Keywords: Federated health registers, Electronic health record, Message-based integration, Federated architecture.

Abstract: Electronic Health Records (EHR) are a collection of all individuals health data, in an electronic form, generated during relevant interactions with the healthcare system. The federated database systems provide intercommunication between different and autonomous data units, which enables sharing data. This paper aims to be a state-of-art on the requirements to take into account when developing a federated system. For that, we did a literature review on PubMed, ISI Web of Knowledge, Scopus and Google Scholar. Federated systems must ensure interoperability using open standards; guarantee the system value through high quality services; have modular architecture to allow developments, maintenance and evolutions, and finally, enable the "monotonic" systems with an incremental evolution. When developing these systems we have to avoid semantic, functional and instance conflicts to ensure the correct functionality. We concluded that federated systems are a good option in health's domain. They allow a high volume of data storage in healthcare that can be accessed in any place, at any time, by health professionals. Thus, we believe that federated systems are a tool to improve the quality and efficiency of health care.

1 INTRODUCTION

With the growth of healthcare volume data at multiple locations for a wide of users, the need for integrate the information emerge and the concept of Electronic Health Records (EHR) as a central solution appears.

EHR is a collection of all individual's lifetime health data in an electronic form produced during relevant interactions with the healthcare system (Tsiknakis et al., 2002). The EHR allows electronic documentation of current and historical health like tests, referrals and medical treatments, as well, enable practitioners to order tests and medications electronically. The improvement of communication between physicians and patients is one of the potentiality of EHRs. They can make data more readily available, at a corporate, regional, national or even international level. Population mobility is increasing, and the construction of an EHR at a high level could be an improvement for all, specially those people.

Federation system is a process that allows sharing information provided by different and independent units. In health environment, the federated approach should be capable of providing uniform ways for accessing authentic, physician-generated, patient record information that is physically located in different clinical information systems (Katehakis et al., 2001). A federated database system is constituted by a multiple and autonomous databases systems integrated transparently into a single federated database. These databases are interconnected via a computer network and are geographically decentralize. It is a virtual database, fully integrated, logical composite of all constituent databases in a federated database system (Muilu et al., 2007).

Through a literature review, we aim to study federated electronic health records to understand this way of sharing and archiving information.

1.1 Background

The development of federated EHR brings some benefits (Tsiknakis et al., 2002) such as vital health information available at any time; patient's relevant medical history be accessed by health practitioners what provides more efficient and effective treatment and more quality-time with the patient; reduction of
Sharing medical records has the interoperability between systems as a prerequisite and consists in a technological challenge (Katehakis et al., 2001). The implementation of such a system requires agreement between the various equipment suppliers and will certainly increase the costs. So, the operability of systems and services based on standards is a key point in order to achieve the network’s integration of medical care (Katehakis et al., 2001).

Modern systems are highly distributed and heterogeneous. Interconnect data from different sources optimize resources and enable services to exchange information and use it in different systems in an easier way; ensure the understanding and preservation of the context and meaning of information exchanged and allows coexistence of different systems, without forcing the conversion to a single format.

The aspects referred below, leads to the concept of “interoperability” defined by Healthcare Information Management Systems Society (HIMSS) briefly as follows (Portuguese Health Ministry, 2009):

"Interoperability is the ability of information systems in health work together, either within organizations or across organizational boundaries in support of an effective health care to individuals and the community."

Interoperability can be materialized at various levels like technical and semantic.

Technical interoperability ensures the integration of different systems at the technical level, infrastructure, media, transportation, storage and data representation.

Semantic interoperability enables the encoding, transmission and use of information relating to health services among the various stakeholders, ensuring the understanding of information, either by their own systems, or by users.

Interoperability can be achieved by messages or by a more advanced approach based on federated autonomous systems (Katehakis et al., 2001). The federated approach is used primarily to provide a virtual view of the Integrated Electronic Health Record (I-EHR) without replicating unnecessary information while on the message approach there is data redundancy.

2 METHODS

A systematic review, between 27th December 2010 and 3rd January 2011, was performed on PubMed, ISI Web of Knowledge and Scopus. The first step was defining our keywords: federated, health record and health database. After combining these terms, we construct our search query: (“federated” AND (health record OR health database)). Searching by article title, abstract and keywords, it was returned 42 articles on Scopus, 17 on ISI, at PubMed 44 articles and 3 articles on Google. After reading the title and abstract, we excluded all the articles containing only one specific information databases like genome, molecular. We only choose articles whose content was related to federated systems focused in patient’s health history. At the end, we selected 16, 8, 12 and 3 articles respectively. The final result was 14 articles. The search process is represented in Figure 1.

3 RESULTS

Through a literature search, we identified some fundamental principles that must be respected (Katehakis et al., 2001). Federated systems must ensure interoperability using open standards; make
sure of systems value through high quality services; have modular architecture to allow developments, maintenance and evolutions and so, enable “monotonic” systems with an incremental evolution. The creation of distributed clinical information, maintaining autonomy, needs to be tested to avoid conflicts that can occur in three levels (table 1) (Román et al., 2006).

Table 1: Description of problems related to the different levels of interoperability.

<table>
<thead>
<tr>
<th>Levels</th>
<th>Description of conflict</th>
</tr>
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<tbody>
<tr>
<td>Semantic</td>
<td>Originate on different databases schemas that were created independently. Interoperability is only possible in previously common semantic concepts.</td>
</tr>
<tr>
<td>Functional</td>
<td>Different components usually have different functionalities and interfaces. A federated system is based in a single identification and view. The information must be exported functionality according to the normalized interfaces.</td>
</tr>
<tr>
<td>Instance</td>
<td>Happens when the same person information’s stored in different systems has to be merged. The corresponding Personal ID handled by each system must be found with the guarantee that it refers the correct person and prevent a value conflict.</td>
</tr>
</tbody>
</table>

3.1 Messaging versus Federation

Interoperability between systems can be made through messages or federation.

3.1.1 Message-based

The message-based communication, in particular based on HL7/DICOM, is considered as a mechanism that facilitates the functional integration of clinical information systems and administration, institutional or regional level, resulting in the automation of medical processes (Katehakis et al., 2001).

This form of messaging is mainly used to share only portions of the I-EHR and uses various locations to store information, what results in redundancy of information generated (which, in many cases, can lead to inconsistencies) because it focuses on episodes of care and referrals and facilitates rapid entry of data, to cover a fairly large number of end-user requirements.

3.1.2 Federated Approach

The federated approach is mainly used to promote the virtual view of IEHR, without information replication.

Any federated approach to an I-EHR environment should be able to supply uniform means of authentication, providing quick and authorized access to personal health records; be physician-generated and dispose patient record information that is physically located in a different clinical IT system (Katehakis et al., 2001).

3.2 Reference Architecture for the Health Information Infrastructure (HII)

The development of global information societies led many countries to give high priority to create and permit access to the I-EHR of a citizen. Therefore, another priority is the creation of a health information infrastructure (HII) to support the provision of a variety of telematics and healthcare services electronically (Tsiknakis et al., 2002).

A medical institution regional/national HII is fundamentally about bringing timely health information and aiding communication that brings benefits for health decision, their families, their patients, and their communities. By this way, individuals and public health professionals are HII stakeholders and users, and the applications that meet their respective needs are important components of the infrastructure (Tsiknakis et al., 2002).

Taken as a whole, the HII draws upon principles, best practices, partnerships and necessary laws, but is based on the use of standards, systems, applications, and technologies that support personalized healthcare services through the effective information integration of networked information sources (Tsiknakis et al., 2002).

The system’s architecture is a formal description of an IT system, organized in a way that supports reasoning about the structural properties of the system. It defines the components that make up the overall information system, and provides a plan to implement the overall system. Usually is represented by means of an architecture model. The Reference Model Open Distributed Processing (RM-ODP) is an architecture model used actively by industry in the domain of healthcare that sets a standard of reference for an open distributed processing (Tsiknakis et al., 2002).

The purpose, therefore, of an architecture regarding the technical aspects for developing a HII is to provide and enable interoperability; modularity; migration; stability; maintenance and cost-effectiveness.
3.2.1 Reference Model for Open Distributed Processing (RM-ODP)

RM-ODP is a reference model in computer science, which provides a coordinated framework for the standardization of open distributed processing (ODP). It supports distribution, interworking, platform and technology independence and portability, together with an enterprise architecture framework for the specification of ODP systems. The RM-ODP view model provides five generic and complementary viewpoints on the system and its environment (Tsiknakis et al., 2002).

3.2.2 Components of I-EHR

Components of I-EHR can be distinguished in generic and specific (table 2 and 3) (Katehakis et al., 2001); (Tsiknakis et al., 2002).

<table>
<thead>
<tr>
<th>Generic components</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Identification (PID)</td>
<td>Unique association of distributed patient record and correlating their IDs across different clinical information systems.</td>
</tr>
<tr>
<td>Auditing (AUD)</td>
<td>Record all performed interactions between middleware services and final-user applications.</td>
</tr>
<tr>
<td>Authentication (AUT)</td>
<td>Control access.</td>
</tr>
<tr>
<td>Encryption (ENC)</td>
<td>Secure communications of personal information on Virtual Private Network (VPN) as well on the Internet;</td>
</tr>
<tr>
<td>Resource Location</td>
<td>Identify availability of related resources</td>
</tr>
<tr>
<td>Terminology (TER)</td>
<td>Interpret and translate terms between different coding schemes, terminologies and internal semantics.</td>
</tr>
<tr>
<td>User profiles (UPR)</td>
<td>Maintain personalized settings and preferences</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specific components</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indexing Service (IS)</td>
<td>Direct access of primary healthcare clinical systems where the complete and original clinical information is kept.</td>
</tr>
<tr>
<td>Primary Health Information Access Services</td>
<td>Propagation to the IS of all modifications pertaining to clinical information</td>
</tr>
</tbody>
</table>

Components like AUT, TER and REL in conjunction with others services can be used in implementation of structures for telemedicine, home care, clinical messaging, etc. (Katehakis et al., 2001).

3.3 Standardization and Projects

A large variability of institutions like IEEE (Institute for Electrical and Electronics Engineers), WHO (World Health Organization), ANSI (American National Standards Institute) and ASTM (Association for Standards and Technology Management) are working on the production of standards in health domain. The results were the creation of standards like HL7 (Health Level Seven), CEN TC251 (European Standards for Health Informatics), ISO TC215 (International SDO for Health Informatics), GEHR (OpenEHR) and DICOM (Diagnostic Imaging Communications).

“The diversity of standards difficult interoperability. Data integration from heterogeneous sources is difficult because information systems differ in their functionality, terminology, semantic, interface and internal data representation” (California Healthcare Foundation: Clinical Data Standards Explained. November 2004).

Some European projects of federated systems are using some standards referred before like Synapses, a pan-European project funded under the EU Health Telematics Programme (Grimon et al., 1998); (Tsiknakis et al., 2002); (Bisbal et al., 2003), that is using GEHR, CEN/TC251 (Toussaint et al., 1997). HYGEIAnet (Katehakis et al., 2001); (Katehakis et al., 2001) in Crete, use OMG COAS (Object Management Group -Clinical Observation Access Service) (Tsiknakis et al., 2002). EHR in Portugal is using OpenEHR, HL7, DICOM, CEN/TC251 – EN13606. Medis (Sucurovic) is a project in Serbia and Montenegro, that develops a prototype secure national healthcare information system; and IHE XDS (Dogac et al., 2007) is an idea to store the healthcare document in an ebXML registry/repository architecture to facilitate sharing.

3.3.1 Portuguese Project

The Portuguese Electronic Health Record (Portuguese Health Ministry, 2009) by 2015 will incorporate issues of consolidation in Europe and it is an example of a federated register. It’s estimated that by 2012 it will be already in operation on a set of public and private entities. The solution provided by that date, will then be gradually expanded, functional and technologically, to all healthcare providers.
This model fits into a class that may be called "federated model" because considers a distributed form of delivery or data repositories, both physical and logical resources that will give body to the whole system and considers a form of management that provides distinct areas of authority for different sets of information and resources, cooperating, according to commonly accepted rules, which compliance is subject to verification and monitoring of a central authority.

User's Health relevant data to the I-EHR are stored in local repositories in the entities where they are produced, at various healthcare consultations and occurrences;

The transaction of the identified data is made by Push form, e.g. the different entities systems push data to the central EHR.

Model of distributed architecture based on three levels of aggregation and information delivery:

Level 1 (Common Core): where the information resides (central data repository) that will be available centrally to all users, Citizens and Healthcare Providers, including:
  - A Minimum Set of Data (Summary);
  - An "index" of the clinic history of the Citizen, which will contain links to level 2 sites, where the information related to various episodes of care will be stored.

Level 2 (Sharing Level): where transitional information will be provided, standardized, produced by a particular entity as a result of caregiving (data conceptually divided by domains of responsibility associated with the various entities that at this level would provide in a standardized manner, the relevant information).

Level 3 (Specific Level): internal level and reserved for a particular institution, where detailed information produced within that institution will be, residing in their own specific systems (data stored in the repositories of their "clinical process" place under the jurisdiction of each entity).

Ofélia, in Portugal, is a project to manage federated identities and authorized mechanisms.

### 3.4 Security of I-EHR

Healthcare is a security sensitive domain with confidential information.

Non authorized access to medical information violates medical confidentiality or cause alterations of medical data that may put patient’s health at risk. Certification of the medical identity must be considered essential for the final granting authentication of medical doctors and is crucial for any federated system.

This question may be solved using some mechanisms of protection such as digital signatures to protect validity, authenticity and integrity of medical information as well as non-repudiation; use of cryptography assures confidentiality and recipient identification. To prevent access violations a reliable auditing mechanism has to be employed (Tsiknakis et al., 2002).

Minimal requests to respect in a secure domain are described (Portuguese Health Ministry, 2009):

1. Confidentiality: Must allow definition of sensibility levels and the classification of information in sensibility levels; ensure the confidentiality of the information in every step of his life cycle; need a strong encryptions mechanisms and resent in every versions of the information.

2. Integrity: Support the existence of versions to save and modified information.

3. Availability: Should be able the application of physical and logical mechanisms that ensure high level of availability when occur need of access and utilization.

4. Identity: Require mechanisms that ensure unique and persistently the verification of user’s identity; verification must be ensure in a integrated way with national identity registration; Support electronic signature associated to each user; allows control about user’s identity and ensure permanently compliance of the access control laws defined; register and alert any deviation or try of rules violation and access mechanism in emergency situation.

5. Access Control: Must allow a definition of utilization profile associated to users profession and definition of access control by each user or profile.

6. Auditability: Register, monitoring and auditing access activity must exist in a integrate way and all operations must be auditable and registered on system.

### 4 DISCUSSION

To develop infrastructures as the Federated Health Register is necessary overcome some challenges (Tsiknakis et al., 2002). The first one is a definition/ adoption of federated schemas that are capable of supporting and providing effective solutions to immediate needs without imposing significant constraints in dealing with the issue of incorporating new systems in the federation. So, the establishment of the required consent from all
organizational units enable exporting and mapping of their local schema. This process involves concept mapping, the implementation of the corresponding data extraction gateways, and the registration of the new feeder systems into the federation's resource directory. This enables clinical information systems to push information to the middle layer of the health information infrastructure.

The use of standardized interfaces for accessing clinical information, either directly by the end user or through the set of components residing at the middle level of architecture's, managing the required minimum data sets, allows the appropriate Human Computer Interaction environment to support easy and efficient access to the EHR data, as well as indexing.

The implementation of the required mechanisms enable information consistency and guarantee the required Quality of Service and ensure an adequate security system, with the consent management being part of the overall security policy.

5 CONCLUSIONS

The future challenge for researchers and system developers (Tsiknakis et al., 2002) is to provide a new organizational framework that possibilities integrate a diversity of heterogeneous resources; increase the availability of previously inaccessible information and address the demanding information processing requirements of modern medical applications.

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