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Implementing standards for the interoperability among healthcare providers in the public regionalized Healthcare Information System of the Lombardy Region

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ABSTRACT

Information technologies (ITs) have now entered the everyday workflow in a variety of healthcare providers with a certain degree of independence. This independence may be the cause of difficulty in interoperability between information systems and it can be overcome through the implementation and adoption of standards. Here we present the case of the Lombardy Region, in Italy, that has been able, in the last 10 years, to set up the Regional Social and Healthcare Information System, connecting all the healthcare providers within the region, and providing full access to clinical and health-related documents independently from the healthcare organization that generated the document itself. This goal, in a region with almost 10 millions citizens, was achieved through a twofold approach: first, the political and operative push towards the adoption of the Health Level 7 (HL7) standard within single hospitals and, second, providing a technological infrastructure for data sharing based on interoperability specifications recognized at the regional level for messages transmitted from healthcare providers to the central domain. The adoption of such regional interoperability specifications enabled the communication among heterogeneous systems placed in different hospitals in Lombardy. Integrating the Healthcare Enterprise (IHE) integration profiles which refer to HL7 standards are adopted within hospitals for message exchange and for the definition of integration scenarios. The IHE patient administration management (PAM) profile with its different workflows is adopted for patient management, whereas the Scheduled Workflow (SWF), the Laboratory Testing Workflow (LTW), and the Ambulatory Testing Workflow (ATW) are adopted for order management. At present, the system manages 4,700,000 pharmacological e-prescriptions, and 1,700,000 e-prescriptions for laboratory exams per month. It produces, monthly, 490,000 laboratory medical reports, 180,000 radiology medical reports, 180,000 first aid medical reports, and 58,000 discharge summaries. Hence, despite there being still work in progress, the Lombardy Region healthcare system is a fully interoperable social healthcare system connecting patients, healthcare providers, healthcare organizations, and healthcare professionals in a large and heterogeneous territory through the implementation of international health standards.

1. Introduction

The advent of information technologies (ITs) in medicine and healthcare is now facing a scenario in which a variety of healthcare providers have introduced ITs in their everyday workflows with a certain degree of independence [1–14]. This independence may be the cause of difficulty in interoperability between information systems [15–19]. This difficulty stems also because heterogeneous generations of IT systems were acquired through time, even over decades. At the same time, the development and adoption of medical IT standards were evolving, and the evolution is still underway [19–25]. The lack of clear and definite political guidelines favoured the emerging difficulties in obtaining interoperable systems able to exchange and share data [5,26,27].

Besides hospitals, the actors of healthcare processes include patients, general practitioners, specialists, nurses, and pharmacists, each characterized by a specific profile, with specific aims and specific needs of data, information, and services.

In this general scenario, the adoption and implementation of standards is a possible solution.

In this manuscript, we present the case of the Lombardy Region, in Italy, that has been able, in the last 10 years, to set up the Regional Social and Healthcare Information System (SISS, from the Italian acronym of Sistema Informativo Socio Sanitario). This system

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connects all the healthcare providers within the region, and provides full access to clinical and health-related data and documents wherever and whenever generated. This goal, in a region with almost 10 millions citizens, was achieved through a twofold approach: first, the political and operative push towards the adoption of the Health Level 7 (HL7) standard within single hospitals and, second, providing a technological infrastructure for data sharing based on regionally recognized interoperability specifications.

1.1. Case background

The Lombardy Region is positioned in the North of Italy, with a large, heterogeneous territory (23,863 km^2), spreading from the Po valley to the Alps, and almost 10 millions citizens.

In the Italian healthcare system, regional governments cover the healthcare costs of each Italian citizen resident in the region. Costs of drug therapies, surgical interventions, laboratory examinations, and all healthcare services are almost fully covered. In Lombardy, healthcare organizations consist of hospitals, either public or private, private laboratories, general practitioner (GP) offices, private practices, and all the facilities providing healthcare services to the citizen. The "Local Healthcare Units" (ASL – Azienda Sanitaria Locale, in Italian) are committed to the management of all the services for healthcare and assistance in a specific geographical area within the region. Healthcare workers include pharmacists, GPs, hospital physicians, specialists, nurses, front office personnel, Regional Call Centre personnel, and they are the users of the Regional Healthcare Information Systems. For primary care, each citizen refers to a GP, who is chosen within the local healthcare unit where the patient resides.

In 2000, the Lombardy Region started the implementation of the CRS–SISS (Italian acronym indicating Regional Healthcare Card-Healthcare Information System – Carta Regionale dei Servizi–Sistema Informativo Socio Sanitario), that, at present, provides healthcare IT services to 9,900,000 citizens, 150,000 Health and Social Care Workers, 7800 GPs, 2600 pharmacies, 35 public hospitals, 15 local healthcare units, and over 2500 private healthcare organizations.

Table 1 describes the milestones of the regional information system development. At the end of 1970s, the preliminary steps of clinical and administrative data collection of patients living within the region were started. Information regarding hospitalizations, outpatient visits, and medications were collected on a monthly basis by the Regional government. In 1982, the central patients' and GPs' registries were set up. The unified vision of the CRS–SISS project started in 1999. At present, it covers the 100% of Lombardy citizens. The system was designed, implemented, and managed by Lombardia Informatica, an IT service company, founded in December 1981, and fully owned by the Lombardy regional government.

In 2010, the Lombardy Region, in response to a national government initiative, introduced the Life-long personal health record (PHR), consisting of the collection of all the electronic documents regarding the healthcare of a single citizen, with the aim of making available to any healthcare provider the full and updated clinical documentation regarding a patient, also in the case of emergency, regardless to the healthcare organization where the document was produced. The model proposed by the Italian law can be considered as a kind of "integrated PHR" [28]: the patient owns healthcare data and decides who has the right to access their life-long PHR, but the record is lifelong and is built up from the documents created by different providers. The Lombardy information system has implemented the lifelong PHR following the Italian national guidelines recently issued.

2. Conceptual framework

The implementation of the system in the Lombardy Region followed a conceptual framework based on these working hypotheses:

a. The system should provide large-scale integration among different healthcare organizations within the region, to serve the patients.
b. The system should manage basic digital healthcare services for citizens, particularly the centralized exam booking system, e-prescriptions, the life-long PHR, and the centralized citizen registry. As shown in Fig. 1, these basic services are needed to implement all healthcare processes, starting from the patient who needs health assistance: if there is no emergency, the patient goes to their GP who prescribes a drug therapy (to be taken to the pharmacy), or an exam, or a consultation with a specialist. The GP sends an e-prescription to the central registry, through the e-prescription service. In the case of a drug prescription, the e-prescription is retrieved by the pharmacy, and the medication is given to the patient. In the case of an examination request or of a visit to a specialist, the patient can book using the centrally managed booking service; either personally over Internet or with the help of the Regional Call Centre, the patient retrieves the prescription electronically, and books the examination. Any clinical electronic document (CED) produced in any healthcare organization within the region is indexed in the Central Registry of Clinical Data, to populate the life-long PHR of each patient, together with e-prescriptions. In the case of emergency, the emergency doctor can access patient's lifelong PHR, and obtain a full picture of patient's history.
c. Even though health IT systems are already widespread, they are fragmented because IT local systems differ from healthcare organization to healthcare organization, and also within the same organization: hospitals are usually composed of

Table 1
CRS–SISS project milestones.

Year	Milestone of the Lombardy information system development
1978	Collection and filing of information relative to hospitalizations: All public hospitals send monthly files listing patient hospitalizations
1982	Establishment of Regional Personal Data Registry for Citizens and General Practitioners: A registry of personal data (tax-code, name, surname, date of birth, address, ...) of all Lombardy citizens; a registry of all Lombardy GPs; the association between citizens and GPs
1985	Collection and filing of information relative to pharmaceutical distribution: All pharmacies send monthly files listing drugs dispensed to citizens
1997	Collection and filing of outpatient visits data: All public hospitals send monthly files listing outpatient visits
1999	CRS–SISS project requirements definition and feasibility analysis
2000	Start of the onsite pilot project in the Lecco District (300,000 citizens)
2002	Project Financing and beginning of the expansion to all Districts
2004	Two million citizens involved in the CRS–SISS System: The CRS (Carta Regionale dei Servizi – Regional Services Card) is distributed to two million citizens
2005	100% citizens involved in the CRS–SISS System: All Lombardy citizens receive their card
2008	Healthcare Private Sector interfacing: The Project involves the Private Sector as well as the Public Sector
2010	Lifelong personal health record started

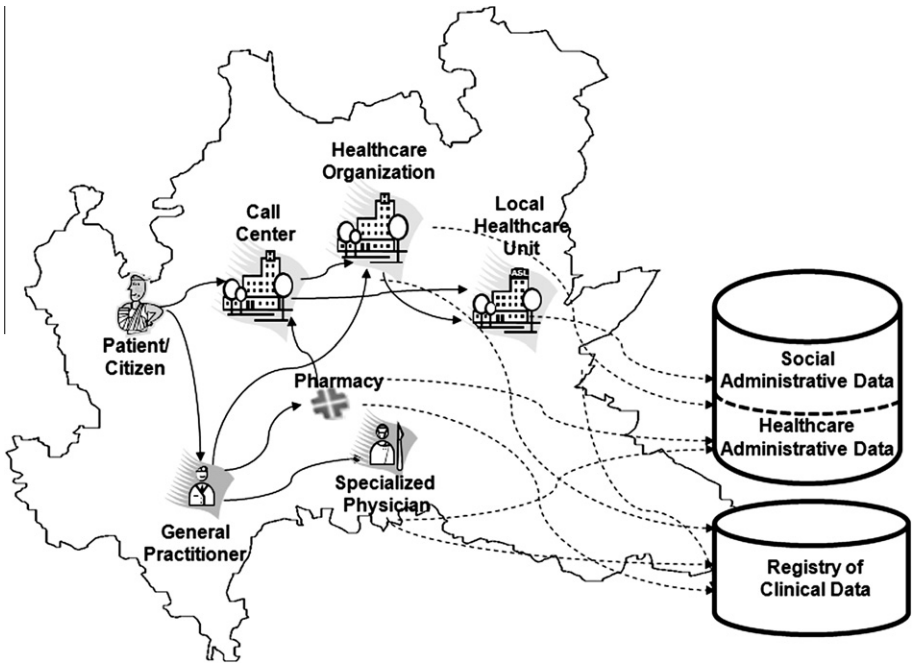

Fig. 1. Healthcare actors and processes managed through the CRS–SISS system. The term "actor" specifies a role that entities of the process adopt interacting within the system. Actors are human (e.g. healthcare workers and patients) and non-human (e.g. hospitals and call centre).

several departments, each of them equipped with a specific system for electronic health records, or clinical workflow management systems. This situation was due to the lack of centralized guidelines on IT adoption in hospitals.

d. The integration scenario should be implemented without disrupting the previous health-IT solutions already present locally. Conversely, interoperability guidelines should be defined in order to provide a set of requirements to which these health-IT solutions should comply.
e. Documents shared through the system should be in a standard format, to facilitate information exchange.
f. The roadmap of system implementation should take into account the heterogeneity of the geographic area, and of the baseline situation of health-IT adoption. Hence, the project should be developed area by area, trying to decrease the execution time while proceeding in new areas.

These working hypotheses produced a strategy split into two main steps:

(1) The standardization and integration of information flows within single healthcare organizations (e.g., hospitals). In particular, each hospital had local repositories for administrative and clinical data, and each department within the hospital had its own administrative and clinical departmental repositories too. The integration architecture should hence first ensure that administrative data, both at the hospital and at the departmental levels, are synchronized with a central citizen registry, that contains the updated information of all the citizens in the region, to avoid unwanted erroneous or duplicated data; second, ensure that CEDs produced within single departments of the hospital are securely stored in a hospital repository, and, possibly, in a standard format. Within-hospital processes are well described in Integrating the Healthcare Enterprise (IHE) integration profiles which refer to HL7 standards. As mentioned in working hypothesis (d), there are two possibilities to obtain standard adoption within hospitals: one is to completely change the current hospital information system to a new "Regional system", facing the problem of a total disruption of past workflows and habits, with increasing barriers to adoption and long learning phases [29]; the other one is to maintain current information systems at the departmental or hospital level, and to provide an integration middleware able to satisfy standard requirements. This second possibility was implemented in the Lombardy Region.
(2) Exchange data among different organizations, to provide the basic services described in the scenario of Fig. 1. The regional healthcare system should ensure the existence of updated central repositories of administrative data, and also of clinical data and documents, like prescriptions, discharge summaries, exam results, etc. This architecture must be designed according to specific healthcare processes that depend on national and regional regulations and that are not usually mapped in international recognized standards. Hence, ad hoc interoperability specifications are defined in a top-down approach, and any health-IT system developer have to adopt them in order to implement systems whose messages are compatible with the central management of healthcare workflows.

The next sections describe the specific solutions implemented in the Lombardy Region, first at the level of regional infrastructure architecture and, then at the level of single hospital. Finally, some privacy issues are discussed.

3. Interoperability at the regional level

The regional system serves as an infrastructure, integrating all the different technologies available in single hospitals within a common framework.

The system implements a three-level architecture (Fig. 2). In the highest level, both administrative and clinical data of each citizen are managed. Administrative data for social services (for instance residences for geriatric care, advisory centres for health assistance,

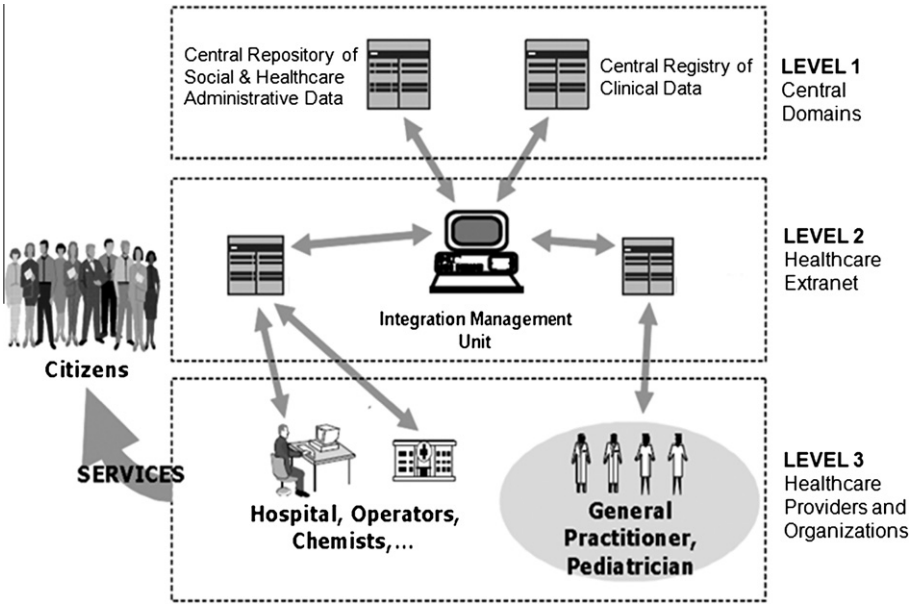

Fig. 2. The Lombardy Region architectural framework of the Healthcare Information System.

Table 2
Web services available for the communication between the single organization/healthcare worker and the regional information system.

Actor	Web service		
	Action	Receiver	Object
Hospital, Regional Call Centre	Search identify	Central domain	e-Prescription
Hospital	Notify	Central domain	Ambulatorial event (laboratory exam, radiology, specialist visit)
Hospital	Notify	Central domain	Hospitalization event (admission, transfer, discharge)
Hospital	Notify	Central domain	Emergency event
Hospital general practitioner other worker	Identify	Central domain	Citizen registry
Hospital	Insert Modify	Central domain	Citizen administration data registry
Physician	Register	Central domain	e-Prescription
Physician	Delete	Central domain	e-Prescription
Physician	Sign	Workstation	Clinical electronic document
General practitioner hospital	Time stamp	Central Domain	Clinical electronic document
General Practitioner Hospital	Publish	Central domain	Clinical electronic document
Physician	Read	Central domain	Life-long personal health record
Physician	Read	Hospital	Clinical electronic document
Pharmacy	Read	Central domain	Drug dispensation
Regional Call Centre Citizen Pharmacy	Dialogue	Hospital	Negotiation with hospital to book an exam
Regional Call Centre Citizen Pharmacy	Communicate	Hospital	Appointment confirmation
Hospital	Communicate	Central domain	Service catalogue
Hospital	Communicate	Central domain	Directly booked appointments (without Regional Call Centre mediation)

or for women) and healthcare services (for instance, e-prescriptions, exam booking, healthcare rights, reimbursement rights, ...) are stored in the central repository of Administrative data together with name, address, and other contact information. The Central Registry of Clinical Data does not physically store all the clinical electronic documents (CEDs) generated within the region but only indexes them. The index is built according to standard messages sent by the clinical repositories located in hospitals (or other organizations) where the CEDs are generated. Hence, the original document is stored locally, whereas the Central Registry of Clinical Data contains the information that the document exists and is located in a specific organization.

A connective infrastructure, the Extranet, provides communication between the different actors, and represents the intermediate level between the central domain (first level) and local healthcare providers and organizations (third level). The Extranet is a virtual private network (VPN) with encryption software able to exchange information among different users through a public network. Each single provider or organization uses specifically designed services exposed by the intermediate layer as an interface with the central domain (Table 2).

The messages exchanged through services exposed by the integration level (intermediate layer) follow interoperability specifications provided by the region.

The adoption of such regional interoperability specifications has enabled the communication between the central domain and the local domain through XML-based messages, independent of the IT company that has produced the specific hospital IT system (Fig. 3). Specifications were developed by the region according to the SOAP protocol (Simple Object Access Protocol) as recommended by the World Wide Web Consortium (W3C, http://www.w3.org) since 2003 (http://www.w3.org/2003/06/soap12-pressrelease.html.en), and were provided as guidelines to all the developers of software for healthcare organizations in Lombardy.

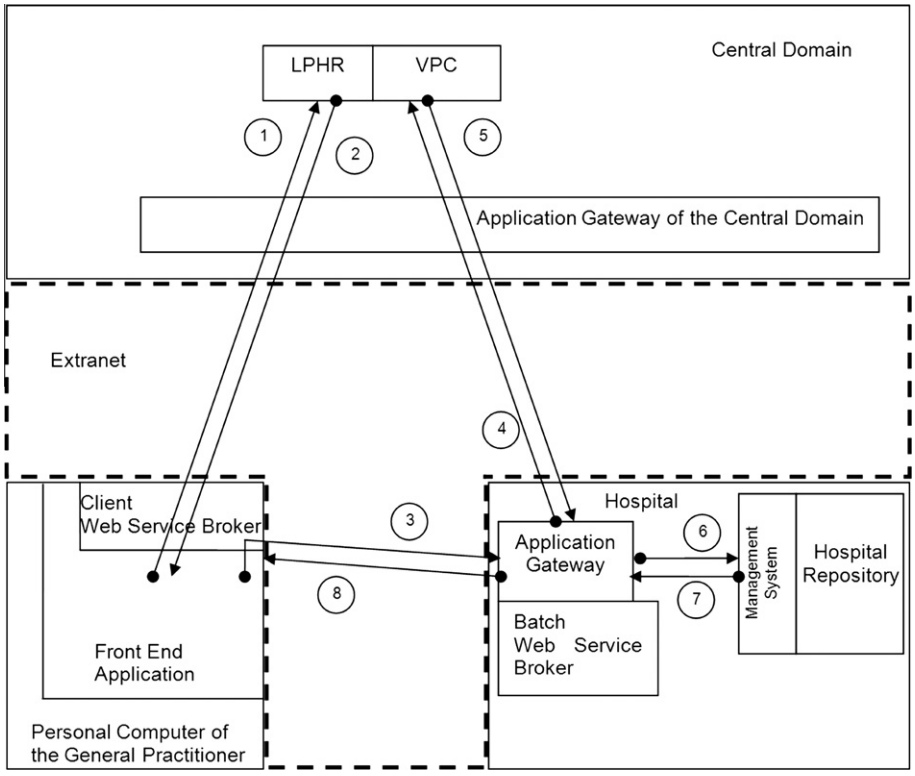

Fig. 3. Accessing the Hospital Archive from a GP software application. Numbers 1–8 represent the sequence of messages exchanged in the process (see text). VPC = Verification of Privacy Criteria; LPHR = life-long PHR.

The content of different messages was chosen to represent specific regional healthcare processes.

The use of the regionally specified messages is illustrated in the following examples.

A physician interrogates the Central Registry of Clinical Data in order to discover which CEDs are available for a specific citizen (life-long PHR) through the Client Web Service Broker. The Client Web Service Broker is installed on all the PCs of healthcare workers in the region. The software on the PC requests web services of the Client Web Service Broker, which uses a catalogue to identify how to route the web service invocation to the structure that actually offers that service. In some cases, the Client Web Service Broker may also perform some value-added functions; for example, according to the catalogue a specific service may require the generation on-the-fly of a document to be digitally signed by the healthcare worker invoking the service.

With the information gained from the Central Registry of Clinical Data (typically the unified resource identifier – URI – of the CED), the physician sends a request to the front-end of the hospital that has produced the CED. The front-end uses a regionally standardized message to query the hospital repository. The Application Gateway, a component of the front-end that interfaces the Extranet and the hospital Intranet, receives requests for web service invocation from clients on the Extranet, and routes them to the specific server on the Intranet of the hospital (or other organization) that offers the service. It also performs authorization controls according to the web service catalogue (for instance, is a healthcare worker of role "nurse" authorized to access the web service "read CED"?). In some cases, the Application Gateway may also perform some value-added functions; for example, according to the catalogue, a specific service may require the transmission of a digitally signed document; in this case, the Application Gateway will perform a validity check on the signature before routing the request through the Intranet. Another component of the front-end that interfaces the Extranet and the hospital Intranet is the Batch Web Service Broker. It is used when messages are sent by hospital servers instead of the PCs used by healthcare workers.

This process, and the standardization of the final message from hospital front-end to CED repository, enables the physician to obtain CEDs in a standard way independent of the IT company that has produced the specific hospital repository.

Another example is the Regional Call Centre for examination booking: the worker of the Regional Call Centre queries the central database in order to discover which hospitals are available to perform a specific service for a specific citizen. With the information so gained, the worker of the Regional Call Centre sends a request to the front-end of the hospital that offers the service. The front-end uses a regionally standardized message to query the hospital appointments system, and, in the event the system's proposal satisfies the patient, to confirm the appointment. This process, and the standardization of these messages, enables the worker of the Regional Call Centre to book appointments in a standard way independent of the IT company that has produced the specific booking system of the chosen hospital.

Table 2 lists the web services available for the communication between the single healthcare organization/healthcare workers and the regional information system.

4. Interoperability at the hospital level

As one line of action was the creation of a technological infrastructure for data exchange and sharing within the region, the other one was focused on single hospitals and other healthcare organizations that, locally, would need to produce electronic documentation to be exchanged or shared, if needed.

The adopted integration architecture is shown in Fig. 4. All the processes and functions for system integration are based on the Java Composite Application Platform Suite (JCAPS, http://developers.sun.com/javacaps/) middleware. JCAPS was used to implement

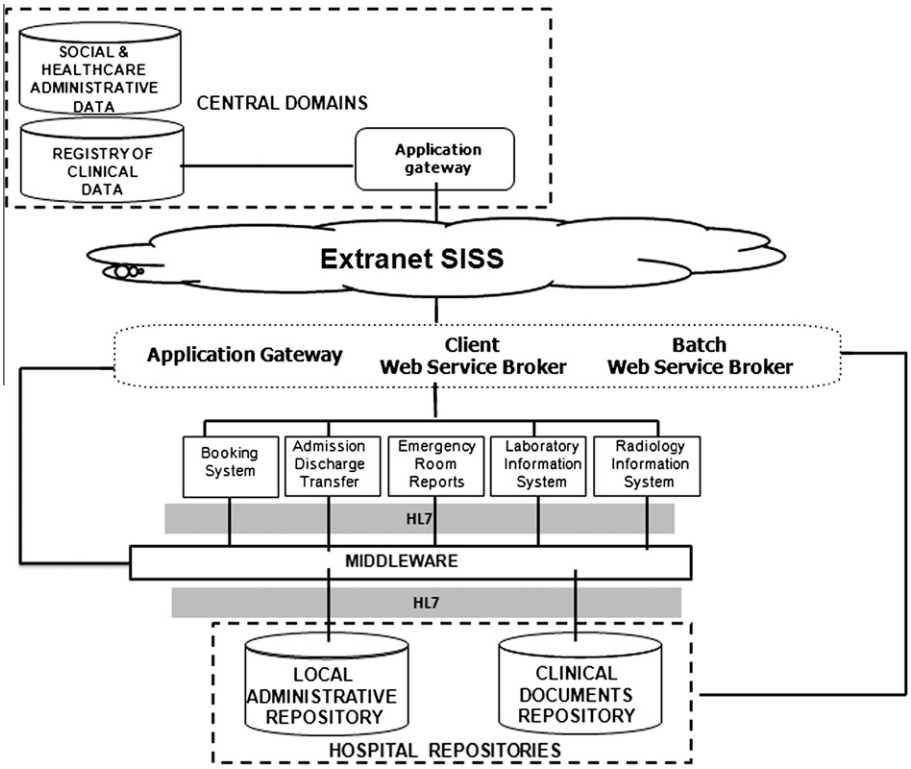

Fig. 4. System architecture for interoperability within hospital departments and its relationship with the regional information system.

HL7 support. Lombardia Informatica (i.e., the regional healthcare information service provider) provided the middleware based on JCAPS to all the healthcare organizations that needed to be connected to the regional Healthcare Information System. JCAPS, which is based on a Service Oriented Architecture (SOA), provides the integration of different applications through HL7 messaging, the creation of integration adapters to be used in non-HL7 native applications, and the management of server side services for integration [30].

There are two kinds of applications to be integrated: the applications with a native HL7 interface and the applications without a native HL7 interface. In both cases, technological adapters are used as integration media: in the first case, the technological adapter does not intervene on the content of the message, whereas, in the second case, the technological adapter creates HL7 messages from the native non-HL7 application.

JCAPS is essentially a hub, managing and integrating all the HL7 messages exchanged among different hospital departments. It is composed of two elements, the Logical Host and the Enterprise Manager. The Logical Host is an elementary software unit, developed and installed to manage a specific integration activity. Examples of activities are:

- the integration of all the departmental CED producers to the hospital clinical repository;
- the management of the booking process from the Regional Call Centre to the local booking system of a single hospital;
- the support of HL7 integration of order entry procedures.

The Enterprise Manager is a web application that can be run from any local client to monitor HL7 transactions on the middleware, the status of the configured logical hosts, and the queue of HL7 messages.

HL7 version 2.5 was adopted [30]. In fact, even though HL7 version 3 already existed, no hospital or other healthcare provider within the region had adopted it, and imposing such a change would have become a barrier against the implementation of the system. However, HL7 2.5 rarely defines fields as mandatory, and often leaves open possibilities in positioning single data within the message [30]. To reduce such freedom (and further guarantee interoperability), the Lombardy Region defined precise guidelines for the integration scenarios and the messages to be used within single hospitals [31]. Also, some data that the regional information system needed to exchange were not foreseen by the HL7 standard. Hence, two strategies were implemented: either information was included in fields of the message that had been conceived as containing other kinds of information, or information was carried in the "note" field. The specific solution adopted for different kinds of data was specified in the regional guidelines [31]. Examples are reported in more details in the next paragraphs.

4.1. Patient administration management

The integration between departmental patient administration data repository and the patient administration data repository of the hospital follows the IHE patient administration management (PAM) profile [32], in particular through the Patient Identity Management Workflow. Hence, anytime a change is made or a new patient identification is created, the hospital administrative repository and all the departmental administrative repositories are directly updated and, vice versa, when a change is made in the departmental administrative repository, the hospital administrative repository and, in turn, all the other integrated departmental administrative repositories are updated. The transaction ITI-030 is implemented, with the following messages:

- ADT^A28^ADT_A05 – create a new patient.
- ADT^A31^ADT_A05 – update patient information.
- ADT^A40^ADT_A39 – merge two patients.
- ADT^A47^ADT_A30 – change patient identifier list.

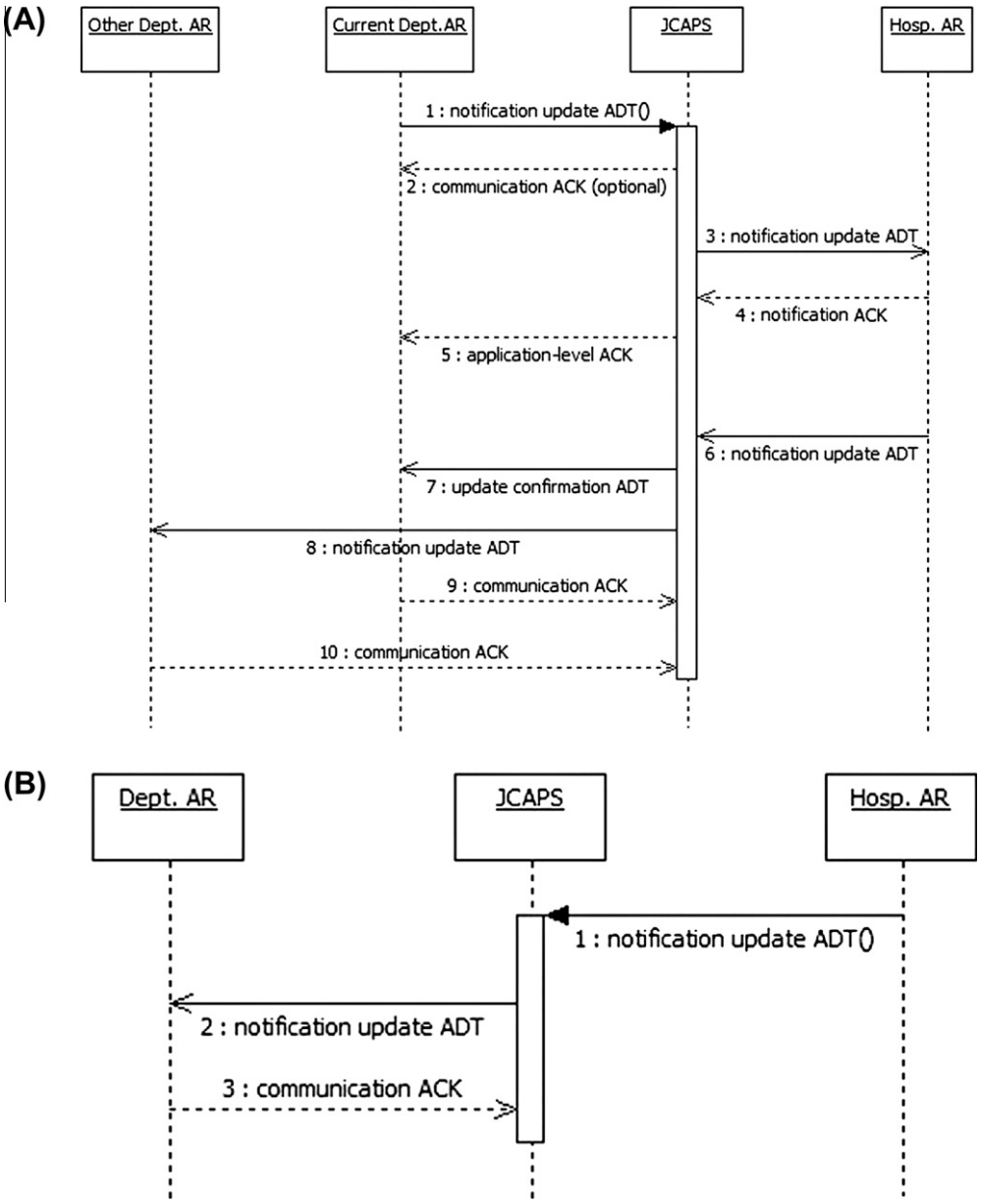

Fig. 5. Transactions for the update of departmental administrative repository (A) and the hospital administrative repository (B). Dept. AR is the departmental administrative repository; Hosp AR is the hospital administrative repository.

- ADT^A24^ADT_A24 – link patient information.
- ADT^A37^ADT_A37 – unlink patient information.

Fig. 5 shows the sequence of transactions to update the departmental administration data repository (A) and the hospital administration data repository (B). When a patient is admitted in a hospital Department, the departmental administrative repository is updated, and, in turn, the hospital administrative repository is updated through the mediation of the JCAPS-based middleware (Fig. 5a). Conversely, if a change is directly performed on the hospital administration repository, this change will be broadcast to all departmental patient administration repositories (Fig. 5b).

4.2. Patient management

Transactions regarding patient management follow the IHE PAM profile [32], according to the Patient Encounter Management workflow (ITI-031).

The message ADT^A01 is generated once the patient is admitted. In this specific case, the code of the department where the patient was admitted was needed for administrative purposes. Because the HL7 standard does not contain any such field, the standard was violated and the department code was inserted in the PV1-3 PL7, originally designed to carry the code of the building. The message ADT^A11 is used when a patient's hospitalization is canceled. This case can occur in Italy only if there has been an erroneous decision to hospitalize the patient. Other messages used in this scenario are listed in Table 3.

4.3. Order management

Order management is characterized by the interaction between two IHE actors, the Order Placer, representing the system that orders the service, and the Order Filler, representing the system that provides the service after having received the order [33]. The Order Placers are the Central booking system, the departmental procedures, and the Emergency Department. The Order Fillers are the

Table 3
Messages in use for the patient administration management.

Message	Operation	Note
ADT^A02	Patient transfer notification	
ADT^A03	Patient discharge	
ADT^A04	Patient registration	
ADT^A05	Pre-admission phase	
ADT^A06	Notify hospitalization	
ADT^A07	Notify status of external patient	
ADT^A08	Update data regarding a clinical event	
ADT^A11	Patient hospitalization canceled	Only if an error occurred in the decision to hospitalize the patient
ADT^A12	Rollback of transfer notification	Delete the effects of an erroneous ADT^A02
ADT^A13	Rollback of patient discharge	Delete the effects of an erroneous ADT^A03
ADT^A38	Rollback of pre-admission	Delete the effects of an erroneous ADT^A05

Radiology, the Laboratories, and the Ambulatory Units. There are two management profiles: the Order Placer Management, managing the communication from the Order Placer to the Order Filler, and the Order Filler Management, managing the communication from the Order Filler to the Order Placer. In the Order Placer Management, transactions included are RAD-2 for integration with radiology systems, LAB-1 for laboratory systems, and AMB-1 for ambulatory systems. In the Order Filler Management, transactions included are RAD-3 for integration with radiology systems, LAB-2 for laboratory systems, and AMB-2 for ambulatory systems. Besides standard integrations, another transaction supported by the integration platform is between the Emergency Department (Order Filler) and the Hospital Booking System (Order Placer). Transactions AMB-1 (Placer Order Management) and AMB-2 (Filler Order Management) are implemented for this integration.

The integration with the radiology systems is implemented through the Scheduled Workflow profile, with the following transactions:

RAD-1: Patient Registration.
RAD-2: Order Placer Management.
RAD-3: Order Filler Management.
RAD-12: Patient Update.
RAD-48: Appointment Notification.

The IHE "Laboratory Technical Framework" [34] describes the interaction between laboratory systems and the rest of the hospital. The implemented profile is the Laboratory Testing Workflow, with transactions LAB-1 (Order Placer Management), LAB-2 (Order Filler Management), LAB-3 (Order Results Management), and LAB-62 (Query for Label delivery instruction) in the case the laboratory also collects specimens.

The integration with ambulatory systems is implemented through the Ambulatory Scheduled Workflow profile [32,33].

4.4. Report management

HL7 messages are used to manage the flow of messages and CEDs (including exam reports, letters of discharge, prescriptions,...) to the hospital repository, and to update CED metadata. In addition, they are used to notify the logical link of the CED/image in the repository to the structure that has requested the service (i.e., the logical link to the laboratory test report is notified to the department that had requested the laboratory exam), and to update the notification status.

In the flow to the hospital repository two messages are used:

- MDM^T02 – to archive a standard CED or to update a CED draft. In response, the hospital repository will send a MDM^T01 message.
- MDM^T06: to archive a CED with an addendum or to update a CED with an addendum draft. In response, the hospital repository will send a MDM^T05 message.

The flow to the hospital repository uses the Enhanced Mode Acknowledgment (ACK) type, whereas the flow from the hospital repository can use both the Enhanced Mode and the Original Mode Acknowledgment types.

In the flow to the hospital repository, after receiving the MDM^T02 message, the hospital repository generates two ACKs. The first ACK is the commit, where the MSA-1 field can be:

- CA: if the HL7 message was correctly received by JCAPS.
- CR: if there was an error in the transmission.
- CE: if the HL7 message was incorrect.

The second ACK is the application-level ACK, that conveys only the result of the operation and it is sent only if the MSA-1 field of the first ACK contains CA. Hence, the MSA-1 field can be:

- AA: report correctly archived.
- AE: failed report archiving. The description of the error occurred is given in the ERR segment.

Once the report has been archived, the hospital repository sends the MDM^T01 response message, containing the logical link to the CED. In the life-long PHR, each CED may be in text format together with a structured format of the same document. The chosen standard for the structuring of documents was HL7-CDA release 2 [22]. Documents are hence organized with the classical Header and Body structure. So far, the region has provided guidelines for the creation of three kinds of documents for system developers: the Discharge Summary, the Laboratory Report, and the Patient Summary [31].

5. Regional privacy issues and HL7

Healthcare workers are identified through personal smart cards. Different workers have different user profiles, depending on their role in the healthcare processes. Through the card, the worker puts the digital signature on the documents under their own responsibility. Digital signature is implemented through the Public-Key Cryptography Standards #11 protocol (PKCS #11: Cryptographic Token Interface Standard, available at RSA laboratories webpage http://www.rsa.com/rsalabs/node.asp?id=2133), as recommended by the Italian Centre for Information Technology in the Public Administration.

The citizen has a personal health smartcard, too. The citizen uses the card to be identified and to give evidence of having the right to receive medical care. It can also be used to book exams, visits, hospitalizations, and consult the PHR. The citizen card contains basic information regarding the citizen, structured according to the results of the Netlink project, in which the Lombardy Region participates [35]. Netlink is a European project involving some regions in different countries that aims at validating and coordinating interoperable systems of healthcare smartcard and at giving basic specifications on information to be stored in such smartcards.

A particular problem regarding privacy of healthcare information arose with the introduction of the life-long PHR. The general reasoned purpose of that initiative was to make digital personal

health-related data and documents effectively accessible and shareable amongst the appropriate stakeholders. However, the citizen holds the right to decide who can access the life-long PHR, and which CEDs should be published on it. The Healthcare Information System infrastructure should hence implement such rights.

In fact, anytime a CED is generated, according to the workflows described above, the hospital repository sends a message, in a standard format established by the Lombardy Region, to the Regional Central Registry of Clinical Data, to include the logical link of the CED in the citizen's life-long PHR.

When the GP (or another authorized physician) makes a query to the Central Registry of Clinical Data to retrieve a CED indexed in the life-long PHR, the workflow is as follows (Fig. 3):

1. Using the front end application, the GP enquires the life-long PHR to obtain the reference of a CED.
2. The GP software application obtains the link to the CED (Unique Reference Identifier – URI of the CED).
3. Using the URI link, the software application of the GP sends a request for the CED to the Application Gateway of the Hospital where the CED was generated and is stored.
4. Before sending the request to the archive, using the function VPC (Verification of Privacy Criteria) of the central domain the Application Gateway of the Hospital verifies whether the GP has the right to access the CED (following the established privacy criteria).
5. If the GP has the right to access the CED, the central domain acknowledges the request.
6. The Application Gateway sends a request for the CED to the hospital repository.
7. The management system of the hospital repository delivers the CED to the Application Gateway.
8. The Application Gateway delivers the CED to the GP software application through the Extranet.

The verification of privacy criteria is a crucial point in this process. As the citizen is the owner of all the data in the life-long PHR, they have the right to hide any document he wants. The personal decision to hide a CED in the life-long PHR is given for each document, when generated, through a signed request. In addition, CEDs related to drug addiction, abortion, sexual violence, and HIV must be hidden by law. The right to hide a CED regards only the life-long PHR, which contains the links to documents. By law, any CED must be stored in the local repository of the healthcare organization that produced the CED and the CED must be visible to its author (i.e., the healthcare worker who signed it). Hence, the hidden CED will not be published on the life-long PHR, but it will be stored in the local repository. To implement this requirement the Lombardy Region decided to use the segment NTE [31], defined to carry notes: the field NTE-3 contains "Yes" if the document is hidden (either by law or by personal decision) or "No" if it is visible to doctors having access to the life-long PHR. The field NTE-4 contains the reason why it was hidden (personal decision, HIV-related, sexual violence-related, drug addiction-related, abortion-related).

6. Present statistics

At present, in the Lombardy Region about 9,900,000 citizen cards have been distributed, that correspond to 100% of the population. The 73,000 healthcare professionals working in the public sector now have a healthcare worker's card and 26,100 workstations were set up. 97% of GPs and Paediatricians, 100% of pharmacies (2593), 100% of public hospitals (35), 100% of local healthcare units (15), and 60% of private healthcare organizations (178) have joined the CRS–SISS. The system manages 4,700,000 pharmacological e-prescriptions, and 1,700,000 e-prescriptions for laboratory exams per month. It produces, monthly, 490,000 laboratory medical reports, 180,000 radiology medical reports, 180,000 first aid medical reports, and 58,000 discharge summaries.

7. Discussion

Standards implementation was one of the key elements to obtain an interoperable healthcare system in the Lombardy Region. Starting from a situation in which the majority of healthcare providers had their own, and fairly un-interoperable, information systems, the Lombardy Region has now a fully integrated platform, enabling citizens and providers to see and use healthcare information wherever it exists within the region.

The integration infrastructure and platform (JCAPs) was one of the enabling factors for the successful development of standards in the Regional System. The JCAPs platform provides a middleware for mediating message exchange within hospitals, integrating heterogeneous departmental systems, with or without native adoption of HL7. In this way, the introduction of standardized messaging within hospitals did not have a disruptive impact on the departmental information systems that already existed. Together with this, another success factor was the choice of the version of HL7 most frequently adopted in the already existing systems (HL7, version 2.5).

Another important element was the idea of providing clear regional interoperability guidelines for implementation. IT companies developing hospital/departmental systems had, in this way, clear requirement specifications for system implementation, without any degree of freedom, even though the original standard was open to interpretative solutions. This choice also enabled the use of HL7 message fields to manage information not specifically included in the standard, using segments conceived for other purposes (like privacy information in the note segments). Otherwise, this kind of information would have been treated in different ways by different developers, decreasing the interoperability levels.

The project itself suffered from some limitations, mainly due to time and costs, especially in terms of process re-mapping and training of users.

During the development phase, the time needed for training developers (i.e., who developed the departmental systems in use in hospitals), was not properly taken into account, as well as the need to integrate and adapt available standards to the real clinical and administrative data-flows used by different healthcare providers. During the release phase, the testing activity was much longer than planned. Healthcare providers needed proper training to the new workflows introduced. The time needed for the process of responsibility re-mapping within the single healthcare organization depended on the degree of cooperation among different actors that could not be forecast. A significant example of such process remapping is the introduction of the mandatory digital signature on CEDs for physicians working in hospitals. Digital signature was based on the use of the healthcare worker's smartcard. The paper-based signature was of course perceived as easier and less time-consuming. Also, physicians were not used to taking their smartcard with them all the time. Hence a certain resistance to change had to be faced. The introduction of mandatory goals (for instance, 90% of CEDs digitally signed) for hospital administration managers helped to overcome this problem: failing to achieve such goals would have compromised the quality level of the hospital and, in turn, would have decreased the reimbursement level. The same happened with the introduction of e-prescriptions to be filled-in by GPs. The barrier to adoption was overcome providing an incentive payment. A new problem recently arose regarded the requests of special laboratory exams being placed from one hospital to an-

other one. At present, these orders are manually requested, in written form, from one hospital to the laboratory of another hospital. Hence, it is difficult to trace them. To solve this traceability problem, the Lombardy Region started developing a solution based on the use of HL7, instead of being based on messages following regional interoperability guidelines, even though the communication is between hospitals and not inside them. This will require the introduction of an electronic order placement in daily workflows, instead of a human-based request, as presently happens anytime a special examination is needed.

Finally, Italian laws on privacy and security were difficult to interpret and, hence, time was needed to clarify the ways to apply them. At present, the life-long PHR was introduced, and privacy requirements were satisfied also thanks to the adoption of regional interoperability guidelines. The introduction of the life-long PHR raised the issue of storing structured documents with digital signature. At present, the use of structured documents following CDA release 2 is still facing a learning phase, even though Regional guidelines for the Discharge Summary, the Laboratory Report, and the Patient Summary are available. More frequently, CEDs are pdf documents with the digital signature. Hence, to be consistent, both the pdf and the structured document should be stored. However, the digital signature is not directly associated to both of them but only to the pdf format. Hence, the Lombardy Region has submitted a proposal to HL7-Italy to insert the CDA structure of the report in the pdf file, thus guaranteeing the integrity of the document.

8. Conclusions

Despite there still being work in progress, the Lombardy Region healthcare system is a fully interoperable social healthcare system connecting patients, healthcare providers, healthcare organizations, and healthcare professionals in a large and heterogeneous territory through the implementation of international health standards in intra-hospital settings, and through regional interoperability guidelines for information exchange among providers.

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