System for Electrophysiology Integration with Other Departments Using Clinical Document Architecture Technologies and HL7 V3

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Abstract

In the electrophysiology laboratory (EPH-Lab) data collection of implanted devices is mandatory for documentation and clinical reporting. At present, computerized systems are not commonly used in the EPH-Lab, but they can allow clinicians to obtain a proper documentation from an integrated information system, gathering data from ambulatory activity, wards and EPH-Lab archives. The aim of our work was to create an informative system to exchange clinical information using HL7 Clinical Document Architecture (CDA) release 2, defined in HL7 V3 standard. EPH-Lab facility has been introduced as part of our hemodynamic information system (SIE) in order to track work flow, device implantations, electrophysiologic studies, interventional electrophysiology procedures and electronic medical records for anesthesiology.

1. Introduction

Cardiac electrophysiology evaluates the electrical system of the heart, and is mainly concerned with the study of cause and treatment of abnormalities in heart rhythm. Arrhythmias are diagnosed and treated by electrophysiologists, cardiologists who are specialized in the diagnosis and treatment of cardiac arrhythmias.

In an EPH-Lab data collection of implanted devices is mandatory for administrative and clinical purposes and can be troublesome in a busy laboratory dealing with many procedures/day. Traditional paper archiving, commonly used so far, may become inadequate mostly when the workflow requires management of clinical and administrative patient data from other Electronic Health Records (EHR) available in a wide Health System.

EPH-Lab informative system facilitate data collection procedures in order to reach an adequate level of document management.

Our EPH-Lab manages activities through a dedicated Hospital Information System (HIS) interface that allows a real time tracing of the work process features (waiting list, procedure protocols, medical reports, image files, administrative and organization procedures). SIE [1], the information system of our cath lab, makes clinical work easier by organizing information data flow and data viewing, improves clinical data interpretation, reduces decision-making process and increases operators efficiency.
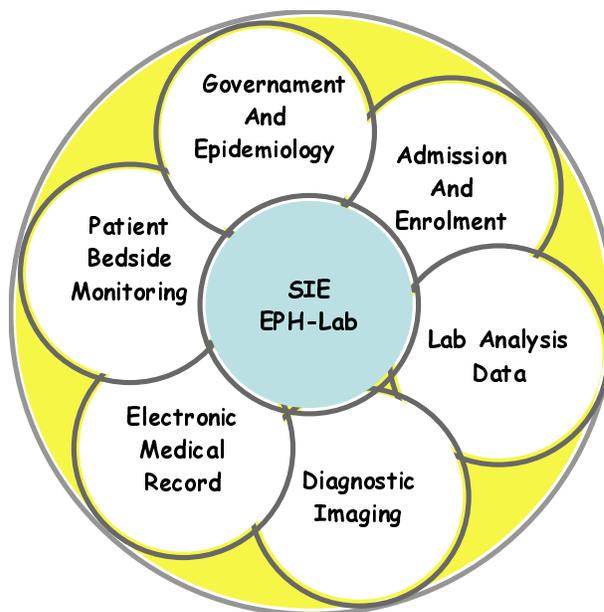

Figure 1. EPH-Lab System Overview

Extensions of this informative system address issues of sharing complex information with other EHR systems.

On line check of the implantable device disposable in the EPH-Lab is of utmost importance in the outpatient setting, when patient with already implanted devices are followed after implantation on a routine basis. Therefore, information collected through a dedicated Electronic Medical Record (EMR) system for outpatient [2] needs to be shared with the EPH-Lab informative system for planning and timing of changes of the device for end-of-life.

To activate a rapid communications between EPH-Lab, EHR and outpatient EMR, a new informatics integration middleware technology HL7 v3, based on exchange of XML document, has been chosen. Structured documents adopted are based on CDA [3,4].

The aim of this work was to validate this new architecture in our complex environment.
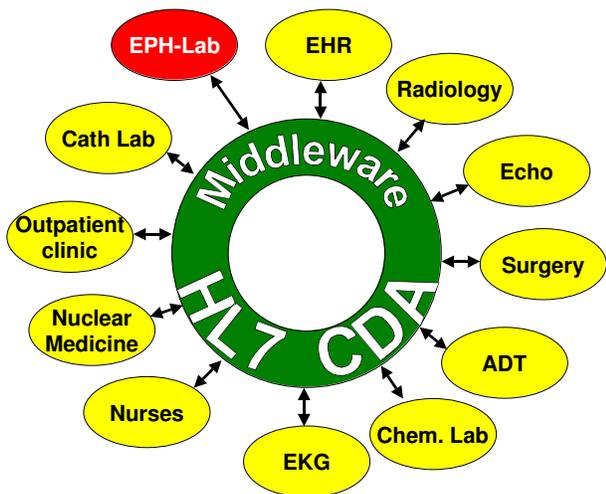

Figure 2. Integration scheme of EPH-Lab in a wide HIS using HL7 CDA Middleware

2. Methods

Clinical data set is a motivated collected group of entries that may be stored, shared or presented together within clinical applications, messages and electronic health records [5].

CDA is basically independent from the detailed clinical content, and description of detailed clinical content (including clinical data sets) is managed and registered under the responsibility of external organizations, according to procedures defined by the standard developing organizations. Clinical Data Sets are a kind of "soft standards" oriented towards particular human tasks and knowledge management.

Due to the lack of established dataset in Electrophysiology we built a set of electrophysiological specialized components able to satisfy our longitudinal EHR, which shared data with many other systems: ADT Patient Registration, Department System Scheduler, Order Filler, Specialized Ambulatory EMRs, Wards etc.

When a CDA related to a specific EPH procedure is generated, an internal validation is required in order to test correctness of XML document.

This task is accomplished by a developed internal procedure, available as a WEB service for our Institute and even external customer [6].
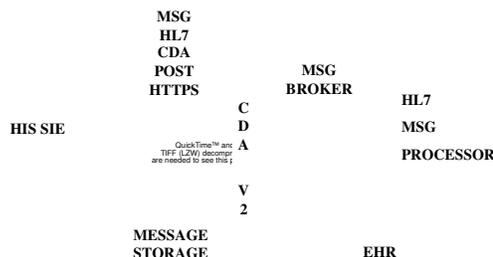

Figure 3. Data Exchange Architecture

A valid CDA is sent to a Message Broker that handles the structured data and filtered qualified data for longitudinal EHR. To transport clinical document we used secure connections based on HTTPS and POST of multipart form data. On EPH-Lab local Document Registry and Document Repository was created to manage data workflow.
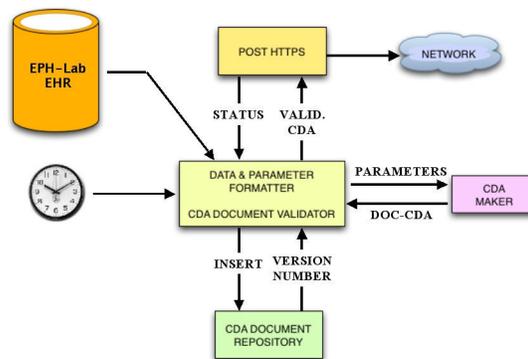

Figure 4. CDA Message Manager

FileMaker Pro 6.x database, a multiplatform environment, together with two library extension for HTTP/S communications and XML parser, was used to produce the CDA Message Manager System.

3. System overview

The EPH-lab workstations enable the authorized personnel to manage all patient information regarding clinical history, physical examination, instrumental and biochemical data. Patient data and clinical history were collect from each available EHR repository of our Health System. Moreover EPH-lab workstations offer the opportunity to record clinical journals during procedure, managed clinical variables and data such as characteristics of implantable devices. Data were collect and organized directly by operators and automatically

from standard devices via network protocol. The SIE at the end of each procedure, provide an electronic report, ready to be archived and transmitted to our wide HIS (Figure 2). At the same time a report is generated to send instructions to nurses staff for patient care (treatment and drugs prescriptions). The EPH-lab workstations permit management of used material by a bar-code facility. These facilities reduce the incidence of errors, typical of manual insertion of specific device codes and serial numbers.

4.   EHR integration

Our EPH-Lab Clinical Data Set is oriented to track particular activities and data coming from medical devices: pacemakers, implantable cardioverter defibrillators, electrophysiological catheters etc., each with the specific measured value, according to the procedure (time, periods, potential, current, impedance and temperature). A CDA Pattern coming from an analysis of requested data definition in order to establish a set of clinical data to be exchanged was defined to send CDA documents with structured body to EHR system we had to define. This clinical dataset was submitted to public evaluation, in order to share a dataset standard definition, on MOBIDIS web repository [7] that manage the inventory of Italian public available packages with clinical data sets.

4.1.   Shared Clinical data set

The components that we have structured in order to share clinical data with other EHR were:
- ID procedure and clinical report
- Pace makers codes
- Defibrillators codes
- Implanted devices reports
- Right ventricular electrocatheter implantation reports
- Atrial electrocatheter implantation reports
- Coronary sinus electrocatheter implantation reports
- Basic electrophysiological study reports
- Electrophysiological study reports during pharmaco-logical stimulation
- Diagnostic electrocatheters reports

Our EPH-Lab CDA is a complex XML document. A header, allows document to be validated (Table 1).

A fully qualified document identification are present in CDA: ID, title, author, custodian, responsible Party, record Target and parent Document (Table 2).

Table 1. XML Header of CDA Document

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument
templateId="2.16.840.1.113883.3.27.1776"
xmlns="urn:hl7-org:v3"
xmlns:fo="http://www.w3.org/1999/XSL/Format"
xmlns:msg="urn:hl7-org:v3/mif"    xmlns:voc="urn:hl7-org:v3/voc"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3
http://www.ifc.cnr.it/hl7/CDA_Schema/Files/CDA.xsd">
```

Table 2. XML fragment of CDA Document

```
<ClinicalDocument>
...
    <bodyChoice>
     <StructuredBody>
      ...
      <component>
       <section>
        <entry>
         <entryChoice>
          <CodedEntry>
               <id>Exam_Internal_ID</id>
               <code>IDP01.000.001</code>
          </CodedEntry>
         </entryChoice>
        </entry>
       </section>
      </component>
      ...
      <component>
       <section>
        <entry>
         <entryChoice>
          <Observation>
               <id>Pre_Implant_Symptoms</id>
               <code>CPMI01</code>
               <value>B1</value>
          </Observation>
         </entryChoice>
        </entry>
       </section>
      </component>
      ...
     </StructuredBody>
    </bodyChoice>
 ...
 </ClinicalDocument>
```

Clinical Data was organized as a collection of multiple

segments called components, each one planned as a collection of entries that specify the single structured data as shown in XML fragment examples below (Table 2).

4.2. Ward activity integration

Information regarding the specifics of procedure, possible complications, drugs administration, nurse activities during invasive examinations and suggestions for post-procedural assistance were organized in a structured document. This was automatically generated and sent to the nurse database of the cardiologic department and to the patient bedside monitoring system [8].

4.3. Ambulatory activity integration

EPH-Lab patients are followed on ambulatory outpatient basis. They can be referred from outside the department or after discharge from our infrastructure when periodical follow-ups are requested. For these reasons, the integration of all available patient data segments with our hemodynamic and electrophysiology informative system, is very important. The automatic and single insertion of structured data in our SIE, reduces drastically clinician's work.

5. Results

Our EPH-Lab manage 15 diagnostic and 30 interventional procedures monthly.

This EPH system increase overall safety, through the collection of a wide range of patient data coming from our SIE, including ward and integrated information collected from the outpatient archives.

The introduction of a new workflow was easily accepted by medical doctor, nurses and technicians. At present, the internal organization has been fully upgraded.

The daily monitoring of post procedural complications allow a fine analysis of these events from a clinical and prognostic point of view. Medical staff could improve controlled protocols of surveillance and patient care.

A very important part of this vertical HIS for EPH-Lab is finalized to monitor the daily use of specialized and very expensive biomedical devices, in order to allow a rational warehouse and avoid unnecessary expenses.

6. Discussion and conclusions

This experience, from a deployment perspective, offers some suggestions on how to undertake a rapid migration to standard EHR infostructures [9].

Adoption of CDA r2 and HL7 V3, is the fastest way to integrate in a standard EHR infrastructure new and old EMR segments of clinical data, tasks and knowledge management.

Today a lot of developer tools are available to move to CDA and HL7 V3 standards.

The prospective collection of quality data related to pacemaker and ICD implantations seems to be able to improve quality of care in our EPH-Lab.

From the clinical point of view, the adoption of these systems may provide a useful tool not only for clinical data collection, mostly in emergency situations, but also for a better management and provision of highly delicate and expensive devices.

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