Implementing the lifelong personal health record in a regionalised health information system: The case of Lombardy, Italy

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ABSTRACT

Background: The use of personal health records (PHRs) can help people make better health decisions and improves the quality of care by allowing access to and use of the information needed to communicate effectively with others concerning their health care.
Objective: This work presents the lifelong PHR system of the Lombardy region as an example of the implementation of an e-health solution that is capable of providing personal clinical documents from a lifelong perspective, integrating different healthcare providers over a large territory.
Methods: The lifelong PHR is embedded in the regional healthcare information system of Lombardy, which is characterised by a large and heterogeneous territory, a large number of different healthcare providers and organisations, and a significant population.
Results: The lifelong PHR makes clinical documents available to healthcare professionals and citizens when needed, and it is automatically updated with all of the documents regarding a clinical event regardless of which healthcare provider is currently taking care of the patient. Present statistics show that the lifelong PHR has experienced a wide diffusion in a short period of time, and at the end of 2010, it was active for more than five million Lombardy citizens. Digital reports and e-prescription transactions have almost doubled since 2007 and have reached a coverage of almost 100%.
Conclusions: The qualified and exhaustive collection of patient clinical data and documents should impact daily medical practice, as well as the care pathways and services provided to patients, and should help in the renewal of health assistance and the simplification of patients' access to care.

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1. Introduction

Making digital personal health-related data and documents effectively accessible and shareable amongst the appropriate stakeholders at the right time is one of the ways in which e-Health can help improve the safety, quality, and efficiency of care [1]. There has been increasing attention paid to the potential of personal health records (PHRs) to improve maintenance and availability of patient data [2]. In 2007, a joint position statement by the AMIA and AHIMA emphasised the value of the personal health record (PHR) as a "tool for collecting, tracking, and sharing important, up-to-date information about individuals' health or the health of someone in their care" [2–5]. The joint position stated: "a PHR helps people make better health decisions and improves the

quality of care by allowing them to access and use information that is needed to communicate effectively with others regarding their healthcare" [3].

PHRs substantially differ from Electronic Health Records (EHRs) in that they are personal collections of health-related documents of an individual or family, independent of which healthcare provider created the documents. Conversely, EHRs are collections of health and care documents that have been created and stored by single care providers in a digital form. The required secure storage of EHR information is ensured by the care provider itself. EHRs are used by healthcare professionals as planning tools that support the care process, from order entry to results management [6–8].

Whereas EHRs are limited to the time frame in which an individual is a "patient" and requires care, PHRs are "lifelong" because the period considered for the collection of documents is the entire life of the individual.

Although PHRs are "personal" collections, models of PHR systems are heterogeneous and vary in the extent to which the content of the record, the data/documents uploaded, and the rights of access are controlled by the patient or by a healthcare

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provider. Simple examples include the health and lifestyle record generated directly by the patient/family [9,10] (and managed by web applications or personal computers) or the records generated and stored within the healthcare provider through health kiosks or digital copies that the patient can access with read-only rights.

Currently, PHR systems are being used in Europe and the USA. There are examples of systems developed (1) by healthcare institutions, (2) by companies that are acting in the health-ICT business area, (3) by Governments, as well as (4) by large companies such as Google and Microsoft. As an example of (1), HealthConnectOnline, managed by the Kaiser Permanente care organisation, records information about allergies and immunisations, as well as laboratory results and past visits and can be used for appointment booking, prescription reordering, and email communication with healthcare professionals (http://xnet.kp.org/newscenter/aboutkp/healthconnect/index.html). As an example of (2), in Europe, the LifeSensor product was developed by a health-ICT company and is available in Germany, Switzerland, Austria, and Bulgaria. Although it is not directly linked to the patient records of healthcare providers, it allows patients to store and manage information about their current health status, medical history, results, images, and documents. Authorised healthcare team members or caregivers can view, add, or update information (http://www.icw-global.com/de/intercomponentware-ag/lifesensor-gesundheitsakte.html). As an example of (3), in the UK, the National Health System proposed NHS HealthSpace, which closed on March 31st 2013. NHS HealthSpace was an online personal health organiser and booking service, which was offered after email registration to people who lived in England and were older than 16. HealthSpace provided access to the Summary Care Record (SCR) containing important information taken from the electronic medical records held by the NHS. Currently, it is thought that the decision to close HealthSpace will not affect the SCRs, which had been created for 24 million citizens up to mid-March 2013. The main reason for closing the system was infrequent use. The data have now been securely destroyed as required by the Data Protection Act (http://www.connectingfor health.nhs.uk/systemsandservices/healthspace). The UK Department of Health is developing new strategies for better and personalised care, relying on improved information provision to all of the stakeholders of the healthcare process (http://informationstrategy.dh.gov.uk/). As an example of (4), Microsoft HealthVault allows patients to collect and store health information at a family level, and they may then choose to share that information with healthcare providers. In addition, apps and devices that are able to integrate data into the personal health record of a HealthVault user are available.

As an unsuccessful example, Google Health was a PHR system proposed by Google in 2008 and terminated in January 2012. The service was provided free of charge for anyone with a Google account. Personal health records could be created either by manually uploading or by integration with digital services provided by healthcare organisations who partnered with the initiative. Google Health merged personal separate health records into the user's Google Health profile, including allergies, medications, laboratory results (http://www.nytimes.com/2011/06/25/technology/25health.html?_r=0). There are various opinions regarding the reasons why the service was stopped. One is the limited use of the tool and its inability to meet patient's expectations regarding the automatic data upload and the management of prescriptions (http://readwrite.com/2011/06/24/google_health_why_its_ending_what_it_means). Others underline the difficulty of healthcare professionals in relying on the information included in Google Health, as well as the low number of healthcare providers and insurance companies that partnered with the initiative (http://searchenginewatch.com/article/2099923/Google-Health-Shutting-Down-Doesnt-Mean-Google-Has-Abandoned-Health).

In 2007, the Italian government made the decision to push towards the adoption of a Lifelong PHR ("Fascicolo Sanitario Elettronico", in Italian).

In the Italian government definition, the lifelong PHR consists of a collection of all of the electronic documents regarding the healthcare of a single citizen, aimed at making the full and updated clinical documentation regarding a patient available to any healthcare provider, including in the case of emergency, regardless of which healthcare organisation produced the documents. The citizen is the owner of all of the data and documents included in the lifelong PHR and has the right to decide which documents should be included and who can access them. Hence, the model proposed by the Italian law can be considered a type of "integrated PHR" [11]: the patient owns the healthcare data/documents and decides who has the right to access their lifelong PHR, but the record is updated with the documents created by different providers, without the patient's mediations, during the document upload process.

This model differs from all of the examples of PHRs described above in several ways: (1) it is not provided by a single healthcare institution, but it integrates the documents from all of the regional healthcare providers; (2) it is updated directly with original documents, without the patient's mediations and upload responsibility; (3) it provides citizens access to all of the documents regarding their health, and it can be integrated with other systems providing booking services and information; and (4) it is run on a public basis.

In Italy, because the government is in charge of drafting laws, whereas healthcare delivery is the responsibility of the regions, the real implementation of the lifelong PHR is regional and follows a guideline document that was issued in February 2011 [12]. In particular, the Lombardy region is one of the most advanced regions in Italy regarding the development of the regional healthcare and social service information system [13,14], and in 2010, the Lombardy region started the development of a full lifelong PHR.

The lifelong PHR developed in the Lombardy region now serves 10 million citizens, and it makes clinical documents available to healthcare professionals when needed, thus representing a success story in the PHR adoption scenario.

The aim of this work is to present the lifelong PHR system of the Lombardy region as an example of the implementation of an e-health solution that is capable of providing personal clinical documents in a lifelong perspective, integrating different healthcare providers over a large territory.

2. The Italian healthcare system and the Lombardy healthcare information system

The healthcare system in Italy is based on the public universal insurance model; it is sustained by taxation and is run on a regional basis. Each Italian region refers directly to the Central Government and covers healthcare costs for each Italian citizen assisted by the region. Costs for drug therapies, surgery, laboratory examinations, and all healthcare services are fully paid by the National Government.

Lombardy is located in the north of Italy, with a large, heterogeneous territory (23,863 Km^2) from the Po river valley to the Alps with almost 10 million citizens.

In Lombardy, healthcare organisations consist of hospitals and laboratories, either public or private, General Practitioner (GP) offices, private practices, and all of the facilities providing healthcare services to citizens. The "Local Healthcare Units" (ASL – Azienda Sanitaria Locale, in Italian) are committed to the administrative management of all of the services for healthcare and assistance in a specific geographical area within the region.

In Italy, most of the hospitals are publicly owned, whereas only some are private. In principle, the access of Italian citizens to healthcare is free of charge. Nevertheless, each Italian Region decides autonomously whether citizens pay an additional charge to access private hospitals.

The system is based on fees that the region reimburses to the single hospital when a healthcare service is provided to the citizen. For public hospitals, the reimbursement fee covers 100% of the sustained cost. For private hospitals, reimbursement fees are pre-negotiated by the regional healthcare system with the single private hospitals.

In the case of the Lombardy region, the present healthcare regional law, according to the Italian law DPR 14/1/97, establishes an "accreditation" process to be applied both to public and private healthcare providers, to obtain full reimbursements. Each specific hospital, both private and public, must be recognised by the region as "accredited" to obtain service reimbursement. This accreditation procedure aims to apply the same regulatory status to both private and public hospitals, so that each Lombardy resident is free to apply, without differences to the personally sustained cost, to public or private hospitals. The accreditation process is not applied to the entire hospital but to single healthcare services/treatments, for specific overall annual amounts of service, for given levels/complexity of biomedical instrumentation, etc. When "credited", the private hospitals that are active in Lombardy are enrolled within the healthcare information system of the Lombardy region, without operational differences with respect to public hospitals.

For primary care, each citizen refers to a General Practitioner (GP) or a paediatrician who is chosen from within the local healthcare unit where the patient resides.

Healthcare workers include pharmacists, GPs, hospital physicians, specialists, nurses, front office personnel, and regional booking system personnel, and these workers are the users of the Regional Healthcare Information Systems.

The Regional IT infrastructure (named CRS-SISS, Italian acronym for Regional Healthcare Card and Healthcare Information System – Carta Regionale dei Servizi – Sistema Informativo Socio Sanitario) was started in 2000.

Currently, the CRS-SISS provides healthcare IT services to 10,050,000 citizens, 150,000 Health and Social Care Workers, 7800 GPs, 2650 pharmacies, 35 Public Hospitals, 15 Local Healthcare Units, and over 2500 Private Healthcare and Welfare Organisations. Lombardia Informatica S.p.A. is a publicly owned Information Technology (IT) service company that was founded by the Lombardy regional Government in December 1981. With some 550 staff, Lombardia Informatica is primarily involved in the development, design, and maintenance of the CRS-SISS system.

At the beginning of project implementation, the Lombardy region faced the problem of heterogeneous healthcare information systems adopted in different hospitals and organisations. The adoption of the Health Level 7 (HL7) standard within single hospitals, the integration of different systems and technologies available in single hospitals through a middle-layer infrastructure, and the definition of interoperability specifications recognised at the regional level were the basis of the political strategy to overcome this problem [14].

The regional system is hence now able to manage basic digital healthcare services for citizens, i.e., the centralised exam booking system, e-prescriptions, and the centralised citizen registry. The lifelong PHR implementation was built upon this technological infrastructure (Fig. 1).

The CRS-SISS implements a three-level architecture [14]. Level 1 is the central level that stores administrative data (citizens' contact information and details of social and healthcare services, e.g., residences for geriatric care, advisory centres for health assistance, healthcare and reimbursement rights, etc.) and clinical
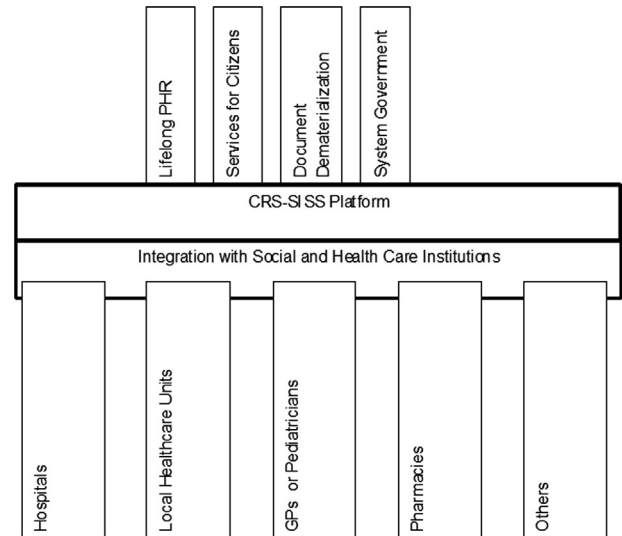

Fig. 1. The Lifelong PHR (LPHR) in the structure of the Healthcare and Social Service Information System – SISS (Regional Law DGR n VIII/010512 – November 9, 2009).

data. The clinical data consist of the index of all of the clinical electronic documents (CEDs) generated in any healthcare organisation within the region. Level 2 is the connective infrastructure that provides communication between different actors ("the Extranet", a secured Virtual Private Network, VPN). Level 3 are healthcare workers who provide healthcare services to citizens and connect to the Extranet through workstations equipped with the middleware provided by the region.

Identification, authentication, and access are implemented through the use of smart-cards [13]. The citizen is identified through the so-called CRS card, whereas the healthcare workers are identified through the so-called SISS card. The citizen uses the card for identification and to provide evidence of the right to receive medical care. He can book clinical exams, visits, hospitalisations, and he can access emergency care. Healthcare professionals use the card to be recognised, to access patients' health records, to sign clinical reports, and to access the information system.

3. The lifelong PHR: aims, requirements, and specifications

The overall aim of lifelong PHR implementation was to provide a collection of all of the healthcare documents of all of the citizens of the Lombardy region, independent of the location of the healthcare provider that produced the CED. The lifelong PHR follows the citizen throughout their entire life, thus creating a complete and controlled patient history that is able to facilitate the care process.

In particular, the lifelong PHR was adopted to achieve the following processes:

(a) Provide a complete, integrated and contextualised patient history that is available at any point of care, for real time decision support including in the case of emergency. Anywhere in the region that a patient is admitted, the lifelong PHR can be accessed, after the patient's consent, by the healthcare professional taking care of him/her at that moment.
(b) Provide clinical documents to increase the efficacy and efficiency of care. For instance, recent examinations are all stored in the lifelong PHR, thus decreasing the need and the costs related to repeated exams during emergency care.

(c) Support the direct availability of healthcare and clinical information to the citizen. The citizen has the right to establish the access policies and to allow any healthcare professional they want to view the reports of all of their other visits, thus replacing the traditional paper-based file that is presented during specialist's visits.

(d) Improve information collection, sharing, and exchange among healthcare professionals.

(e) Support secondary uses of healthcare information. These include education purposes, research, epidemiology, administration, and public health policies.

To achieve these aims, the content of the lifelong PHR was defined in national guidelines [12].

The lifelong PHR has several sections:

- Patient's demographic information, uploaded from the Central Patient Registry, defined by the Italian Ministry of Finance.
- Patient's administrative information. The lifelong PHR contains administrative information regarding the patient, such as the name of selected GP, the rights to special reimbursements (e.g., for chronic illness), and other healthcare rights. This information can be updated only by the Regional Healthcare Information System.
- E-prescriptions. These are be used by pharmacists to provide medications to patients.
- Clinical documents. These are the clinical electronic documents (CEDs) and the patient summary. Mandatory CEDs to be stored include clinical examination reports, letters of discharge, emergency care reports, pathology summaries, therapeutic plans, and vaccination reports. The patient summary is a special document that summarises a patient's history, current status, and a predefined set of emergency data, including all of the information relevant for patient care at any time. The patient summary is exclusively managed by the GP [12]. The patient summary aims to contextualise the information contained in the documents stored in the lifelong PHR, giving information on the patient current and past clinical history.
- Information about patient's consent, particularly written informed consents signed to undergo surgical treatments, or participate in experimental trials, and the consent for tissue and organ donation.
- Uncertified data. The lifelong PHR may also include a section that is exclusively managed by the patient, called the "patient notebook". This is the only part of the lifelong PHR in which information is completely uploaded and managed by the patient. The guidelines do not provide any type of mandatory structure for the patient notebook but suggest that information included can be related to allergies, lifestyle, diet, or any other documents that the patient considers relevant. Because the manager of such information is the patient, this information might contain errors [10] and is thus defined "uncertified".

The most important feature of the Italian lifelong PHR model is that the document update is not delegated to the patient but is automatically performed every time a new CED is generated in any healthcare organisation. CEDs in the lifelong PHR have to be digitally signed by their author (healthcare worker) who is responsible for the CED content. Because all of the documents in the lifelong PHR are the original reports of a patient's clinical event, they can be considered to be "reliable" information.

4. Lifelong PHR use cases

Fig. 2 shows some processes managed by the CRS-SISS system through the lifelong PHR.
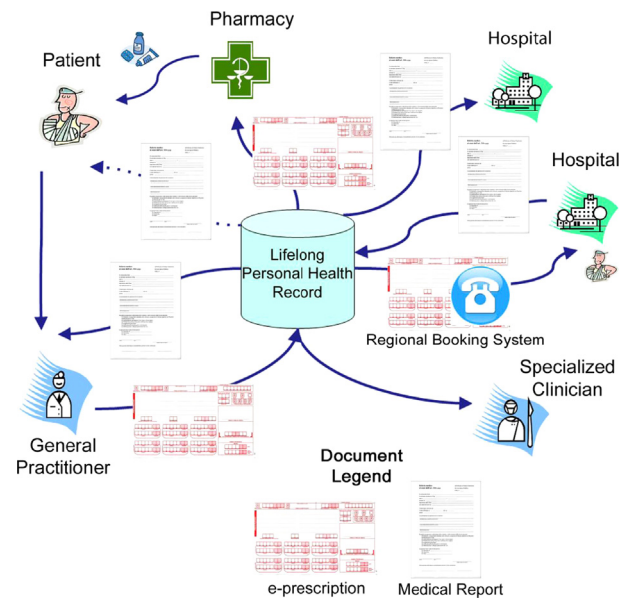

Fig. 2. Processes managed by the Lifelong PHR in Lombardy. The red form is a prescription; the written document is a report. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article).

4.1. Use-case 1: e-prescription

The patient visits the GP to obtain a prescription (for instance, a drug prescription). The GP prescribes the drug to the patient using specific software that is not provided by the region [15] and electronically signs the e-prescription. Then, the GP publishes the signed e-prescription in the patient's lifelong PHR. The patient goes to the pharmacy and presents his/her CRS card to the pharmacist to access the lifelong PHR. The pharmacist, after authentication with the SISS-card, can see the e-prescription and can dispense the prescribed medication to the patient.

4.2. Use-case 2: examinations

The diagnostic/instrumental examination must be prescribed by the GP to be reimbursed by the regional healthcare system. Similar to drug prescriptions, the examination e-prescription is published on the lifelong PHR, and the patient can contact the central booking system to book the examination. The central booking system operator, after authentication with the SISS card, retrieves the e-prescription and negotiates the appointment with all of the healthcare organisations available for the required service in the region and provides the best choice to the patient. Once the patient has undergone the prescribed examination, a signed report is produced by the responsible healthcare professional and is published on the lifelong PHR.

4.3. Use-case 3: document retrieval from the lifelong PHR by the GP

The GP, who requested the examination, can see the report on the patient's lifelong PHR. To do so, the GP should be authenticated through his/her SISS card, and the patient should have been given the GP their CRS card at least once to obtain access permission. All of these processes are managed through access policies, guaranteeing that the patient, who owns all of the data/documents stored in the lifelong PHR, gives consent to allow the specific healthcare workers to access their PHR.

4.4. Use-case 4: document retrieval from the lifelong PHR by the patient

The patient can access the lifelong PHR through a web portal provided by the region. To do so, the patient must request registration to the service. Once registered, the patient will access the lifelong PHR using a personal password and a one-time password (OTP) sent by the system to the patient's mobile phone by text message. The lifelong PHR exists even though the patient does not ask to be registered for access.

5. Lifelong PHR implementation

In the lifelong PHR in Lombardy, demographic and administrative data are retrieved from the Central Repository of Social and Healthcare Administrative Data that is synchronised with the demographic database of the Ministry of Finance, which also stores all of the information regarding the patient's consent.

Clinical documents are collected in the lifelong PHR as links to all CEDs produced in different healthcare organisations within the region (Fig. 3); these links are stored at the central level (level 1 in the three-level architecture described above) in the Central Registry of Clinical Data. Documents are stored locally, in the healthcare organisation where they are produced. In the lifelong PHR, each document is classified by type and each is qualified based on attributes and metadata. Documents regarding the same clinical event (for instance, a hospitalisation) are grouped together and can be viewed searching for the specific clinical event. Documents can be retrieved either chronologically or grouped by medical speciality.

Because of the CRS-SISS, currently, all of the clinical documents generated in recognised healthcare organisations are digitally signed. Hence, all CEDs in the lifelong PHR are digitally signed. The CRS-SISS digital signature service is based on the Public Key Cryptography Standard (PKCS#11, http://www.rsa.com/rsalabs/node.asp?id=2133) and is implemented through healthcare professionals' blue smart-card. The CED is usually a signed PDF, generated either from an original document in textual format or from a structured document following HL7-CDA release 2. In fact, the region has started to require structured CEDs instead of only text-based documents. The HL7-CDA release 2 standard has been chosen for structured documents. Currently, Letters of Discharge, Laboratory Reports, and the Patient Summaries are the only structured documents required by the region.

A detailed technical description of the standards implemented in the Regional Healthcare Information System is provided in [14].

Once a CED is generated, it is stored in the local repository of the healthcare organisation. Then, the local repository of the healthcare organisation sends a message, in a standard format established by the Lombardy Region, to the Regional central registry, to include the logical link of the CED in the citizen's lifelong PHR.

CEDs generated before the introduction of the lifelong PHR can be included, following a citizen request. In this case, the Region handles the updating process, publishing in the lifelong PHR the links to CEDs that already exist in local repositories of all of the healthcare organisations in Lombardy.

To retrieve a CED from the lifelong PHR, an authorised healthcare professional (for instance the GP, see Fig. 4), using a front-end application, searches the central registry (Master Patient Index) to obtain the CED reference. The GP's software application obtains the link to the CED (Unique Reference Identifier – URI of the CED); using the URI, the GP software application sends a request for the CED to the Application Gateway of the Hospital where the CED was generated and is currently stored. The Application Gateway is a component of the front-end that interfaces between the Extranet and the hospital Intranet; it receives requests for web service invocation from clients (or servers) on the Extranet and routes them to the specific server on the Intranet of the hospital (or other organisation) that offers the service. It is used mainly to perform authorisation controls according to the web service catalogue (e.g., is an operator with a "GP" role
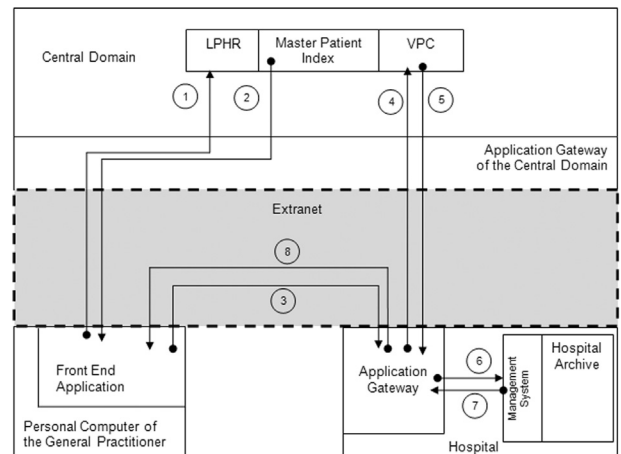

Fig. 4. Accessing the Hospital Archive from a GP software application. Numbers from 1 to 8 represent the sequence of messages exchanged in the process. VPC=Verification of Privacy Criteria; LPHR=Lifelong PHR.
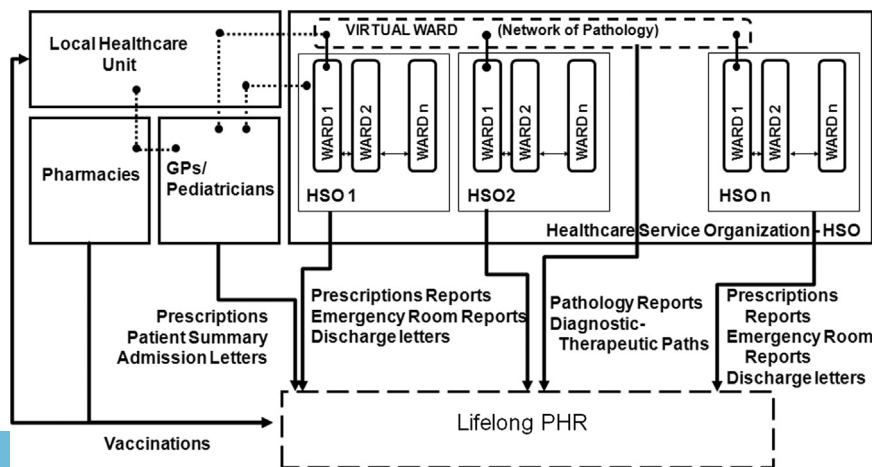

Fig. 3. The links (black arrows) to all clinical electronic documents (CEDs) produced in different healthcare organisations within the Region feed the Lifelong PHR.

Fig. 5. Citizen's personal page in the lifelong PHR. The figure is a snapshot of the present implementation and it is in Italian. (A) – The homepage has a main panel of Healthcare Documents ("Documenti Sanitari") listing all of the healthcare documents available for the citizen in the lifelong PHR. In the right panel, the citizen's data ("I tuoi dati") is summarised. In the lower panel, there are a Schedule ("Prossimi appuntamenti") and the Personal GP data ("Il tuo medico" and "Scegli o cambia il medico di base"). (B) – The personal notebook page ("Taccuino"), in which the citizen can upload personal documents that are not directly created within the regional healthcare information system. Other data are managed using the available tabs of Vaccinations ("Vaccinazioni"), Prescriptions ("Prescrizioni"), Contacts with healthcare professionals ("Contatti con la sanità"), and Healthcare Documents ("Documenti sanitari").

Fig. 6. General Practitioner's page in the lifelong PHR. The figure is a snapshot of the present implementation and it is in Italian. (A) – Snapshot of the GP view of all of the documents available for a single citizen. Using the left menu, the GP can choose the document type. In the example, all of the documents related to hospitalisations ("Ricoveri") are selected and visualised in the right panel. (B) Timeline visualisation of the citizen's documents in the GP view. The central panel shows the year 2012 divided by months.

authorised to access the web service "read CED"?). Before sending the request to the hospital local repository, the Application Gateway of the Hospital verifies whether the GP has the right to access the specific CED (following the established privacy criteria) using the Verification of Privacy Criteria (VPC) function of the Central Domain. The VPC function is run at the central level. If the right to access is verified, the Central Domain acknowledges the request, and the Application Gateway sends a request for the CED to the hospital local repository. Then, the management system of the hospital repository delivers the CED to the Application Gateway, which sends the CED to the GP's software application through the Extranet (Fig. 4).

The citizen's notebook (uncertified data, see above) is now being implemented. It will be a place for storing information or documents that the citizen considers relevant for their healthcare or wellness.

Figs. 5 and 6 show the current lifelong PHR interface for the citizen (Fig. 5) and for the GP (Fig. 6). The citizen has a home page that shows the list of the healthcare documents, characterised by a short description, the creation date, and the institution in which they were created. In the example, there are three documents: one specialist report from the oncology department of the "Istituto dei Tumori" of Milan, and two radiology reports from two other hospitals in Lombardy. Prescriptions and vaccines are visualised in separate tabs. Moreover, the citizen has a calendar to keep track of future appointments, and an icon to view/change the GP (Fig. 5A). The citizen's notebook (Fig. 5B) was implemented as a storage area in which the citizen can upload and label documents as, for instance, healthcare documents obtained in regions other than Lombardy (that are not included in the healthcare information system, CRS-SISS). The GP can browse the document list by type (diagnostic reports, hospitalisations, therapeutic plans, prescriptions, etc.) and filter the list, for example by date (Fig. 6A). Additionally, the GP has a timeline view (Fig. 6B) that summarises the healthcare documents of the citizen in a wide time window (one year maximum).

6. Lifelong PHR access policies and privacy issues

The introduction of the lifelong PHR raised several issues regarding the privacy of healthcare information. Although 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, the citizen holds the right to decide who can access the lifelong PHR, and which CEDs should be published on it. The healthcare information system infrastructure must hence implement such rights.

A first point is that the lifelong PHR is a citizen's right (and not a duty) and, hence, it can be created only with the citizen's written consent. It is possible that a citizen does not want to have a lifelong PHR. In that case, it cannot be created. In Lombardy, a citizen's consent is obtained either through a web application running on the Extranet requiring insertion of the CRS card or through a paper-based signed form that is available at any Local Healthcare Unit office.

Once created, the lifelong PHR allows the consultation of all of the CEDs of the single citizen, who establishes the access policies. Access policies are based on user type, providing different views on the lifelong PHR depending on the type of user recognised through the SISS card. The patient provides a list of the healthcare professionals that can access their lifelong PHR. In particular, the patient provides the consent for the access of the GP and the physician taking care of him/her during a hospitalisation or emergency, independently from the name of the doctor. Any other healthcare professional, even if recognised by the regional system and holding the blue smartcard, is not authorised to enter the lifelong PHR, unless explicitly indicated by the patient. The

verification of privacy criteria is a crucial element to guarantee citizen rights.

Another point was raised in July 2009, when the Italian Authority for Privacy issued a document stating that the patient has the right to hide any document in the lifelong PHR and also to hide that something was hidden [16]. Hence, the lifelong PHR architecture implemented in Lombardy includes the possibility for the citizen to decide whether to hide a single document. The patient can decide to hide the document either immediately when it is generated or at any time he wants through a signed request. Some special documents are confidential by law: HIV reports, abortions, sexual abuse history, and drug or alcohol addiction. The right to hide a CED applies only to the lifelong PHR, which contains the links to the documents. By law, any CED must be stored in the local repository of the healthcare organisation that produced it and it must be readable by its author (i.e., the healthcare worker who signed it). Hence, the hidden CED will not be published on the lifelong PHR, but it will be stored in the local repository.

6.1. Current statistics

Currently, in the Lombardy Region, approximately 9,900,000 citizen cards have been distributed, corresponding to 99% of the population satisfying the required criteria. The 80,000 healthcare professionals working in the public sector now have a blue health-worker smart-card and 37,000 workstations have been set up. Overall, 98% of the GPs and paediatricians, 100% of pharmacies (approximately 2650), 100% of the hospitals (35), 100% of the local healthcare units (15), and 80% of the private healthcare organisations (280) joined the CRS-SISS. The system manages monthly 5,800,000 (71%) pharmacological e-prescriptions and 2,100,000 (83%) e-prescriptions for laboratory exams. It produces monthly 650,000 (100%) laboratory medical reports, 205,000 (94%) radiology medical reports, 210,000 (90%) first aid medical reports, 63,000 (75%) discharge letters and 360,000 (64%) other reports (the percentages indicated are estimates for 2012, comparing reports published to total reports produced in the public hospitals of the region). A total of 17,900,000 CEDs are currently included in 6,050,000 active lifelong PHRs. GPs have started using the lifelong PHR, with 3,800,000 reports remotely consulted accessing patient's lifelong PHRs. The patient summary and the patient notebook are presently implemented but they still lack widespread diffusion and use. In particular, the patient summary has to be managed by GPs, who need training and workflow re-organisation to perform this new activity. In Figs. 7–9, the time evolution of e-prescriptions, digital reports, and lifelong PHR in the last 6 years is shown. Current statistics show that the lifelong PHR has experienced widespread diffusion in a short period of time,
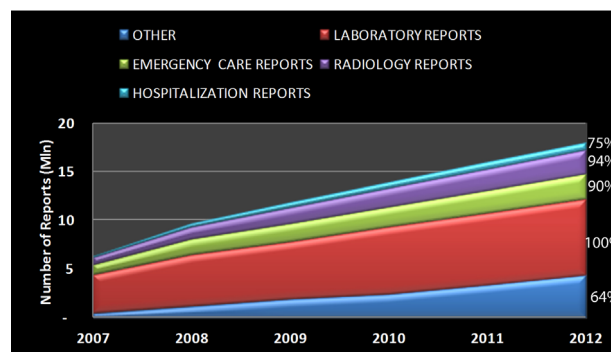

Fig. 7. Digital reports from 2007 to 2012. The percentages on the right represent the number of digital reports (for each type, i.e., emergency care reports, hospitalisation reports, laboratory reports, radiology reports, and other reports) with respect to the total number of reports of the same type created in Lombardy in 2012.
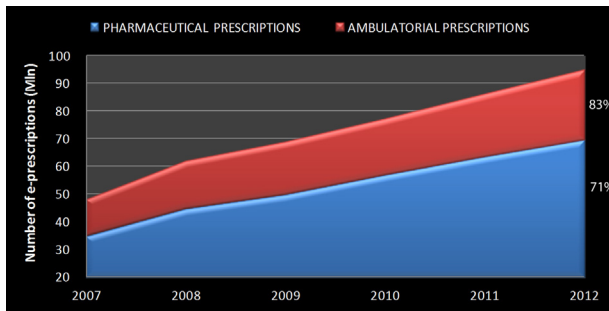
Fig. 8. E-prescriptions from 2007 to 2012. The percentages on the right represent the number of digital reports (for each type, i.e., pharmaceutical e-prescriptions and ambulatory e-prescriptions) with respect to the total number of reports of the same type created in Lombardy in 2012.
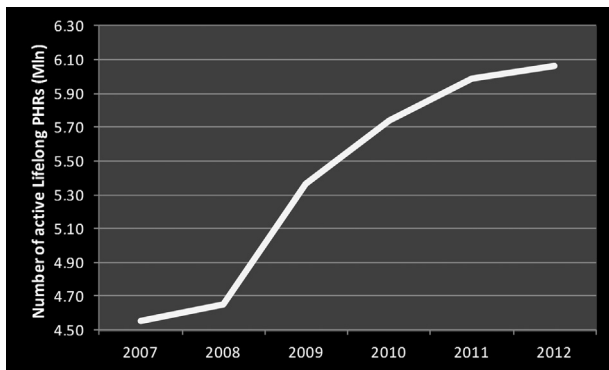

Fig. 9. Lifelong PHR from 2007 to 2012. In 2007, lifelong PHRs were available only to healthcare professionals and not to citizens.

and at the end of 2012, the lifelong PHR was used by 65% of Lombardy's population. Reports almost tripled and e-prescription transactions almost doubled since 2007.

7. Discussion

In this work, we have presented the implementation of a lifelong PHR embedded in a regional healthcare information system within a region characterised by a large and heterogeneous territory, a large number of different healthcare providers and organisations, and a significant population.

The PHR model adopted is lifelong and makes all of the clinical electronic documents of a patient available to healthcare professionals when needed, but it is not managed by the patients themselves. Its rapid and widespread diffusion in the Lombardy region are evidence of a successful implementation.

The lifelong PHR provides, in fact, a qualified and exhaustive collection of patients' clinical data and documents. This should impact the daily medical practice as well as the care pathways and services provided to patients and should help to renew health assistance and simplify patient's access to care. Integration was obtained using international standards (HL7, version 2.4) and regionally developed interoperability guidelines allowing information sharing among heterogeneous information systems in different healthcare organisations.

7.1. Comparison with other systems

The general limitation of any lifelong PHR system is the well-known low healthcare literacy of the average citizen/user: whereas all of the data and documents are owned by the citizen, their use, as well

as their generation, is delegated to healthcare professionals [17]. This has an impact on the success of PHR systems in terms of patient use, both for private enterprises, such as Google Health or MS HealthVault, and for public portals, such as the NHS HealthSpace.

In the case of the lifelong PHR in Lombardy, the success rate is not measured through its activation/use by the citizens because the creation of the system is mostly automatic, once the patient's consent is given. Moreover, the system is loaded with the original documents generated by healthcare professionals, thus decreasing the possibility of errors that could occur if the patient were in charge of updating the PHR. Hence, data and documents included in the Lombardy lifelong PHR can be considered "reliable" and can be trusted by GPs and other healthcare professionals when used.

This automatic loading is possible due to the healthcare information infrastructure (the CRS-SISS) that connects all of the healthcare providers in the Region. This strategy overcomes the barrier faced, for example, by Google Health that could not find proper cooperation from Hospitals and insurances (http://search enginewatch.com/article/2099923/Google-Health-Shutting-Down-Doesnt-Mean-Google-Has-Abandoned-Health).

One of the current limitations of the system is that patient use is not yet highly diffused, whereas GPs work with the lifelong PHR daily. This could be overcome in the future not only by proper communication strategies to empower citizens, as suggested by the NHS strategy (http://informationstrategy.dh.gov.uk/), but also by better integrating the present system with tools to improve the direct interaction of patients with healthcare professionals. Additionally, other tools for family document management [10] could be included in the personal area, to allow better personal management of data and documents, also by the citizen. The system also lacks solutions to improve the patient understanding of medical terminology, such as specific lexicons or ontologies to connect the family lexicon with the specialised medical lexicon [17].

Other countries in Europe, such as Finland and Denmark, have promoted eHealth roadmaps aimed at ensuring direct access by citizens to their healthcare data and documents. In Denmark, the MedCom messages system allows the digital exchange of healthcare data and documents, with very high percentage rates of digital documents transmitted to/from the GPs (99% discharge letters, 99% laboratory results, 85% e-prescriptions, 99% reimbursement requests to public health insurances) [18]. These percentages are fully comparable with the transactions managed by the Lombardy system (see Fig. 5). The e-Journalen system was developed to provide access to patients and healthcare professionals to hospital EHRs, as well as notes on treatments, covering almost the 85% of the population in 2011. In addition, the Sundhed.dk portal provides healthcare services to the patients, including the access to e-Journalen, and a handbook to understand medical terminology, which the Lombardy system lacks. However, the Denmark eHealth solution covers only the access to hospital EHRs and not to other documents (such as laboratory reports or bioimages) that is conversely already provided in the Lombardy system. This access and the medication management features are the next steps already planned in the Danish roadmap.

Also in Finland, the transmission of healthcare data and documents to GPs has been widespread (90% of the GPs can receive digital laboratory results) since 2007 [19]. The digital exchange of other documents, including administrative data, is less diffused, but the coverage is increasing. Since 2006, in Finland, the eArchive system was introduced to enable EHR access and patient information exchange across healthcare providers. The system, which is based on international classification terminologies such as the International Classification of Diseases (ICD) 10th Revision and the International Classification of Primary Care second edition (ICPC-2), should be fully implemented by 2015. The system has a structure similar to the Lombardy one and will likely include a Patient Summary as well.

7.2. Lessons learnt

A major problem encountered during lifelong PHR introduction involved the barriers to its adoption [6]. Education of users and developers must never be underestimated, especially for the need to integrate and adapt available standards to the actual clinical and administrative data-flows used by different healthcare providers.

The lifelong PHR (as the last leaf of the regional healthcare information system) introduced the need for new workflows, particularly for GPs, and for actions towards process re-mapping. One example is the lack of diffusion of the patient summary that is fundamental to contextualise the CEDs collected in the lifelong PHR. In fact, the lifelong PHR contains a huge amount of clinical information that may produce noise, thus hiding important information in a bulk of unorganised information. This is a great risk. A correct patient summary, conversely, would help to focus on both the patient's history and current status, highlighting important clinical events that can drive the research of information throughout the index of documents. Despite its importance, the patient summary has to be managed by GPs who are not used to it. This is similar to the introduction of e-prescriptions to be completed by GPs. The barrier to adoption can be overcome by providing an incentive payment. Another example involves the introduction of the mandatory digital signature on CEDs for physicians working in hospitals. The paper-based signature was of course perceived as easier and less time-consuming. Additionally, physicians were not used to carrying their smartcard with them all of the time. Hence a certain resistance to change had to be overcome. 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. Another point is that the introduction of the lifelong PHR raised the issue of storing structured documents with a digital signature. CEDs are usually pdf documents with a digital signature, whereas the structured document is stored in a separate file, that is not subject to a signature. The Lombardy region has therefore submitted a proposal to HL7-Italy to insert the CDA structure of the report into the pdf file.

Finally, Italian laws on privacy and security were difficult to implement and hence time was needed to clarify the ways to apply them. Currently, the lifelong PHR is almost fully operative, and privacy requirements were satisfied also thanks to the adoption of regional interoperability guidelines.

7.3. Perspectives

Completing its diffusion is of course the main objective of the Lombardy Government in the next few years. This should be accompanied by a correct educational campaign for citizens, who do not have enough knowledge of the potential and the benefits of the use of the lifelong PHR, and also for healthcare workers, who need to fully introduce the use of the lifelong PHR into their daily practice.

Ways to improve its adoption and use should be addressed in terms of "consumerisation" and "empowerment" [20]. Consumerisation refers to a lifelong PHR that is opened also to citizens who are not necessarily patients. User interfaces for citizens should be improved based on the suggestions of focused user groups for example. Applications favouring one-to-one communication between the citizen and the healthcare professional should be developed. Empowerment refers to the need of a citizen's contribution that is based on patient education. The lifelong PHR does not currently contain any specific tool for helping patients in the use of their healthcare information, such as vocabularies or ontologies that are specifically developed for the family environment [17], but they should be developed and included to sustain citizens in the use of this tool.

Another forthcoming line of development would be moving towards mHealth [21,22]. The market tendency towards mobile devices (presently known as "phablets", a neologism for phone+tablet) and applications and the widespread diffusion of them among the population suggests their potential to become valuable media for ICT-enabled healthcare, in a scenario in which both the patient and the physician will likely have the same mobile personal computing device that offers access to the same sets of information and tools for healthcare decision making [23]. In this situation, the creation of specific applications on mobile tablets/phones to access the Lombardy Healthcare Information System and the lifelong PHR, available for multiple user profiles, would be valuable.

8. Conclusions

The lifelong PHR is now active for more than half of the citizens living in Lombardy. The major achievement of the implemented lifelong PHR is that it places the citizen at the centre of the system. The Lombardy region has implemented the lifelong PHR as a pillar of a healthcare system that is able to make proper health information available to guarantee the best possible continuity of care. The qualified and exhaustive collection of patient clinical data and documents should, in fact, impact the daily medical practice as well as the care pathways and services provided to patients, thereby helping the renewal of health assistance and simplifying patient access to care. Although there is still work in progress, the Lombardy lifelong PHR can be considered a reference for other regions and countries that face the problem of heterogeneous territory and heterogeneous diffusion of information systems among healthcare providers.

Conflicts of interest statement

Fulvio Barbarito, Antonio Barone, Fabrizio Pizzo, Riccardo Ranza, and John Mason are employees of Lombardia Informatica S.p.A., Milan, Italy, which is a publicly owned Health ICT company and is responsible for the development and management of the Healthcare Information System of the Lombardy region.

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