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Mariangela Contenti *Campus Bio Medico University, Faculty of Biomedical Engineering,* m.contenti@unicampus.it

Gregorio Mercurio National Research Council, Institute for Biomedical Technology, gregorio.mercurio@itb.cnr.it

Fabrizio Ricci National Research Council, Institute for Biomedical Technology, fabrizio.ricci@itb.cnr.it

Luca Serbanati National Research Council, Institute for Biomedical Technology, luca@serbanati.com

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LUMIR: THE EHR-S IN THE BASILICATA REGION

Contenti, Mariangela, Campus Bio Medico University, Faculty of Biomedical Engineering, Via Àlvaro del Portillo 21, I-00128, Rome, Italy, m.contenti@unicampus.it

Mercurio, Gregorio, National Research Council, Institute for Biomedical Technology, Circonvallazione Nomentana 496, I-00162, Rome, Italy, gregorio.mercurio@itb.cnr.it

Ricci, Fabrizio, National Research Council, Institute for Biomedical Technology, Circonvallazione Nomentana 496, I-00162, Rome, Italy, fabrizio.ricci@itb.cnr.it

Serbanati, Luca, National Research Council, Institute for Biomedical Technology, Circonvallazione Nomentana 496, I-00162, Rome, Italy, Iuca@serbanati.com

Abstract

The Lucania – Medici in Rete (LuMiR) project aims to support the changing environment in the Italian National Health Systems, embodying a shift from organisation-centric to patient-centric healthcare service delivery in the Basilicata Region. The project main objective is to foster collaborative, cross-organizational and patient-centric healthcare processes, with a suite of shared e-services supporting the interoperability of active stakeholders' IT applications and the exchange of patient related clinical information. In the paper the LuMiR project approach and its aim to overcome some limitations of the EHR-S national recommendation are discussed. The methodology adopted in the design and development of the LuMiR system to comply with institutional constraints and to better support a gradual change in the daily working practice of healthcare professionals is described, together with details on the LuMiR system architecture and remarks on the interventions scheduled to cope with possible hindrances for the large scale adoption of the LuMiR system itself.

Keywords: Electronic Health Record System, Service Oriented Architecture

1 INTRODUCTION

Recent trends in healthcare service delivery emphasize integrated and patient-centric care, i.e. the continuity and co-ordination of care, along the continuum of a disease, within multidisciplinary teams and across multiple points of care (Kodner and Spreeuwenberg, 2002). Individual medical encounters are encompassed within complex processes of care (e.g. in the disease management), and the timely provision of patient related medical information at the points of care assists professionals in taking more informed decision, in delivering more appropriate care and in preventing medical errors. In this respect a promising strategy to protect the economic sustainability of the healthcare sector and to improve the quality of services is the systematic adoption of ICTs along the whole value chain, and in particular in the service delivery (e.g. Europe's Information Society Thematic Portal - ICT for Health, http:// ec.europa.eu/information_society/ehealth/).

The LuMiR39 project intends to support this changing environment embodying a shift from organisation-centric to patient-centric models of service delivery in the Basilicata region. The project primary objective is to foster collaborative and cross-organizational healthcare delivery processes, supporting them with a suite of e-services for the communication and sharing of patient related clinical information. It also aims to assist other business activities (e.g. administration and governance of healthcare organization, epidemiology, public health, etc.) by providing ICT support for the secondary use of (de-identified) patient related clinical data.

³⁹ The Lucania – Medici in Rete (LuMiR) project is jointly carried out by the Institute of Biomedical Technologies of the Italian National Council of Research and the Basilicata Region (website: www.sanitaelettronica.cnr.it/lumir (in italian)).

Section 2 describes the Italian e-Health institutional initiatives which frame the LuMiR project. Section 3 introduces the Basilicata region and the heterogeneous environment in which the LuMiR project has been carried out. In Section 4 the LuMiR approach is presented together with its incremental three-phased life cycle. Architectural details on the LuMiR system are provided in Section 5, and additional details on the ongoing implementation activities conclude the paper in Section 6.

2 EHEALTH INSTITUTIONAL INITIATIVES IN ITALY

Several countries worldwide are heavily involved in managing and monitoring national roadmaps to innovate the healthcare sector (e.g. see (eHealth ERA, 2007)), and novel eHealth infrastructure and applications are pervading both the front-office and the back office of the healthcare delivery system. At the heart of many complex platforms there is the Electronic Health Records System (EHR-S) (Tang, 2003), which serves the operational provision and management of healthcare services and addresses a subset of interdependent clinical, relational, administrative, and managerial needs , where the subset varies with the specific implementation goals and supported business processes.

In Italy, numerous eHealth programs and projects have been carrying out. Whereas the precursors started by autonomous regional or local initiatives (e.g. (Tubertini and Darchini, 2008), (Servicio Andaluz de Salud, 2006)), several others are now following European directives and national roadmaps (briefly described in (eHealth ERA, 2007)). Actually, since 2005, an Italian permanent eHealth Board, the so called Tavolo di Sanità Elettronica (hereby TSE), was established to carry out a national strategy for eHealth in order to:

- i. harmonize the individual eHealth initiatives promoted in the federated regional governments; and
- ii. support a coordinated implementation of interoperable ICT infrastructures and applications.

To this aim the TSE issued a general and comprehensive eHealth conceptual framework (TSE, 2005), as well as an architectural framework for a software infrastructure supporting distributed healthcare processes, namely the eHealth Basic Infrastructure (Infrastruttura di Base per la Sanità Elettronica, hereby IBSE) (TSE, 2006).

Among the several initiatives undertaken in Italy, the GP's Network Pilot Program (Rete di Medici di Medicina Generale, hereby RMMG) targets the primary care settings in 9 Regions located in the centre and in the south of the country. The program was jointly funded by the Ministry of Technological Innovation and the Ministry of Economy and Finance in 2006; its aims is to foster the implementation and adoption of ICT solutions which, in compliance with the TSE specification, stimulate and support the cooperation of general practitioners (GPs) and paediatricians with other healthcare professionals in the delivery of ICT-enhanced integrated healthcare services.

3 THE BASILICATA REGION AND THE LUMIR PROJECT

The LuMiR project is the enactment of the RMMG Program in the Basilicata Region. The Basilicata is a region in the south of Italy, administratively divided in two provinces (Potenza and Matera), with a population of 596,546 citizens, mainly concentrated in the major cities⁴⁰. The Region has a negative demographic growth, an aging of population and a strong depopulation of the hinterland villages towards the more developed areas. The territories, predominantly mountainous, present a wide environmental diversity and an insufficient development of transport infrastructures. In the Basilicata there is in fact a single little airport, railroads are nearly completely lacking, and only five important highways serve the street traffic.

⁴⁰ 56% of the citizens live in the 12 major cities of the region, 27% live in medium towns (with a population comprised between 5,000 and the 9,999 inhabitants), and the remaining 17% live in the smaller villages.

The institutional structure of the Regional Healthcare System has been recently reorganized and two provincial Local Health Authorities (LHAs) (ASM and ASP), absorbed the pre-existing smaller five. The two LHAs are entitled of the delivery of primary care and public health services as well as specialized medical attention. To this last aim they administer and manage, respectively, 3 and 4 complex structures, which provide both inpatient and outpatient care, as well as many other smaller structures for outpatient care. More in details primary care is in charge to a total of 510 general practitioners, 70 paediatricians, 108 among ambulatories and laboratories for specialist outpatient services, and 140 points of medical guard. Inpatient and outpatient care is also provided by the San Carlo Hospital Trust, a public hospital, autonomous from the LHAs, and by the Crob Oncology Regional Hospital, a regional institute for research and care. Reflecting the geographical and demographical characteristics of each area, as well as the organization and distribution of the local healthcare facilities, the business processes supporting the service delivery in the daily working practice sensibly vary from site to site.

Regarding the diffusion of ICTs in healthcare, many software vendors operate in the market providing products and services to the different Points of Care (PoCs), even if the level of automation is not uniform. Adopted products include a couple of integrated Hospital Information Systems, a certain number of specialized applications supporting the operational activities of specific hospital departments and/or individual ambulatories, and several Electronic Medical Records for GPs and paediatricians offices. Also, some other ICT systems for healthcare have been developed and managed centrally by the Region. The more relevant for the LuMiR project are:

- a) a registry of citizen anagraphical records specific for healthcare purposes;
- b) a cross-organization booking system for ambulatory healthcare services,
- c) a cross-organization system for first aid/hospital admission and discharge;
- d) a distributed authoring tool and a centralized repository for medical reports; and
- e) a specialised asynchronous teleconsulting service for cardiology.

In this heterogeneous environment the LuMiR project main objective is the design, development, and deployment of the LuMiR system, an EHR-S which interconnects at application level the computerized information systems running in the individual PoCs (Figure 1), and also integrates some other preexisting healthcare IT applications supporting specific regional information flows (registries and/or repositories). The LuMiR project is constrained by institutional guidelines and recommendation issued by the TSE and by an RMMG harmonisation workgroup, part of which initially under development and still in continuous evolution; in the long term all the public PoCs and professionals operating in the territory will be involved, as well as the citizens who could be able to freely access the information on their own health status.

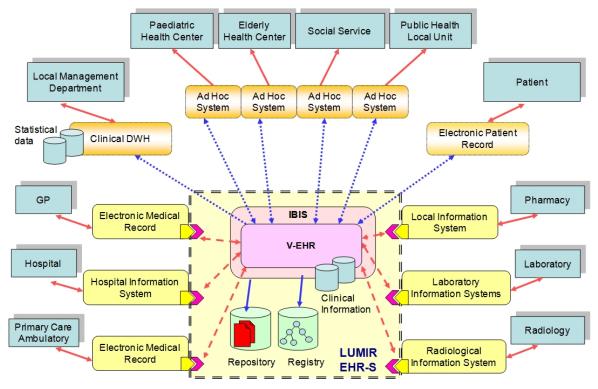


Figure 1: The LuMiR system conceptual architecture

4 THE LUMIR SYSTEM APPROACH

The LuMiR system design was based on the following principles capturing business domain and/or software engineering meaningful aspects:

- a) support to patient-centric care;
- b) use of multiple views on EHR contents;
- c) promotion of technical and semantic interoperability;
- d) integration of legacy applications;
- e) enforcement of national guidelines and international standards;
- f) promotion of re-usability;
- g) easy adaptability to changes in the environment; and
- h) assurance of information security and privacy by policy-based configurable models.

To incarnate these principles the LuMiR system is a suite of shared eServices, enabling the interoperability among active stakeholders' IT applications in order to support integrated and patient centred care delivery.

The design and development of the LuMiR system was constrained by the TSE recommendations for the EHR-S (part of the IBSE architectural framework) and due to the many institutional, organizational and technological issues claiming attention, an incremental life cycle has been followed. It was enriched with a socio-technical perspective based on the awareness that healthcare services are produced and delivered through interaction of people, technologies and business processes and, that changes in one of the elements produce further changes in the others. Actually three incremental releases of the LuMiR software infrastructure were planned (LuMiRp0, LuMiR1, and LuMiR2) with the aim not only to

implement the TSE architectural and functional specifications but also to extend them in order to overcome some limitations.

The TSE specification considers the EHR-S as a document-oriented healthcare information system. More in details a core component of IBSE is the Health Individual Broker (InfoBroker Individuale Sanitario, hereby IBIS) which implements an efficient storage and routing of digitally signed electronic clinical documents, by storing, referencing, notifying, and making them available to the authorized healthcare providers.

It relies on a federated Registry/Repository system in which: *(i)* a Registry stores document content metadata; and *(ii)* a Repository is a storage where electronic documents (pointed at by Registry records) reside and are retrieved by their name or properties. In this approach, the software applications at the PoCs produce clinical documents compliant with the HL7 CDA r2 standard, load them in the IBIS Repository and register their metadata in the IBIS Registry for future access by the interested and authorized healthcare professionals. Figure 2 depicts the IBIS main components and services.

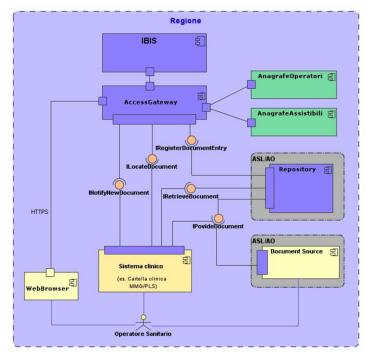


Figure 2: IBIS main components and services (edited from TSE)

This approach enforces the legal value and is compliant with the Integrating the Healthcare Enterprise initiative's Cross Enterprise Document Sharing profile (IHE-XDS) for cross-organization exchange of citizen related digitally signed clinical documents. Nevertheless, it is not completely responding to the real environment constraints and end-users needs encountered in Basilicata. Actually in the assumption of the IBIS architecture, the legacy system of an individual PoC is able to produce, provide and register clinical documents, but also to import and internally process the metadata related to clinical documents produced by other PoCs, which are registered in the IBIS Access Gateway (AG) and then notified to all those PoCs who subscribed for them.

In the Basilicata experience some of the software vendors have been not technologically ready or strategically willing to introduce part of these changes in their software applications, especially for what concern the processing of metadata related to documents produced by other PoCs. It means that in the short term the sole interface through which healthcare professionals can navigate and manage the EHR contents is via a Web Browser. But the number of clinical documents related to a single citizen can grow sensibly, especially if a chronicle disease affects him/her. The lack of support services through which classify and organize his/her EHR documents and contents from a clinical perspective, could return the search and collection of relevant information in a procedure which does not fit the daily working

practice, is not efficient and effective and at high risk to be refused by healthcare professionals. To overcome these limitations, in the LuMiR approach the IBIS specification has been extended in two opposite directions:

- On one side some additional key concepts, i.e *Contact, Episode of Care* and *Health Issues*, were introduced in the LuMiR system design. Briefly, a Contact is a set of healthcare services (HCService), provided by a care professional during an encounter with the patient, considered relevant for the patient's healthcare status documentation and described in a clinical document. An Episode of Care is a sequence of correlated and chronologically ordered HCServices associated with a patient Health Issue. These concepts have a quite long tradition in the healthcare literature (Solon et al. 1967, Claus et al. 1997) and have been also introduced in some healthcare standards (e.g. CEN TC/251 EN 13940-1:2006). They offer a mean to classify and organize patient related clinical document, and can be used to simplify the consultation of a patient EHR. In order to support these additional concepts in the LuMiR system an additional component, namely the LuMiR Infobroker, was introduced. It is further described in Section 5;
- On the other side, additional functionalities have been introduced in the LuMiR system with the objective to refine the course granularity of documents. Actually in order to answer complex and longitudinal user-requests, as for instance in the synthetic grouping or charting of some biological parameters, a set of documents can reveal hard to process. For these kinds of user-request it is preferable to manage smaller chunk of content or atomic structured data and aggregate them according to pre-defined or on-demand forms. In order to cope with this additional functionalities, in the LuMiR architecture the Virtual Healthcare Record (VHR) component has been introduced (Serbanati et al., 2008). The description of this component is outside the scope of this paper.

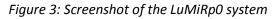
5 PHASING THE LUMIR SYSTEM DEVELOPMENT

The development of the software infrastructure was subdivided in components with well-defined interfaces, and different software houses were entrusted of their implementation. Other software houses, providers of the legacy systems running in the PoCs enrolled in the project, were also involved in order to implement integration components for the LuMiR system. In the following LuMiR p0 and LuMiR1 are briefly presented and discussed.

LuMiRpO is an early prototype, used as a sort of trial environment to carry out a field experiment. With a relaxed implementation of the non-functional technological aspects (e.g. security, privacy and reliability), it serves small groups of selected healthcare professionals, providing them with all those patient related medical information and documents promptly available and easily collectable, because already archived in digital format in some regional or local healthcare information systems. To this aim the LuMiRpO system integrates minimal services for sharing and storing patient related clinical data, but introduces to the end-users the key concepts of Contact, Episode of Care and Health Issue.

Figure 3 presents a screenshot of the Viewer physicians operate for browsing patient related medical data. Thanks to the release of the LuMiR p0 prototype, care providers were involved in the project since the first phase, and this makes it possible to: (*i*) better elicit when and how clinicians cooperate together and exchange documents and information in order to promote a paradigm shift toward integrated care, more centred on communication and collaboration among professionals; (*ii*) identify how and in which contexts the LuMiR system could simplify and empower daily working practices; and (*iii*) identify some quantitative indicators to measure the improvement resulting from the new approach to patient care.

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LuMiR1 is a distributed and component-based software system more focused on the interoperability, security, privacy and reliability issues. It is based on a peer-to-peer communication infrastructure and implements a Service Oriented Architecture (SOA). By using (i) software adapters it integrates the PoCs IT applications, each of which is a producer and/or consumer of clinical information. The LuMiR1 components also include: (ii) the actual implementation of the TSE recommendations for the EHR-S, including the IBIS document-oriented Registry/Repository for the storage and sharing of digitally signed clinical documents as well as the Public Cooperative System software framework (Sistema Pubblico di Cooperazione), a technical and organizational nationwide large scale e-Government SOA providing network, communication, basic interoperability, application cooperation and security services among jurisdictionally independent public administrations (Domains); (iii) the LuMiR Infobroker, which support the management of the LuMiR approach additional concepts. Figure 4 depicts the functioning of the LuMiR Infobroker. Morever, the interaction among the LuMiR1 system, any PoC application (whatever a legacy system or an ad-hoc application), and the IBIS AG are the following:

- During the storage phase
 - 1. The PoC application captures all related medical information about a patient-doctor encounter, produces one or more HL7-CDA documents and via an ad hoc software driver passes them to a standard Adapter;

- The standard Adapter encapsulates (in an HL7 v3 message) information on Contact, Episode of Care and Health Issue as well as the HL7-CDA document(s) as attachment(s) and forwards it to the LuMiR InfoBroker via a dedicated, document-style web-service interface. The standard Adapter is implemented by using messaging-based integration patterns (Hohpe and Woolf, 2003);
- 3. The LuMiR Infobroker processes the messages received, extracts the attachment document(s), stores them in appropriate repositories, and registers their metadata in the IBIS AG's registry. Then the Infobroker stores the information related to Contact, Episode of Care and Health Issue, together with the links to the document(s) metadata in the Viewer's repository;
- 4. The LuMiR Infobroker also forward a notification of the information related to Contact, Episode of Care and Health Issue and document(s) metadata to other PoCs, whose interest was expressed in advance(subscribers).
- During the retrieval phase
 - Healthcare professionals consult the contents of a patient EHR via the Viewer that, apart from technological changes transparent to the end users, looks and behaves as the LuMiRpO Viewer. More in details the information related to Contacts, Episodes of Care and Health Issues are retrieved from the LuMiR1 Registry, the documents metadata from the IBIS Registry and the documents by the IBIS Repository (Figure 3).

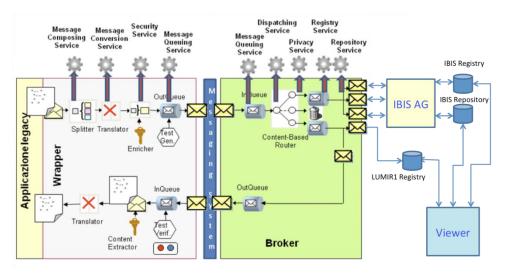


Figure 4: The LuMiR1 InfoBroker

Due to the fact that also the IBIS AG internally contains another Infobroker, this infrastructure actually realizes a two level broker-based architecture in which:

- multiple distributed IBIS AGs, one for each of the SPCoop Domain, interact with each other via the IBIS Infobroker, and
- a centralized LuMiR Infobroker plays the role of an intelligent mediator between PoCs software applications and the IBIS AG infrastructure.

Figure 5 is an UML sequence diagram exemplifying the interactions triggered by the arrival at the LuMiR InfoBroker of a message sent by the Standard Wrapper.

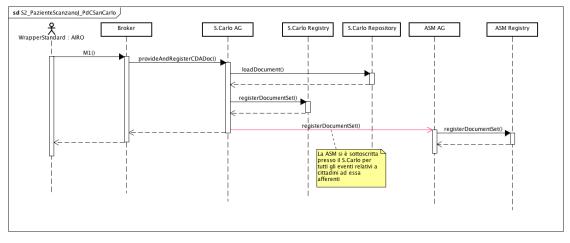


Figure 5: The LuMiR1 InfoBroker

6 REMARKS AND FUTURE WORKS

At the moment the field experiment with LuMiRp0 is near to be concluded in two different public healthcare organizations of the Basilicata Region. The development of the LuMiRp0 and its adoption in the field experiment were burdensome but fundamental activities. On one side, the simplification of the technological aspects facilitated the tasks in charge to the software vendors and allowed a rapid development of the integration adapters. Also the software vendors' involvement since the early stages of the project has been profitable for the establishment of a collaborative environment and business partnerships, strategic for the subsequent more complex phases of the project. On the other side, the design and development of the LuMiRp0 system, supported with narrative scenarios and focus groups, put the focus on the socio-technical dimensions and the actual business processes, enabling to elicit important system requirements. Also, the set up and execution of the field experiment provided important lessons learned on possible hindrances for the final adoption.

The release of the LuMiR1 system is scheduled for this summer, and the field experiences brought us to define a specific roadmap for the large scale adoption of the LuMiR system, in which key activities and their interdependencies were pointed out, and to organise a task force, in charge to support and monitor the adoption process. Actually, at the beginning the LuMiR project was mostly driven by the goal to develop and deploy a software platform implementation, nevertheless the additional efforts spent in disseminating and fertilizing the ICT-enhanced patient-centric idea, in supporting the redesign of more patient-centred primary care business processes, and in assisting and coordinating the software vendors for integrating their legacy application during the field study revealed even more important.

The design of LuMiR2 system, which will integrate data from the clinical documents into a VHR for each citizen, is in progress. Further development of the LuMiR architecture will incorporate other extensions, mainly focused on: (i) e-Services dedicated to the citizens and devoted to support their empowerment, (ii) healthcare process support with ICT capabilities to define, edit, enact, and monitor citizen care pathways.

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