

# An architecture for regional health information networks addressing issues of modularity and interoperability

Manolis Tsiknakis, Dimitrios G. Katehakis, Stelios Sfakianakis, Georgios Kavlentakis, and Stelios C. Orphanoudakis

**Abstract**—A fundamental pre-requisite for the establishment of a scaleable regional health information network (RHIN) is the development of an architectural framework and tools for the integration of specialized autonomous systems and e-health service platforms supported by an underlying health information infrastructure (HII). In this context, HYGIEAnet, which is the RHIN of Crete in Greece, has identified and utilized a number of critical software components enabling integrated access to clinically significant information, based on an open architecture addressing successfully the various interoperability challenges at hand. HYGIEAnet provides the framework for the reuse of standardized common components and public interfaces, thus enabling integrated and personalized delivery of healthcare.

**Keywords**— regional health information networks, health information infrastructure, e-health services, interoperability.

## 1. Introduction

Healthcare is a sector that currently experiences a number of pressures, both from inside and outside. The continuing innovation in medicine and technologies results in new methods and tools in healthcare. The demographic changes of an ageing European population, combined with citizen empowerment, stretch the limits of what countries can afford to offer as services of their national health systems. Governments are confronted by the urgent need to find means to limit the rise in healthcare costs without compromising quality, equity and access. Consequently, new ways to organize and deliver health services are being investigated and experimented with. Citizens and patients are given more responsibility in the management of their own health and chronic illnesses.

Health consumes a significant portion of national budgets in developed countries. Between 1960 and 1996, the percentage of gross domestic product (GDP) spent on healthcare by the OECD countries nearly doubled, rising from an average of 3.9% to 7%. There is no sign of any slowing down, and countries such as the United States are predicting increases of over 15% per annum [1]. The expenditure on health in Europe was over 700 billion euros in 1999, of which an estimated 14 billion or 2% was spent on ICT. The prediction is that this market is set to double over the next 5 years [2]. This growth is due to many factors including the maturing of the market and the rapid develop-

ments in medical science itself, resulting in new treatments and therapies. The gap between the demand for healthcare from an increasingly well-informed and expectant public, and the ability of the state and healthcare organizations to meet this demand is widening all the time. Efficiency and cost-effectiveness are the two key drivers in healthcare today, with the twin aims of delivering enhanced quality of care at the same or reduced cost. There is documented evidence from a number of trials that patients who are encouraged to take responsibility and assume an active role in their own healthcare management do better, enjoy a better quality of life, have fewer complications, and cost less [3]. Paternalism is giving way to partnership; process centered healthcare is giving way to patient centric care; and consumer healthcare is emerging as a significant driver in the sector.

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 all sectors of the healthcare system. The shareable, ubiquitous and integrated electronic health record (I-EHR) is a fundamental requirement for integrated care [4]. This is being accompanied by a very significant growth in home care which is increasingly viable even for seriously ill patients through sophisticated e-health services facilitated by intelligent sensors, monitoring devices, handheld technologies, and the Internet. It is seen as better for patients by providing a more comfortable and familiar environment, and better for the healthcare system as a whole by reducing costs. The emphasis is gradually shifting to a system which is concerned with promoting wellness rather than treating illness.

At the same time, medical errors are a growing cause for concern and a number of countries and healthcare organizations are mounting major campaigns to significantly reduce the number of errors. Approximately 100 000 Americans die each year from preventable errors in hospitals [5] which is more than the combined number of deaths from breast cancer, acquired immune deficiency syndrome (AIDS) and motor vehicles [6]. Medical errors generally result from a complex interplay of multiple factors and reducing their frequency requires a combination of technical, social and organizational approaches. However, one single solution, which has been proven to significantly reduce medication

errors, is the replacement of manual ordering systems by reliable automated ones [7].

In today's challenging, dynamic, information and knowledge intensive environment, it is not surprising that information and communication technologies (ICT) are increasingly viewed as central to any strategy aimed at increasing productivity, controlling costs and improving care. As a result networking of the various organizations delivering health and/or social care into RHINs is a central objective of many European administrations.

Such a vision was behind the development of HYGEIAnet in Crete, with the fundamental objective being to enable information sharing and medical collaboration among all stakeholders of the regional health economy and assist in the re-organization of the health care system based on innovative technological solutions and e-health services [4]. This paper begins with a brief overview of the identified application domains within a regional health information network (RHIN) and its services. Then, it focuses on the health information infrastructure (HII) required in order to support the efficient development of integrated services both within the context of a healthcare enterprise, as well as across co-operating healthcare enterprises that are part of a RHIN (RHIN infrastructure for integrated e-health services). Subsequently the case of HYGEIAnet is presented (HYGEIAnet: The RHIN of Crete) together with a range of novel e-health services deployed. Finally, it concludes by briefly discussing critical factors related to a successful implementation of a RHIN and observed benefits resulting from HYGEIAnet and its services (Section 5).

## 2. Regional health information network and its services

Today healthcare organizations, in most developed countries, are urgently trying to respond to the challenges arising from three global factors:

- changing operating environment comprising a number of issues like the *new economy* leading to institutional changes, informed citizens demanding personalized health services and the legislation and guidelines on privacy and security of personal information;
- changes in healthcare delivery comprising the move towards evidence-based care and, as part of that, best practice guidelines and care protocols, provision of integrated health services (citizen-centered services, seamless care) across organizational boundaries, making the patient a member of the care team (especially in the case of chronic diseases), and moving from care to health, or wellness management;
- technology push from the quick advancement in Internet and wireless technologies combined with the emergence of content providers and new business

models for information technology (IT) services (e.g., application service providers, Internet service providers, Internet portals, e-health).

All these combined provide both the push and pull towards the development of RHINs. In the past, it was enough for the care providers in a region to collaborate loosely and to use electronic data interchange for administration commerce and transport (EDIFACT) and/or health level seven (HL7) based messages to support their electronic information exchange. Today the collaboration needs to be tighter. Tighter coupling in health services delivery requires the evolution of the regional healthcare information infrastructure by incorporating additional, regionally available common healthcare specific services.

### 2.1. The regional health economy

The structures within which healthcare is carried out vary from country to country – and sometimes even within national boundaries. In some European countries, the various healthcare entities, e.g., general practitioners (GPs), hospitals, payers, etc., are structured formally and hierarchically in a defined organizational context, headed by a regional authority of some form, usually with executive powers regarding the governance of the bodies within its jurisdiction. In other countries, the organization of the healthcare entities, which collectively provide healthcare into a (formally or informally) defined geographic *region* or population group are informally structured, i.e., they are a *loosely coupled* set of independent organizations, which have come together by mutual arrangement to co-operate in the delivery of healthcare to their client population.

It therefore follows, in the latter case, that the regional grouping of healthcare organizations will not behave in the manner of a classic *enterprise*, where major issues of policy and standards are prescriptively defined and enforced from the parent body at the top of the organizational structure. Furthermore, the funding model for care differs between countries. Accordingly, to define an umbrella term for the groups of organizations (both providers and payers or purchasers) that collectively form a *European healthcare region* the term *regional health economy* (RHE) is introduced [9], in order to embrace both the formal and informal structures that exist within Europe.

Another way to represent these relationships is presented in Fig. 1. From top-down, the healthcare organizations of a region form a RHE in order to co-operate in health service delivery. In doing so they implement laws, policies, goals and strategies defined by national and regional (if such exist) authorities. The result of this is a set of regional healthcare services (or processes) aimed at meeting the health needs of the population at an affordable cost and acceptable level of quality. For these selected processes (or health services) they will need ICT support in the form of a RHIN. To formulate their ICT needs they will have to develop and maintain a regional ICT strategy that guides

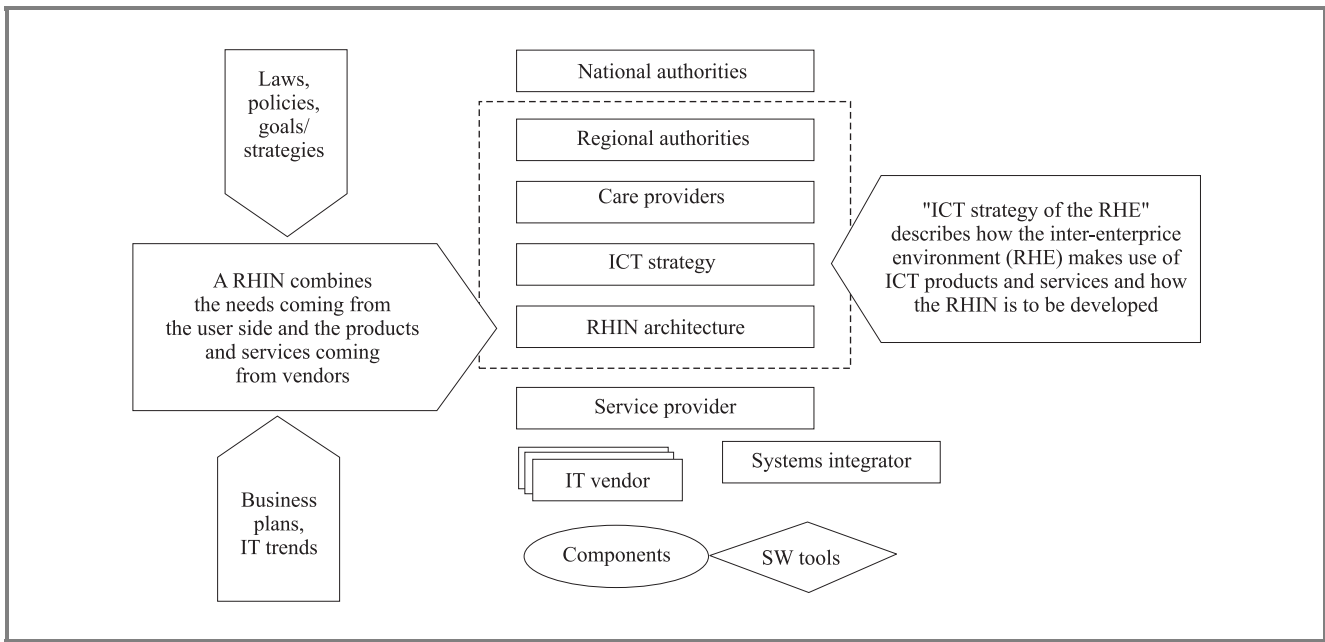


Fig. 1. The business model for creating the RHIN.

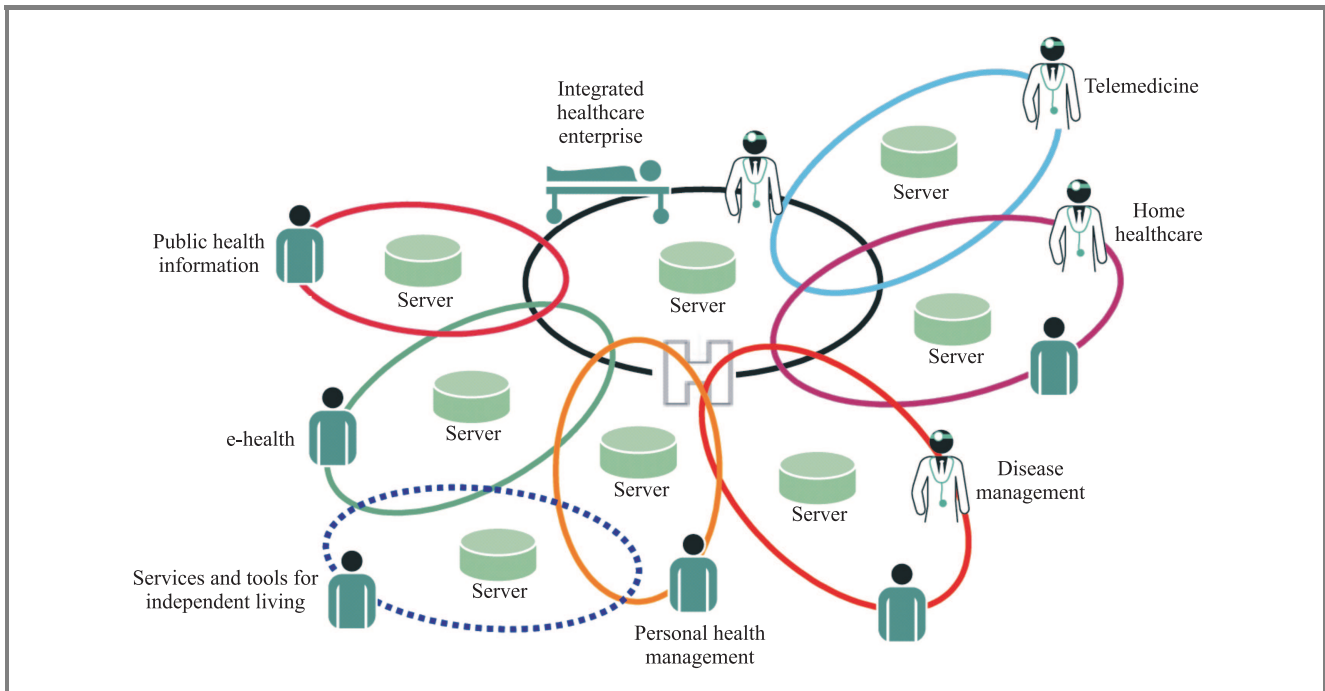


Fig. 2. Extension of care outside hospital walls creates additional needs for collaboration between providers in order to provide high quality, cost-effective services.

in the process of procuring new functionality to the RHIN that they deploy.

From bottom-up, the RHIN is a result of integrating products from different vendors into an interoperable HII using systems integration services and making this network available to users by a IT service provider, which is committed to maintain and manage it for the RHE.

The RHE concept has been used to emphasize that the regional grouping of healthcare organizations will not be

have in the manner of a classic enterprise. Rather RHEs are formed by a loosely coupled set of independent organizations (enterprises), which have come together by mutual arrangement to co-operate in the delivery of healthcare to their client population.

The range of health services that can potentially be available in a RHE is illustrated in Fig. 2. The healthcare organizations are increasing their degree of integration through enterprise application integration and making use of ex-

isting generic and healthcare specific standards. The integrated healthcare enterprise (IHE) initiative is an example of the co-operation of industry and user communities in furthering this goal. Healthcare enterprise applications and their integration comprise a large set of clinical information systems for specific medical domains such as laboratory, radiology, intensive care, and anesthesia and operating rooms. Within these, someone can find another set of systems such as decision support systems and computer assisted or remotely guided diagnostic and therapeutic procedures based on, e.g., virtual reality. The integration of the systems includes interoperability and connectivity at the functional and semantic level, including vocabularies and, of course, standards. At the process level, it comprises clinical guidelines and pathways, protocol-based care, including evidence based medicine (EBM).

Parallel to this trend the number of healthcare services delivered outside the *hospital walls* has increased tremendously. Telemedicine has been a very popular field of experimentation in the last decade. Today it is mostly seen as a technology enabling the collaboration of healthcare providers over a distance in delivering a service to the customer. This can take place either in a store and forward mode or in real time. Home healthcare is often seen as a modality of telemedicine. Examples include the *home hospital* for episodic and chronic care and follow-up and monitoring of patients after hospital discharge. These operations can be performed with the real or virtual presence of care personnel in the homes. The main characteristics of these two are the extension of the hospital concept towards a virtual hospital (i.e., hospital without walls) and that healthcare professionals are clearly in the loop caring for the patients.

Disease management programs bring the patient to the centre of the process as the most important actor in the care team. Although disease management involves normally a large team of healthcare professionals from primary to secondary care the outcome of the process is determined mostly by the actions and activities of the patient in complying with the recommended care guidelines. In this area, a number of applications have been created to support collaboration and sharing of information. Disease management is a step towards a comprehensive health management regime. Its primary objective is to prevent disease episodes. Wellness or health management in general is a natural corollary of this where the objective is to assist an individual to maintain her/his health status. Today ITs that apply in this context include, e.g., smart environments utilizing ubiquitous computing techniques combined with embedded and wearable sensors.

## 2.2. The architecture of regional health information network

It is by now apparent that a RHIN, offering the range of services described previously, is a very complex system. In any system complex enough to ask for 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, since the whole is more than the sum of its parts.

An architecture, been a formal description of an IT system, should be organized in a way that supports reasoning about the structural properties of the system. It should identify the *components*, or *building blocks*, that make up the overall information system, and provide a plan from which products can be procured, and systems developed, that will work together to implement the overall system.

The purpose, therefore, of an architecture 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 and maintenance;
- cost-effectiveness by leveraging main stream technologies and products.

Therefore, the most promising approach to the development of a RHIN architecture is the adoption of an open systems approach (OSA). OSA is an integrated business and technical strategy that employs a *modular design* and, where appropriate, defines *key interfaces* using widely supported, *consensus-based standards* that are published and maintained by a recognized *industrial standards organization*.

Modular designs are characterized by the following:

- functionally partitioned into discrete, scalable, reusable modules consisting of isolated, self-contained functional elements;
- rigorous use of disciplined definition of modular interfaces to include object oriented descriptions of module functionality;
- designed for ease of change to achieve technology transparency and, to the extent possible, makes use of commonly used industry standards for key interfaces.

Open systems approach is a means to assess and implement widely supported commercial interface standards in developing systems using modular design concepts. It is an enabler that supports program teams to:

- design for affordable change;
- employ evolutionary acquisition;
- develop an integrated roadmap for an integrated system.

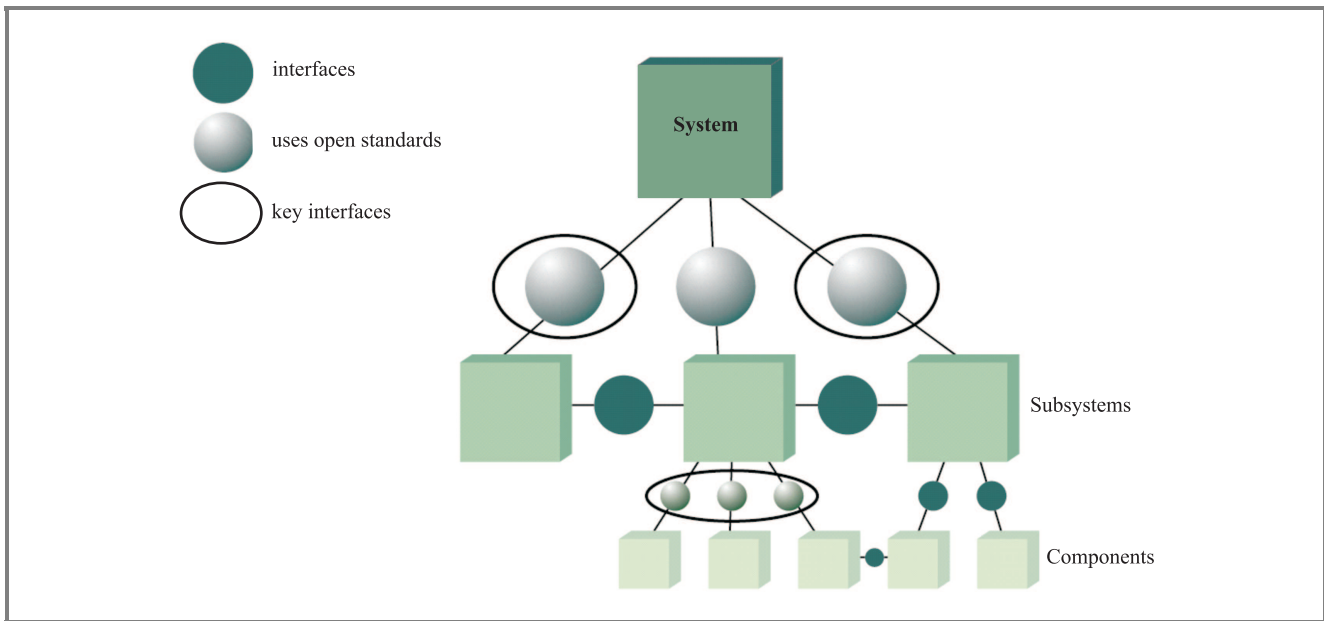


Fig. 3. Key interfaces.

This approach supports achieving the following:

- reduced acquisition cycle time and overall life-cycle cost;
- ability to insert cutting edge technology as it evolves;
- commonality and reuse of components among systems;
- increased ability to leverage commercial investment.

Partitioning a system appropriately during the design process to isolate functionality makes the system easier to develop, maintain, and modify or upgrade. Given a system designed for modularity, functions that change rapidly or evolve over time can be upgraded and changed with minor impact to the remainder of the system. This occurs when the design process starts with modularity and future evolution as an objective.

Interface standards specify the physical, functional, and operational relationships between the various elements (hardware and software), to permit interchangeability, interconnection, compatibility and/or communication. The selection of the appropriate standards for system interfaces should be based on sound market research of available standards and the application of a disciplined systems engineering process.

Special emphasis should be given to *key interfaces*. Key interfaces are interfaces between modules for which the preferred implementation uses open standards. Open specifications and standards are those that are widely used, consensus based, published and maintained by a recognized industrial standards organization. These interfaces are selected for ease of change based on a detailed understanding of the maintenance concepts, affordability concerns, and

where technologies or requirements are intended to evolve. Key interfaces should utilize open standards in order to produce the largest life cycle and cost benefits.

Conceptually, key interfaces are illustrated in Fig. 3. Interfaces at and above key interfaces are those that should be designated on open interface standards. Standards for interfaces below this level may also be open; however, selection should be left to the supplier as part of detail design.

In order to take full advantage of modularity in design, interface standards must be well defined, mature, widely used, and readily available. In general, popular open standards yield the most benefit in terms of ease of future changes to the system and should be the standards of choice.

Standards should be selected based on maturity, market acceptance, and allowance for future technology insertion. As part of the open systems approach, preference is given to the use of open interface standards first, the de facto interface standards, and finally government and proprietary interface standards. Open standards allow programs to leverage commercially funded or developed technologies and to take advantage of increased competition. They also allow faster upgrade of systems with less complexity and cost.

The bottom line is that designing a system for affordable change requires modularity.

### 3. RHIN infrastructure for integrated e-health services

A RHIN focuses in inter-enterprise integration and provide integration for enterprises that want to share data and information for providing health services to patients/citizens in a regional setting (see Fig. 4). They are not concerned

with how the enterprises are internally integrated, although the same principles can be applied to integrating healthcare organizations at a national level and across national borders (Pan-European).

Level 1 (local)	Enterprise wide integration
Level 2 (regional)	Inter-enterprise wide integration
Level 3 (national)	Inter-enterprise and inter-regional integration
Level 4 (European)	Inter-enterprise, inter-regional and inter-national integration

**Fig. 4.** Integration levels from local (enterprise wide) to Pan-European.

The basic principles behind the RHIN concept are the following:

- Healthcare organizations will retain their independence and their collaboration with each other is determined by their interests. There will be competing interests, i.e., healthcare organizations offering similar services.
- ICT technologies deployed by the various healthcare organizations will be different. They will have different technology platforms for the integration of their respective enterprise applications. There is no one technology platform that fits all needs.
- There is no single owner of the RHIN. Its development will depend on how the healthcare organizations can reach consensus and agreements on where to collaborate and where not. 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.

The RHINs require the cooperation of healthcare facilities that offer complementary set of services and involve dealing with complex issues mainly related to patient data confidentiality, semantic heterogeneity, and the diversity of systems and services requirements.

This further urges for the creation and/or adoption of certain interoperability protocols and standards that will enable information exchange, and consequently raises the issue of developing an open, scalable and evolvable HII. The creation of an HII is also driven, among other factors, by the need for automating routine tasks to place the focus on patient needs rather than paperwork. It is also driven by the need to ensure continuity of care by providing flexible remote access to relevant information and resources and to support research in order to enable all involved stakeholders to make effective choices.

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.

### 3.1. Technological challenges

It is commonly accepted that care capacity, available at local level, is greatly enhanced when local practitioners have access to a patient's healthcare record and, as the need arises, when specialists can assist them. Important objectives in any effort toward establishing RHINs consisting of co-operating health enterprise networks involve:

- the promotion of the coordinated and harmonized development of healthcare enterprises;
- the adoption of a common architecture of reference for the development of advanced services within the health enterprise;
- the interconnection of cooperating health enterprises for the purpose of creating RHINs;
- the definition of medical and operational procedures for sharing resources and expertise over such inter-enterprise health information networks, so that patient mobility and improved care practices can be supported effectively;
- the development of environments for information exchange among health enterprises based on agreed information exchange protocols for the medical domain.

The most important initiative, with regard to enterprise application integration, is related to the integrating the healthcare enterprise (IHE) initiative [10]. 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, by documenting the integration profiles supported by available products (statements of their conformance to relevant standards) at a hospital level, to support plug-and-play interoperability. Typical such example is the patient information reconciliation (PIR) profile that provides the means to match images acquired for an unidentified patient with the patient's registration and order history, involving enterprise-wide information systems that manage patient registration and services ordering, radiology departmental information systems that manage department scheduling and image management/archiving, as well as acquisition modalities.

Regarding inter-enterprise application integration, one of the most advanced approaches is the one that has resulted out of the European Union (EU) co-funded research and technology development (RTD) project PICNIC (professionals and citizens network for integrated care) [11], that developed a model for the future regional health care networks, in order to prepare the regional health care providers

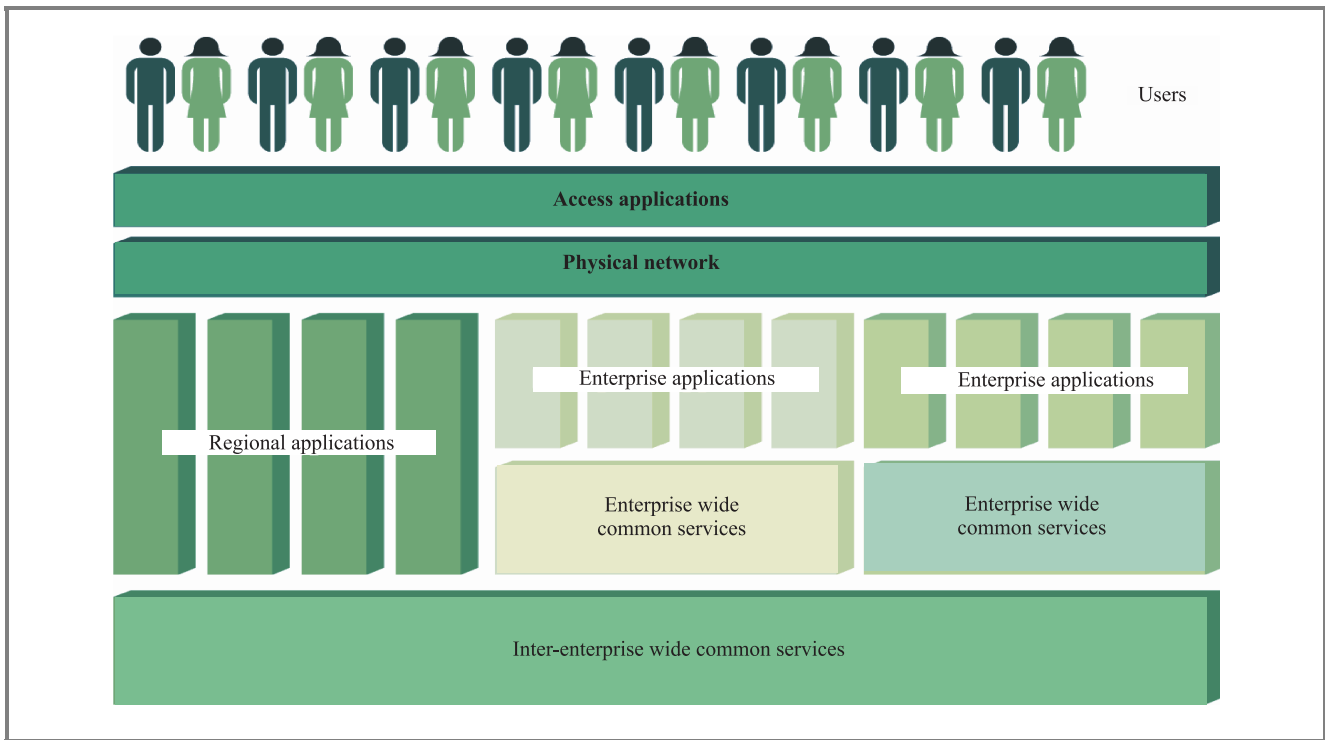


Fig. 5. Architecture of a RHIN.

to implement the next generation of secure, user-friendly health information networks. Basic characteristics of a typical architecture (see Fig. 5) include:

- Users (healthcare professionals and citizens) that have access to applications and services through alternative access devices. This access is performed through a secure physical network.
- Users that have access either to enterprise applications and services or to regional applications and services.
- Enterprise applications that are supported by enterprise wide middleware services.
- Regional applications and services that are supported by the corresponding common inter-enterprise wide services (regional HII).

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, medical terminology, etc., whereas generic components are required to support low level, essential, platform-dependent functionalities

like, e.g., concurrency control, event handling/notification, licensing, security (authentication, encryption, auditing, etc.), timing, transaction management, etc.

In practice the architecture tends 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 make this (i.e., tighter coupling versus federation). Therefore, the common IT services infrastructure depends on the existing health information infrastructures of the healthcare organizations that make up the RHIN of providers and related organizations. The same applies for regional applications. These will, in most cases, be created at the cost of enterprise applications. The healthcare organizations may agree that some functions can be supported by a joint, regional application.

### 3.2. Component view of a RHIN architecture

As software systems grow larger, healthcare delivery systems become more complex and interdependent. Today software component technology has emerged as a key enabling technology. “A component is a nontrivial, nearly independent, and replaceable part of a system that fulfils a clear function in the context of a well-defined architecture. A component conforms to and provides the physical realisation of a set of interfaces” [12].

Essential components that have been identified [8] to be required for the proper delivery of integrated e-health services in the context of RHINs include:

- patient identification (ID) components used for the unique association of distributed patient record segments to a master patient index;
- collaboration components used for establishing a collaboration context that enables not only the active sharing of clinically significant information, but also receiving feedback, feed through and awareness information from all participating actors;
- resource components used for identifying available resources and the means for accessing them;
- I-EHR indexing components used locating clinically significant information dispersed throughout the RHIN;
- I-EHR brokers used to provide prompt and consistent propagation of indexing information to the I-EHR indexing components;
- clinical observations access components used for obtaining clinically significant information captured at the point of care, directly from the corresponding clinical information systems;
- message brokers used for message validation, transformation and routing using a set of built-in and/or user-defined message formats and message processing rules, which may include functionality such as publish and subscribe, message auditing, message flow analysis, and message enrichment;
- user profile components used for tracking the long-term interests of users and maintain personalized preferences;
- terminology components used for information acquisition, information display, mediation, indexing and inference, and composite concept manipulation.

Beyond relational databases that today are used extensively for storing enterprise data, technologies for the integration of information related to the electronic health record (EHR) also involve directories for creating distributed, hierarchical structures of accessible resources (with the most promising being X.500 and light directory access protocol – LDAP of the International Telecommunication Union – ITU), distributed object computing to implement advanced modular functionalities (like, e.g., the platforms of common object request architecture – CORBA or Java two enterprise edition – J2EE), Internet and Java to glue pieces of information scattered throughout the world, portable devices and mobile communications to enable access from anywhere at any time, extensible markup language (XML) technologies to allow for dynamic browsing according to personalized preferences and authorities, together with human computer interaction (HCI) technologies to support access for all.

### 3.3. Security issues in RHINs

The main focus in dealing with RHIN security is related to control of the information, especially as it deals with private and confidential patient information. Security (resilience) of the hardware, operating system and the application software, while being equally important, 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* provides the basis for security protection. An information domain is defined as a set of users, their information objects, and a security policy. Security within each information domain must be established in accordance with the respective security policy. For communication between the information domains, a trusted end-to-end communication policy must be established.

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. Finally, the choice of what security features to implement must be based on *risk assessment* in the context of the intended service.

In order to access system resources and patient data users must be identified (i.e., access to resources and data must be controlled so that unauthorized access is prevented). Access rights can be managed on two levels:

- authentication (the person is who (s)he claims to be);
- authorization (permitting access to resources and data based on a qualified role, role-based access).

Information may not be made available or disclosed to unauthorised individuals, entities or processes without the consent of the patient. This is a fundamental right of individuals that they shall have the power to keep information about themselves from being disclosed to anyone. Therefore, the individual (patient) must agree/consent to disclosing her/his private information.

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 final results. The records can also be used to track system usage and detect and identify intruders.

A public key infrastructure (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 is used in order to enable two entities that do not know each other to exchange information using an insecure network such as the Internet. The infrastructure is based upon asymmetric cryptography and each entity (user, information system, etc.) is provided with a pair of keys (a private and public key).



A certification authority (CA) is a trusted party that can vouch for the binding between names or identities and public keys. In some systems, certification authorities generate public keys. The public key certificate binds a user's name to a public key signed by a trusted issuer.

Smart cards are mostly associated with PKI and CAs as an access card containing encoded information and sometimes a microprocessor and a user interface. The information on the code, or the information generated by the processor, is used to gain access to a facility or a computer system.

Digital signature is a means to guarantee the authenticity of a set of input data the same way a written signature verifies the authenticity of a paper document. Digital signatures are required in many cases during the provision of 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. To sign a document, the document and private key are input to a cryptographic process, which outputs a bit string (the signature). To verify a signature, the signature, document, and user's public key are input to a cryptographic process, which returns an indication of success for failure. Any modification to the document after it is signed will cause the signature verification to fail (integrity). If the signature was computed using a private key other than the one corresponding to the public key used for verification, the verification will fail (authentication).

Digital signatures can be attached to any electronically transmitted message, including ones transferring EHR data. 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 the portion of the document for which they are responsible.

## 4. HYGEIAnet: the RHIN of Crete

HYGEIAnet represents a systematic effort towards the design, development and deployment of advanced e-health and m-health services at various levels of the healthcare hierarchy, including primary care, pre-hospital health emergency management, and hospital care on the island of Crete, Greece (Fig. 6). Specifically, e-health and m-health services support the timely and effective management of patients, the synchronous and asynchronous collaboration of healthcare professionals, and the remote management of selected patients at home. Finally, e-health services are being used to support continuity of care across organizational boundaries by providing access to the life-long I-EHR.

HYGEIAnet is fundamentally designed to provide access to health information when and where this may be required, and to facilitate communication among all actors committed to informed decision making in the health sector. From the technological point of view, a diverse set of state of the art technologies have been developed and deployed as part of the scalable HII of HYGEIAnet. These include fixed, as well as wireless and mobile communications, distributed computing and middleware, web technologies and services

(i.e., XML, simple object access protocol – SOAP, universal description, discovery and integration – UDDI), peer-to-peer computing, H.323, X.500, X.509, and also a number of other healthcare specific standards.

The deployment and use of HYGEIAnet services has demonstrated significant economic and clinical benefits. Specifically, a reduced number of referrals to specialists has resulted in less travel and fewer days of hospitalization, while the number of workdays lost by family members and relatives is reduced. Furthermore, unnecessary duplication of medical examinations is avoided, while access to care and quality of service are greatly improved in all cases in which e-health services are employed.

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.

### 4.1. Integration at the inter-enterprise level

The development of the HII services of HYGEIAnet was based on CORBA, since it seemed to offer a unique combination of advantages over other distributed object oriented technologies. Such advantages include:

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

In particular the work of health domain task force (DTF) of the object management group (OMG) [13] was very important in the definition of the information integration architecture for creating the I-EHR. This architecture was based to the following services defined by the health DTF:

- person identification service (PIDS), enabling the unique identification of patients;
- lexicon query language (LQS), enabling efficient management of medical terminologies and coding schemes;
- clinical observation access service (COAS), enabling seamless access to the various clinical information systems, the primary sources of medical information.

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

- I-EHR indexing service (I-EHR IS), for managing indexes to the primary information sources so that the efficiency and scalability aspects of the architecture are reinforced;

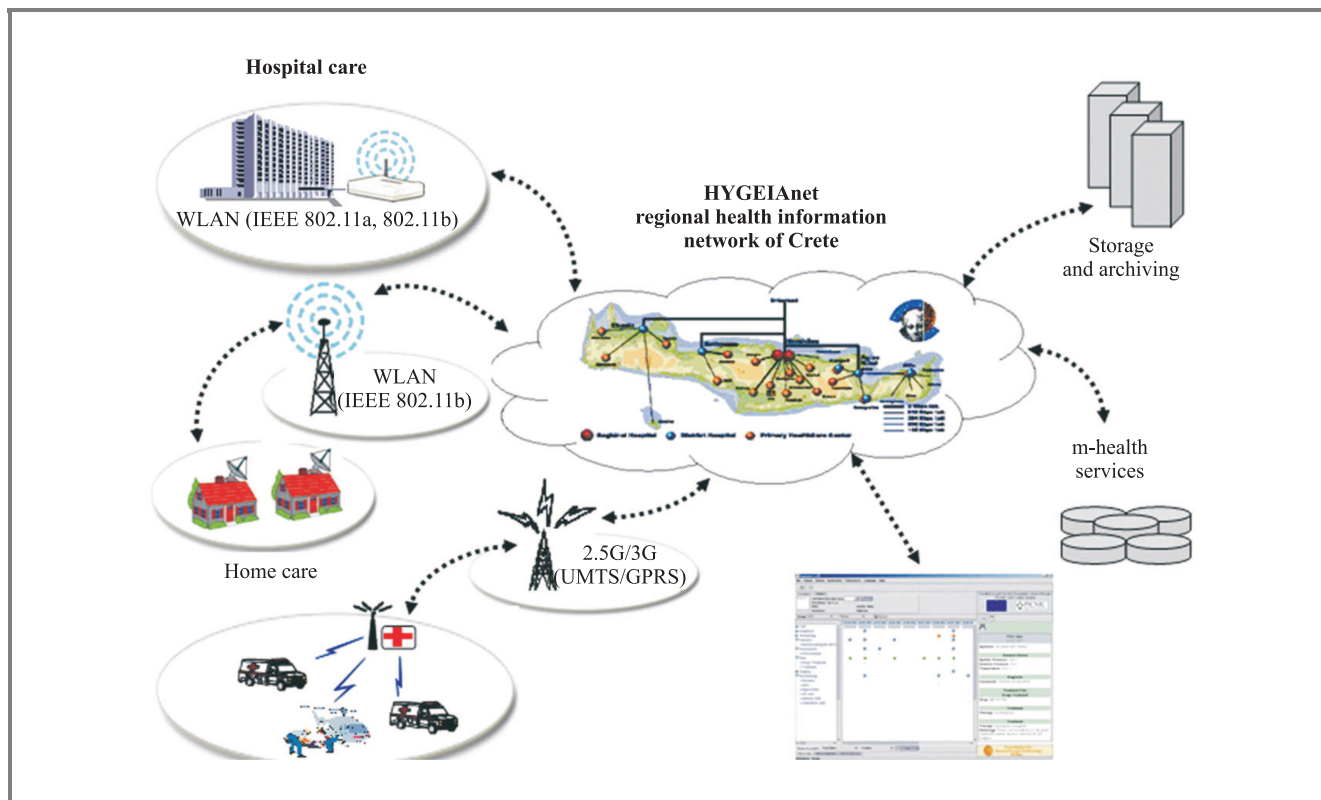


Fig. 6. E-health and m-health services in HYGEIAnet.

- I-EHR update broker (I-EHR UB), for keeping I-EHR IS up to date with new or modified information and consistent with the information accessible through COAS;
- health resource service (HRS), for the unique identification and management of clinical resources in the context of I-EHR, such as medical staff, health care facilities;
- collaboration service (COLS), to support collaboration among healthcare practitioners.

At the inter-enterprise level, web services technologies have been utilized in HYGEIAnet, over the already existing enterprise service components, comprising the backbone of a component based computing environment, that treats medical information systems and services as information sources to be integrated at a regional level. Currently, within the context of HYGEIAnet, a number of sub-domains attract attention:

- **Home care.** Aiming at providing e-health services for the remote management of chronic diseases [14]. Various such services have been delivered, ranging from the provision of telemonitoring for patients undergoing kidney hemodialysis to asthma suffering children.
- **Primary care.** A primary healthcare network is already in operation. The primary health care centers

of the island are all fully equipped and support efficiently all patient related clinical processes.

- **Pre-hospital health emergency care.** An integrated system has been developed and is currently operational providing e-health tools and services for the optimal planning, and response management of pre-hospital health emergencies.
- **Hospital care.** Clinical information systems have been developed or acquired and installed in various clinical departments.
- **E-health.** E-health services in the domains of cardiology [15] and radiology are available today throughout HYGEIAnet, making medical expertise instantly available to remote and isolated populations.
- **The integrated electronic health record.** The required infrastructure is in place and a large number of clinical information systems are currently supported, ranging from primary health care and nursing to specialized departmental information systems [16].
- **Education and information to the citizen.** The development and operation of any RHIN is not only a matter of applying new ICT technologies. Above all, it requires the continuous education and innovative training of medical, nursing and administrative personnel from all involved healthcare organizations.

- **Health monitoring and surveillance.** A fundamental objective is to provide the technological infrastructure (networks, information systems, analysis tools, etc.) for the routine collection of primary health data and their analysis for the extraction of the relevant health indicators [17].

**4.2. Role-based access to information**

The use of any RHIN 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 integration and communication technologies used, like the transport layer security (TLS), or the CORBA security service. However the need for authorization and access control requires security measures at the application level in addition to those offered by the communication platform.

For all RHIN service access control lists are maintained within the HYGEIAnet authentication server. All HYGEIAnet applications and services are declared within the HYGEIAnet’s HRS and are issued a unique ID. Each user of the RHIN services must also register within HRS, and is issued with a unique username, together with the corresponding password, which are used for the facilitation of single-sign-on all applications and services within a RHIN. Groups and permissions are maintained and managed locally by each individual RHIN service. Passwords are maintained and managed by the corresponding RHIN authentication server, while certificates are provided and maintained by the regional certification authority. The role of each involved actor is listed in Table 1.

Table 1  
The role of regional certification authority

Actor	Role
Certification authority	Issues certificates.
Authentication service	Maintains and manages passwords; issues passwords for every new healthcare person; performs user authentication.
HYGEIAnet HRS	Maintains and manages public health resource information; activates all applications and services by issuing them a unique ID; registers all healthcare persons and organizations; issues a unique user name for all healthcare persons it maintains; associates healthcare persons and organizations.
Any RHIN service	Maintains and manages roles (groups) and role-based permissions.

Two user management modules may be in place; one from within the RHIN service environment and handles all RHIN

service specific access rules, and one through the overall domain management administration GUI. Those modules cooperate with a set of infrastructure components like HRS, CA, the authentication service (AS), and the certificate revocation list (CRL).

An IT service user is authenticated through the appropriate AS and gets his/her access rights validated through the individual RHIN service specific access control manager. When a new *healthperson* is added in HRS, the user management module automatically creates an active account for him in AS and provides him a digital certificate from CA. A new user account for any RHIN service 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. In order for the whole process to guarantee maximum security a user must have an account activated in three different places:

- HRS;
- AS;
- CA (activate a revoked certificate).

This permits a new user to access the RHIN service, and allows the administrator to find and select all users associated with any particular RHIN service from the RHIN HRS.

The user is then assigned to certain roles based on organizational (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;
- the kind of clinical information that this rule applies.

It is therefore feasible to grant access to users based on the location that the information is hosted and also based on the type of the information. This model in spite of its simplicity has been proved to be powerful enough for the most common use case scenarios. Extensions to the definition of the rules that, for example, allow combination of rules and creation of more complex rules using conjunctive and disjunctive constructs, although feasible, have not needed in practice.

**5. Discussion**

HYGEIAnet takes advantage of the increasing capacity of terrestrial networks, wireless and mobile communications and the development of advanced e-health services, to provide continuity of care in the different phases of healthcare, from prevention to care itself, to rehabilitation.

In the framework of HYGEIAnet, medical information systems and services are treated as information sources

to be integrated under the common reference architecture. To meet this challenge, an execution architecture was defined and implemented in order to support the seamless integration of information.

A large number of re-usable software components (middleware services) have been identified and developed so far, capable of supporting the ICT evolutionary and migration strategy at the regional level. Our experience has shown that re-usable components make the deployment of new clinical information systems and e-health services easier and faster, while at the same time allowing for a more efficient management of the ICT infrastructure. Still, decisions have to be formulated about how and when to upgrade the platform itself and whether the expected benefits and savings outweigh the costs involved.

However, the deployment and use of HYGEIAnet services has to date demonstrated significant economic benefits. Referrals of patients to specialists were significantly reduced, since expert opinion was available through services provided over the RHIN, and hospitalization days have been reduced. Loss of workdays of family members has also been reduced, while unnecessary examinations have been avoided. Considering the rather limited use of technology in the region of Crete prior to the deployment of HYGEIAnet systems and services, the actual economic benefits can be accurately quantified after the transients die out and the regional system of health is allowed to operate as a RHIN in a steady state. However, the evaluation of the cost benefits of e-health services, relative to patient outcome, is and ought to be a continuous process.

Access to care has greatly improved in all categories where e-health services have been employed. The findings to date are extremely encouraging and suggest that e-health services can benefit not only the patients, but also health professionals by fostering their collaboration and serving as a tool for continuing education. In tele-cardiology, 10% of the cardiac patients were involved in a tele-consultation session during a period of 6 months, thus making medical expertise instantly available to remote and isolated populations. Furthermore, 65% of pre-hospital health emergency episodes are managed by paramedics. Given that the first 60 minutes (the golden hour) are the most critical regarding the long term patient outcome, the ability to remotely monitor the patient, thus allowing experts of the coordination centre to guide the paramedical staff in their management of the patient, is facilitating access to care by specialists. In addition, different evaluation studies have demonstrated improvements in the quality of care itself, with respect to the application of e-health services in pre-hospital health emergency management, the remote management of chronic diseases, and in supporting tele-consultation in selected clinical disciplines.

## References

- [1] PriceWaterhouseCoopers, "Healthcast 2010 smaller world, bigger expectations", Nov. 1999.
- [2] Deloitte & Touche, "The emerging European health telematics industry, market analysis", assignment of European Commission-Directorate General Information Society, Febr. 2000.
- [3] J. Grimson, "Delivering the electronic healthcare record for the 21st century", *Int. J. Med. Inform.*, vol. 64, issue 2-3, pp. 111-127, 2001.
- [4] D. G. Katehakis, M. Tsiknakis, and S. C. Orphanoudakis, "A healthcare information infrastructure to support integrated services over regional health telematics networks", Health IT Advisory Report, Medical Records Institute, vol. 4, no. 1, pp. 15-18, Dec. 2001 - Jan. 2002.
- [5] L. T. Kohn, J. M. Corrigan, and M. S. Donaldson, "To err is human: building a safer health system", Committee on Quality of Health Care in America, Institute of Medicine, Apr. 2000.
- [6] "Reducing medical errors and improving patient safety; success stories from the front lines of medicine", The National Coalition on Health Care, The Institute for Healthcare Improvement, Febr. 2000.
- [7] D. W. Bates, "Using information technology to reduce rates of medication errors in hospitals", *Br. Med. J.*, vol. 320, pp. 788-791, 2000.
- [8] M. Tsiknakis, D. G. Katehakis, and S. C. Orphanoudakis, "An open, component-based information infrastructure for integrated health information networks", *Int. J. Med. Inform.*, vol. 68, issue 1-3, pp. 3-26, 2002.
- [9] Professionals and citizens network for integrated care (PICNIC-1999-10345), project deliverable 2.4, PICNIC architecture, 2003.
- [10] Integrating the healthcare enterprise initiative, <http://www.rsna.org/IHE/index.shtml>
- [11] Professionals and citizens network for integrated care (PICNIC-1999-10345), <http://www.medcom.dk/picnic/> and <http://picnic.euspirit.org/>
- [12] W. Kozaczynski, "Composite nature of component", in *Proc. 1999 Int. Worksh. Comp.-Bas. Softw. Eng.*, Los Angeles, USA, 1999, pp. 73-77.
- [13] Object management group, <http://www.omg.org>
- [14] A. Traganitis, D. Trypakis, M. Spanakis, S. Condos, T. Stamkopoulos, M. Tsiknakis, and S. C. Orphanoudakis, "Home monitoring and personal health management services in a regional health telematics network", in *Proc. 23rd Ann. Int. Conf. IEEE Eng. Med. Biol. Soc. (IEEE-EMBS 2001)*, Istanbul, Turkey, 2001.
- [15] C. E. Chronaki, P. J. Lees, N. Antonakis, F. Chiarugi, G. Vrouchos, G. Nikolaidis, M. Tsiknakis, and S. C. Orphanoudakis, "Preliminary results from the deployment of integrated teleconsultation services in rural Crete", in *Proc. IEEE Comput. Cardiol. Conf.*, Amsterdam, The Netherlands, 2001, pp. 671-674.
- [16] D. G. Katehakis, S. Kostomanolakis, M. Tsiknakis, and S. C. Orphanoudakis, "Image management in an integrated electronic health record environment", in *Proc. 20th Int. EuroPACS Conf. (EuroPACS 2002)*, Oulou, Finland, 2002, pp. 87-92.
- [17] D. G. Katehakis, S. Sfakianakis, M. Tsiknakis, and S. C. Orphanoudakis, "An infrastructure for integrated electronic health record services: the role of XML (extensible markup language)", *J. Med. Internet Res.* 2001;3(1):e7, <http://www.jmir.org/2001/1/e7/>



**Manolis Tsiknakis** received a B.E. degree in electronic engineering, a M.Sc. in microprocessor engineering, and a Ph.D. in control systems engineering from the University of Bradford, UK. In 1992, he joined ICS-FORTH, where he is currently a Principal Researcher, coordinating the activities of the Center for eHealth Tech-

nologies. He has been ICS-FORTH's Principal Researcher of in many collaborative R&D projects and is currently coordinating the development of HYGEIAnet, the integrated health telematics network of Crete. Since March of 2002, he has been chairing ERCIM's Health Information Technology Working Group (HIT WG) and is the initiator and co-chair of the ERCIM Biomedical Informatics Working Group. His current research interests are in the areas of biomedical informatics, component based software engineering, information integration, ambient intelligence of e-health and m-health service platforms and signal processing and analysis. He is a member of IEEE and ACM.

e-mail: tsiknaki@ics.forth.gr

Center for eHealth Technologies

Institute of Computer Science (ICS)

Foundation for Research and Technology –  
Hellas (FORTH)

Science and Technology Park of Crete

Vassilika Vouton, P.O. Box 1385, GR 711 10

Heraklion, Crete, Greece



**Dimitrios G. Katehakis** – FORTH – senior telecommunications engineer, with a diploma in electrical engineering (telecommunications and electronics) from the Technical University of Patras, Greece (1991), and an M.Sc. in electrical engineering (computers) from the University of Maryland at College Park (1993). His

work focuses on data integration analysis and the design of object-oriented systems and distributed architectures for advanced integrated electronic health record (I-EHR) services. Past participation in related European RTD projects includes: PICNIC (IST-1999-10345), TEMeTeN (DGXVI – RISI 2), RETRANSPLANT (DGXIII – health telematics), HECTOR (DGXIII – health telematics), and CreteCT (Ministry of National Economy & INTERREG II). Past experience includes also working with the Medical School of the University of Maryland at Baltimore for the IONDT (US Federal), and MCR (MD State, Dept. of Health and Mental Hygiene – CDC) projects, as well as the National Defense Ministry, and the Hellenic Telecommunications Organization (OTE). He is a member of IEEE, ACM, and the Technical Chamber of Greece.

e-mail: katehaki@ics.forth.gr

Center for eHealth Technologies

Institute of Computer Science (ICS)

Foundation for Research and Technology –  
Hellas (FORTH)

Science and Technology Park of Crete

Vassilika Vouton, P.O. Box 1385, GR 711 10

Heraklion, Crete, Greece



**Stelios G. Sfakianakis** received his B.Sc. in computer science in 1995 and his M.Sc. with highest distinction in advanced information systems in 1998 from the University of Athens. In January 2000 he joined the FORTH's Center for eHealth Technologies group, where he works in the design and implementation of a component based architecture for the integrated electronic healthcare record using CORBA and web services as the middleware technology. His interests and work span from the design of relational or hierarchical databases to visual modelling with UML, open source operating systems, distributed object computing, and service oriented architectures.

His interests and work span from the design of relational or hierarchical databases to visual modelling with UML, open source operating systems, distributed object computing, and service oriented architectures.

e-mail: ssfak@ics.forth.gr

Center for eHealth Technologies

Institute of Computer Science (ICS)

Foundation for Research and Technology –  
Hellas (FORTH)

Science and Technology Park of Crete

Vassilika Vouton

P.O. Box 1385, GR 711 10

Heraklion, Crete, Greece



**Georgios Kavlentakis** received an electrical and computer engineering diploma with computer and electronics specialization from the Aristotle University of Thessaloniki in 1996. In April 1999 he joined the FORTH's Center for eHealth Technologies group, where he works in the implementation of an integrated electronic health-

care record using CORBA as the middleware technology. His interests involve the design of relational or hierarchical (like X.500/LDAP) databases, distributed computing and programming using C++, Visual Basic, PowerBuilder. His interests also involve the design and implementation of web-based applications.

e-mail: gkab@ics.forth.gr

Center for eHealth Technologies

Institute of Computer Science (ICS)

Foundation for Research and Technology –  
Hellas (FORTH)

Science and Technology Park of Crete

Vassilika Vouton

P.O. Box 1385, GR 711 10

Heraklion, Crete, Greece



**Stelios C. Orphanoudakis**

was the Director of the Foundation for Research and Technology-Hellas (FORTH) and Chairman of its Board of Directors, until his death in 2005. He was also President of ERCIM (European Research Consortium for Informatics and Mathematics). He held a Ph.D. degree in electrical

engineering from the Thayer School of Engineering, Dartmouth College, USA, a M.Sc. degree in electrical engineering from the Massachusetts Institute of Technology (MIT), and a B.A. degree, *magna cum laude* with highest distinction in engineering sciences, from Dartmouth

College. From 1986, he held a faculty appointment as Professor of computer science at the University of Crete, Greece. Furthermore, from 1991 until 1994, he was Acting Director of the Institute of Computer Science-FORTH (ICS-FORTH) and, from 1994 until 2004, he was Director of this Institute. At ICS-FORTH, he was the scientific leader of the Center for Medical Informatics and Health Telematics Applications and the Computational Vision and Robotics Laboratory. He held a faculty appointment in the Departments of Diagnostic Radiology and Electrical Engineering at Yale University, USA, from 1975 until 1991. Professor Orphanoudakis was a member of many honorary and professional societies and a Senior Member of the Institute of Electrical and Electronics Engineers (IEEE). He was the author of more than 120 publications in international scientific journals, refereed conference proceedings and books.