

# OPHTHALMOLOGIC ELECTRONIC HEALTH RECORDS SYSTEM USING HL7/CDA AND DICOM - TELEOFTALWEB

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**Keywords:** Clinical Document Architecture (CDA), Digital Imaging and Communications in Medicine (DICOM), Electronic Health Record (EHR), Extensible Markup Language (XML), Health Level 7 (HL7), Java.

**Abstract:** Electronic Health Record (EHR) refers to the complete set of information that resides in electronic form and is related to the past, present and future health status. Health Level Seven (HL7) and Digital Imaging and Communications in Medicine (DICOM) are intensively influencing EHRs standardization. This article describes the development, experience and evaluation of a web-based application, TeleOftalWeb 3.2, to store and exchange EHRs in ophthalmology. We apply HL7 Clinical Document Architecture (CDA) and DICOM standards. EHRs and fundus photographs are stored in a database Oracle 10g. The application has been built on Java Servlet and Java Server Pages (JSP) technologies. For security, all data transmissions were carried over encrypted Internet connections such as Secure Sockets Layer (SSL) and HyperText Transfer Protocol over SSL (HTTPS). The application verifies the standards related to privacy and confidentiality. TeleOftalWeb 3.2 has been tested by ophthalmologists from the University Institute of Applied Ophthalmobiology (IOBA), Spain. Nowadays, more than one thousand health records have been included to verify the web application usability.

## 1 INTRODUCTION

Electronic Health Records (EHRs) are a secure, real-time, point-of-care and patient-centric information resource for physicians (HIMSS, 2003). EHRs include information such as observations, laboratory tests, diagnostic imaging reports, treatments, therapies, drugs administered, patient identifying information, legal permissions and allergies. Currently, this information is stored in all kinds of proprietary formats through a multitude of medical information systems available on the market (Eichelberg et al., 2005). EHR systems can incorporate clinically useful features such as electronic alerts, guideline reminders and automatic monitoring of quality of care indicators (Bostrom et al., 2006). The primary purpose of EHR is the support of continuing, efficient and quality integrated health care. Amongst EHRs benefits are their universal access, coding efficiency and

efficacy, easier and quicker navigation through the patient record (Smith and Newell, 2002). There are several barriers to their adoption such as training, costs, complexity and lack of a national standard for interoperability (Gans et al., 2006).

Ophthalmology is an ideal specialty for testing EHRs due to the use of images and objective measures during diagnosis of eye diseases. It is an ideal specialty for telemedicine. EHRs systems can assist ophthalmologists in improving the quality of care being provided as well as assist the ophthalmologists in building solid relationships with their patients. Physicians who have shared EHRs available yet fail to consult them before beginning treatment could face increasing liability in the future (Yogesana et al., 1998).

International and European institutions are working in EHR standardization such as the International Standards Organization Health Informatics Standards Technical Committee

(ISO/TC) 215, European Committee for Standardization Technical Committee (CEN/TC) 251, Health Level Seven (HL7), Extensible Markup Language (XML), Digital Imaging and Communication in Medicine (DICOM) and others (Bott, 2004). The development of HL7 and DICOM standards has also been of great benefit in the telemedicine services and applications.

HL7 standard is used for many different medical environments. It is a not-for-profit organization involved in development of international healthcare standards. HL7 Document is intended to be the basic unit of a document-oriented EPR. The patient medical record is represented as a collection of documents. HL7 Clinical Document Architecture (CDA) is a XML-based document markup standard that specifies the structure and semantics of EHR for the purpose of exchange. Clinical Document Architecture – Release One (CDA–R1), became an American National Standards Institute (ANSI)–approved HL7 Standard in November 2000, representing the first specification derived from the HL7 Reference Information Model (RIM). CDA – Release Two (CDA–R2), became an ANSI–approved HL7 Standard in May 2005 (Dolin et al. 2006). CDA standard provides an exchange model for clinical documents. Many CDA documents comprise an individual EHR.

DICOM is a cooperative standard. It was developed from 1990 to 1996, mainly by the American College of Radiology (ACR) and National Electrical Manufacturers Association (NEMA) committee in the United States, with contributions from European standardization organizations, the Japanese Industry Radiology Apparatus (JIRA), the Institute of Electrical and Electronics Engineers (IEEE), HL7 and ANSI as well as from European manufacturers and societies. This standard allows the exchange of medical images and related information between systems from different manufacturers.

EHRs have a great potential to improve safety, quality and efficiency in medicine. EHRs systems often involve many institutions. Most previous studies addressing this issue have been done in primary care (Lo et al., 2007). In our application, EHRs are shared between ophthalmologists, endocrinologists, and primary care physicians.

We reviewed articles about EHR systems in different specialities such as pediatric (Ginsburg, 2007), emergency departments (Amouh et al., 2007), ophthalmology (Chew et al., 1998) and oncology (James et al., 2001). In these systems, HER standardization applying HL7/CDA and

DICOM was not presented.

We have designed, developed and evaluated a web-based application to store and exchange EHRs in ophthalmology, TeleOftalWeb 3.2. We apply HL7/CDA and DICOM standards. The application has been built on Java Servlet and Java Server Pages (JSP) technologies. EHRs and fundus photographs are stored in Oracle 10g database. Its architecture is triple-layered. The application server is Tomcat 5.5.9. The application is platform-independent thanks to using Extensible Markup Language (XML) and Java technologies. For security, all data transmissions were carried over encrypted Internet connections such as Secure Sockets Layer (SSL) and HyperText Transfer Protocol over SSL (HTTPS). The application verifies the standards related to privacy and confidentiality. It has been tested by ophthalmologists from the University Institute of Applied Ophthalmobiology (IOBA), Spain. Currently, more than one thousand health records have been included.

## 2 METHODS

Firstly, we describe the application data modeling in Oracle 10g database. Then, we show the application architecture.

### 2.1 Data Modeling

In Oracle 10g database, we stored all the user data and access information to the web application. It has three tables: “users”, “permissions” and “records”. The table “users” contains personal user data. The user identification, user name, password, and user type appear in table “permissions”.

EHRs are stored in Oracle 10g database according to the ANSI/HL7 CDA R2.0-2005 template. The data modeling in the Oracle database is shown in Figure 1.

Oracle 10g introduced a new datatype, XMLType, to facilitate native handling of XML data in the database. It supports comprehensive models (i.e., structured, unstructured and binary XML storage models) to server diverse XML use cases with different requirements. For table “records” (see Figure 1), we use this datatype. XMLType is stored in Large Objects (LOBs). LOB storage maintains content accuracy to the original XML (whitespaces and all). When we create an XMLType column without any XML schema specification, a hidden CLOB column is

automatically created to store the XML data. The XMLType column itself becomes a virtual column over this hidden CLOB column. It is not possible to directly access the CLOB column.

Oracle XML database provides efficient support of SQL/XML XMLTable function and its COLUMNS clause for mapping XML data into relational views. By taking advantage of XQuery rewrite technology, storage models, indexing schemes, downstream processing on a relational view created with XMLTable function can approach pure-relational-performance (Oracle, 2008).

## 2.2 Application Architecture

TeleOftalWeb 3.2 architecture is a triple-layered. Oracle 10g is used as database server and Apache Tomcat 5.5 as application server. Figure 2 shows the application architecture. Oracle 10g provides high-performance, native XML storage and retrieval technology.

We employ an Oracle Java Database Connectivity (JDBC) driver to connect to the database instance. A free open-source application server to process the requests is used. The web-based system was built on Java Servlet and JSP technologies, which enables rapid development of web-based applications. In Oracle database, we stored all the user data, access information to the web application and records with fundus photographs.

The development environment was NetBeans IDE 4.1 of Sun Microsystems. The application is platform-independent thanks to using XML and Java Technologies. Java was the basis application programming language. XML is an open standard that provides a unified model for data, content and metadata. It is being used to manage mission critical information.

We included all tools and Application Programming Interface (API) as Javascript, JSP, Java Servlets and JDBC. The evolution of Java Technology brings more features to the Java development tools. This facilitates the creation of telemedicine applications and reduces the time of developing programs (Fedyukin et al., 2002). XML technology is employed to store and exchange EHRs. Some XML advantages are: easily readable, self-describing and interoperable.

Column	Data Type	Nullable	Default	No Nulls	Data per Instance
ID	VARCHAR2	NO		NO	
NOMBRE	VARCHAR2	NO		NO	
APellidos	VARCHAR2	NO		NO	
CALL	VARCHAR2	NO		NO	
TELEFONO	VARCHAR2	NO		NO	
EMAIL	VARCHAR2	NO		NO	
FECHANACIMIENTO	VARCHAR2	NO		NO	
EDUCACION	VARCHAR2	NO		NO	
MANEJADOR	VARCHAR2	NO		NO	
HOSPITAL	VARCHAR2	NO		NO	
SEXO	VARCHAR2	NO		NO	
PROFESION	VARCHAR2	NO		NO	
PROFESOR	VARCHAR2	NO		NO	
COPIESISTA	VARCHAR2	NO		NO	
FECHANACIDOS	VARCHAR2	NO		NO	
FECHANACIDOS	VARCHAR2	NO		NO	

Column	Data Type	Nullable	Default	No Nulls	Data per Instance
ID	VARCHAR2	NO		NO	
LOGIN	VARCHAR2	NO		NO	
PASSWORD	VARCHAR2	NO		NO	
SEXO	VARCHAR2	NO		NO	

Column	Data Type	Nullable	Default	No Nulls	Data per Instance
REF_COLUMN	VARCHAR2	NO		NO	
XML_COLUMN	XMLTYPE	NO		NO	

Figure 1: Data Modeling.

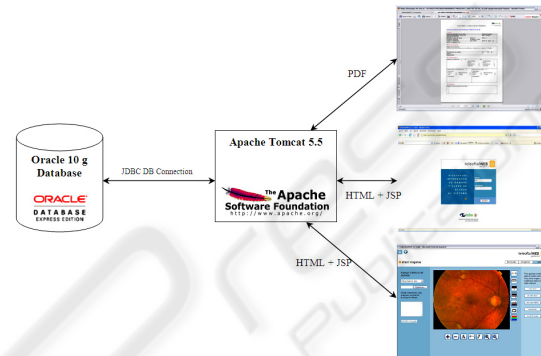


Figure 2: Architecture Application with Oracle 10g.

CDA Release 2 model is richly expressive, enabling the formal representation of clinical statements (such as observations, medication administrations and adverse events) such that they can be interpreted and acted upon by a computer (Dolin et al., 2006).

As it was indicated in the introduction, CDA documents are encoded in XML. The CDA is only the first example of HL7's commitment to the advancement of XML-based e-healthcare technologies within the clinical, patient care domain. The CDA specification prescribes XML markup for CDA Documents: CDA instances must be validated against the CDA Schema and may be subject to additional validation. The document can be sent inside or outside a HL7 message. CDA also supports the semantically interoperable exchange of complex medical information between healthcare applications by virtue of its adherence to the HL7 V3 development methodology (Chronaki et al., 2002). CDA does not specify the creation or management of documents, only their exchange mark-up.

The XML-based architecture described in the CDA v2.0 standard has been used to define the health information format. Thanks to the use of XML-based technologies and HL7 specifications, our application fulfils the EHR standards. Its development methodology is a continuously evolving process that seeks to carry out

specifications that facilitate interoperability between healthcare systems.

### 3 RESULTS

We present the two application modules: manager and user. Then, we describe the experience of introducing diabetic patient's health records from a screening program of diabetic retinopathy in a rural area of Spain (Hornero et al., 2003).

#### 3.1 Manager Module

The manager can access the web platform with any browser. Login and password have to be introduced by users. The two user roles are: manager and user. Application manager allows to:

- Create new users.
- Show user information.
- Erase users.
- Modify physician's information.
- Show user statistics.
- Show the user patient records.
- Search users by different criteria such as surname, identification number, type of user, and member number.

#### 3.2 User Module

The authorized physicians can access to this module. They have their login and password. They can do the following actions:

- Create new records (see Figure 3). They have to introduce the necessary data: patient affiliation information, patient precedents, medical exploration and diagnostic.
- Erase records and revisions.
- Create new revisions in a record.
- Search different EHRs and revisions,
- Add new images in different records. Physicians can add new images in an EHR. These may be in different formats such as DICOM, Joint Photographic Experts Group (JPEG), Graphics Interchange Format (GIF), DIB file format (BMP), Tagged Image File Format (TIFF) amongst others.
- Search images according to different criteria: image identification number, surnames, image creation and comments.

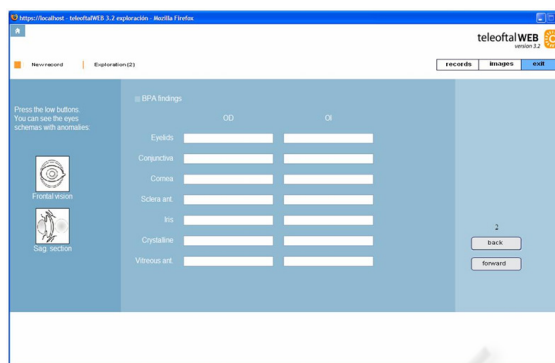


Figure 3: Exploration in a new EHR.

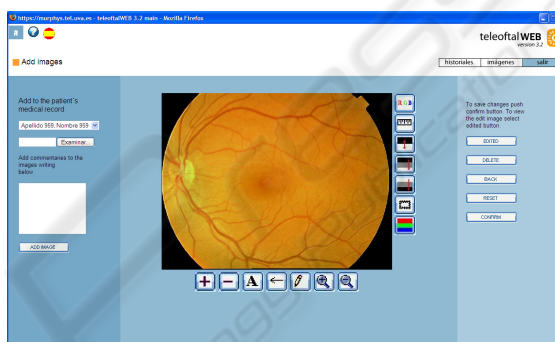


Figure 4: DICOM fundus photograph.

- Edit and erase images. The images editor (see Figure 4) shows images and allows us to change their shape and colour, zoom in or zoom out. It supports image editing of brightness and contrast. Other editor functions are: RGB (Red, Green, Blue) scale, add and delete text, and arrows. It supports all type of images (DICOM, JPEG, GIF, etc.).
- Print EHRs in Portable Document Format (PDF). We employ Extensible Stylesheet Language Formatting Objects (XSL-FO) to format XML data. XSL-FO is a complete XML vocabulary for laying out text on a page. An XSL-FO document is a well-formed XML document that uses this vocabulary. EHR output format is a PDF. First, the XML must be fed to an XSLT processor with an appropriate stylesheet in order to produce another XML document which uses the XSL-FO namespace. It is intended for an XSL-FO formatter. The second stage is to feed the output of the first stage to the XSL-FO formatter that can produce a printable document styled for visual presentation (Pawson, 2002).

### 3.3 Practice Case

TeleOftalWeb 3.2 has been tested by physicians from the University Institute of Applied Ophthalmobiology (IOBA), Spain. Nowadays, more than one thousand health records were introduced. All the patients were diabetic and they participated in a telemedicine program for diabetic retinopathy screening in a rural area of Spain (Hornero et al., 2003). Diabetic retinopathy is the most common diabetic eye disease and a leading cause of blindness in adults. It is caused by changes in the blood vessels of the retina (National Eye Institute, 2008). Our application allows to store and exchange all the records and fundus photographs. Physicians used the application with different web browsers to store and exchange the EHRs. In each record there are the following parts: anamnesis, exploration, diagnosis and treatment. The EHR is associated with the fundus photographs in all type of digital formats.

A survey with ten questions about the application usability was done (see Figure 5). We used System Usability Scale (SUS) to make the questionnaires. It is a Likert scale. SUS has proved to be a valuable evaluation tool, being robust and, reliable. It correlates well with other subjectives measures of usability (Brooke, 1996). Six physicians used the application. The SUS score is major than fifty for all the physicians. Its average value is seventy four. The questions such as: clinical records are organised and legible, access to EHRs from any place, information quality in the application were strongly agreed. The results can be viewed in Table I. According to these results, our web-based application is useful for the physicians because SUS score is always major than 50.

## 4 CONCLUSIONS

In this study, a web-based application has been developed to store and exchange EHRs and fundus photographs in Ophthalmology by using HL7/CDA and DICOM standards. EHRs have several distinct advantages and disadvantages over paper health records. One advantage is the fact that there are increased storage capabilities for longer periods of time. EHRs can also provide medical alerts and reminders. Some of the disadvantages include such items as the startup costs, which can be excessive. Another disadvantage to an EHR is that there is a substantial learning curve and it is helpful when the users have some type of technical knowledge (Gurley, 2004).

Table 1: Satisfaction survey results.

Questions	Physicians					
	1	2	3	4	5	6
1	4	4	4	4	4	4
2	3	4	4	3	4	4
3	3	4	4	4	3	3
4	3	3	3	4	3	3
5	4	3	3	3	4	4
6	4	4	4	4	4	4
7	4	4	4	4	4	2
8	2	2	1	2	2	4
9	2	2	2	2	2	2
10	4	4	3	4	4	4
SUS Score	67,5	75	67,5	80	80	75

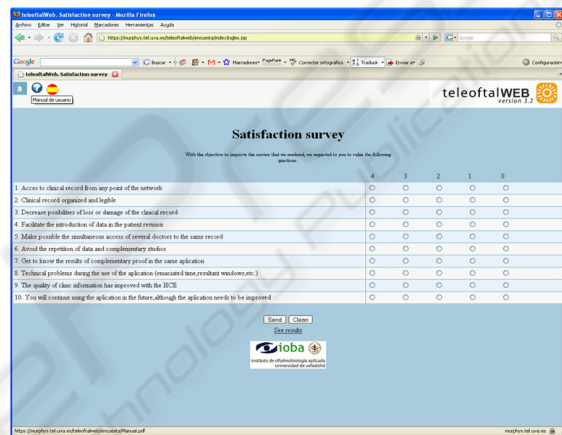


Figure 5: Users satisfaction survey.

TeleOftalWeb 3.2 advantages are: its adaptation to the HL7/CDA and DICOM standards, the interoperability facilitation between institutions and applications and its security. The physicians can analyze EHRs everywhere. The application verifies the standards related to privacy and confidentiality. However, the application speed depends mainly on the Internet connection and the number of users in the system. When this number is high, the application speed is lower.

DICOM and HL7 are well-accepted healthcare industry standard. DICOM is used in diferent medical fields, such as pathology, endoscopy, dentistry, ophthalmology and dermatology. It is a success for radiology and cardiology, and it is now beginning to be used for other clinical specialties (Kuzmak and Dayhoff, 2003).

According to our review, we analyzed several studies about EHR systems. These systems have been presented using XML-based Clinical Document Architecture to exchange discharge summaries (Paterson et al., 2002). There are EHR applications in different specialties such as pediatric

(Ginsburg, 2007), ophthalmology (Chew et al., 1998), emergency departments (Amouh et al., 2007) and oncology (James et al., 2001). In the telematic system for oncology, they use a data warehouse as EPRs server. The authors do not present a EHRs standardization process. Information system for emergency department has been implemented by prototyping a web-based application. It makes uses the XML-based *openEHR* standard.

In summary, we have designed, developed and evaluated a web-based application to store and share EHRs in ophthalmology by using HL7/CDA and DICOM standards. Our application treats to solve some of the barriers to the EHRs adoption in ophthalmology. The records and the fundus photographs in all type of formats are continuously updated and are available concurrently for use everywhere. We verified that the application was useful for the physicians.

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