular, the interconnection of the interoperability infrastructure with the EHR systems requires the creation of two types of wrappers:

- a wrapper able to interconnect the *Federated Index Registry* component with the registry of the regional EHR systems. The main objective of this wrapper is to map the metadata of the InFSE information model with those used by the local EHR systems;
- a wrapper capable of interacting the *Document Manager* component with the legacy repositories of the healthcare facilities.

The functionalities that the experimental infrastructure offers are the following:

1. allowing the publication of a clinical document in the EHR system of a regional domain according to the InFSE information model;
2. enabling a physician of another regional domain to search for patient clinical documents, wherever they are stored;
3. allowing the retrieval of the desired clinical document.

These functionalities can be invoked by the regional EHR systems at the request of medical software applications or, alternatively, directly from these ones.

4.1. Publication of a clinical document

After producing a digital clinical document of a patient in HL7 CDA Rel. 2 format, a physician, through its software application, stores it in the EHR system of the region. In order to make the document available to other EHR systems, the software application, or the regional EHR system, interacts with the *Access Interface* component. This indexes the document in the regional registry according to the InFSE information model through the *Federated Index Registry* component.

4.2. Search for a clinical document

The experimentation involves the creation of a static federation. Therefore, the modalities to search for a document are based on sending federated queries.

In order to search for clinical documents of a patient stored at different regional domains, a physician asks its software application to send a query containing the patient identifier to the *Access Interface* component of the regional domain. An example of a query for searching the information inherent to all clinical documents of a patient (corresponding to the *ClinicalDocument* objects of eBRIM *ExtrinsicObject* type), identified by the identifier 'XXXXXXXXXXXXXXXXXX', is shown below:

```
Select eo.* from ExtrinsicObject eo, ExternalIdentifier ei where eo.id=ei.registryobject and ei.identificationScheme='urn:uuid:58a6f841-87b3-4a3e-92fd-a8ffeff98427' and ei.value='XXXXXXXXXXXXXXXXXX'
```

In particular, the identification scheme of the *patientId* object has the UUID 'urn: uuid: 58a6f841-87b3-4a3e-92fd-a8ffeff98427', defined in the IHE XDS profile for the *XDSDocumentEntry* concept. It is important to note that is also possible using stored queries to perform queries with the aim of increasing performance.

After receiving the query, the *Access Interface* component anonymizes the patient identifier and submits the query to the *Federated Index Registry* component. This one queries its own registry, obtains the references to the *Federated Index Registry* components that are part of the federation, and propagates them the query. Each of such components submits the query to their own registry and returns the results to the caller *Federated Index Registry* component.

Finally, this component aggregates the results and returns them to the *Access Interface* component, which in turn provides them to the application software of the physician. Figure 5 reports a UML sequence diagram showing the interactions between the infrastructure components.

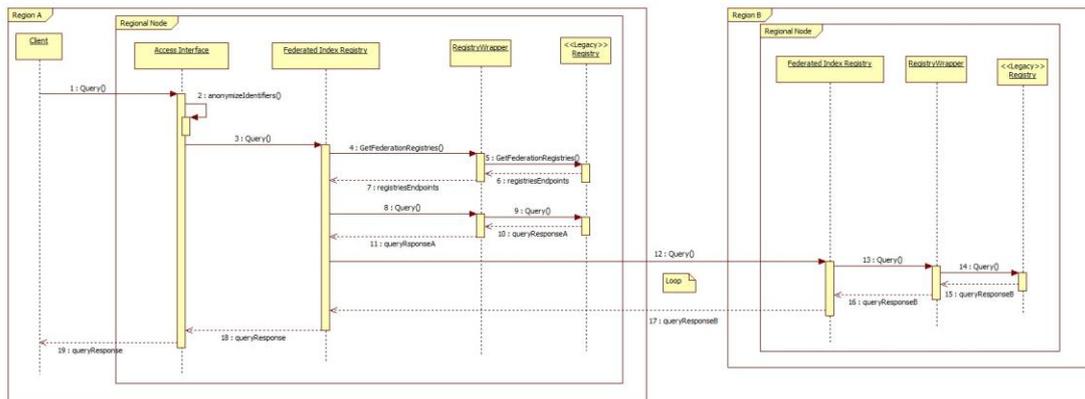


Figure 5. Interactions between the infrastructure components for the federated query functionality

4.3. Retrieval of a clinical document

After obtaining the list of information related to the patient clinical documents, the physician can ask the retrieval of a specific document. In this case, the software application sends a request to the *Access Interface* component of its own regional domain containing the reference to the *Access Interface* component of the region where the document is available (*regionalServiceEndpoint*), the reference to the *Document Manager* component that interfaces to the correct repository (*repositoryServiceEndpoint*), and the document identifier (*uniqueId*). At this point, the desired clinical document is returned to the software application of the physician. The interactions between the infrastructure components are shown in the UML sequence diagram of Figure 6.

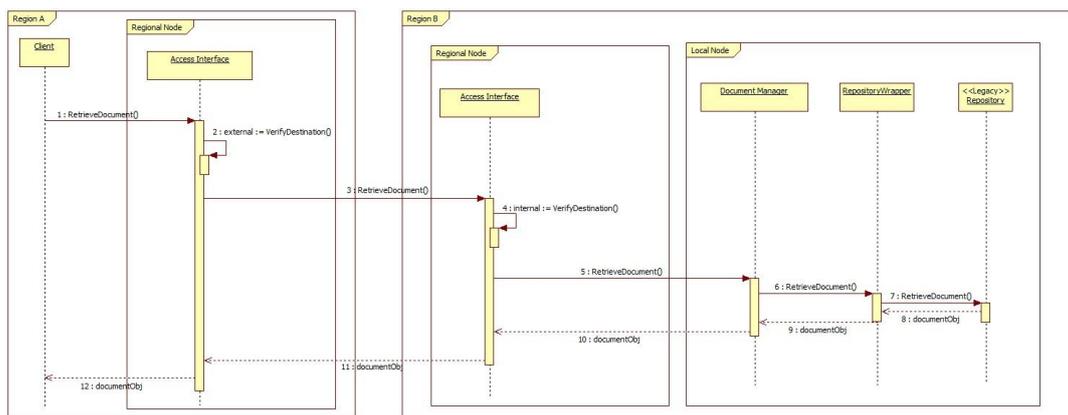


Figure 6. Interactions between the infrastructure components for the document retrieval functionality

5. Conclusion

In this paper, the metadata information model of InFSE is presented. InFSE is the interoperability infrastructure for the EHR systems of the Italian regions approved by technical working groups and transposed into Italian law.

This infrastructure uses metadata to index, in the regional registries, the clinical documents archived at the repositories of the healthcare facilities and to manage the registry federations.

The information model is obtained by specializing the concepts defined in the OASIS ebXML Registry Information Model specifications from a source model, which includes concepts belonging to the following domains:

- the HL7 CDA R-MIM domain for structuring clinical documents, enriched with some information included in the HL7 RCMR domain; in particular, both models are obtained by refining the HL7 RIM Version 3 standard;

- the IHE ITI TF-3 domain, which describes the metadata model used in various IHE profiles, including XDS.

The interconnection of the InFSE infrastructure with the EHR regional systems is made possible through the implementation of specific wrappers, able to map the metadata of the shared information model with those used in the local systems.

Through the proposed information model, the InFSE infrastructure can allow the publication of clinical documents in the EHR, their search on the entire national territory, and the retrieval of the desired documents.

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