Towards an electronic medical record for precision oncology: information and knowledge management

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***Abstract*— Paper medical records are still widely used in Italian hospitals and their use contributes to the reduced efficiency of the clinical process. Appropriate standards can improve the functioning of Health Information Technology and contribute to the improvement of quality and patient safety. A global architecture scheme was implemented by harmonising health services as proposed by HL7 to achieve interoperability between distributed and heterogeneous applications and devices belonging to independent organisations. A client application was developed that led to the improvement of the quantity and quality of information that may be relevant for the treatment of patients suffering from colorectal cancer. A tailoring application was designed and developed to meet the needs of medical personnel, especially as regards the management of visits, and the creation of a clinical diary in compliance with the standards currently in use. This work is the basis for an integration of medical records and genomic data that can lead to an improvement in cancer prevention, diagnosis, prognosis and treatment (precision oncology).**

***Keywords*— EHR, standard, HL7, CDA, interoperability, genomics**

I. INTRODUCTION

One of the key challenges in health information systems concerns the integration of different and heterogeneous data sources. Appropriate standards allow to connect different systems within and across organizations to achieve the aim of Health Information Technology (HIT), that is to bring the right information at the right time and at the right place. HIT contributes to the improvement of quality and patient safety, thanks to the availability of more accurate documentation and rapid retrieval and management of information, including complex information, and to the reduction of healthcare costs [1].

Electronic Health Record (EHR) is one of the most widely used HITs that replaces paper medical records to keep track of people's health information. The adoption of EHR has been promoted in many countries, both at government level and in the private sector. However, in spite of the fact that the adoption of EHR will lead to savings in health care to the reduction of medical error the adoption of EHR is still rather limited. Problems related to EHR adoption include lack of standardization and certification, high costs and concerns about privacy. Their potential health benefits mainly relate to prevention and disease management. It has been found that the adoption of standards based EHR systems could reduce healthcare spending to a great extent [2]. In USA the adoption of EHR system both in hospital and in primary care has been rather slow, even though satisfaction and confidence by physician is high. Moreover, it is felt that EHRs can improve safe practice and patient care and reduce the risk of errors. Barriers for their implementation mostly are legal problems, dependence on built in clinical tools for decision making leading to medical errors, copy and paste actions which may lead to mistakes and implementation costs [3]. In Europe the Organisation for European Cancer Institute, the Italian Network of Comprehensive Cancer Centres and the European Association for Cancer Research have focused on precision medicine. An Education and Training Working Group has been set up [4] and "Precision Medicine for Cancer" meetings are being organised. Moreover, several activities were carried out in EU members states, such as UK Germany, France. In 2016 the Personalised Medicine in Brussels focused on many such projects [5]. More specifically, it has been found that complex organizational

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and human factors can accelerate or hind the adoption of EHRs and the role of providers employers, patients and govern institution is important [6]. In addition, one significant aspect of EHR systems is the interface aspect. Many solution have been developed, such as IP, HL7, DICOM, SNOMED, LOINC and others [7]. The need for generic and interoperable EHRs has been recognized internationally, specially with respect to interoperability, in order to provide solutions for the preservation of clinical information across heterogeneous system [8]. Barriers for the increase in adoption of an EHR system have been extensively considered, in order to recognize how to address them [9-12].

Most EHRs contain three main kind of data that is quantitative data (such as clinical data), qualitative data (text documents) and medication records. The amount of data, which is being collected and digitally stored, is rapidly expanding, and big data technology has great potential in this respect. Some of the main aspects that can be addressed are the capacity to generate new knowledge by natural language process and other computational techniques, knowledge dissemination and clinical decision support, integration of genomics and systems biology with EHRs data, and delivering information to patients, facilitating a more active role by them [13]. A patient's genomic data is becoming increasingly important for clinical decision-making; however, clinical genomic data is often separate from clinical data, which requires direct contribution from clinicians. It would be desirable to extend EHRs supporting genomics and related information. This would enable to integrate genotype and phenotype information, insertion of genomic information in clinical workflows, and enable outcome analysis [14]. Genomic integration into EHRs has relevant advantages. The easy access to EHRs facilitates the evaluation of the effect of genetically enabled care by health systems. The adoption of genomically targeted therapies and immunotherapy has changed oncology practice to a great extent, and at the same time the complexity of cancer treatment has made the use of EHR an important tool for communication among different teams. Genomics plays a fundamental role in cancer medicine, as relates to prevention, diagnosis, prognosis and treatment [15]. The present paper focuses on an EHR for precision oncology.

To this purpose an EHR has been designed with a view to the integration of cancer genomic data and taking into account tailoring it to the necessary information and the habits of the hospital ward [16, 17].

A web application has been created to retrieve the automated data from the hospital information system (HIS), reducing as much as possible the manual input of necessary data into paper-based medical records. An example of the integration of data from the HIS and clinical research by a web based application for management, sharing and analysing data in this respect given by a regional clinical network [18] on which has been used for several years. Moreover, the introduction of EHRs facilitates the re-use of the data for research or subsequent analysis. The project concerned the oncology department of the IRCCS AOU San Martino hospital in Genoa. Specifically, the automated incorporation of clinical data relating to patients suffering from colorectal carcinoma in the newly created ColoElectron database was considered. Data may be extracted for use in a series of clinical studies.

By using standards such as Health Level 7 (HL7), it has been possible to develop a computerized medical record capable of supporting interoperability between the main components of the San Martino hospital HIS, that is the Laboratory Information System (LIS) and the Pharmaceutical Information System (PIS). Subsequently, is it intended to extend the project involving several hospital oncology departments located in the Liguria Region, in which Genoa is the main town.

II. Materials and Methods

The software tool that has been developed has been implemented taking into account the specific needs of the oncology division of San Martino hospital. Before its development, an analysis of the visit path was carried out. This analysis included the patient identification through a software application (Medtrack), which requires information to the HIS; the control of laboratory analyses by paper check or by querying the hospital LIS (Laboweb) and the verification of the therapy stored in the PIS of the hospital managed by an external company through the SOFIA software. It should be noted that the data are stored on different platforms not communicating with each other, and their use is proving to be cumbersome and not without misunderstandings. This is also due to the use of paper-based clinical information, which contributes to the lack of efficiency of the clinical process.

In this respect, in order to solve the problem, a system based on a relational database developed with Microsoft SQL Server 2017 has been developed, which made it possible to create a consistent and logical representation of information. A software application including the creation of a web client and a web service has been developed in Visual Basic .NET using Microsoft Visual Studio 2015 software. In order enable the connection among systems interoperability plays a key role. Standards are needed to implement interoperability between systems.

A global architecture scheme was adopted, implementing a harmonisation of health services, proposed by HL7 in the HSSP (Healthcare Services Specification Project). The overall objective of the HSSP programme is to use the SOA (Service Oriented Architecture) approach to implement effective interoperability between distributed and heterogeneous applications and devices belonging to independent organisations of the healthcare and social system. Service Oriented Architecture (SOA) is the most widely adopted design strategy to support technical interoperability between real-time applications implemented in large-scale distributed environments. The main reason for the widespread of SOA paradigm is that it proposes a highly feasible strategy to easily promote the integration and alignment of new and existing solutions in a cohesive architecture, with minimal impact for service consumers, resulting in a highly reduced economic cost [19-21]. For

these reasons, this approach was successfully adopted in distributed healthcare architectures [22, 23]. Compliance with these standards guarantees a wide reuse of the efforts made to produce the suggested architecture and its stability of use over the years. Specifically, the HL7 Clinical Document Architecture (CDA) has been used to encapsulate clinical data that can be easily exchanged between applications, while maintaining their semantic significance [24].

Each hospital associates each clinical parameter with its own name and internal code. In order to allow different hospitals to communicate with each other, the individual codes used by different hospitals have been translated into LOINC language with regard to clinical trials [25], international ATC and national AIC for drugs, ICD9 for diagnosis and ISO Country 3166-1 for the classification of the nationality of origin of patients.

The network infrastructure of the San Martino hospital (which is the academic hospital of the University of Genoa) consists of two non-interconnected Local Area Networks (LANs): the hospital LAN and the university LAN. The components of the HIS are located in the hospital LAN, and for security reasons the hospital firewall prevents access to data from external networks. By a virtual private network (VPN) it was possible to allow access to the information requested also by the client belonging the university network.

VPNs use tunneling protocols and advanced encryption to provide a protective barrier around the original data before they are shipped over a potentially dangerous infrastructure such as the Internet. Tunneling is a multi-protocol (IPsec) data encapsulation process within another IP packet that is shipped over the network. The data is packaged twice in order to be transmitted only to authorized end recipients. This was achieved by an authentication system with different levels of access based on the role of the user.

III. RESULTS

In order to make all the components of the system interact in a transparent way, a client application was developed that led to the improvement of the quantity and quality of information that may be relevant for the treatment of patients suffering from colonrectal cancer. The computerised medical records developed in this project are hosted in the university network. The architecture of the client application developed is illustrated in Fig. 1.

The Client that has been implemented is divided into several parts, each concerning a specific section of the medical visit. After logging in, the caregiver is redirected to the patient selection page. After selecting the patient from the list, the actual examination can then be started. Once access permission has been obtained, it is possible to choose to manually enter the personal data of a new patient or view the data of a patient already in the database.

In the event of a new entry, the personal and clinical data of the new patient are retrieved from the hospital database and sent to the Coloelectron web service. After their translation into LOINC through the standard interface for the

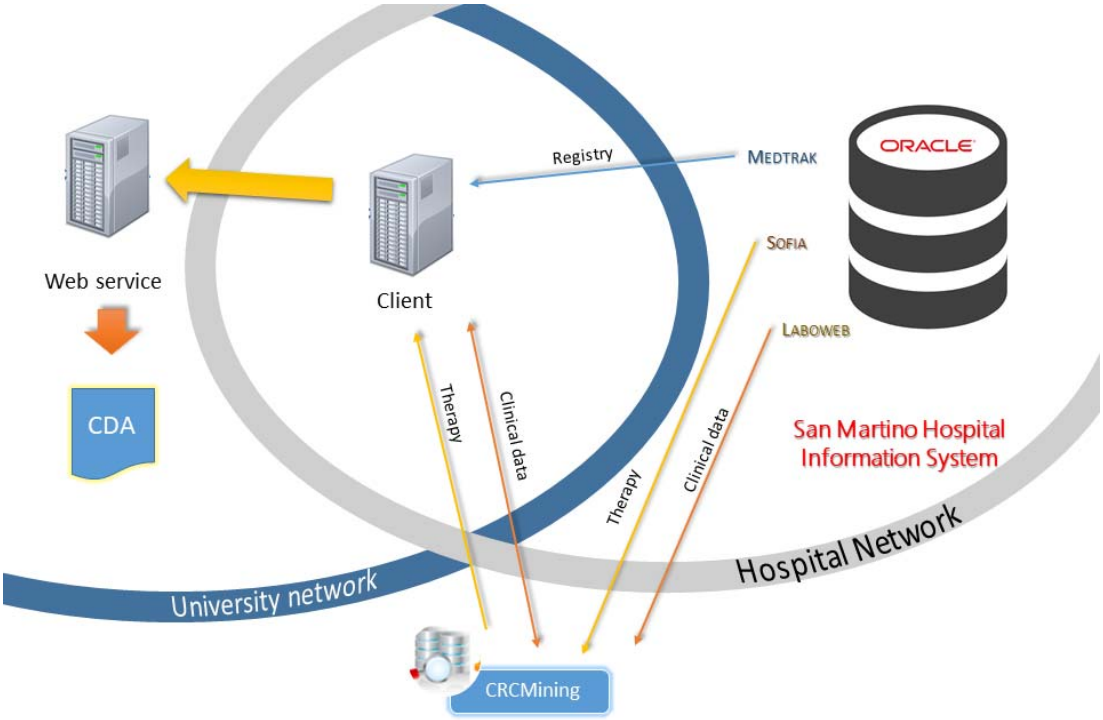

Fig. 1. Project outline

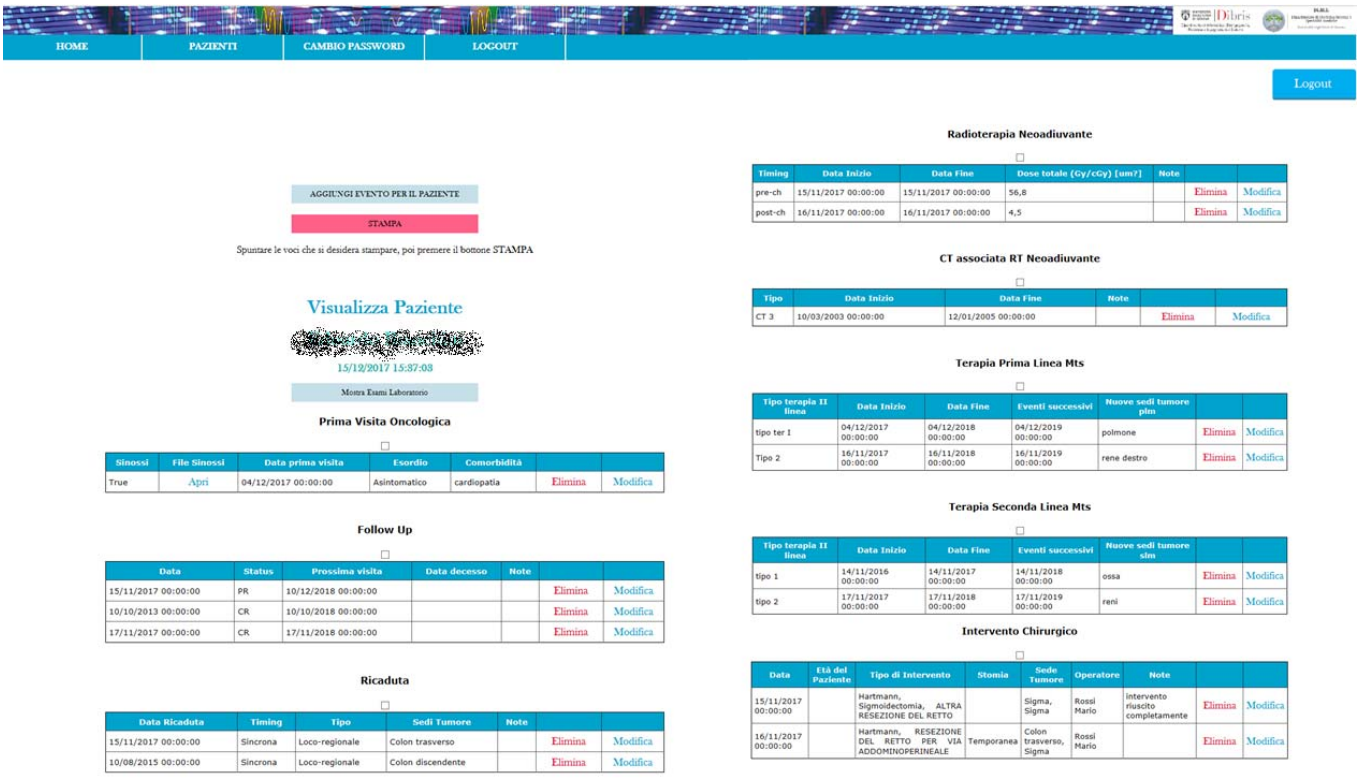

Fig. 2. Patient clinical record

use and management of HL7 Common Terminology Services ver.2 (CTS2), the data is saved in the Coloelectron database

Clinical parameters are obtained from the LIS. When a new patient is saved, the history of the laboratory test results must be included in the database. For this reason an array of CDA is built is sent to the web service that deals with the storage of content within Coloelectron.

A section on the clinical diary has been implemented, allowing the physician to consult the list of examinations and examinations carried out by the patient. Specifically, each patient is shown the history of all outpatient visits, with its date and parameters.

The data for each clinical event is automatically retrieved and updated from the databases already in use at the Department of Colorectal Oncology by the algorithms implemented according to the permissions obtained from the hospital's ethical committee.

In addition, for the daily update of the exams on the Coloelectron database, the launch of a "console application" type executable has been planned. This application is therefore performed daily and its main task is to check whether any of the patients in one of the clinical studies described above has undergone laboratory tests during the day. A screenshot of EHR is shown in Fig. 2.

IV. Discussion and Conclusions

A tailoring application was designed and developed to meet the needs of medical personnel, especially as regards the management of visits, and the creation of a clinical diary in compliance with the standards currently in use.

The web application developed allows the automatic entry of personal and clinical data of patients suffering from colorectal carcinoma under treatment at the San Martino hospital in Genoa within a database called Coloelectron.

The use of this system will simplify the doctor's work: in the administration and management of treatments, in the patient follow-up and in the multicentric tracking for patients who are also followed in other hospital facilities, as well as for the conduct of clinical trials. It will also save time and resources that the doctor can use to better treat the patient, thanks to the use of a single application for the management of visits. The present work is regarded as a basis for the integration of EHR and genomic data, so that complex cancer genomic data can be made compatible with traditional clinician – patients interaction.

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