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An open, component-based information infrastructure for integrated health information networks

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Abstract

A fundamental requirement for achieving continuity of care is the seamless sharing of multimedia clinical information. Different technological approaches can be adopted for enabling the communication and sharing of health record segments. In the context of the emerging global information society, the creation of and access to the integrated electronic health record (I-EHR) of a citizen has been assigned high priority in many countries. This requirement is complementary to an overall requirement for the creation of a health information infrastructure (HII) to support the provision of a variety of health telematics and e-health services. In developing a regional or national HII, the components or building blocks that make up the overall information system ought to be defined and an appropriate component architecture specified. This paper discusses current international priorities and trends in developing the HII. It presents technological challenges and alternative approaches towards the creation of an I-EHR, being the aggregation of health data created during all interactions of an individual with the healthcare system. It also presents results from an ongoing Research and Development (R&D) effort towards the implementation of the HII in HYGEIAnet, the regional health information network of Crete, Greece, using a component-based software engineering approach. Critical design decisions and related trade-offs, involved in the process of component specification and development, are also discussed and the current state of development of an I-EHR service is presented. Finally, Human Computer Interaction (HCI) and security issues, which are important for the deployment and use of any I-EHR service, are considered.

Keywords: Integrated electronic health record; Message-based integration; Federated architecture; Healthcare information infrastructure; Integrated regional health information networks; Component architecture; Component-based software engineering

1. Introduction

The healthcare environment is currently changing with increased emphasis on prevention and early detection of disease, primary care, intermittent healthcare services provided

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by medical centres of excellence, home care, and continuity of care. This requires the definition of wellness pathways and the provision of personalized healthcare services based on best practices and evidence-based medicine.

In such a dynamic environment, information and communication technologies (ICT) are taking on a leading role and are currently having a significant impact on the practice of healthcare at all levels. The catalyst for change in the health sector, based on the use of ICT, is the need for improved quality of healthcare services and the containment of related costs. Also, as citizens become better educated and informed, they will increasingly have higher expectations regarding access to care and the quality of healthcare services. Furthermore, the traditional healthcare delivery structures flatten. Instead of the three or four level hierarchy (primary, secondary, tertiary, and university hospital level care), only two are likely to exist in the future, i.e. centres of excellence specializing in technology-intensive procedures and primary care (front line) facilities. At the same time, part of the responsibility of care is shifting into the hands of the citizen, with emphasis on wellness or health maintenance. This change in healthcare service provision has been ongoing for several years and has undergone several paradigm shifts.

One must also take notice of the fact that we are living in an increasingly mobile society. As a result, 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. Millions of healthcare transactions take place in developed countries every day, involving lab tests, diagnostic imaging examinations, and hospital in-patient visits, while some tens of thousands of doctors are seeing 30–50 patients a day, as reported in [1].

Other important trends in healthcare include the movement towards shared or integrated care in which the single doctor-patient relationship is giving way to one in which an individual's healthcare is the responsibility of a team of professionals across organizational boundaries within the healthcare system. This is being accompanied by a very significant growth in home care, which is becoming increasingly feasible even for seriously ill patients, through sophisticated telemedicine services facilitated by intelligent sensors, monitoring devices, hand-held technologies, the Internet and wireless broadband communications. Within such an environment, the need for a single I-EHR for every citizen becomes the cornerstone for supporting continuity of care and the evolving, novel health telematics and e-health services of today.

This paper begins with a brief overview of the expected benefits from the creation and use of the I-EHR, together with corresponding requirements, and a presentation of certain international efforts towards its design and development. Then, it focuses on the definition of a scalable HII to provide support for efficient service development within the context of a corporate, regional, national, or trans-national health information network, and presents arguments regarding the need for defining an architectural framework and a component-based software engineering approach for the gradual, evolutionary development of the HII.

An on going effort towards the development of HYGEIAnet, the regional health information network on the island of Crete is also presented and related results are discussed. The fundamental software components of the corresponding HII are described, focusing on those components required for the creation of an I-EHR. The process, as well as critical design decisions of component identification, specification and development, receives particular emphasis. Finally, the current status of development of a federated I-EHR environment is presented and critical HCI and security issues are considered.

2. Integrated electronic health record

A scalable I-EHR would provide the means to access all available clinical information, at a corporate, regional, national or even international level, and to meet challenges posed by patient mobility and the fact that an individual's health data may reside at many geographically dispersed information systems.

An I-EHR is a collection of all of an individual's lifetime health data in electronic form, generated during relevant interactions with the healthcare system. 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.

2.1. I-EHR service: expected benefits

There are a number of envisaged benefits from the development and deployment of an I-EHR service, provided that the need for citizen consent, user authentication, and the required levels of security is properly addressed. Envisaged benefits include the following:

- Vital health information would be available and accessible 24 hours a day, 7 days a week, regardless of where the person requiring care happens to be.
- Since healthcare practitioners would be able to view a patient's relevant medical history, they would be better positioned to offer more effective and efficient treatment, and could spend more quality time with the patient. Contrast this with the current situation, where medical practitioners have access, if at all, to a partial or inaccurate patient history and may recommend a course of treatment that could potentially be life-threatening.
- Access to information on previous medical or lab examinations would reduce the number of redundant procedures and result in greater cost savings. Certain procedures may also pose a health risk to patients, if repeated unnecessarily, and ought to be avoided.
- The information that an I-EHR would provide to researchers (with safeguards built in to protect the identity of patients and obtain their consent) would result in improved quality of care, based on an enhanced ability of health planners and administrators to develop relevant healthcare policies for the future. Population health statistics, developed from the information contained in the I-EHR, can be instrumental in the formulation of such policies.
- An I-EHR would greatly empower individuals by giving them access to their own personal health records. It will enable them to make informed choices about options available to them and give them the opportunity to exercise greater control over their own health.

Anticipated benefits of the I-EHR, together with the related information technology (IT) supporting features, are listed in Table 1.

2.2. I-EHR service: features and technological challenges

Any successful I-EHR realisation requires, from a technological point of view, the existence of certain supporting features. Those

Table 1
Anticipated benefits for the I-EHR, together with the related IT service supporting features

Benefit	Supporting features
Dissemination and distribution of essential patient/client information without professional time wasted in search of such information	Open communication standards over transparent platforms allow for fast response times across health information networks
Improved protection of personal data	Encryption and authentication mechanisms provide secure and authenticated access to sensitive personal information. Auditing capabilities allow tracking back all interactions with the IT service environment infrastructure
Informed decision-making resulting in improved quality of care	Semantic unification and multimedia support provide for a more concise and complete view of patient history
Prompt and appropriate treatment	Fast response times enable this to happen over transparent networks and by means of open interfaces
Reduction of risk. Now professionals have access to a wider patient/client knowledge base highlighting risks, medication and crucial information	Awareness of contextual factors is important for the development of appropriate and usable human-computer interfaces
Facilitation of the co-operation between professionals in different levels of the health and social care organization	Role based access mechanisms and propagation of access privileges will allow authorized only users to have access to patient/ client record segments
Reduction in the duplicated questioning of clients for relevant information	A robust and scalable underlying HII allows the I-EHR service to be easily extended from corporate/ hospital, to regional and national level
More appropriate and focused use of resources as assessment and care plan information can be shared	Having access to all diagnostic information by means of adaptive user interfaces, allows better assessment on the patient case
Improved communication between professionals	Multimedia information is communicated at the best available format directly by the clinical information system that maintains it, without any quality loss
Improvement of efficiency and quality in the healthcare process	Supporting quality and management indicators enable the development of a knowledge-base of the care process, accessible from different level of users
Security and guarantee of continuity of care for the patients and their caretakers	Permanent access and control of interventions
Identification of a single patient/client across multiple systems resulting in a complete picture of the patient/client's medical history	The system provides a mechanism for identifying a single patient/ client and associated records although they may be stored on various source systems using different identifiers
Consistent shared language between professionals	As semantics and terminology will vary greatly between systems, the system must provide a mapping tool to display information in a generic format

features impose specific requirements that ought to be met, in order to achieve user acceptance and meet the foreseen benefits. Certain technological requirements for the I-EHR service, imposed by end-user needs and/ or expectations, as documented by the Professionals and Citizens Network for Integrated Care (PICNIC) [2] project, are listed below:

- round the clock availability;
- provision of fast responses even at high workload periods (therefore, workload balancing and redirection be considered);
- restricted access to information;
- easy maintenance (remotely in some cases—automatic notification in place);
- low usage cost;
- role-based access to information;
- secure communication of information;
- activity monitoring;

- access to reliable, and up-to-date information;
- native user interface;
- support direct access to multimedia clinical data communication;
- scalable (new IT systems should be easily incorporated in the federation);
- support for standardized coding (semantic unification is a real need);
- customisable user interface (both adaptive and adaptable to the expertise level of the end user—allow for the isolation and identification of clinical significant information); and
- highly available (i.e. across various networks and platforms).

The data, populating the I-EHR, reside in a variety of highly heterogeneous, autonomous and decentralized information systems. The realization of an I-EHR depends on the ability to provide integrated access to the different segments of one's electronic health record (EHR) and not necessarily to physically integrate them. Effectively, what is required is a federated approach where individual participants in the federation (the various clinical information systems) are self-contained and autonomous, but together form part of a wider picture: the federation.

Federation is the normal state of affairs in healthcare, as the practice of medicine and the organization of the health system includes a number of specialized health units, each with their own organization, and rules. Specialization has also allowed them to adjust their operations to better meet the needs of the stakeholders they are serving. For such specialized domains to interoperate, they need to make concessions and agree to manage certain things together with other domains. Federation can also 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.

2.3. Current international efforts in developing an I-EHR

So compelling are the arguments for an I-EHR service that a number of countries around the world—including the United States (US), the United Kingdom (UK), Canada, Australia, and some European Union (EU) countries—are striving to develop workable models. The UK has earmarked approximately 2 billion Euros, over a 7-year period, for developing an I-EHR for every citizen in the country by the year 2005.

In the US the national committee on vital and health statistics has stated that 'along with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) financial and administrative transaction standards, a comprehensive set of Patient Medical Record Information (PMRI) standards can move the Nation closer to a healthcare environment where clinically specific data can be captured once at the point of care with derivatives of this data available for meeting the needs of payers, healthcare administrators, clinical research, and public health. This environment could significantly reduce the administrative and data capture burden on clinicians; dramatically shorten the time for clinical data to be available for public health emergencies and for traditional health purposes; profoundly reduce the cost for communicating, duplicating; and processing healthcare information; and, last but not least, greatly improve the quality of care and safety for all patients' [3].

In the US, it is expected that the National Health Information Infrastructure (NHII) initiatives will provide, among other things, convenient, reliable, and secure access for individuals and others authorized by them to a lifelong personal history of health care, risk factors, occupational and environmental exposure, and health status information, across geography and across time.

Similarly, the Canadian Infostructure project [4] launched in 1999 explains that 'the Canada Health Infoway or health infostructure. . .refers not just to the use of information and communications in health. . .[but also] to the available information, whether in the form of text, sound, images, data. . ., and the applications and software needed to access, manipulate, organize and digest it, the policies governing the use of this information, and the people and organizations who create the information and use this infrastructure'. 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 EHRs across the continuum of care.

The National Health Service (NHS) information strategy for health [5] identifies six levels of EHR ranging from simply providing support for clinical administrative data at level 1, through remote order entry and results reporting at level 3, to comprehensive telemedicine and multimedia services at level 6. This particular classification represents what might be described as an evolutionary approach to the development of an I-EHR service. A similar approach is taken by the Canadian Infostructure project when they state that 'The initial challenge with implementing EHRs is knowing where to start. The pragmatic approach is to start small and then incrementally expand the implementation of the EHR system over time' [6]. It is indeed our view that both the development of the next generation regional healthcare networks, providing a number of integrated services to end users, as well as the development of the I-EHR service, within such regional or national networks providing truly uniform access to integrated information, can only be evolutionary.

As the cornerstone of shared care and the point of reference for any exchange of medical information, the I-EHR is a central element in many R&D efforts. Significant efforts related to the development of an I-EHR include those of the Good European Health Record (GEHR) [7], Synapses [8], SynEx [9], InterCare [10], PICNIC [2], OpenEMed [11], openEHR [12], as well as the standardization efforts made by the European Committee for Standardization (CEN) TC251 [13], Health Level Seven (HL7) [14], the International Organization for Standardization (ISO) TC 215 [15], and OMG [16].

It becomes apparent from the short presentation of some national strategies towards the development of I-EHRs, that the process for such a development is actually seen as being an evolutionary or long term process. As a result, an important consideration has to do with the commitment to evolve at every step from the currently available infrastructure, while adding new capabilities as soon as they become available and can become part of the local culture [17]. Therefore, the goal of developing an open, scalable and evolvable HII at a corporate, regional or national level, as well as defining a reference architecture to support it, is strategically important. The HII must primarily provide the framework for the effective integration of distributed and heterogeneous components, ensuring overall integrity in terms of functional and information inter-working, while advances in network technology should enhance and extend applications, rather than replace them or make them obsolete [18]. This HII must also be able to provide integrated support to clinical, organizational, and managerial activities, and in the not so distant future, to provide a single user interface for access to the global healthcare-related information space.

3. Reference architecture for the HII

3.1. Healthcare information infrastructure

A corporate/regional/national HII is fundamentally about bringing timely health information to, and aiding communication among, those making health decisions for themselves, their families, their patients, and their communities. Individuals, healthcare providers, and public health professionals are key HII stakeholders and users, and the applications that meet their respective needs are important components of the infrastructure.

Since IT can be useful only when the non-technical elements are well established, a corporate/regional/national HII is only partly about technology. 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 personalised healthcare services through the effective information integration of networked information sources. Although this is true, this paper focuses on the technical challenges involved in developing the HII, within the context of a regional health information network. As described in [19], fundamental prerequisites for the establishment of a scaleable regional health telematics services network, is the development of the architecture and tools for the integration of specialized autonomous applications, and a HII to support them.

3.2. Reference architecture

In any system complex enough, to need guiding rules for design and implementation, an architecture is needed. An architecture needs to create simultaneously the basis for independence and cooperation. Independence of system aspects is required to enable multiple sources of solution parts. Cooperation between these otherwise independent aspects is essential in any non-trivial architecture: the whole is more than the sum of its parts.

But what is an architecture? Architecture is the technical foundation for an effective IT strategy. An 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 or building blocks that make up the overall information system, and provides a plan from which products can be procured and systems developed, that will work together to implement the overall system [20].

The purpose, therefore, of an architecture regarding the technical aspects for developing a HII is to provide and enable

- interoperability;
- modularity, so that the infrastructure can be assembled piece by piece;
- migration, so that pieces that are outdated can be replaced with new ones;
- stability, management & maintenance; and
- cost-effectiveness by leveraging main stream technologies and products.

An architecture is usually represented by means of an architecture model. Such an architecture model is the Reference Model of Open Distributed Processing (RM-ODP) [21–23], which defines the standard reference model for open distributed processing systems. RM-ODP is used actively by industry in the domain of healthcare. It is also a foundation for the Object Management Group (OMG) Object Management Architecture (OMA) [24]. RM-ODP defines five 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. For the needs of this paper we will be focusing on the computational viewpoint of the architecture, which is a viewpoint on the system and its environment that enables distribution through functional decomposition of the system into objects that interact through interfaces.

This type of multi-tier approach [25], which heavily depends on the existence of both generic and healthcare specific middleware services/components, 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 e.g. appropriate health-oriented protocols like HL7), health resource(s) location(s), collaboration between healthcare professionals and patients/experts, authorization for accessing healthcare-related resources, medical terminology etc., whereas, generic components are required to support low level, essential, platform-dependent functionalities like e.g. concurrency control, directories, event handling/notification, licensing, security (authentication, encryption, auditing, etc.), timing, transaction management etc.

3.3. A component system architecture

Therefore, the HII can only be developed optimally in an evolutionary manner based on a component architecture. It should be noticed that today software component technology has emerged as a key enabling technology. A software component is a unit of third-party composition, sufficiently self-contained, independent of deployment that interacts with its environment through well-defined interfaces and no persistent state [26]. There are, mainly, two engineering drivers in the development of a component-based system:

- re-use, i.e. the ability to re-use existing components to create a more complex system; and
- evolution, i.e. the ability to localize changes with little or no effect on the remaining components.

There are also important operational and financial benefits which should be considered [27] when deciding on whether to decompose a system into a set of interconnected components. Such benefits are:

- for a system of considerable size and complexity, the problem can be partitioned into smaller pieces that are easier to comprehend one at a time;
- decomposing helps define natural and narrow interfaces between parts of the system;
- part of the system may be implemented by using Commercial-Off-The-Shelf (COTS) products; and
- partitioning allows getting the most of a distributed development among several geographically dispersed teams.

Reusable components of the HII may exist in a number of alternative forms; e.g. they can be a data base schema, a software module performing pre-determined actions, an EXTENSIBLE MARK-UP LANGUAGE (XML) Document Type Definition (DTD), a standardized object-interface, and/ or a communications standard.

4. Messaging versus federation

The Institute of Electrical and Electronics Engineers (IEEE) defines interoperability as ‘The ability of two or more systems or components to exchange information and to use the information that has been exchanged' [28]. Such a definition separates interoperability into two categories, functional and semantic. Functional interoperability means that the systems are able to exchange information. Semantic interoperability implies that the systems are also able to use the information that has been exchanged, i.e. act based on it. The domains of these communicating systems are said to be federated (overlap) to the extent that this semantic sharing of meaning is possible.

Message-based communication facilitates the lose coupling and integration of clinical and/or administrative information systems at institutional or regional level, thus, resulting in the automation of medical processes, such as patient admission, transfer and discharge, ordering of laboratory and radiological examinations or medication, and automatic or on demand (solicited or unsolicited) receipt of results. It is, therefore, best suited for the support of transactional services. The first step in achieving message-based communication is modelling of the workflow(s), the associated exchanged messages, and their content. This way, clinical and/or administrative information is shared among departments or organizations closely assimilating their traditional paper-based communication.

HL7 [14] is today the largest health information standards developer in the world. It focuses on the electronic interchange of clinical, financial and administrative information among independent healthcare-oriented computer systems. Version 3 of HL7 is expected to carry important semantic improvements from its predecessors, and uses an object-oriented development methodology and a Reference Information Model (RIM) to create messages. Work that influences HL7 and has a strong impact on this development is the work related to the development of the 1999 standard for electronic healthcare record communication (ENV 13606) of CEN [29]. As far as medical imaging is concerned, version 3 of the Digital Imaging and Communications in Medicine (DICOM) standard [30] specifies a network protocol utilizing the Transmission Control Protocol with Internet Protocol (TCP/IP) to permit the transfer of medical images in a multi-vendor environment, and to facilitate the development and expansion of Picture Archiving and Communication Systems (PACS) and interfacing with medical information systems.

Quite recently CEN/TC251 created a new Task Force on the EHR, planning to publish a full European standard by early 2004 [31], while ISO started drafting the requirements for the development of an EHR reference architecture [32]. At the same time an extended GEHR architecture is being developed in Australia [33].

Although the pure message-based approach can be suitable when the number of possible inter-system communications is kept low, when this rises, an underlying infrastructure is also required to effectively support message based integration in a highly distributed and complex environment. The message-based approach is tailored to the needs of professionals who explicitly need to select the type of information to be communicated and shared, as well as the destination. This way messaging is mainly used for sharing segments of one's EHR, but provides no technical means for the seamless creation and transparent access to an I-EHR.

An alternative to messaging, therefore, in our attempts to create the I-EHR is to adopt a federated approach with tighter coupling. Such an approach is based on a common normalized schema (the federated schema) to which part (or the whole) of the schema of each information system participating to the federation is exported (export schema) and mapped to the federated schema. Such an approach is gaining more and more attention during the past few years in a variety of R&D efforts. 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. Furthermore, it must be able to provide fast and authorized on-line access to longitudinal views of one's individual personal health record, in order to allow for the timely delivery of health care.

The main challenges that need to be effectively addressed in any effort to create the infrastructure for the support of a federated I-EHR include:

- The definition/adoption of a federated/global schema that is 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.
- The establishment of the required consent from all organizational units to enable exporting and mapping of their local schemata to the federated/global 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 (or meta-information) to the middle layer of the HII.
- 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 the 'architecture' managing the required minimum data sets, as well as indexing.
- Implementation of the required mechanisms to enable information consistency and guarantee the required Quality of Service (QoS). This is implemented by means of scheduled as well as active information update services.
- The implementation of an adequate security system, with consent management being part of the overall security policy.
- The implementation of the appropriate HCI environment to support easy and efficient access to the I-EHR data.

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, so as to increase the availability of previously inaccessible information and to address the demanding information processing requirements of modern medical applications.

In the following sections, we present the experiences from the design, specification and implementation of an HII within the context of a regional health information network, the reference architecture on which such an implementation is based, as well as the implementation of the scalable technical infrastructure to support advanced I-EHR services in an evolutionary way.

5. Building an HII: the HYGEIAnet experiences

In this section current results from an on going effort in developing HYGEIAnet, the Regional Health Information Network on the island of Crete are presented. Fundamental software components of the HII are described, focusing on those components required for the creation of I-EHR. The process, as well as critical design decisions, of component identification, specification and development is been presented; Also, the current status of development of a federated I-EHR is been presented and discussed, with special emphasis on critical HCI and security issues.

The public healthcare model for the region of Crete consists of a large number of healthcare facilities, ranging from a University Hospital, to a number of general hospitals, primary healthcare centres, and numerous community doctors' offices, without counting health emergency units, as well as the private sector (see Fig. 1). The development of the regional health telematics network of Crete (HYGEIAnet) [34] is a long-term effort 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 are being 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.

The objective of the installed I-EHR environment is to deliver an encounter-centred view of a citizen's I-EHR. The technological approach followed in the currently installed pilot implementations includes common object request broker architecture (CORBA) interfaces (for data acquisition, patient identification, and semantic mapping), and X.500/ Lightweight Directory Access Protocol (LDAP) (for security services, naming services, user profiles, EHR and healthcare resources indexing). Dedicated gateways (e.g. Structured Query Language (SQL)/Open Data Base Connectivity (ODBC)-LDAP) have been implemented for scheduled directory updates, and XML is used for presenting

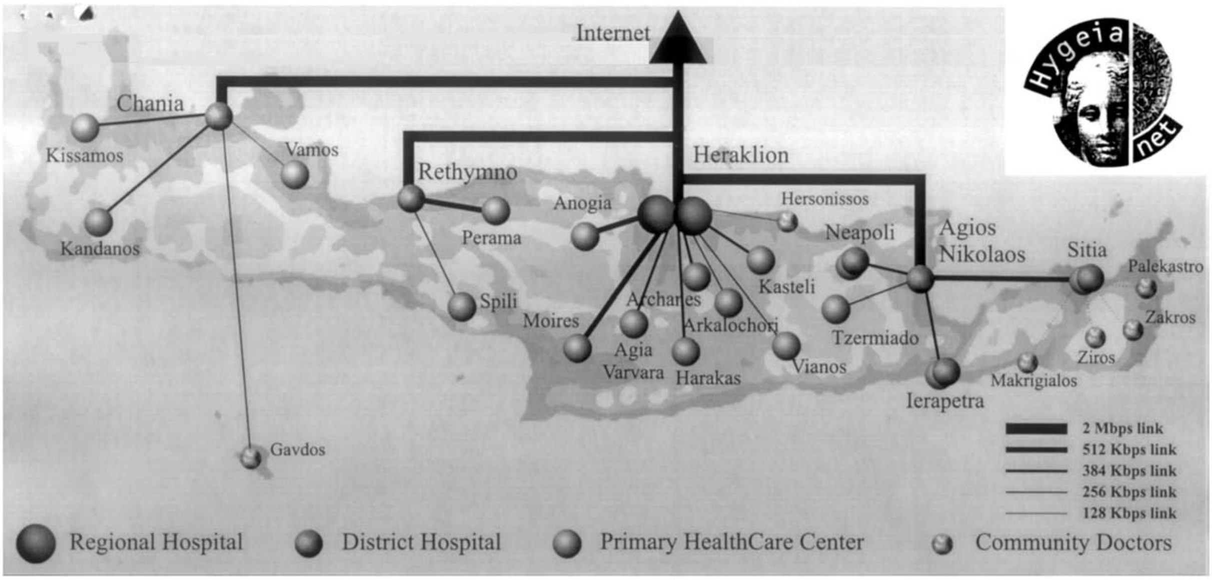

Fig. 1. HYGEIAnet, the regional health information network of Crete.

collected clinical information in a consistent manner [35].

5.1. HII components required for an I-EHR service

A number of components have been identified, as core HII components, required for the creation of an I-EHR service. They are diagrammatically shown on Fig. 2. They are:

5.1.1. Patient identification service (PIDS)

Patient identification services allow for the unique association of distributed patient record segments to a master patient index. This is a very challenging task to perform and one of the major barriers in developing a reliable I-EHR environment. This is because no global, unique person identification exists worldwide today. In addition, even for countries that have one, event notification in the case of modifications occurring in a single site must be propagated seamlessly to the rest of the federation to guarantee availability of up-to-date patient demographics. Apart from person identifiers, identifiers are also needed for employees, providers, devices, applications, services, etc.

5.1.2. Health resource service (HRS)

Resource services are useful for sharing resource information through a common reference point. Examples of resources include pharmacies on-duty, hospitals and clinics, clinical information systems available at a regional level, methods and technologies available for accessing primary information, and protocols for exchanging information with them. A resource service is also providing information about equipment/devices available at each facility.

5.1.3. I-EHR indexing service (IS)

I-EHR indexing services are used to manage the data, determined by the selected federated schema. The indexed information is related to existing encounters, allergies, personal information of relevance, etc. In this context, encounter is the term used for describing clinical information that is produced during the communication about the patient, between two or more individuals, at

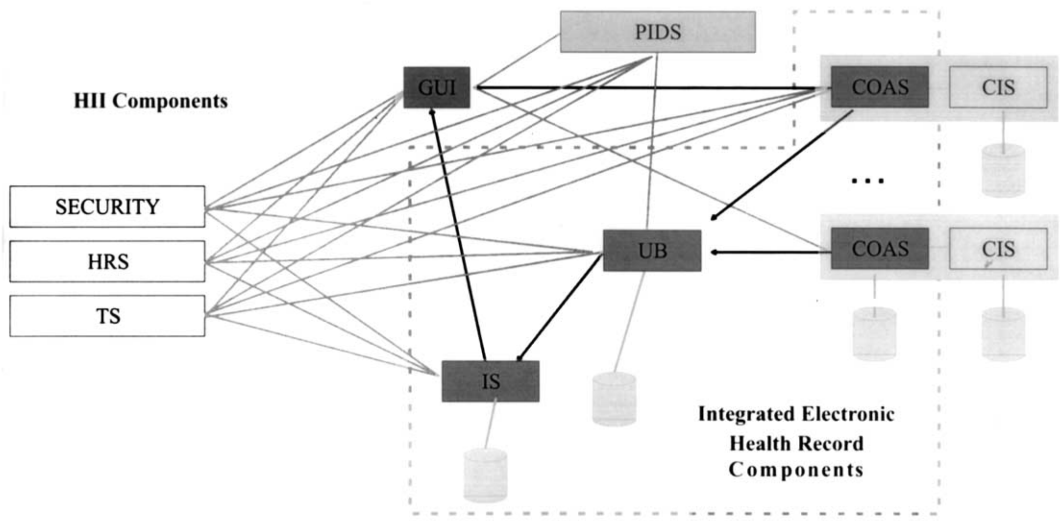

Fig. 2. The I-EHR architecture component synergies.

least one of whom is a member of the responsible healthcare team.

5.1.4. I-EHR update broker (UB)

A service responsible for the prompt and consistent propagation of information from the feeder systems to the I-EHR Indexing Server. This component is necessary since information can be propagated to the federation either periodically or on demand, and can be initiated either by the update broker itself or by other external actors, i.e. active update policies implemented by the feeder systems. In the latter case, the update broker guarantees consistency between information managed by the indexing server, and information to be inserted/updated/deleted.

5.1.5. Clinical observation access service (COAS)

The COAS service implements the standardized, public interfaces to all feeder systems. It requires the implementation of standardized gateways for each CIS for securely importing/exporting/propagating/indexing patient record data.

5.1.6. Terminology service (TS)

A TS may be used in several alternative ways. The TS component is typically used for: (a) information acquisition: assisting in the process of entering coded data; (b) mediation: transforming messages or data elements from one form or representation into another; (c) indexing and inference: inquiring about associations which may or may not pertain between various data elements and (d) composite concept manipulation: to aid in the entry, validation, translation, and simplification of composite concepts.

In addition to the above components, a number of other, more generic in nature, services (components) are also required so that the 'global system' exhibits the required behaviour in terms of security (authentication, encryption, auditing, etc.), concurrency control, event handling, transaction management, workload balancing, etc.

5.2. Component specification methodology

A formal way to identify the exact nature and role of each of the components required by any complex software system, such as access to a citizen's I-EHR, is necessary. The unified software development process [36] is a methodology, describing how to elicit, organize, and document required functionality and constraints; track and document tradeoffs and decisions; and easily capture and communicate business requirements. The notions of use case and scenarios proscribed in the process has proven to be an excellent way to capture functional requirements and to ensure that these drive the design, implementation and testing of software, making it more likely that the final system fulfils the end user needs [37].

The unified modelling language (UML) [38] is an essential tool to specify, visualize, and document models of software systems, including their structure and design, in a way that meets all of these requirements. UML is the tool used to transform system capabilities into requirements, and use cases including both basic and alternative flows of events in the form of interaction diagrams. Interaction diagrams are used to construct the overall model (class diagram) of the system, where certain functionalities can be isolated and delivered as part of self-consistent software modules, or components. In addition, the interfaces to the component need to be defined and made publicly available.

In specifying components, adequate care was taken so that their internal semantics are neutral, in the sense that each component ought to be able to be configured differently under the different execution environments it is expected to operate in. A typical such example is the OMG Person Identification Service (PIDS) [39] specification (Fig. 3 presents the conceptual model of the component) where the internal class diagram, encapsulating data, comprises classes that represent the concepts required. Classes that are used as 'facades' [40], or boundary classes, serve as the interfaces with other systems and are the gateways through which clients can communicate with the component. These classes are described, together with all of their operations, through an interface definition language (IDL) (Fig. 4 shows how such an IDL interface is expressed for the OMG PIDS) and describe in more concrete terms the functionality and the interface of the component in question.

Similar considerations were taken in specifying all remaining components of the HII, needed to support the I-EHR service.

5.3. Federated schema

As discussed earlier, the federation depends on a canonical model into which the underlying data models (or the export data models) are mapped, in order to present a uniform view of the data at the federation layer. In the case of the I-EHR this schema ought to be rich enough to be useful in delivering meaningful services to end users, while at the same time its complexity should be reduced to enable integration of additional systems into the federation with a relative ease. Depending on what someone wants to achieve, i.e. the services required by end-users, a trade-off exists between semantic richness and easiness of adaptation. Two extreme cases exist.

- The federated schema is extremely simple. This enables the rapid introduction of a large number of feeder systems with a minimal effort.
- The federated schema includes all information managed by all feeder systems, in essence becoming a data-warehouse.

Data from the disparate and heterogeneous feeder systems must be merged at five different levels. The data must:

- be co-located on a single platform;
- have a common data structure and format;

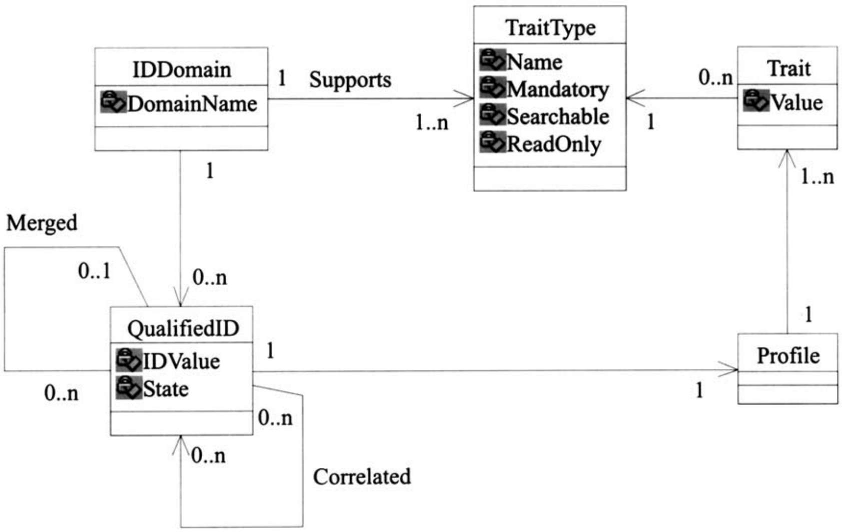

Fig. 3. The adopted OMG PIDS [39] conceptual model.

```
interface IdMgr :
        IdentificationComponent
{
        PersonIdSeq register_new_ids(in ProfileSeq profiles_to_register )
                raises (ProfilesExist, DuplicateProfiles, MultipleTraits );
        PersonIdSeq find_or_register_ids(in ProfileSeq profiles_to_register )
                raises (DuplicateProfiles, MultipleTraits );
        void register_these_ids(in TaggedProfileSeq profiles_to_register )
                raises (NotImplemented, IdsExist, DuplicateIds, ProfilesExist, DuplicateProfiles, MultipleTraits );
        PersonIdSeq create_temporary_ids(in ProfileSeq profiles_to_register )
                raises (MultipleTraits );
        PersonIdSeq make_ids_permanent(in PersonIdSeq ids_to_modify )
                raises (InvalidIds, DuplicateIds, RequiredTraits );
        IdInfoSeq merge_ids(in MergeStructSeq ids_to_merge )
                raises (InvalidIds, DuplicateIds );
        IdInfoSeq unmerge_ids(in PersonIdSeq ids_to_unmerge )
                raises (InvalidIds, DuplicateIds );
        IdInfoSeq deprecate_ids(in PersonIdSeq ids_to_deprecate )
                raises (InvalidIds, DuplicateIds );
};
```

Fig. 4. The ID Manager (IdMgr) Interface of the OMG PIDS [39] expressed in IDL.

- use the same or compatible data vocabularies;
- be normalized, so that the same value for a test result has the same clinical meaning regardless of data source; and
- be ordered or indexed.

Our experiences to date indicate that successful deployment of an I-EHR service is dependent upon the ability to assemble standard service encounter information from many disparate clinical systems. In its simplest form a service encounter 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. As a result, important entities included in the I-EHR schema include:

- The subject of care: the entity that corresponds to the client of a medical act.
- The healthcare agent: the entity being responsible for the direct or indirect provision of healthcare services, or involved in the provision of healthcare related services.
- The software entity: the clinical information system where primary clinical information is stored.
- The health record segment: the entity containing either clinical information together with the context in which the corresponding medical act took place, or just indices to it. It corresponds to a representation of the clinical findings resulting from a clinical encounter between the subject of care (i.e. the patient) and the involved healthcare agents. Indexed information is contained as a list of qualified codes indicating existence of specific types of clinical information without immediate knowledge of actual values. This entity may be composite in the sense that it can contain other (composite or atomic) segments and, thus, builds a 'composition tree' of clinical information segments pertinent to the subject of care.
- The location: the entity that represents a location from where the original information is managed and should be retrieved, if required.

The generality of this model allows the incorporation of different schemata, and deployment across different settings. In addition, provided that terminology neutrality is desired, the use of terminological services, which are implied by the use of qualified codes, is inevitable. In other words, the degree of abstraction of the federated schema defines the easiness of evolution in the number and type of concepts that could be added in the model at a later stage, aiming at maintaining backwards compatibility.

5.4. Requirements for their integration of feeder systems into the federation

The fact that each feeder system has its own internal semantics makes the introduction of a new feeder system into the federation, a process that requires human mediation. The human mediated process is related to the required mapping of the export schemata of the feeder systems to the federated schema. Introducing a system to the federation involves:

- the registration of the new feeder systems in the federation's resource directory;
- the implementation of the corresponding data extraction gateways.

In this context, HRS is required for identifying available software entities and the means for accessing them. In the future one could envisage a situation where the federated schema has become broad and possibly standardised (e.g. the HL7 RIM model). In such a situation plug compatibility specifications could become publicly available.

5.5. Access to clinical information

The problem of accessing clinical information (pulling operational data from its physical locations for presentation to the end users) is equivalent to the problem of communicating segments of the EHR, and, therefore, it can be handled in a similar way. That means that when dealing with legacy systems, a number of alternative methods for accessing primary information from their place of origin are required. The easy way for doing this is by means of proprietary ODBC or World Wide Web (WWW) access links. This way the means for accessing segments of primary information have the form of a Hyper Text Transfer Protocol (HTTP) Uniform Resource Locator (URL) or an SQL query. This approach suffers mainly due to the fact that information communicated is not structured in a standardized way, and consequently it cannot be used for further processing. This problem is alleviated by providing alternative, more advanced access mechanisms, and by adopting standardized interfaces to the feeder systems. In HYGEIAnet the OMG COAS specification [41] has been adopted.

Therefore, emphasis ought to be placed in standardization since we expect in the future to have all clinical information systems that are developed as part of the HII environment to provide standardized COAS-like interfaces. In this context clinical information is considered to be any measurement, recording, or description of the anatomical, physiological, pathological, or psychological state or history of a human being or any sample from a human being, and any impressions, conclusions, or judgments made regarding that individual within the context of the current delivery of health care [41].

5.6. Active propagation of clinical information

The next issue is the question of policies (including frequency of update) and technology required to enable the efficient and timely propagation of operational data to the federation, in order to assure information consistency in the wider federated domain. Propagation of updated meta-data to the indexing server is performed either periodically or actively, following a pull and a push model. In order to maintain consistency between information available to the federation and information just propagated, the requirement of an intermediate component arises (i.e. the update broker), being responsible for all the related consistency checks and updates.

Since batch update requires the communication of large data sets to achieve consistency, an alternative to this is active propagation of information, when and if needed. The process is initiated by the feeder systems themselves and performs much better than batch updates, since the size of propagated data is significantly smaller. The disadvantage of this scenario of use is the fact that it is almost impossible to implement with legacy systems.

It is our experience that the optimum scenario is to use a combination of the above two. Scheduled, periodic, batch updates enable a higher level of information consistency, whereas active propagation of information enables the immediate availability of new information to the federation. A hybrid 'push and pull' model is, therefore, thought to be most effective.

5.7. HCI issues

As we move towards providing uniform access to multimedia clinical information (electrocardiogram (ECG), medical images, etc.) through the I-EHR environment, important decisions need to be addressed regarding standardization of multimedia data formats, and the provision of the appropriate viewer components through the I-EHR graphical user interface (GUI). In addition, due to the vast amount of indexed information that needs to be displayed through the GUI of the I-EHR, innovative HCI metaphors need to be employed to avoid information overload and a friendly user interface.

When the health record is read from a computer screen instead of from a bundle of pages, the user interface is critical. Reading of text is about 25% slower from screen than from paper [42]. The physician's task is complex. He/she listens to the description of symptoms, questions the patient, performs physical examinations, and prescribes actions, treatments and medications. The main part of a physician's work is an intellectual effort comprising the evaluation of different hypotheses, estimation of probabilities, assessment of risks, decision making based on partially uncertain information, and planning of actions several steps ahead [43]. Poor presentation of patients' data can lead to poorly informed clinical professionals, medication errors [44], inappropriate repetition of investigation, and unnecessary referrals and waste of clinical time and other resources [45]. Records contain a wide range of patient data. A physician searches records both for facts, relevant to the current decision as well as for broader impressions—e.g. has there been a previous episode? According to [46], 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.

Therefore, quick browsing and interpretation of large numbers of time-oriented clinical data is needed. Reducing the information overload involved in such tasks is a major GUI design objective, since the interface designer must understand the 'cognitive processes involved in human-computer interactions in order to design interfaces that are more intuitive and more acceptable' [47]. Cognitive issues are also relevant to designing the presentation of clinical information in ways that facilitate rapid assimilation and analysis. A conceptual architecture and software implementation specific to the task of interpretation, summarization, visualization, explanation, and interactive exploration of time-oriented clinical data should be developed.

The interface of the I-EHR ought to support various ways of ordering data referring to individual patient encounters' data. Some physicians prefer problem-oriented views [48], while others may prefer ordering by place of origin.

A skilled physician can consider a number of different hypotheses simultaneously and search for specific health care parameters before settling on a decision [49]. A major risk is that important health care data get buried in the timeline [50]. The phenomenon is known as 'cognitive tunnel vision'. The 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. Example would be for filtering to show only pathology lab results and for highlighting to highlight sections on the timeline where data contain blood sugar parameter over a threshold value.

For the design and development of the HCI environment of Fig. 5, a usability context analysis was performed, that provided design input for the GUI of the I-EHR, and has documented design decisions. It has also been used for sharing knowledge and supporting common understanding between persons, of different user groups, involved in the project. Functionalities of the HCI environment include filtering for supporting the proper isolation of medical encounters containing relevant information to the end user needs; bookmarks for storing links to certain parts of the EHR, clinical e-mail providing the means for the exchange of selected I-EHR snapshots between properly authorized users; user profiles, supporting personalized information presentation; security for the management and administration of security rules; and auditing for recording all end-user interactions with middleware services of the HII.

5.8. Security issues

Healthcare is a security sensitive domain. Not authorized access to medical information may lead to violation of medical confidentiality or to serious non-authorized alterations of medical data that may put a patient's health in risk. Access and use of medical information managed by clinical information systems under different authentication domains is subject to strict confidentiality policies. Enforcement of such policies requires cooperation of certain medical services, certi-

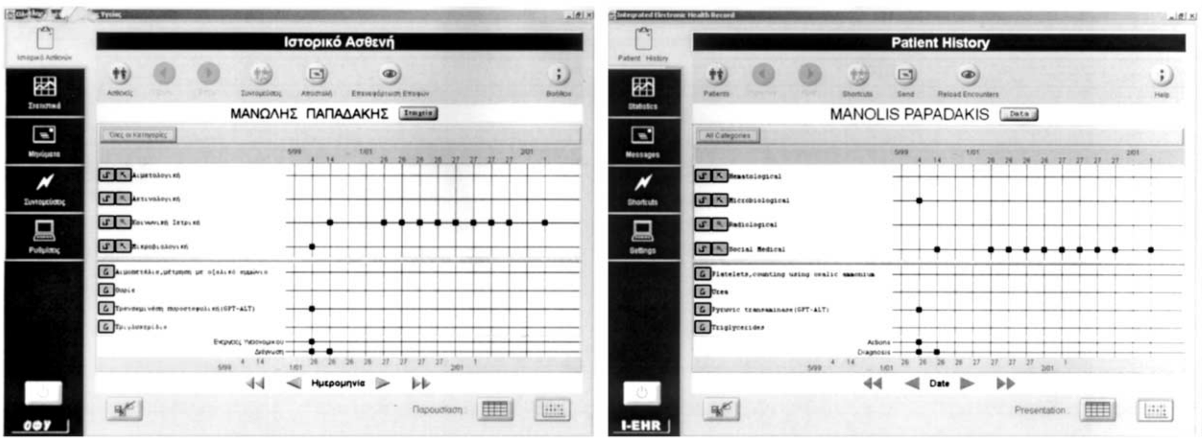

Fig. 5. The HCI environment for the I-EHR in HYGEIAnet.

fication and authorization processes. Certification of the medical identity must be considered essential for the final granting of authentication of medical doctors and is crucial for the security of the whole HYGEIAnet virtual private network (VPN). With this as a prerequisite, digital signatures can be used for the protection of validity, the authenticity, and the integrity of medical information, as well as non-repudiation. The use of symmetric/asymmetric cryptography is been used for assuring confidentiality and recipient identification.

In the past, role-based access to clinical observations has been controlled through both the functional and architectural I-EHR environment that was developed as part of the InterCare project [51]. Despite the fact that all possible precautions have been taken, in order to detect unauthorized users, it is extremely difficult to determine if a valid user is performing unauthorized tasks. As a means for protecting access violations from authorized users, a reliable auditing mechanism has also been employed with the purpose of tracking all interactions between end users and the middleware enabling services of the infrastructure.

A major challenge for both users and vendors is to implement security in a way that meets the healthcare needs cost-effectively. In order to meet this challenge, the improvement of already existing methods is necessary by identifying and analysing possible threats and risks, and by specifying, designing and implementing the appropriate security policies. As part of that effort the EU CORAS project [52] focuses today on HYGEIAnet, aiming to develop a risk analysis framework of security critical systems through adapting, refining, extending, and combining methods for risk analysis already developed.

6. Discussion

According to [5] the compelling arguments for a move towards electronic records are because they tend more likely to be legible, accurate, safe, secure, and available when required, and they can be more readily and rapidly retrieved and communicated. Additional benefits from an I-EHR system/ service include the support for shared care, high quality of care and decision support. Despite the fact that today WWW provides the means for global access to all kinds of information, personal health information remains fragmented, and not directly accessible in a unified and consistent way.

The message-based approach is tailored to the needs of professionals who explicitly need to select the type of information to be communicated and shared, as well as the destination. This way messaging is mainly used for sharing segments one's EHR, but provides no technical means for the seamless creation and transparent access to the I-EHR. It is nevertheless, by far the most prevalent in the health care community today, relies on defining a set of standard messages that allow different health care information systems to exchange data via standardized messages. Such an approach provides a useful way of solving basic communication problems between systems and support transactional services (referral, booking, reimbursement), but it does not provide adequate solution to the problem of information integration, an ultimate objective in the attempts to provide a single, lifelong I-EHR.

On the other hand, several efforts are been made internationally aiming at resolving the many technical as well as non-technical issues for the creation of a federated I-EHR. Such approaches are based on an underlying HII populated with both generic and health-related services to support the provision of integrated shared record services and a minimum common/federated data model. Since mapping from local schemata of the attached feeder systems to the federated schema is a prerequisite, a serious schema translation effort is required. The most important efforts towards standardization in this domain is mainly carried out by the American Society for Testing and Materials (ASTM) E31 [53], ISO TC215, CEN TC 251, and the health domain task force of the OMG.

Table 2 provides a list of similarities and differences between message-based and federated integration. Both approaches require the definition of minimum data sets, so that information can be shared. Both approaches require significant administration and management effort so that they truly become part of the health delivery process, and it is a generic requirement that no compromises should be made as far as security is concerned. The need of an underlying infrastructure is quite evident in both cases, and seems to converge towards one that benefit from component technologies to allow personalized delivery of information, while maintaining individual systems' autonomy.

In developing an HII for the next generation health information networks, the following issues need to be considered carefully:

- A software engineering architecture is required, being a strategic resource with the potential of enabling and supporting a health information network in meeting its goals. It facilitates communication and information management.
- Access to the software components of the HII should be standardized and tailored to the needs of both users and service developers; when developed, components realize their potential as more of them become available, since component-based software development shifts the focus from new software development to the integration of existing components to perform new tasks. At the same time issues related to large-scale system development in the areas of coupling, distribution, and the utilization of multiple platforms are addressed.
- Special emphasis is required when developing the HII; the needs for stability, manageability, maintainability and most importantly ability to evolve are of paramount importance.
- Whatever the HII technical platform is in real life, its selection is only part of the solution. The other part of the solution is migration. An implementation strategy or migration path as part of the overall information management and technology strategy is necessary to manage the complex processes involved in creating a scalable and evolvable HII.

The US Institute of Medicine in its report on computer-based patient record [54] predicted that 'current trends in healthcare delivery, management, and research will likely broaden the vision of computer-based patient records in two areas: population-based management of health through computer-based management of health through another variant of the computer-based patient record, the personal health record'.

It is the view of the authors that both these requirement presuppose the resolution of the technical and other issues, so that a life-long I-EHR for every citizen in our countries is been created. It should then be, technically, a straightforward process to move towards the creation of the population-based health record (through the integration of anonymous health data at a corporate/regional or national level) as well as the personal health record of an individual.

Table 2
Message-based integration vs. federated integration

	Message based integration	Federated integration
End-User	Medical staff (doctors, paramedical staff)	Healthcare professionals or citizens
Needs covered	Electronic ordering for observations, and request for or receipt of observation results	The provision of a uniform way to access patient record data that are physically located in different clinical information systems
Requirements	Fast, secure and authorized delivery of requests for various examinations and automatic or on demand receipt of results	Fast, secure and authorized access to distributed patient record segments
Not to be confused with	Client-server access to common centralized data repositories	Store and forward communication of EHR data, centralized clinical data repositories, or monolithic information systems
Features	Provides the environment to easily incorporate into a clinical information system the ability to order automatically various kinds of examinations. It also provides the ability to request for results or receive automatically the results for previously placed requests	Provides the environment for integrated access to clinical information, which is kept at the place where it is produced. This information is maintained by the most appropriate clinical information system
Prerequisites	Standardized messages, and the existence of the corresponding interface engines by each clinical information system that wants data exchange	Mappings between local and federated schemas, and the existence of the corresponding data extraction gateways by each clinical information system that wants to be part of the federation

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