LuMiR: The region-wide EHR-S in Basilicata

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Abstract

The Lucania – Medici in Rete (LuMiR) project aims to support the shift from organization-centric to patient-centric health-care in Basilicata, a region in the southern Italy. Main objective of the project is to foster collaborative, multidisciplinary and cross-organizational healthcare processes by developing and stimulating the adoption of a region-wide, software infrastructure, the LuMiR system,. It is a suite of e-services that facilitates the sharing of patient related clinical data among authorized professionals, by enabling the interoperability among Electronic Medical. In the paper the LuMiR project approach is discussed, pointing out the methodology adopted in the design and development of the LuMiR system, the peculiarities of the system architecture and interventions scheduled to mitigate the risks related to the large scale adoption of the LuMiR system itself.

Keywords:

Electronic health record system, Service oriented architecture.

Introduction

Recent trends in healthcare service delivery promote integrated and patient-centric care, i.e. the continuity and coordination of care, provided by multidisciplinary teams, along the continuum of a disease, and across multiple points of care (e.g. [1]). In these complex processes the timely availability of patient related medical information assists professionals in recomposing the fragmented activities, taking more informed decision, delivering more appropriate care and preventing medical errors. In this perspective the systematic adoption of Healthcare Information Technologies (HITs) is a promising opportunity to innovate the healthcare sector, to protect the economic sustainability of healthcare services and to improve their quality. The LuMiR project[1] intends to support the shift from organisation-centric to patient-centric models of service delivery in Basilicata, by promoting collaborative, multidisciplinary and cross-organizational healthcare delivery processes and supporting them with a software infrastructure that provides services for sharing patient related clinical data among authorized healthcare professionals.

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[1] 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 (in italian): www.sanitaelettronica.cnr.it/lumir).

Our format introduces the Italian e-Health institutional initiatives which frame the LuMiR project, followed by describing the Basilicata region, its healthcare system, and the heterogeneous environment in which the LuMiR system is to be deployed. The next section describes how the LuMiR approach is presented together with its incremental three-phased life cycle. Architectural details on the LuMiR system are then provided, and additional details on the ongoing implementation activities conclude the paper.

eHealth Institutional Initiatives in Italy

The planning and programming of strategies to innovate the healtcare sector (e.g. [2]) has well as their carrying out has been keeping busy many industrialized countries all over the world. e-Health applications are pervading both the back-office and the front-office of the healthcare delivery systems. At the heart of many complex platforms there is the Electronic Health Records System (EHR-S) [3], a system for recording, retrieving and manipulating information in electronic health records. Such an EHR-S serves a variable set of interdependent clinical, relational, administrative, and managerial needs, according to the specific implementation goals and business processes to support.

Numerous eHealth programs and projects have been carrying out in Italy. The precursors started by regional or local autonomous initiatives (e.g. [4, 5]). The more recent are following European directives and national roadmaps (as described e.g. in [2]). Actually, since 2005, a national permanent eHealth Board (Tavolo di Sanità Elettronica, hereby TSE), was established to carry out a national strategy for eHealth in order: i) to harmonize the eHealth initiatives individually promoted by each of the 23 federated regional governments; and ii) to support a coordinated implementation of a cross-regional interoperable HIT infrastructure.

To this aim the TSE issued an high level conceptual framework [6], as well as an architectural specification for a software infrastructure for distributed healthcare processes, namely the eHealth Basic Infrastructure (Infrastruttura di Base per la Sanità Elettronica, hereby IBSE) [7].

The LuMiR project is the enactment in Basilicata of the GP's Network Pilot Program (Rete dei Medici di Medicina Generale, hereby RMMG). The RMMG program targets the primary care settings in 9 regions of the central and southern Italy. It was funded by the Ministry of Economy and Finance in 2006 and managed by the Department of Technological Innovation

of the Presidency of the Council of Ministers. It aims to foster the implementation and adoption of interoperable regional software infrastructures in order to stimulate and support the cooperation among general practitioners (GPs) or paediatricians and the other healthcare professionals in the delivery of ICT-enhanced integrated healthcare services.

The Basilicata region and the LuMiR Project

The Basilicata region covers 9,992 km², has a population of 596,546 citizens and a very low population density compared to that of Italy as a whole (in 2001about 61 vs 192)[2]. It is the most mountainous region in the southern Italy with citizens mostly concentrated in the major cities and the hinterland villages under-populated. Transport infrastructures are scarcely developed with railroads nearly completely lacking, and only five important highways serving the street traffic.

The Regional Healthcare System has been recently reorganized in two Provincial Health Authorities (PHAs) (the ASP and the ASM), which are entitled of managing and carrying out the delivery of healthcare services for all the welfare beneficiaries. The PHAs directly manage respectively 3 and 4 hospitals, each of which providing both inpatient and outpatient care, as well as many other smaller clinics for outpatient care disperse in the territories. More in details in the Basilicata region primary care is in charge to a total of 510 general practitioners, 70 paediatricians and 140 points of medical guard. Secondary outpatient care is also provided by 108 among public ambulatories and laboratories as well as many more authorized private ambulatories[3]. Secondary and tertiary care is also provided by the San Carlo Hospital Trust, a public hospital autonomous from the PHAs, and by the Crob Oncology Regional Hospital, a regional institute for research and care.

The healthcare processes supporting the daily services delivery sensibly vary from site to site, reflecting the geographical and demographical peculiarities of each area, as well as the distribution and organization of the local healthcare facilities. Also the diffusion of HITs and the level of automation in the healthcare value chain is heterogeneous, even if many local software vendors operate in the market. The software systems deployed in islands of automation include: (i) a certain number of specialized applications supporting operational and clinical activities in hospital departments and/or ambulatories, each one isolated from the others; (ii) only one fully integrated Hospital Information Systems, and (iii) several different EMR for GPs and paediatricians offices. The more relevant existing systems for the LuMiR project are: a registry of welfare beneficiaries' personal data; a cross-organization booking system for outpatient services; a networked service for the management of first aid/hospital admission, discharge and transfer; a distributed authoring tool for medical reports connected with a centralized repository; and a specialized asynchronous cardiac

teleconsulting system. In this heterogeneous environment the LuMiR project targets the design, development, and deployment of the LuMiR system, an interoperable EHR-S which interconnects at application level both software-intensive information systems running in individual points of care (Figure 1) and existing repositories which support specific regional information flows.
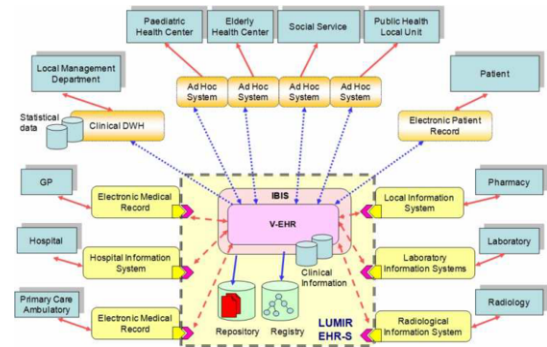

Figure 1- The LuMiR system conceptual architecture

More in general the LuMiR project intends to promote the diffusion of eHealth all over the region, accelerating the modernization process in all the points of care, stimulating the re-engineering of business processes and the development of novel services for professionals and citizens. According to the LuMiR project vision, in the long term all the public points of care in the region will be interlinked together via the LuMiR system and all the citizens will be able to freely access the information on their own health status. Other business activities which will indirectly benefit of the LuMiR system are those related with the secondary use of de-identified and aggregated clinical data and information (e.g. management and governance of healthcare organization, epidemiology studies, biomedical and healthcare research, etc.).

The LuMiR System approach

The design of the LuMiR system was influenced by the business requirements described above. It was also constrained by the guidelines issued by the TSE and the technical specification issued by a restricted RMMG harmonisation workgroup, part of which under development at the beginning of the project, and in continuous evolution during the project lifetime. The more relevant principles inspiring the LuMiR system design are: (i) use of multiple views on EHR contents; (ii) promotion of technical and semantic interoperability; (iii) integration of legacy applications; (iv) enforcement of national guidelines and international standards; (v) promotion of reusability; (vi) easy adaptability to changes in the environment; and (vii) assurance of information security and privacy by policy-based configurable models.

Due to the many institutional, organizational and technological issues, the development of the LuMiR system has been based on an incremental life cycle model. In this way a prototype implementing the core functionalities was early available.

It was used to better elicit the LuMiR system requirements with the direct involvement of the end-users following a socio-technical approach. Actually three incremental releases of the LuMiR software infrastructure were scheduled as described in the next section.

The LuMiR system was developed with the aim not only to receive the TSE guidelines and technical specifications, but also to extend them with some additional functionalities, in order to overcome some limitations they present.

The EHR-S is, in the TSE specification, a document-oriented healthcare information system. Actually the core component of IBSE is the Health Individual Broker (InfoBroker Individuale Sanitario, hereby IBIS), which implements an efficient storage of digitally signed clinical documents, by referencing, routing, notifying, retrieving and making them proactively and/or on-demand available to the authorized healthcare providers. This approach is compliant with the Integrating the Healthcare Enterprise initiative's Cross Enterprise Document Sharing profile (IHE-XDS) for cross-organization exchange of patient related clinical documents. In addition, the mandatory requirement that each document circulating in IBIS have to be digitally signed (e.g. by its author) reflects an important business rule in the healthcare domain. Actually it is intended to enforce the legal value of clinical documents (e.g. prescription, referral, certificates) which, in the paper-based daily working practice need to have handwritten signatures. At the same time this approach is coherent with the larger process of paper dematerialization. Nevertheless, it is not completely responding to the end-user need as emerged in the real environments observed in Basilicata. Actually the number of clinical documents related to a single citizen can grow sensibly, especially if a chronicle disease affects him/her. This means that healthcare professionals need value added services through which classify and organize, from a clinical perspective, the huge amount of IBIS contents. Actually if these services are missing the search and collection of a restricted set of meaningful patient related clinical information could reveal not sufficiently efficient and effective. This in turn implies that the overall software system runs the risk to be refused by healthcare professionals. Thus, in order to overcome these limitations, in the LuMiR approach the IBIS specification was extended in two opposite directions:

[1] some additional concepts, i.e. Contact, Episode of Care and Health Issues, were introduced to support different level of classification ;

[2] other additional functionalities were introduced with the objective to refine the course granularity of documents.

In respect of the former intervention, a Contact is a set of Healthcare Services (HCService), each of which provided by an healthcare professional during an encounter with the patient, considered relevant for the patient's healthcare status documentation and described in one or more clinical documents. 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 [8] and also recur in some healthcare standards (e.g. CEN TC/251 EN 13940-1:2006). They offer a mean to classify and organize patient related clinical docu-

ments, and can be used to simplify the consultation of a certain patient's IBIS content. In order to support these concepts in the LuMiR system an additional component, namely the LuMiR Infobroker, was introduced. It is described in the next section.

On the other side 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 requirement, in the LuMiR architecture the Virtual Healthcare Record (VHR) component has been introduced [9]. The description of this component is outside the scope of this paper

Phasing the LuMR system development

In the following LuMiRp0 and LuMiR1 are briefly discussed. LuMiRp0 is an early prototype where large part of the non-functional requirements (e.g. security, privacy and reliability) were neglected. It was rapidly developed in order to be used as a sort of trial environment to carry out a field experiment. It served small groups of selected healthcare professionals, providing them with all the medical information and documents about a restricted set of volunteer patients that where easily collectable, because already archived in digital format in some regional or local healthcare information systems. To this aim the LuMiRp0 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 described above.

Figure 2 presents a screenshot of the Viewer that 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 early phases, and this made possible to:

- better understand in which situations GPs (paediatricians) and clinicians effectively cooperate together in the care of their patients;

- identify how and in which contexts the LuMiR system could promote a paradigm shift toward integrated care, more centred on communication and collaboration among professionals; simplifying and empowering the daily working practices; and

- identify some measurable quantitative indicators to evaluate the improvement resulting from the new approach to patient care.

LuMiR1 is a distributed, component-based system 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). To integrate legacy as well as new client-applications LuMiR1 promotes a standard adapter and various specific drivers that adjust the peculiarities of any of these client-applications at the uniform, standard-based LuMiR1 internal space requisites.

On the server-side the LuMiR1 components include:

Figure 2- Screenshot of the LuMiR p0 system

- the Public Cooperative System software infrastructure (SPCoop);
- the IBIS components for sharing of digitally signed clinical documents;
- the LuMiR Broker which provides high-level services of message dispatching, event notification, document management, and security.

SPCoop is 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). IBIS is the document-oriented federated Registry/Repository system in which: *(i)* a federated ebXML-based Registry stores document content metadata; *(ii)* Repositories are storages where electronic documents (pointed at by Registry records) reside and are retrieved by their name or properties; and (iii) Access Gateways (AG) demarcate jurisdictional domains by controlling accesses in/from the domain . According to the TSE recommendations, in the actual implementation of IBIS, the exchanged clinical documents are compliant with the HL7 CDA r2 standard and the ad-hoc restriction defined by the RMMG harmonisation workgroup. Figure 3 depicts the functioning of the LuMiR Infobroker.

From a behavioral point of view, the interaction among the LuMiR1 system, any PoC EMRs (whatever a legacy system or an ad-hoc application), and the IBIS AGs is described in the followings.

During the storage phase:

- The doctor captures with his/her PoC application all the medical information about each encounter with his/her patients. For each encounter he/she, produces one or more correlated HL7-CDA documents, and via an ad-hoc software driver passes them to the LuMiR standard Adapter;
- The standard Adapter encapsulates in an HL7 v3 message the information on the Contact, the Episode of Care and the Health Issue, as well as the HL7-CDA document(s) in attachment, and forwards it to the LuMiR Broker via a dedicated, document-style web-service interface. The standard Adapter is implemented by using messaging-based integration patterns [10];
- The LuMiR Broker processes the received message, extracts the attached document(s), asks to the appropriate AG to store them in appropriate repository and register their metadata in the ebXML Registry. Then the Infobroker stores the information related to Contact, Episode of Care and Health Issue, together with the unique identifiers of the stored documents in the Viewer's repository;
- The LuMiR Broker also notify the information related to Contact, Episode of Care and Health Issue and document(s) metadata to all PoCs who subscribed their interest in receiving the notification ,.

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 LuMiRp0 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 2).

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.
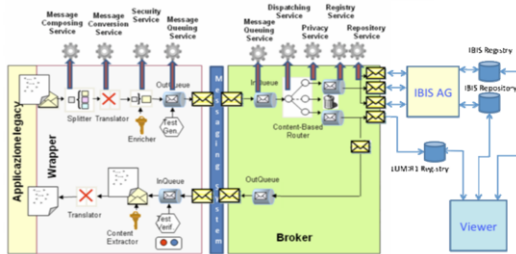

Figure 3-The LuMiR1 InfoBroker

For the system development two different software houses were entrusted of the implementation of different component. Also those software houses providing one of the legacy systems running in the PoCs enrolled in the project, were involved in order to implement software adapters for the integration of their products with the LuMiR system.

Discussion and Conclusion

At the moment the field experiment with LuMiRp0 is 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 involvement of the software vendors 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 LuMiR1 system is released 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.

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