A Holistic Approach for the Delivery of the Integrated Electronic Health Record within a Regional Health Information Network

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Abstract

Within a changing healthcare environment, characterized by increased patient mobility, emphasis is placed on prevention and early detection. Efficient access to the Integrated Electronic Health Record (I-EHR) of the citizen is considered the cornerstone for the support of continuity of care, the reduction of avoidable mistakes, and for the provision of tools and methods to support evidence-based medicine. This work presents all the aspects related to the delivery of an I-EHR, focusing on the technological infrastructure required to deliver advanced I-EHR services within a Regional Health Information Network (RHIN), and across the boundaries of the healthcare organizations it consists of, by implementing World Wide Web Consortium (W3C) technologies. The underlying Health Information Infrastructure (HII) is described, together with the HYGEIAnet I-EHR, as developed on the RHIN of Crete, in Greece.

1. Introduction

The catalyst for change in the health sector, based on the use of Information and Communication Technologies (ICT), is the need for improved quality of healthcare services and the containment of related costs. As citizens become better educated and informed, they increasingly have higher expectations regarding access to care and the quality of healthcare services. In the future, healthcare professionals will continue to deliver care, but will also be increasingly required to share their knowledge and expertise with other colleagues, while citizens will demand that they actively participate in medical decision making their own health a concern by seeking for better information regarding medical procedures and wellness pathways [1]. Allowing access to services for patients will require significant organizational commitment at the early stages in order to improve the quality and usability of information. In this context, services and information must be accessible without (visible) organizational boundaries in order to support seamless and personalized information delivery.

An individual's I-EHR is a collection of lifetime health data in electronic format, generated during relevant interactions with the healthcare system [2]. In addition to providing support for continuity of care, the I-EHR may prove to be a valuable tool in basic and clinical research, medical decision-making, epidemiology, evidence-based medicine, and in formulating public health policy.
Anticipated benefits of an I-EHR include:

- availability and accessibility of vital health information twenty-four hours a day, seven days a week, regardless of where the person requiring care happens to be;
- more effective and efficient treatment since healthcare practitioners will be better positioned to spend more quality time with their patients;
- reduction of the number of redundant procedures and therefore less health risked for the patient and greater cost savings;
- empowerment of individuals to exercise greater control over their own health, by giving them access to their own personal health records, and by enabling them to make informed choices about options available to them; and finally
- improved quality of care, as a result of the formulation of relevant healthcare policies, by means of collectively anonymized information contained within individual I-EHRs.

Today, a big number of healthcare organizations offering similar services exist within the boundaries of a RHIN. Because of their competing interests, they retain their independence and collaboration with each other is usually determined by their interests. It is also a fact that ICT deployed by healthcare organizations to support internal integration of their respective enterprise applications is different, as far as the integration platforms is concerned (no one technology platform fits all needs). It is also accepted that no single owner of the RHIN exists. Its development depends on how the healthcare organizations can reach consensus and agreements on where to collaborate and where not.

Because of the fact that we live in an increasingly mobile society, each citizen may have a number of encounters with the system of health at different times and with different healthcare facilities, over the course of a lifetime. The task of the RHIN is to make data and information securely available in the inter-enterprise environment where it is needed, when it is needed and in the format it is needed. Within such an environment, the need for a single I-EHR for every citizen becomes the cornerstone for supporting continuity of care and providing content to evolving health telematics and e-health services.

The realization of an I-EHR depends on the ability to provide integrated access to different parts of one's Electronic Health Record (EHR) and not necessarily to physically integrate them. Effectively, what is required is to keep the various healthcare enterprises self-contained and autonomous, but still put in place the mechanisms and the infrastructure that will support continuity of care, based on a federated model that can be applied on demand. In such terms, federation can be viewed as a continuum. At one end, nothing is shared and the domains work independently, resulting in islands of information. At the other end, everything is shared and the domains overlap totally, forming a unified domain.

Therefore, within a RHIN there exists a continuous tension between regional and enterprise needs. Since the regional inter-organizational environment continues to be distributed and heterogeneous, different technology (execution) platforms will have to co-exist and have to be bridged by gateway solutions to enable interoperability of applications (information systems) running on different execution platforms.
Today Web Services [3] provide an open and standardized way to achieve interoperation between different software applications, running on a variety of platforms and/or frameworks. Therefore, they constitute an important technological tool towards the incremental delivery of advanced inter-enterprise services.

This paper begins with a brief overview of work, conducted internationally, towards the integration of EHRs (Section 2). Then Section 3 focuses on the architecture required to be in place in order to support efficient service development, both within the context of a healthcare enterprise, as well as across co-operating healthcare enterprises that are part of a RHIN. Section 4 focuses on the building blocks of an I-EHR, considering critical Human Computer Interaction (HCI) and security issues. An ongoing effort towards the development of HYGEIAnet, the RHIN of the island of Crete, Greece, is presented in Section 5 and fundamental HII software components, towards the delivery of an I-EHR, are described. The process, as well as critical design decisions of component identification, specification and development, receives particular emphasis, especially in relation to Web Services technologies. Issues related to Role-Based Access Control (RBAC), as well as performance are also considered. Section 6, finally, concludes with a short discussion.

2. Background

So compelling are the arguments for an I-EHR service that a number of countries around the world – including the United States (US), Canada, several European Union (EU) countries, and Australia – are striving to develop workable models along with their vision for their national HII [4][5][6][7].

At the end of 2003 the Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 was signed in the US including, among other new initiatives, important provisions for Health Information Technology (HIT). MMA requires the Centers for Medicare and Medicaid Services (CMS) to develop standards for electronic prescribing, which is expected to be a first step toward the widespread use of EHRs [8]. In addition, the MMA requires the establishment of a Commission on Systemic Interoperability to provide a road map for interoperability standards in order for the majority of the US citizens to have interoperable electronic health records within 10 years.

At the same time the American Society for Testing and Materials (ASTM) International [9], the Healthcare Information and Management Systems Society (HIMSS) [10], and Massachusetts Medical Society [11] have joined forces to establish a standard for the Continuity of Care Record (CCR) [12]. This standard addresses more directly the issue of patient data summaries used for transfers, referrals and discharges [13]. The CCR will include basic minimum data such as diagnoses, procedures, medications and care plans and is seen as an intermediate, short-term solution to an interoperable EHR system.

In Canada, the Canadian Infoway [14], an independent, nonprofit corporation initiated, as the result of the Canadian federal government's announcement in September 2000, to accelerate the development and adoption of modern systems of Information Technology (IT) in health care, aims to foster the development of secure and interoperable EHR systems across Canada [15]. Its objectives are to develop mechanisms to enable consumers to access health information that they can use, to facilitate the work of healthcare providers through technology, and to create a unified network of electronic health records across the continuum of care.
In Europe, the United Kingdom (UK) National Health Service (NHS) information strategy for health [16] identified six levels of EHR ranging from simply providing support for clinical administrative data at level one (1), through remote order entry and results reporting at level three (3), to comprehensive telemedicine and multimedia services at level six (6). This particular classification represents an evolutionary approach to the development of an I-EHR service. Already the NHS Information Authority’s, Electronic Record Development and Implementation, Programme (ERDIP) has now formally closed [17], having delivered quite a large number of lessons learned.

In Germany the central associations of self-administration committed themselves in 2002 “to develop a new infrastructure for telematics on the basis of a general framework architecture, to improve and/or introduce the electronic communication (electronic prescription, electronic discharge letter by the physician) and to introduce the former health insurance card as an electronic health card in the future” [18]. The target set is to have 80 millions electronic health cards distributed in 2006 that will be capable of giving access to medical data, and therefore lead-in to the Electronic Patient Record.

Regarding international standardization efforts, the International Organization for Standardization [19] Technical Committee 215 (ISO/ TC215) in its technical report 20514 (Electronic Health Record Definition, Scope, and Context) [20] and its technical specification 18308 (Requirements for an EHR Architecture) [21] provides an EHR definition and delivers a consolidated set of EHR requirements for using, sharing, and exchanging EHRs, independently of technology and current organization structures. The European Committee for Standardization Technical Committee 251 (CEN/ TC 251) [22] has started revising European Prestandard (ENV) 13606 [23] [24][25][26] to provide a rigorous and durable information architecture for communicating EHR to support the interoperability of systems and components interacting with EHR services, by having adopted the OpenEHR methodology [27] and by using ISO 18308 as an EHR architecture standard. The revised CEN European Standard (EN) 13606 will also include compliance with Health Level Seven (HL7) [28] Clinical Document Architecture (CDA) Release 2. At the same time HL7 has approved the Electronic Health Record System (EHR-S) Functional Model to move forward as a Draft Standard for Trial Use (DSTU) [29] intending to provide a summary understanding of functions that may be present in an EHR-S, from a user perspective, in order to enable consistent expression of system functionality.

3. RHIN Architecture

Already since 1996, a standardization project team within CEN/ TC 251 had drafted a European standards proposal for the structuring of information systems within healthcare, referred to as a standard architecture*. A schematic outline of the derived Healthcare Information System Architecture (HISA) is depicted in Figure 1 [30]. According to HISA the architecture of any generic healthcare information system shall be described through three co-operative layers:

- the healthcare application layer;
- the healthcare middleware layer; and

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* CEN/ TC 251 is currently revising ENV 12967-1 to consist of three parts: Enterprise Viewpoint (Part 1), Information Viewpoint (Part 2), Computational Viewpoint (Part 3).
the healthcare bitways layer.

Figure 1: The multi-layered HISA architecture of CEN.

HISA is independent of any specific technological environment and does not imply, either directly or indirectly, the adoption of any specific organizational, design or implementation solution. Furthermore, it is applicable to the information systems of any type of healthcare organization.

Another important effort, with regard to enterprise application integration, is the Integrating the Healthcare Enterprise (IHE) initiative [31]. IHE promotes the coordinated use of established standards such as Digital Imaging and Communications in Medicine (DICOM) and HL7 to address specific clinical needs in support of optimal patient care. IHE documents the integration profiles supported by available products (statements of their conformance to relevant standards) at a hospital level, to support plug-and-play interoperability. IHE technical frameworks currently available for radiology, cardiology, and laboratory define specific implementations of established standards to achieve effective systems integration.

In parallel with the above, the software industry together with a number of EU Research and Technology Development (RTD) activities deal with open technology issues related with both

- enterprise application integration; and
- inter-enterprise application integration.

As far as inter-enterprise application integration, one of the most advanced approaches is the one that has resulted out of the EU co-funded RTD project Professionals and Citizens Network for Integrated Care (PICNIC) [32]. PICNIC has developed a model for the future regional health care networks, in order to prepare the regional health care providers to implement the next generation, secure, and user-friendly health care networks. According to PICNIC, the architecture of a regional network of health care services can be presented as comprising a number of layers (see Figure 2).
Basic characteristics of the PICNIC architecture [33] include:

- users (healthcare professionals and citizens) that have access to applications and services (either enterprise or regional) through a secure physical network by means of alternative access devices;
- enterprise applications that are supported by enterprise wide middleware services; and
- regional applications and services that are supported by the corresponding common inter-enterprise wide services (regional health infrastructure).

This type of multi-tier approach depends heavily on the existence of both generic and healthcare specific middleware services/ components, and imposes a level of common design that varies according to the actual composition of the platform. Healthcare-related components are needed for the proper identification of the subjects of care, the exchange of I-EHR indexing and health data (utilizing appropriate health-oriented protocols like HL7), health resource(s) location(s), facilitation of collaboration between healthcare professionals and patients/ experts, authorization for accessing healthcare-related resources, and the management of common medical terminology. Generic components are required to support low level, essential, platform-dependent functionalities like e.g. concurrency control, notification/ event handling, licensing, security (authentication, encryption, auditing, etc.), timing, transaction management etc.

In practice, the architecture of a RHIN is likely to be much more complex. This is because healthcare providers in a region have applications running supporting their internal operations, as well as intra-enterprise wide integration platforms of messaging and common IT services. In addition, the functionality provided by the RHIN will depend on what IT services the organizations desire to provide to each other and what they are willing to give up, in order to achieve tighter coupling. Therefore, the common IT services infrastructure depends on the existing HIIs of the healthcare organizations that make up the RHIN of providers and related organizations. The same applies for regional applications. These will mostly be created at the cost of enterprise applications. The healthcare organizations may agree that some functions can be supported by a joint, regional application.
The Reference Model of Open Distributed Processing (RM-ODP) [34] is often used as a base for the partitioning of specifications, by focusing on separate concerns/viewpoints. A viewpoint is a subdivision of the specification of a complete system, established to bring together those particular pieces of information relevant to some particular area of concern.

The Institute of Electrical and Electronics Engineers (IEEE) standard 1471-2000 [35] provides the necessary guidelines for the description of a RHIN architecture since it addresses the concerns of the identified stakeholder groups, consisting of the citizens, the regional health planners, the service providers, the users, the designers, the developers, the implementers, the maintainers, and the involved vendors. It is a fact that whatever the technical architecture or platform is, in real life its selection is only part of the solution.

According to [35] there exist multiple viewpoints for the description of the architecture of an integrated system. When the case is a RHIN, besides the Conceptual Viewpoint (which has already been presented at the introduction section of the paper), someone needs to address the following viewpoints, as well:

- The Enterprise Viewpoint, which focuses on the purpose, goal, and policies governing the integrated RHIN applications and services;
- the Information Viewpoint, which focuses on the analytical presentation of how semantic homogeneity of information is achieved, and what concepts and vocabularies are necessary for the implementation of the RHIN;
- the Computational Viewpoint, which focuses on the description of the subsystems the overall system consists of, their functionalities and the precise definition of the subsystem interfaces (encapsulation of capabilities, separation of functionalities);
- the Engineering Viewpoint, which focuses on the interaction between the components of the overall system;
- the Technology Viewpoint, which focuses on the description of the physical implementation of the system; and
- the Security Viewpoint, which focuses on how the system handles issues related to security.

Encapsulation of legacy systems must also be considered carefully. This is because in most cases it is desirable to continue to make use of the databases that store valuable data even though already existing applications and infrastructure components must be replaced/upgraded. Therefore, an implementation strategy or migration path as part of the overall information management and technology strategy is necessary to manage related processes.

4. RHIN Infrastructure for the I-EHR

The development of the I-EHR focuses on the establishment of an integrated environment for healthcare professionals or citizens who need a uniform way to access parts of patient record data in electronic format that are physically located in different clinical information systems managed transparently by cooperating healthcare enterprises of the RHIN. I-EHR should not be confused with autonomous
clinical information systems, message based communication of EHR data, centralized clinical data repositories, portable segments of one’s EHR, or monolithic information systems that have embedded in their structure mechanisms for accessing directly host systems.

Any federated approach towards the creation of an I-EHR environment should be capable of providing uniform ways for accessing authentic, physician-generated, EHR information that is physically located in different clinical information systems within the boundaries of the various healthcare enterprises the RHIN consists of. Furthermore, it must be able to provide fast and authorized on-line access to longitudinal views of one’s individual personal health record to allow for the timely delivery of health care. The main challenges that need to be effectively addressed, in an effort to create the HII required to support a federated I-EHR, include:

- the definition/ adoption of a federated/ global reference schema for the I-EHR that is capable of supporting, and providing effective solutions to immediate needs within the RHIN, without imposing significant constraints with the incorporation of new systems in the federation;
- the use of standardized interfaces for accessing EHR information, either directly by the end user or through a middleware set of components managing the required minimum data sets, as well as indexing;
- the population of the individual components of the software infrastructure by the corresponding, domain specific, workable, and semantically consistent concept models to be used for communicating structures containing values of data;
- the adoption of common terminology and a common naming convention for the use of globally unique concept codes formed by combining accepted coding scheme ids and the local concept code within that coding scheme;
- the use of available technology to support standardized means of communication among different software applications and services;
- the implementation of the required mechanisms to enable information readiness, consistency to guarantee the required Quality of Service (QoS); and
- the implementation of an adequate security system, that will deliver an I-EHR service that its users can trust, with consent management being part of the overall security policy.

Factors that critically affect the overall success of any attempt for the delivery of an I-EHR system include interoperability (both semantic and functional), reliability (quality and accessibility of information), patient consent on sharing personal information (chain of trust), and the legal framework for the protection of healthcare organizations, business units and individuals.

4.1 I-EHR Content

Rector [36] has described knowledge, information and inference as the three classes of entities required in the EHR environment. Subsequently for the I-EHR, a domain model is required to represent a harmonized view of knowledge to be shared by all
accessible entities through the I-EHR service. I-EHR, once instantiated, it can be populated by live data (i.e. recorded information), in order to infer information and to support clinical decision.

When trying to develop a highly adaptable to future requirements EHR system, a clear separation between knowledge and information is required during the design process. Therefore, any such EHR system must be capable of basing its substance on a reference model that will be in a position to endure. At the same time, ephemeral needs must be covered through a clearly specified domain model, capable of working by means of a controlled vocabulary, while certain needs for external communications must be provided through well-defined interfaces (see Figure 3).

![Figure 3: A typical interoperable EHR system must be capable of supporting an ephemeral domain model to enable future domain model extensions, support interoperability without any dependence on external terminology through controlled vocabularies and a communication interface to the outside world.]

The core of I-EHR consists of information related to the care of an individual. The exact content is dictated by the context upon which the I-EHR is instantiated, and therefore a general framework and an overall architecture must be in place, in order to support all kinds of application domains, while at the same time facilitate the integration of all available autonomous systems in a standardized manner. Since the I-EHR has not been defined to be the EHR itself but rather a service that has means through which integrated access to EHR information is provided, the I-EHR must be in a position to resolve difficult indexing and location issues. Access to all types of EHR information must be supported, including support for accessing text and numeric values, structured (e.g. HL7 CDA) and unstructured documents, and multimedia information like waveforms, sound, and image files.

In order to make I-EHR information available outside the strict boundaries defined by each individual EHR system, the standardized interface that has to be defined must be based on a common/ federated domain model, and a corresponding controlled common/ federated vocabulary. Subsequently, part (or the whole) of the schema of each information system participating to the federation must be mapped to that particular common, normalized schema (the federated schema). In order to achieve concept mapping in an efficient manner, a standardized EHR reference model must be in place to support standardized service interface models.
4.2 Conceptual Approach – Components of the Infrastructure

Any I-EHR must be in a position to provide fast, secure and authorized access to distributed patient record information from multiple, disparate sources and an environment for integrated, round-the-clock access to clinically significant information which is kept at the place where it is produced and acquired by the most appropriate clinical information system. From the analysis provided in [2], it has been deducted that the following elements are necessary:

- information propagation from feeder systems to the middle layer of the HII;
- a component residing at the middle layer managing the required minimum data sets, as well as indexing; and finally
- a Graphical User Interface (GUI) to make available the I-EHR service to the end users (see Figure 4).

Main actors identified to be related with the I-EHR service include:

- the *End User* that represents the ultimate user of the system and can be either a *Citizen* or a *Healthcare Professional* and expect the service to be able to offer role-based, secure access to reliable, patient information 24-hours a day;
- the *Maintainer* that represents a person who is responsible for the maintenance, expansion and enhancement of the system with new features; and
- the *Existing IT System* that represents a system that is the source of primary clinical information.

A set of I-EHR features that can be translated into use cases is listed in Table 1.

Table 1: Use cases for the I-EHR IT service.

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Short Description</th>
</tr>
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<tbody>
<tr>
<td>Add New IT System</td>
<td>It adds a new clinical information system to the federation of IT systems. The</td>
</tr>
<tr>
<td></td>
<td><em>Maintainer</em> initiates this use case.</td>
</tr>
</tbody>
</table>
Access Control Rule

It defines, sets and updates the security roles and policies of the users when they try to access clinical information. The Maintainer or the End User initiates this use case.

Keep Information Up-to-date

Accesses the internal data structures so that they are kept up-to-date. It is initiated by the Maintainer or by an Existing IT System. It uses three sub-use cases: “Provide Secure Information Communication”, “Keep Auditing Trails”, and “Semantic Mapping”.

Access Rights Authentication

It relates to authentication and the use of passwords and user groups to validate users and allow them to access clinical information.

Access Clinical Information

It is initiated by the End User to access clinical information. It uses three sub-use cases: “Provide Secure Information Communication”, “Keep Auditing Trails”, and “Semantic Mapping”.

Provide Secure Information Communication

It provides security through all communication paths. It is used by the “Access Clinical Information” and the “Keep Information Up-to-date” use cases.

Keep Auditing Trails

It records every interaction between the various entities of the system. It is used by the Access Clinical Information use case and the Keep Information Up-to-date use case.

Semantic Mapping

Performs the translation between languages and coding schemes. It is used by the “Access Clinical Information” and the “Keep Information Up-to-date” use cases.

Figure 5 depicts the corresponding Unified Modeling Language (UML) [37] diagram.

The I-EHR environment, as it has been developed and set up, provides a decentralized view of the patient medical record, by dynamically composing information that resides in a variety of heterogeneous, self-consistent, clinical information systems that have been optimized with respect to the requirements of different medical specialties.
and levels of care. The initial sets of essential HII services that have been identified as required include:

- patient identification services for the unique identification of patients, based on a commonly agreed set of traits, and for the correlation of identities (IDs) across different identification domains;
- I-EHR indexing services for the provision of necessary means for the location of clinically significant information throughout the participating enterprises’ clinical information systems;
- clinical observations access services for direct access to the sources of clinical information, where the complete, original (physician-generated, or acquired from a medical device) EHR data is kept;
- I-EHR update brokers for the provision of prompt and consistent propagation of indexing information to the I-EHR indexing service;
- health resource services for the unique identification of related resources such as organizations, devices, and/or software and the means for accessing them;
- terminology services for the association of coding schemes in use and to enable the transformation of information from one form or representation to another;
- security services (like e.g. for auditing, encryption, authentication, etc.) under a common public key infrastructure framework to counter all kinds of security threats; and
- user profile services for maintaining personalized settings and preferences.

Figure 6 depicts their synergy. Indexing information can be either extracted by the I-EHR update broker through a clinical observation access service (pull model), or forwarded by locally installed clinical observation access services to the I-EHR update broker (push model). The update broker is responsible for transforming indexing information to an I-EHR indexing service readable format. The end user through the patient identification service identifies the patient under consideration and accesses indexing information through the I-EHR indexing service. Once the location becomes known, the end user uses the corresponding clinical observation access service to access clinical data. In most cases, the synergy of one or more of the auxiliary components already identified is required (e.g. terminology service, health resource service, etc.).
4.3 Implementation Approach – Why Web Services?

Web Services (and peer-to-peer communication) is a major convergence point for a number of issues today. In addition, there is potential for open source, in a technology neutral environment, and major vendors are embracing W3C [3] and the Internet Engineering Task Force (IETF) [38] efforts. The Web Service approach means that vendors can build their IT services in any implementation environment of their choosing as long as they use the web services stack [39][40] and principles for their interfaces in order to guarantee functional interoperability.

The advent of the Web Services and the popularity of the Business-to-Business (B2B) applications and services over the Internet infrastructure dictate the need to rethink about decisions taken and investigate if the new middleware platforms have benefits to offer in the case of the I-EHR. The obvious advantages of using Web Services over any existing middleware solution is the unquestionable support by big companies like Microsoft, International Business Machines (IBM), and Hewlett-Packard (HP) and the acceptance they enjoy between the users. The popularity of Web Services and the excitement that they evoke to enterprise users ease the adoption of relevant applications and frameworks. On the other hand, legacy technologies like Common
Object Request Broker Architecture (CORBA) [41] and Distributed Component Object Model (DCOM) [42] now rest in assurance that they are technologies that simply work within an enterprise environment, despite the various shortcomings of each one of them. The more important middleware players Java Two Enterprise Edition (J2EE) [43], CORBA, and Component Object Model (COM)/ DCOM, are strong and each one enjoys a big share of the installed application base. Therefore, the interoperability problem remains as difficult as any time before and the issue of middleware integration arises [44].

Web Services, with their eXtensible Markup Language (XML) [45] roots, open the door for the next generation, loosely coupled, coarse-grained, document oriented architectures (see Figure 7). The term “loosely coupled” services is used to describe services where the assumptions made by the communicating parties about each other’s implementation, internal structure and the communication itself are kept to a minimum. The expected result is systems that are resilient to change and flexible enough so that they can evolve independently. Asynchronous interaction models are generally better suited in this regard since they free the sender and receiver parties from a commitment to a predetermined dialog agreed in a contract, as is the case in synchronous Remote Procedure Call (RPC) like environments. The asynchronous communication paradigm naturally leads to event-driven exchange of messages and departs the procedural RPC model. Message queues and relevant technologies perfectly fit in these scenarios, where documents are exchanged using a well-defined and general interface (the send/ receive message methods or equivalent) and the importance shifts from the definition of interface contracts to the design of the documents’ schemas.

![Figure 7: Evolution of middleware technologies.](image)

The adoption of Web Services assumes the satisfaction of various horizontal requirements in existing middleware platforms. Some of these requirements follow:

- **Communication protocol interoperability**: Version 1.2 of the Simple Object Access Protocol (SOAP) [46], which is the serialization format of the XML messages on the “wire”, is a major effort to overcome some of the interoperability obstacles produced by the earlier versions of this protocol. Furthermore, specifications such as these produced by the Web Services Interoperability Organization (WS-I) [47] help in formulating the minimal set of criteria so that two independent implementations could communicate with each other.
Secure and auditable conversations in accordance with trust establishment policies: Security should not be considered an afterthought but it ought to be built into the communication platform itself. Web Services (WS) were originally marketed as an easy way to do business across the Internet based on their tunnelling through the Hyper Text Transfer Protocol (HTTP) that usually bypasses corporate firewalls. The use of transport layer security (e.g. Secure Sockets Layer (SSL)/ Transport Layer Security (TLS) [48]) is most of the times not enough to provide the desired levels of authentication, authorisation and trust. Nowadays, the exploitation of technologies like XML-Signature [49], XML-Encryption [50], and WS-Security [51] in general is considered mandatory in order to achieve the necessary quality of protection for message integrity and confidentiality. Additional efforts such as WS-Trust, WS-Policy and WS-SecureConversation [52] are under way.

Naming and Discovery services: Locating Web Services given certain functional, qualitative or other criteria is another important aspect. The Universal Description, Discovery and Integration (UDDI) [53] registry, together with the Electronic Business XML (ebXML) [54] registry constitute the two most prevalent technologies.

More specialized features such as support for transactions, business processes, asynchronous event based information communication, etc, are specified and start to become available both as tools and services. It is envisioned that the convergence of the XML document oriented Web Services with the messaging oriented middleware will be a turning point in the deployment of the inter-enterprise interaction scenarios over the web.

4.4 Security Considerations

The focus in dealing with I-EHR security is related to the control of information, especially as it deals with private and confidential patient data. Although equally important, security (resilience) of the hardware, operating system and the application software is an issue that must be solved in the selection of the software platform and the tools used to create the execution environment and the applications.

The concept of an information domain (defined as a set of users, their information objects, and a security policy) provides the basis for security protection. Security within each information domain must be established in accordance with the respective security policy. In a healthcare information domain, the provision of the patient’s consent is a common security policy. The term consent refers to a communication process between the caregiver and the patient and may refer to consent for treatment, special procedures, release of information, and advanced directives. Additionally, security policies must deal with the informed consent of patients (customers), which is required for legal access to patient data. Consent may also have qualifiers e.g. restricting access to only part of the patient data or restricting the period of time that the consent is given.

For communication between different information domains, a trusted end-to-end communication policy must be established. ISO/ TC 215 has been working on
Technical Report (TR) 21089 (trusted end-to-end information flows) [55], where the main idea is that it is the responsibility of the information domains to negotiate under what terms they are able and willing to exchange information. In general, these terms of collaboration are called access rights and can be managed on two levels:

- authentication, as the process of ensuring that the communicating party is who he/she claims to be; and
- authorization, as the process of ensuring that the communicating party is eligible to request for a specific action.

In addition to the access rights that govern the identity and eligibility of communicating parties, auditing is another important parameter. Audit trails are needed to ensure accountability of actions of individual persons or entities, such as obtaining informed consent or breaching confidentiality. These records can be used to reconstruct, review, and examine transactions from inception to output of results. The records can also be used to track system usage, control authorized users, detect and identify intruders.

Currently the most common technological tool to cover various security aspects is the Public Key Infrastructure (PKI). PKI is used to describe the processes, policies, and standards that govern the issuance, maintenance, and revocation of the certificates, public, and private keys that the encryption and signing operations require. PKI incorporates the necessary techniques to enable two entities that do not know each other to exchange information using an insecure network such as the Internet. PKI is based upon asymmetric cryptography and each entity (user, information system, etc.) is provided with a pair of keys (a private and public key).

The public key security infrastructure comprises the following services:

- Certification Authorities (CAs) that control and manage the PKI, publish public key certificates, and impose policies in their domain of authority;
- registration authorities that act on behalf of the CAs in order to declare registered in the domain of authority the CA manages;
- Certificates Management Systems (CMSs) for management of certificates during their entire duration of validity;
- X.500 directories that store public key certificates and public information for the holders of certificates, and are used for the verification of digital certificates; and
- the certificate of the users, which is published by the CA, and is stored together with the user’s private key, in a microprocessor card.

In order to guarantee the authenticity of a set of input data, the same way a written signature verifies the authenticity of a paper document, PKI uses digital signatures. A digital signature is required in many cases during the provision health services to a citizen. It comprises a cryptographic transformation of data that allows a recipient of the data to prove the source and integrity of the data and protect against forgery.

Building on the digital signature technology, the digital signing of XML based clinical documents is a special instance where the nature of the clinical workflow may require that each participant only signs that portion of the document for which he/she is responsible. Older standards for digital signatures do not provide the syntax for
capturing this sort of high-granularity signature or mechanisms for expressing which portion a party wishes to sign.

The joint standards effort between W3C and IETF includes a standard for XML Signature [56][57]. It is being created with the ability to sign only specific portions of the XML tree rather than the complete document. This is relevant when a single XML document has a long history in which the different components are authored at different times by different parties, each signing only those elements relevant to them.

### 4.5 Usability and User Acceptance

The level of user acceptance relates to the level a system fits the characteristics of its users and the characteristics of the task under consideration. Davis [58] proposed a model that explains how users come to accept and use a technology. His model shows that users’ decision about how and when they will use a software package is related to the perceived usefulness (degree to which a system is believed to enhance job performance) and the perceived ease-of-use (degree to which a system is believed to be free from effort).

Adopting a user-centered design process reduces the risk that the resulting system will fail and leads to a more usable system. User-centered design is an approach to interactive system development, which focuses specifically to investigate exactly what the target health-care audiences do during their daily work and how they do these activities. User-centered systems empower its users and motivate them to learn and explore new system solutions. The benefits include high user acceptance, increased productivity, enhanced quality of work and reductions in support.

According to [59], user-centered design implies:

- early focus on users, tasks and environment;
- the active involvement of users;
- an appropriate allocation of function between user and system;
- the incorporation of user-derived feedback into system design; and
- iterative design whereby a prototype is designed, tested and modified.

The main cost of achieving the benefits of user-centered design is that the user's task initially appears more difficult. Project planning has to allow for iteration and for incorporating user feedback. By this process, users feel a strong sense of ownership of the system that results. Above all, proper consideration of usage issues early on in the project results in a better design and significant savings at later stages when changes are much more difficult and costly in time and resources.

### The Search Process

Physicians search records both for a fact relevant to the current decision – e.g., penicillin allergy in a patient with pneumonia – and for broader impressions – e.g., has there been a previous episode? According to an observational study by Nygren [60], the three most common reasons why physicians search records are to gain an overview of a patient, to search for specific details, and to prompt or explore hypotheses.
Gaining an overview of a patient who has previously treated relies on cues triggering recognition. Any feature that makes the record distinctive, such as a photo or a note, helps to refresh the physician’s memory. Features such as timelines and summaries play an important role on helping the doctor to gain an overview.

**Design Features that Aid Searching**

The physician navigates the record by using knowledge of its structure, the ordering and layout of data. The search speed is fast if the record structure matches expectations. Another aspect of locating clinical data quickly is the need to choose the desired patient quickly as end-users have little tolerance for a complex or slow “patient search” function.

**The Ordering of Patient Encounter Data Views**

The interface of the I-EHR should support various ways of ordering an individual patient’s encounters data. Some physicians prefer problem-oriented views [61], while others may prefer ordering by place of origin. Time-oriented (longitudinal views) per clinical parameter and attending physician further facilitate decision making.

**Filtering and Highlighting Data on the Timeline**

A skilled physician can consider a number of different hypotheses simultaneously and search for specific health care parameters before settling on a decision [62]. A major risk is that important EHR data get buried in the timeline [63][64][65]. The phenomenon is known as “cognitive tunnel vision”. Any I-EHR interface should exploit the possibility of hiding irrelevant parts of data and only display the relevant parts. Filtering and highlighting of data would help physicians to find the data related to their hypotheses. The filtering and highlighting feature should be customizable and easily saved on demand by the physicians. An example would be:

- for filtering to show only microbiological lab results; and
- for highlighting to highlight sections on the timeline where data contain blood sugar parameter over 160.

**Data Organization in the Health Parameters Viewer**

Once the physician has located the part of the patient record that is relevant to his/her hypothesis, he/she needs to view the clinically significant information stored in it. An important issue is the layout of the health parameter data in the viewer. One study found [66] that readers’ performance was disrupted when data items with their labels move, even though the data remained correctly labeled. Thus, health parameters should be layered in fixed positions in the viewer.

In a study of how physicians worked with the paper-based information tools [60] it was found that they are not reading the text pages from top to bottom but shifted rapidly between reading, skimming and skipping parts of the contents. While processing the pages this way, they continuously assessed the relevance of the different paragraphs. Especially when testing a hypothesis against the fact in the record, this kind of very fast processing was observed. A standardized set of headings and subheadings helps doctors locate themselves in lengthy documents. Indenting of subheadings creates visual landmarks and makes specific data items easier to find. Figure 8 depicts a mock-up of the timeline browser put next to the health parameters viewer.
The ease with which data can be used to check hypotheses and take decisions is strongly influenced by the way they are visually presented [67], while in many cases errors result from poor information design [68][69].

**The Citizen as User of the I-EHR**

A citizen-accessible I-EHR improves physician-patient communication and understanding of medical issues and illuminates doctors’ advice, making patients feel more empowered and treatment more effective.

The user interface should be focused to the user and designed after a thorough understanding of their needs and the desired functionality when patients access information in their electronic or paper medical record.

Patients would like to use information to increase their knowledge about their health issues, enter, review and track [70] their medical data over time, and receive alerts or reminders of health care tasks that might otherwise be forgotten.

Providing I-EHR through the web gives the possibility to link personal health information to other external medical resources such as encyclopaedia articles, glossaries and other related educational websites. Availability of this option helps patients to interpret their health records resulting in enhanced comprehension of their medical issues.

Of course, since the I-EHR contains confidential data, access to view their own medical record should be given only to authorised patients excluding, in certain cases, content that may contain pejorative data or other sensitive information.
5. Case: The HYGEIAnet I-EHR

The development of the RHIN of Crete (HYGEIAnet) [71][72] is a long-term effort of Foundation for Research and Technology – Hellas (FORTH), Institute of Computer Science (ICS). Its aim is to provide an integrated environment for healthcare delivery and medical training across the island of Crete.

In the course of designing and implementing HYGEIAnet, special efforts were made to meet the requirements of the various user groups involved and to use state-of-the-art technology and standards at every stage of development. Alternative patient, location, and problem-oriented views for the I-EHR have been considered in an attempt to provide transparent access and secure communication of information between medical specialty areas, as well as in a variety of situations from community to hospital care across the region.

In the above effort, the main challenge has been the design and development of an I-EHR environment [73][74], capable of meeting the requirements of the various user groups involved by using state-of-the-art technology and standards at every stage of development to support consistent and authenticated access to clinically significant, multimedia information in order to assist medical decision-making.

The first I-EHR environment was introduced from 1995-1999 and provided access to the entire set of primary healthcare center information system that had been installed in the co-operating primary health care centers of the island of Crete (thirteen – 13 – in total). It used a centralized indexing mechanism with a fixed structure tailored to the needs of primary care, and was accessible through a single GUI. Access was controlled by means of authentication and role-based access control [75].

An updated version of the I-EHR environment was developed from 1999-2001, having, in addition to the previous one, incorporated in its federation a number of selected autonomous clinical information systems for the domains of pathology, cardiology, paediatrics, and paedo-surgery [76]. A terminology service had been introduced and the initial, internal indexing model had been expanded to support more composite structures [73]. Usability context analysis had been performed and adoption of a software architecture model based on middleware components was adopted in line with the overall architecture of HYGEIAnet [77].

The third (3\textsuperscript{rd}) version of the I-EHR environment was developed from 2001-2003 [2]. The main effort was paid on standardization of the indexing mechanism, through an extensive harmonization process that took place as part of the PICNIC project [32]. A patient identification service was introduced, together with the adoption and use of international standards, mainly from the Object Management Group (OMG) [78] and compliance with the PICNIC architecture [33] was a mandatory requirement. A new, more advanced, multilingual GUI was introduced [79], and several third party systems were incorporated into the federation.

Today ICS-FORTH is delivering the fourth (4\textsuperscript{th}) version of its I-EHR environment, which is the physical evolution of its continuous participation in a number of RTD projects, co-funded by the EU, and its close co-operation with a number of healthcare organizations and authorities throughout Europe. The presented version of I-EHR, which is mainly based on PICNIC infrastructure work, takes into consideration state-of-the-art developments, and uses W3C technologies to deliver integration across enterprises in a standardized, open and platform-independent manner.
5.1 Structure of the HYGEIAnet I-EHR

As Weed has pointed out in [80], features with which patients are presented could be designated as problems. By placing the problem list at the front of the clinical record, everyone involved in patient care can be aware of the list of active and inactive/resolved problems.

HYGEIAnet has based the domain model applied to the construction of I-EHR on the medical encounter which, in its simplest form consists of a health service provided by a service provider to a service recipient to address a health condition at a delivery site at a point or period in time. Therefore indexing information maintained by the federated domain model, refers to patient data that are produced during the communication about the patient, between two or more individuals, at least one of whom is a member of the healthcare team currently involved.

Important entities associated with shared encounter information include the patient, the attending healthcare professional, and the clinically significant information the EHR system possesses. Therefore, indexed information is contained within the HII as a list of qualified codes indicating existence of specific types of clinical information without immediate knowledge of the corresponding actual values. At the same time medical encounter entries follow the Subjective-Objective-Assessment-Plan model, which is a standardized approach for recording clinical data generated during the contact of a patient with a healthcare provider. Subjective refers to the context of the encounter and usually consists of information originating from the patient and is compiled from history, objective data. Objective applies to physical findings and the results of medical examinations. Assessment refers to the clinical diagnosis and associated reports (evaluation of each active problem), and reflects examination results. Plan concludes assessment and refers to the clinical actions that must be taken to confirm or rule out a condition, treatment, and education.

5.2 Components of the HYGEIAnet I-EHR

Traditionally the HII work of the eHealth Laboratory at ICS-FORTH was based on CORBA [41] technology. At the time when the initial effort towards the I-EHR begun CORBA seemed to offer a unique combination of advantages over other distributed object oriented technologies in areas like:

- platform independence;
- programming language independence;
- efficiency; and
- a rich horizontal and vertical service repertoire.

In particular the work of Health Domain Task Force (DTF) of OMG [78] was very important in the definition of the architecture for the I-EHR. This architecture was based to the following services defined by the Health DTF:

- Person Identification Service (PIDS) [81] for the unique identification of patients;
- Lexicon Query Language (LQS) [82] for the management of medical terminologies;
- Clinical Observation Access Service (COAS) [83] for accessing the primary sources of medical information; and

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Moreover, in the context of HYGEIAnet the following services were specified and designed:

- the I-EHR Indexing Service (I-EHR IS), for managing indexes to the sources of primary information, so that the efficiency and scalability aspects of the architecture are reinforced;
- the I-EHR Update Broker (I-EHR UB), for keeping the I-EHR IS up to date with new or modified information, and consistent with the information accessible through COAS; and
- the Health Resource Service (HRS), for the unique identification and management of clinical resources, in the context of I-EHR, such as medical stuff, health care facilities.

All the above-mentioned services comprise the “backbone” of a component based computing environment [2][73][74] for the provision of the I-EHR, as shown in the Figure 9.

![Figure 9: The HYGEIAnet I-EHR software architecture components consist of COAS, I-EHR IS, PIDS, LQS, HRS and I-EHR UB. Generic components are provided by platform specific services.](image)

### 5.3 Migrating to Web Services for cross-Enterprise Integration

The implementation of a Web Service introduces some interesting challenges, especially in the cases where an existing infrastructure is in place and works. This is because, when migrating from an existing infrastructure towards a new one, several issues with associated costs have to be considered and decisions have to be taken on
how and when to upgrade the platform itself, and whether the expected benefits and savings outweigh the costs involved.

The idea of exposing some existing functionality through some new interface is not new and in fact, it reappears every time a new technology emerges. Usually, migration towards a new infrastructure should be planned carefully, and in cases where significant investments are required, the implementation of new interfaces using already existing infrastructure is more appropriate, especially if it is a proven one and it builds on existing human effort and experience. This is more than true for Web Services since they push interoperability in a higher layer: one where different middleware technologies need to interoperate.

When taking the decision to keep an already existing technology, some extra consideration has to be paid regarding the migration policy towards the new architecture. Exposing a “legacy” component through a Web Services interface can be performed through one of the following alternative methods:

- **Incorporation of the Web Services functionality to the existing component**: This approach requires the enhancement of the interface portion of the component so that it can be accessible through both of its “facades”: the legacy (e.g. CORBA) interface and the Web Services interface. This method is depicted in Figure 10. The disadvantage of this approach is that changes to the working code are inevitable, since it is now tightly coupled with the Web Services environment. If the Web Services interface were similar to the legacy interface then it would be desirable to reuse existing code, especially the one related to the business logic. Unfortunately, this is not always feasible, especially if the component’s code does not have a clear separation between the interface part and the business logic part. Also, in case the data structures and algorithms used take advantage of the internals of the underlying technological platform (e.g. COM/ DCOM, Java or CORBA), then it needs a lot of refactoring [85] in order to clean the code and make it independent of the communication technology used.

![Figure 10: Enhancing a component's interface with Web Services functionality.](image)

- **Implementation of another component offering exactly the same functionality, this time through a Web Services interface**: This is actually the extreme opposite of the previous
approach and it is depicted in Figure 11. This requires the implementation of a new Web Service component having access to the same data used by the legacy component. Of course, once the two components do not need to store or share any data then they could operate independently from each other. The problem with this approach is that there is duplication of the business logic and two different source code bases to maintain. If the two components offer significantly different functionality then they could evolve independently. In that case they should also have different data storage models, which make the sharing of data much more perplexed. Even in the case that the two components share the same data, the issue of exclusive use of data can be encountered with the legacy component, once its business logic assumes that it has exclusive responsibility of the data and the functionality it implements requires specific data set locking. This, for example, is the case for a PIDS and has to do with the way it creates new patient IDs: if it just increments a counter or uses some other naive algorithm then this must also be changed because now the Web Service component may cause serious algorithm inconsistency hazards, when working in parallel with the legacy service.

![Figure 11: Implementing a new component with the Web Services interface.](image)

- **Implementation of a new Web Services component that only relays the requests it receives to the already existing component:** In this case, the Web Services component is just a middleman or a wrapper to the legacy component, which in turn implements the core functionality (See Figure 12). This solution has the advantage that no changes are required to the existing infrastructure. The disadvantage is that the Web Services functionality should be implemented in terms of the existing legacy system interface and a mapping/translation logic should be in place in order to transform the Web Services requests to the legacy service calls and the other way round. This transformation phase has an impact on performance but known techniques like caching and pre-fetching could be employed in order to improve efficiency.
From the above-mentioned solutions, the third one seems to be the most adequate in most of the cases since it gives the designers a lot more freedom to implement the Web Services interface. It may be the case, that the new functionality does not directly correspond to any of the existing components and that none of the other options is appropriate. Moreover, this configuration facilitates the implementation of workflows and the orchestration of existing and new services.

The implementation of a Web Service I-EHR presents many challenges since the mapping of an Object Oriented programming model and platform (i.e. CORBA), to a Service Oriented model and platform is not straightforward. There is ongoing work [86][87] from OMG to provide a mapping from the CORBA Interface Definition Language (IDL) [88] to the Web Services Description Language (WSDL) [89] or to define a CORBA binding for WSDL [90], but there are more barriers to overcome since Web Services are not distributed objects [91], like those built with CORBA. More specifically, in the process of mapping the various CORBA IDLs (i.e. for PIDS, COAS, etc.) to corresponding WSDLs, the following issues were encountered:

- **There is no support for objects and object references.** “Singleton” (or “factory”) objects like PIDS IdentificationComponent can be easily mapped to a WSDL 1.1 “portType” (or to a WSDL 2.0 “interface”) but this is not true for “transient” objects like iterators, which are used extensively in PIDS and COAS methods that return an unknown number of results. In order to eliminate the use of the iterator pattern what was chosen was to permit just a client specified upper bound to the number of the returned results. Recently a new specification called WS-Enumeration [92] was published to support the iteration and chunked delivery of large data sets in the domain of the Web Services.

- **There is no support for stateful interactions.** In CORBA and other object oriented distributed middleware platforms there exists the ability for the server to keep state between the client’s invocations because objects do not only have methods but a state as well. It is therefore possible to keep intermediate results, and other “session” related information, like the number of results retrieved so far through an iterator. This is not so easy in Web Services where this kind of functionality should be implemented.
by the interface designer and programmer themselves; essentially, by having the various methods carrying the state or some kind of link to the server managed state information.

- **The mapping of CORBA::Any type presents its own challenges.** In CORBA the Any type is used either as an opaque type, values of which some relay agent can forward without compile-time knowledge of its type, or as a “meta type”, a type that can actually host any other type and communicating parties can insert and extract the “correct” type value based on information that comes from context or environment (i.e. “out of band”). In [86] it is proposed that the mapping of CORBA::Any type is based on the corresponding xsd:anyType which actually complies with its use as a designator of opaque values. In the case of PIDS the CORBA::Any type is used for the definition of the trait values so that any built in CORBA or user defined type, can be used as a trait’s value, e.g. a string for a person’s name or a sequence of bytes for a person’s photograph. In the HYGEIANet implementation of PIDS, only text data are currently managed so, what was chosen was to simplify things by using the type xsd:string as the unique mapping of CORBA::Any for the PIDS trait values. This could not be the case for the COAS. In COAS, an ObservationValue is of CORBA::Any type and different data structures are defined for text observations, multimedia observations, numeric observations, and so forth. For this case, the extension feature supported by the XML Schema [93] is used. An Observation data type is defined and this type is extended by the CompositeObs and AtomicObs data types. Then the AtomicObs is further extended by the NumericObs data type, which is used for numeric data, the PlaintextObs data type, which is used for text data, the MultimediaObs data type, which is used for binary data, and so on (see Table 2). The client and server can thus determine the exact data type of an Observation dynamically at run time, as is the case with the CORBA::Any type.

| Table 2: Portion of COAS data types definition. |
|-------------------------------------------------

```xml
<complexType name="Observation">
  <sequence>
    <element name="code" type="xsd:string" minOccurs="0" maxOccurs="1" nillable="true"/>
    <element name="qualifiers" type="ns1:ArrayOfObservation" minOccurs="0" maxOccurs="1" nillable="true"/>
  </sequence>
</complexType>

<complexType name="CompositeObs">
  <complexContent>
    <extension base="ns1:Observation">
      <sequence>
        <element name="children" type="ns1:ArrayOfObservation" minOccurs="0" maxOccurs="1" nillable="true"/>
      </sequence>
    </extension>
  </complexContent>
</complexType>

<complexType name="AtomicObs">
  <complexContent>
    <extension base="ns1:Observation"> </extension>
  </complexContent>
</complexType>
```
It should be noted that there are efforts for enriching Web Services technologies, such as the WS-Addressing specification [94] aiming to define constructs for the identification of web service endpoints and WS-Resource [95] that tries to enable stateful interactions. Many of these efforts have not been completed yet and some of them are not widely accepted. Also tools generally lack support for these methodologies so it has been opted to confine implementation to what is specified by the WSDL 1.1 and SOAP 1.1 specifications.

5.4 The I-EHR as a Web Service

The decision of what should be exposed through a Web Services interface revolves around what functionalities are expected by the consumers of the service. In the case of the I-EHR the fundamental driving force is the timely, secure, and accurate provision of the patient’s lifetime, clinically significant information to all interested parties. The adoption of a document oriented, coarse-grained architecture has led to the definition of the I-EHR as a single Web Service that encompasses parts of the functionality of:

- I-EHR IS;
- LQS;
- HRS;
- COAS; and
- PIDS.

The I-EHR Web Service provides to a consumer the ability to search for a patient’s identity given a set of demographic criteria and the retrieval of all the related health and medical information pertaining to the patient under consideration. Additional filtering is possible if the consumer of the service is only interested in some part of the patient’s medical record, for example a timeframe or a general clinical category such as cardiology. Based on the basic principle of loose coupling, the I-EHR Web Service offers a small number of methods so that the interface is kept compact and stable. Furthermore, the definition of the syntax and the semantics of the messages exchanged are defined separately and efforts have been made to keep them extensible and evolvable when needed.

In the case of HYGEIAnet, the I-EHR Web Service is built upon the already existing PICNIC architecture; it leverages PIDS for the identification of patients, LQS for the identification of medical terms and the translation of them to descriptions in a natural
language, HRS for the identification of resources, I-EHR IS for locating the interesting information and COAS for retrieving it. The PICNIC architecture is therefore reused and totally hidden behind the I-EHR Web Service. This reuse technique permits the exploitation of the existing infrastructure by compliant consumers, so that backward compatibility is assured, in parallel with the new interface used by other parties that find it more accessible.

As seen on Table 3, the HYGEIAnet I-EHR has the following functions implemented:

- **findCandidates** that searches PIDS in order to find matching person ids;
- **getPreferredText** that contacts LQS and returns the description of a coded term;
- **findFragments** that searches I-EHR IS and returns indexing information matching the supplied criteria;
- **getHCResource** that contacts HRS and returns information about a specific health care resource, like a health care organization (e.g. a hospital) or a physician; and
- **getObservation** that contacts a COAS server and retrieves the observation information given the observation’s identity

Table 3: Portion of the Web Services I-EHR definition.
The I-EHR Web Service has been implemented using the gSOAP toolkit [96], which is an open source tool for developing Web Services in C and C++. For CORBA communication TAO [97] has been chosen as the CORBA Object Request Broker (ORB).

5.5 Graphical User Interface

The prototype developed, was according to design guidelines discussed in the Usability and User Acceptance section. The interface is divided into four main parts:

- patient demographics panel;
- timeline browser;
- clinical data viewer; and
- filtering panel.

It has been designed for colour monitors with screen resolution 1024x768 or higher. Figure 13 shows the four main parts of the GUI.
The patient Demographics Panel contains all the patient data. A photo of the patient is always viewable to help for fast recall and recognition. The field “Name” is designed for the display of the selected patient name, enable searches based on name criteria, as well as to support fast searches through a drop-down list box that remembers previous searches (Figure 14).

The Timeline Browser displays a read-only timeline of the patient's encounter history. The browser dynamically assembles a time-oriented, graphical patient record using data gathered from several different remote locations. It assigns icons as placeholders.
in the chronological record to mark the fragments it finds recorded in the data. The assigned graphic icons are user interface clickable components that support more detailed information viewing. These icons, when clicked, provide access to information on demand, in a similar fashion as hyperlinks.

Figure 15 shows an example. The display shows data spanning about 7 months. The latest date for which information is available is on the rightmost side of the display. Aspects of the record are grouped according to the selected view (SOAP, per clinical information system, per attending physician, etc.) and the user can expand-suppress the record according to his/her needs.

The Filtering Panel helps the end user to filter health care records according to his/her needs, hiding irrelevant parts of data. The panel supports filtering by observation type, by system and by date. When multiple filters are used, the filtering will be cumulative to the records, allowing the physician to create and save a filter for later use. An example could be to filter and show health records created the last 12 months at a specific hospital that contains electrocardiogram data.

Once the physician clicks on the timeline browser, the Clinical Data Viewer viewer presents the record details on demand. The viewer may display information in various forms (see Figure 16). In many cases, for fast review of lab results this window might be sufficient. When a larger window or printed copy is needed, the user may use the print button at the viewer toolbar.
Figure 16: Health parameters viewer.

The viewer may display information in various forms. A green Multimedia toolbar appears if the selected fragment contains Multimedia data. Clicking the button(s) in the Multimedia toolbar, the appropriate Multimedia, ElectroCardioGram (ECG) or DICOM viewer loads.

Finally, a valuable tool for the physician is the Diachronic Parameters Viewer (see Figure 17). This viewer graphically displays health parameters values changes over the time. The viewer is divided in three panes. When the user selects a health parameter of interest at the left pane, a chart with the values over the time is loaded in the middle pane. The same data are also displayed in text format on the right pane.
5.6 Role-based Access to Information

The use of an I-EHR service that transcends enterprise boundaries requires careful consideration of the security issues that may arise. Some of the security aspects like information integrity are enforced by ICT used, like TLS [48], or the CORBA Security Service [41]. However, the need for authorization and access control requires security measures at the application level in addition to those offered by the communication platform.

In adopting an RBAC approach in a RHIN environment for the support of the I-EHR, involved entities, together with corresponding responsibilities have been identified (see Table 4).

### Table 4: Actors involved in RBAC

<table>
<thead>
<tr>
<th>Actor</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Resource Service (HRS)</td>
<td>It issues unique ID information for users and applications. More specifically, it maintains and manages public health resource information, activates all applications and services by issuing them a unique ID, registers all healthcare persons and organizations, associates a unique user name for each healthcare persons (i.e. citizen or professional) it maintains, and associates healthcare persons and organizations.</td>
</tr>
<tr>
<td>Certification Authority (CA)</td>
<td>Issues and maintains certificates for users and applications. The digital certificates are used for digital signing of documents and in the case of users could be stored in smart cards.</td>
</tr>
</tbody>
</table>
Authentication Service | Maintains and manages passwords. It issues passwords for every new healthcare person and performs user authentication.
---|---
I-EHR service | Maintains and manages roles (groups) and role-based permissions.

All HYGEIAnet applications and services are declared within the HYGEIAnet HRS in order to be issued a unique ID. Each user of the I-EHR must also register within HRS in order to be eligible for using HYGEIAnet services like the I-EHR and subsequently a unique username is provided. The user’s password is then communicated to the authentication server for the facilitation of single-sign-on for all applications and services within a RHIN, while a certificate is also issued by the CA. After this registration process, the person becomes a legitimate user of the services provided within the RHIN. Therefore, there is a central administration of identification information, usernames, passwords, certificates, and so on.

The authorization process, on the other hand, follows a decentralized approach: Each RHIN service defines its own rules that permit or deny access to the authenticated users and applications for the information it manages. During the logon phase, an I-EHR user is authenticated through the centrally controlled authentication server. Subsequently his/her I-EHR access rights are validated through the I-EHR specific access control server, which is linked to the I-EHR IS. A new user account in I-EHR can only be created for a user that has already been registered within the RHIN HRS. This includes assignment of roles (and associated permissions) at the IT service level.

The RHIN is thus considered a single security domain so that the user management is simplified and the single sign on concept is enforced, while at the same time all, different RHIN services are free to impose their own access control policies.

At the I-EHR level, the user is assigned to certain roles based on organization (i.e. his/her position in a health care provider) or other criteria. The roles are granted permissions and rights that are expressed by “allow” and “deny” rules. Each rule conveys the following information:

- the type of rule, i.e. if it is allowing or denying access;
- the source of health information (clinical information system) that this rule applies; and
- the kind of clinical information that this rule applies.

The definition of rules requires the existence of an administrator at the RHIN service level that is responsible for associating users with roles and assigning rights to the roles. This administrator uses the user interface that of Figure 18. Through this graphical interface, the administrator is able to create and delete users and roles, allocate users to roles, remove users from roles, and create and delete rules in the form that has been explained above.
It is therefore feasible to grant access to users based on the location that the information resides, as well as its type (see Figure 18). This model in spite of its simplicity seems to be efficient for the most common use case scenarios. Extensions to the definition of the rules that, e.g. to allow for the combination and creation of more complex rules using conjunctive and disjunctive constructs, although feasible, have not been needed in practice.

5.7 Performance Issues

The growth of a RHIN that supports integrated e-health services and groups of users with different quality of service (QoS) requirements and information access rights meets an important degree of complexity. This happens partly because of the wide spectrum of potentially available services, as well as because interoperability requirements that have to be resolved between services and autonomous applications.

The performance factor is usually critical especially in domains such as the health care where, in some cases, “the right answer delivered too late becomes the wrong answer”. In such application domains, middleware components’ developers should pay close attention to performance dimensions such as the following:

- **Throughput**: The component should be able to handle a large number of requests per unit time, e.g. per second or per “busy hour”;
- **Latency**: The component should minimize the request/ response processing delay when a client calls an operation;
- **Jitter**: The component should minimize the standard deviation of the latency in order to increase predictability and determinism;
Scalability: The component should be able to sustain its performance when some external condition changes, such as when the load increases (load scalability) or when the number of hardware units, such as CPUs, increases (system scalability).

Various techniques could be employed to achieve higher efficiency:

- **Concurrency:** multithreading or multiprocessing [98][99] can increase the concurrency of the system, i.e. its inherent parallelism. Study of the more appropriate collaboration patterns between component’s modules should be done in order to minimize the synchronization overhead and the threads’ contention for shared resources. Another way to increase concurrency is to use some asynchronous mechanisms like Asynchronous I/ O [98][100] or asynchronous method calls [101].

- **Caching:** The time required for complex and/ or expensive calculations, or tasks in general, can be minimized by keeping a cache of recent results [102]. Much attention ought to be given to the analysis of what are the system’s resources that should be kept in a cache, in addition to the memory considerations and the cache replacement algorithms.

- **Load Balancing:** Distributing workload in a cluster of computer hosts or some other computation nodes such as threads or process usually increase the real parallelism of the system [103]. Additionally, it minimizes the danger of a single-point failure and increases the availability of the system.

Achieving these goals is a difficult task most of the times because it is a common phenomenon that these different mechanisms do not collaborate in a synergistic manner. A lot of experience and study is usually needed in order to overcome the inherent complexities in developing and maintaining software components that offer the advantages described above. The use of design and architectural patterns [104] leverages the development of robust, efficient, and reusable middleware components.

In the case of the Web Services the performance issues has led to controversy many times in the past. It is frequently argued that the use of XML as the marshalling format of data results in less compact messages that demand more bandwidth in order to be transmitted and more processing power in order to be parsed than certain binary communication protocols such as CORBA’s IIOP. This is more evident when binary data should be transmitted: since XML represents textual data, binary information should be encoded in a text representation using, for example, the Base64 [105] encoding algorithm. These transformations increase the processing time needed for the serialization of the data and also the size of the messages, since base64 encoded messages are generally 33% larger than the original messages. The W3C has proposed the SOAP Message Transmission Optimization Mechanism [106] and the XML-binary Optimized Packaging [107] for treating efficiently binary data inside SOAP and XML messages in general. Furthermore alternative ways to transmit pre-parsed XML messages in a binary format, e.g. ASN.1, so that a receiving application need not have the overhead of parsing the XML stream, are being considered [108][109].
In the case under consideration, the transmission of binary data such as medical images is usually done “out of band”, for example using the DICOM protocol. In the rare cases where a binary information object, such as an ECG snapshot, should be transmitted in a XML message, the simple solution of serializing it in base64 is followed.

6. Discussion

The growing demand for more efficient and effective healthcare services, coupled with an implicit requirement for supporting citizen mobility and continuity of care, is currently setting the stage for the exploitation of ICT in the health sector. Today, the Internet is imposing new integration challenges as it extends into every corner of every organization and the issue of dealing with new platforms and applications that must interoperate with legacy systems becomes more important.

A service-oriented view simplifies virtualization through encapsulation of diverse implementations behind a common interface and makes all components of the environment virtual, despite the fact that a multitude of alternative physical implementations may turn out to produce the same result. Hence, a key challenge facing researchers and system developers is to provide a new organizational framework that can integrate a diversity of heterogeneous resources into what appears to be a uniform conglomeration of data and knowledge, to increase the availability of previously inaccessible information and to address the demanding information processing requirements of modern medical applications.

In deploying a software architecture for the next generation RHIN, the following issues need to be considered carefully:

- A software architecture is a strategic resource with the potential of enabling and supporting a RHIN in meeting its goals;
- A software architecture facilitates communication and information management by providing connectivity and making it possible to access information at any time and at any place (the degree of connectivity depends on the willingness of the parties concerned to share processes and their underlying concepts);
- Access to the software components of the software execution architecture should be as easy as possible and tailored to the needs of users (citizens, patients and health professionals);
- The overall deployment infrastructure needs to be stable, manageable and maintainable; and
- The functionality provided by the execution architecture must be such that the users trust it.

The federated approach that has been implemented in HYGEIA.net depends on a solid architecture that is based upon the fundamental principle that enterprise applications and services must retain their independence, while at the same time they must work in a coordinated fashion, under a commonly agreed framework of operation, in order to deliver advanced, inter-enterprise services, like the I-EHR. Loose control and support for adaptation are important considerations that have dictated the proposed design.

It is also true that many approaches in delivering acceptable EHRs have failed in the past [13]. Issues related to information capture, lack of interoperability (in terms of both interfaces and terminology, both within and across the enterprise) and incentives
(on behalf of all the involved actors) must be dealt with, and perhaps require more time and effort. This is because the sharing of patient information is considered today a crucial factor in reducing medical errors and supporting in a more efficient manner continuity of care.

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