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# Electronic Health Records: From the Management of Patients to the Research Use of Clinical Data

Barbara GIANNINI[a], Francesco CURTAZ[a], Filippo DEL PUENTE[b], Antonio DI BIAGIO[b], and Mauro GIACOMINI[a,c,1]
[a] *Department of Informatics, Bioengineering, Robotics and System Engineering (DIBRIS) – University of Genoa, Genoa, Italy*
[b] *Clinic of Infectious Diseases, Ospedale Policlinico San Martino, Genoa, Italy*
[c] *Centre of Excellence for Biomedical Research, University of Genoa, Genoa, Italy*

**Abstract.** Paper based medical records are still widespread in Italian hospitals and the workflow to manage outpatients' visits is critical. Too many isolated software programs coexist in hospital wards and cause confusion and disorganization. A computerized medical record that unifies all the data contained in the various applications should be of fundamental importance in supporting physician's daily activities. Moreover, with the digital clinical record, data can be re-used for research purposes. The aim of this project is to create a web application for the management of outpatient visits to the Infectious Diseases Unit of the San Martino Hospital in Genoa. In order to orchestrate all the software programs acting in the visit workflow, a client application was developed to speed up the work of the medical staff at the time of the visits, ameliorating the quantity and quality of relevant information from a clinical point of view. A further extension allows standard data exchange between the developed application and the Ligurian HIV Network, which is the main regional research platform.

**Keywords.** EHR, standard, HL7, CDA, interoperability

## 1. Introduction

In the last years, the use of computerized medical records within healthcare facilities gained a prominent role [1]. This instrument is of fundamental importance in the fulfillment of all clinical activities as an almost indispensable support for the work of the physician [2]. The computerized medical record contains the clinical history of a patient.

Thanks to the digitalization of clinical records, data can be automatically collected from the Hospital Information System (HIS), avoiding the manual input process that was necessary for paper-based records. With the digital clinical record, data contained can be re-used for research purposes. This "proactive" nature of computerized medical records is the main innovation that is achieved in the conversion from paper to digital media.

The aim of this project is to create a web application for the management of outpatient visits to the Infectious Diseases Unit of the San Martino Hospital in Genoa. The focus has been on HIV - positive patients, who need constant follow up and represent a significant portion of the patients attending the department.

[1] Corresponding Author Mauro Giacomini. E-mail: mauro.giacomini@dibris.unige.it.

The computerized medical records developed support interoperability both with the main components of the San Martino Hospital information system (Laboratory Information System (LIS) and Pharmaceutical Information System (PIS) and with the main regional platform for clinical trials performance the Ligurian HIV Network. This interoperability is granted by the use of medical ICT standards such as Health Level 7 (HL7).

## 2. Materials and methods

According to data provided by the medical staff, more than 1,300 HIV-infected patients are treated in San Martino hospital. Every day, about 25-30 visits take place, each with a duration of about 30 minutes. Prior to the design of the application, a survey was conducted in the Infectious Diseases ward to analyze the clinical workflow and highlight the main critical issues. A typical visit is divided into the following sections:

- patient identification: the hospital identification code is gathered from the hospital registry via a software application called Medtrak
- check of the laboratory tests executed after the previous visit. This information is stored in the hospital's LIS and can be retrieved through a software called Laboweb
- vital signs check: vital signs parameters are registered on paper based clinical records
- therapy check through a PIS software called Sofia that manages the antiretroviral drugs prescribed. This software does not calculate therapy adherence
- risk factors evaluation, for example smoking and alcohol habits. In evaluating the clinical scenario of a patient, the physician is often supported by online calculators that quickly give an indication of the patient's state of health or provide guidance on the likelihood of adverse events.

Many critical issues arose from the workflow described. In particular, there are too many software applications, which manage different parts of the workflow separately, without communicating. There is still excessive use of paper support that leads to misunderstanding and time wasting. Moreover, it is difficult to retrieve important clinical data concerning previous visits from this paper-based system.

To fix the described problems, a system which relies on a relational database was developed with Microsoft SQL Server 2016. The relational model allows the database designer to create a consistent and logical representation of the information. Consistency is obtained by inserting appropriate constraints in the database project logic scheme. The program application was developed in Visual Basic through Microsoft Visual Studio 2015.

The Ligurian HIV Network is an innovative web-platform to collect clinical data of HIV infected patients undergoing treatment in Ligurian hospitals [3][4]. Laboratory data are collected in an automatic way but data about patients' visits are still uploaded manually. In order to connect the system developed to the Ligurian HIV Network and exchange clinical data, interoperability is an essential feature. The Clinical Document Architecture (CDA) of Health Level 7 (HL7) is a standard document that encapsulates clinical data to be exchanged between different applications in order to maintain the semantic meaning [5]. San Martino uses a local terminology to identify clinical parameters. To fill the CDA document, clinical parameters must be explicated using a standard terminology referring to a codified vocabulary such as LOINC codes for clinical tests, international ATC and national AIC for drugs and ICD9 for diagnosis.

San Martino is an academic hospital of the University of Genoa and has two different web networks: one university and one hospital. The software programs cited above are hosted on the hospital network. The hospital firewall avoid access to data from external networks. The medical record interface is visible only inside the hospital network and a

system of authentication controls and registers the accesses to the platform. The Ligurian HIV Network, which was developed by DIBRIS at the University of Genoa, is hosted on the university network. It is visible from the extern network and its accesses are mediated by a system of authentication with different access levels according to the users' role. The https protocol was used.

## 3. Results

In order to orchestrate all the software programs acting in the visit workflow described, a client application was developed to speed up the work of the medical staff at the time of the visits, ameliorating the quantity and quality of relevant information from the clinical point of view. The computerized medical records developed in this project are hosted on the hospital network but they are also reachable on the university network, in order to directly communicate with the Ligurian HIV Network. The architecture of the client application developed is illustrated in figure 1.

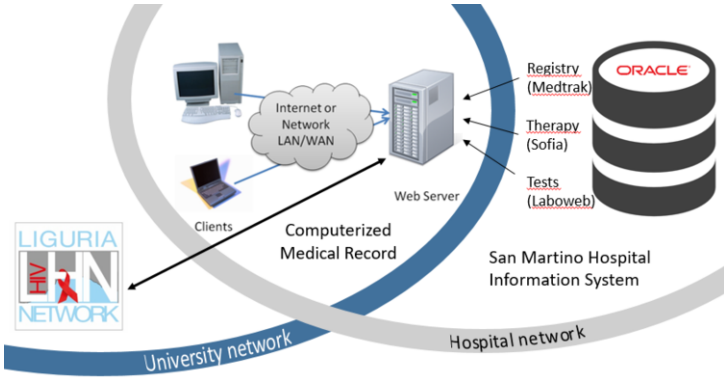


**Figure 1**: Architecture of the client integration between the hospital software components and the Ligurian HIV Network

The client application developed is divided into several parts, each covering a specific section of the medical visit. After selecting the patient from the list, the first section provides a brief view of the patient's clinical history, as shown in figure 2. This section enables the proper management of a standard medical visit. It also contains a summary of the patient's health status including the most important clinical parameters value of the last test performed and the therapy that he is taking. To give physicians a graphical feedback, the main information is colored according to the normality range fitting. The criteria used are summarized in table 1. Next to the therapy section, the adherence to the therapy prescribed is calculated and highlighted with colors. Adherence is calculated according to the formula below (1):

$$Adherence = \frac{1}{\#recurrence} \frac{\#delivered\ doses + \#remaining\ doses}{\Delta days} \quad (1)$$

where:

- #recurrence is the number of doses that the patient has to take daily
- #delivered doses is the number of doses that the pharmacy delivered to the patient

- #remaining doses is the number of remaining doses if the drug was, as desirable, retired before the end of the cycle.
- Δdays is the number of days between the date of delivery of the drug and the expected date of the end of the therapeutic cycle.

**Table 1.** Criteria and thresholds used for clinical parameters alerting

| Parameter | Serious alert | Mild alert |
|---|---|---|
| Lymphocyte CD 4 + cell | <200/µl | 200/µl< TCD-4< 350/µl |
| HIVRNA | >200 copies (twice) or >1000 copies | >200 copies |
| GOT<br>GPT | Variation of 60% between two consecutive measures | Variation of 30% between two consecutive measures |
| Creatinine | Variation of 20% between two consecutive measures | / |
| HBsAg<br>HCV<br>VDRL | Variation from positive to negative | / |

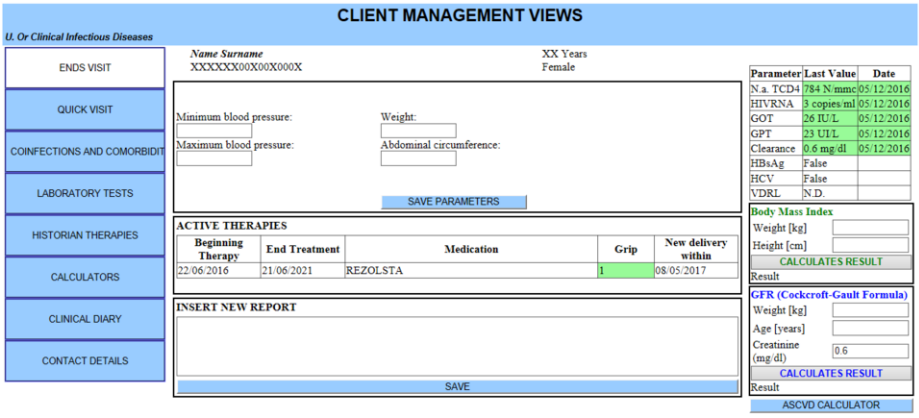


**Figure 2**: Main view of a computerized medical record containing a summary of the patient's health status

The clinical parameters are extracted from the Laboratory Information System (LIS) database. A dedicated section on the client interface provides a view of the last blood test. Clinical parameters are divided into categories. By selecting the Details button of a parameter, it is possible to see a list of all previous values with the corresponding graphical chart showing the temporal ongoing. An example is shown in figure 3.

At the end of the medical examination, the program creates a discharge document in PDF format for the patient and a standard CDA document to upload data in the Ligurian HIV Network. To create this last document, a translation from local codes to standard terminologies is performed. The mappings were manually made and saved in the database. The CDA document is created according to the files containing the XSD schema definitions provided by HL7 V3. The generated CDA does not meet the specifications of any implementation guides as there is currently no implementation guide for the management of outpatient report in Italy.

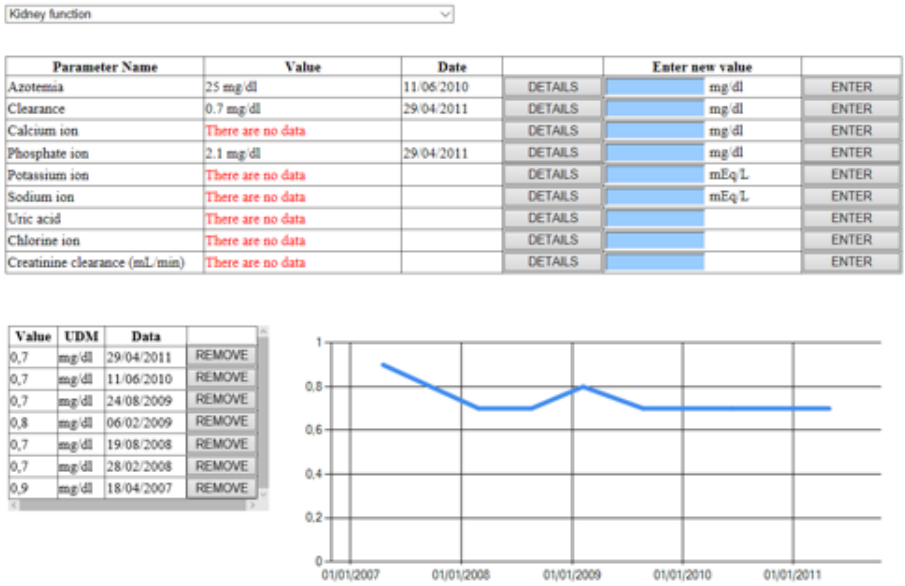


**Figure 3:** Kidney function subsection with focus on the history of clearance values

## 4. Discussion and conclusion

An application designed to meet the needs of medical staff in the management of outpatient visits and to create clinical report documents complying with HL7 standards, was developed and implemented. The use of a single application to manage the visits instead of all the programs described in the workflow will allow physicians to save a large amount of time. The application is now working and is ready to be used for a first testing phase within the San Martino Hospital.

As a future development, the mapping phase between local terms and standardized codes could be performed through a standard terminology service compliant to the Common Terminology Service 2 (CTS2) standard.

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