# ECG Standards for the Interoperability in Patient Electronic Health Records in Italy

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## Abstract

*The Electrical Activity of the Heart is the most studied and useful signal for fast response analysis in actual tele-cardiology and tele-monitoring activities. Actually the trend is to make all device conforming to the Open-ECG or to the SCP standard as the base for interoperability. We think that this solution is not enough and we are trying to promote the HL7 aECG format as the basis for true ECG interoperability, in Italy Patient Electronic Health Record.*

## 1. Introduction

Computers application in clinical data collection first resulted in local informative systems capable of data management related to a single typology of exam or visit. With the widespread of computer use an increasing number of collecting system were developed and adopted by physicians and nurses. This with the direct consequence of a fragmented view of patient status or treatment due to the distribution, other than duplication, of patient data in those systems.

The need of a comprehensive collection system arises in users minds, and become a definition of health informative system which includes numerical processing and digital archiving of images and biologic signals as well as free texts, deployed as a repository of information regarding the health of a subject of care, in computer processable form.

The collection of many EMR (Electronic Medical Records) compose the patient's Electronic Health Record (EHR) systems, thus representing an important support for a comprehensive assessment of patient disease status, capable to integrate clinical data collected during patient care and allowing a rapid evaluation for clinical personnel involved in patient care.

To share data among EMR in necessary a standard capable to collect in a meaningful way every information contained in each EMR; EHR standards is to maximise interoperability between electronic records and systems that are specifically intended to be shareable, irrespective of the technologies they employ and the platforms they reside on.

In cardiology assessment ECG represent an instrumental exam of paramount importance, on which each cardiologist rely starting from the first evaluation of the patient, and the definition of a standard for ECG collection, processing and rendering is necessary to support the life of EHR systems.

One of the common misconception about standards in medicine, is that standards solve all problems in exchanging document among different domains. This is not true when a standard is not widely adopted, this is the case of ECG standards. Another issue is that the adoption of a particular standard is often in contrast to particular commercial strategy, that inhibit its spreading.

At the moment there are a lot of proprietary ECG device with proprietary solutions that are effective but isolate the solution to the field of use, and discourage the data export to a nation wide electronic patient record due to their proprietary, or cryptic formats. For this reason it is necessary to distribute the data in a simple way, or rather in such a way that doesn't impact the life of the technical personnel turned to the treatment of such information.

One of the possible workaround solution to this problem is the conversion of ECG to de facto visual interpretable image standards, like Adobe PDF (Portable Document Format) and Adobe SVG (Scalable Vector Graphics). This kind of solution is the one adopted in IHE Cardiology integration profiles. The ECG is converted in a vectorial representation of the signal into Portable document format, or Scalable vector graphics image. This solution is widely accepted and adopted, but the data in this form is not usable any more, for further computation.

Actually there are more than one standard that face the problem of the ECG communication and sharing, probably the most known is the SCP format, that materialize and become an open standard with the open-ECG effort [12].

Other well known standards are the DICOM Waveform standard [4], and the HL7 FDA annotated ECG standard [8]. While the first is a generic waveform standard suitable for diagnostic ECG modalities including 12-lead ECG , cardiac stress exercise, Holter monitoring and voice, the second is restricted to ECG

cardiac field.

HL7 aECG is the HL7 format for ECG , chosen by FDA and uses the eXtensible Markup Language (XML), it is Open, it is not cryptic either proprietary. In Italy the ministry of health is posing the basis for a new Health Record infrastructure (FaSP: Fascicolo Sanitario Personale) based upon a network of registry and repository using the Service-Oriented Architecture paradigm. In order to make an ECG usable in this architecture we need a reliable way to convert it from Open-ECG or DICOM Waveform or other formats The purpose of this work is to show how this is possible, using simple and affordable methods, to reuse existing ECG devices into the future Electronic Health Record data distribution, and at the same time to be totally independent from the development platform, from the programming language and the operating system used.

The advantage of the HL7 Annotated ECG format is the use of XML language format, and the use of the HL7 RIM Reference Information Model.

## 2. Methods

The use of XML markup language is the de-facto standard in e-government project and in general is the lingua-franca of electronic document sharing. Another technology directly connected to XML in this field is eBxml [6], this is an Oasis standard and has a public free implementation, this is the OASIS ebXML Registry Reference Implementation Project [1] from sourceforge.

The core of the system will be a conversion service that is able to convert between different ECG waveform formats into aECG format, and to deliver it to a document consumer or to the document repository. This simple process at the moment is not addressed by any particular software, but a group of interest is born, and some code is already available [10], the group aims to develop a open-ecg to annotated ECG converter and vice versa, using the Biosig [11] data structure.

The document carrier, chosen in the Italy Patient Electronic Health Record e-government project is the HL7 CDA Release 2. CDA R2 [2], the HL7 Clinical Document Architecture uses the eXtensible Markup Language (XML) with a semantic structure that allows a profitable use of well known multimedia formats joined with the data of clinical pertinence: instrumental examinations reports, chemical laboratories results, administrative data. HL7 CDA offers manifold improvements on the forehead of the interoperability: It is human readable, it is independent from the database implementation or the developing environment used, moreover it offers the availability in the same document of structured and un-structured data elements.

This carrier is the optimal solution for sharing data, and the use of FDA annotated ECG is the direct consequence of the HL7 adoption politic. This is not the only reason, another aspect is the free availability of an xml schema in order to validate the correctness of an aECG document. This is a simple method for example to validate a document, in an easy way without interpreting it with manual intervention. The schema validation is a standard way to automatize the process of storing a correct document in a large repository, and to assure a control over quality.

In fact a PDF format is a good aseptic way to store data but there actually no easy way to check if a PDF document is a representation of an ECG document or on the contrary is a marvelous sea sightseeing.

Another standard that is rapidly arising in the ECG panorama, is the DICOM waveform standard, this is been adopted by some firms due to the availability of radiologic PACS (Picture Archiving & Communication Systems) in a general hospital environment. In Particular an Image manager can support directly the DICOM waveform format, without any particular software upgrade, hence the DICOM network is directly compatible with this new DICOM addenda. The drawback is that on visualization workstations there is essentially no possibility to represent the signal, without upgrade of the software, where and if possible. Even in this latter case the solution could be a DICOM Wado (Web Access to DICOM Persistent Objects) [3] service with the possibility to convert from DICOM Waveform format to PDF or PNG files.

## 3. Italian EHR infrastructure

The network infrastructure of the Italian EHR will be based on a scale-free network model [14], following the ebXML Version 3 rules. One important feature of this system will be the Federation feature that allow multiple, registries to link together and appear as a single logical registry without losing security and local autonomy.

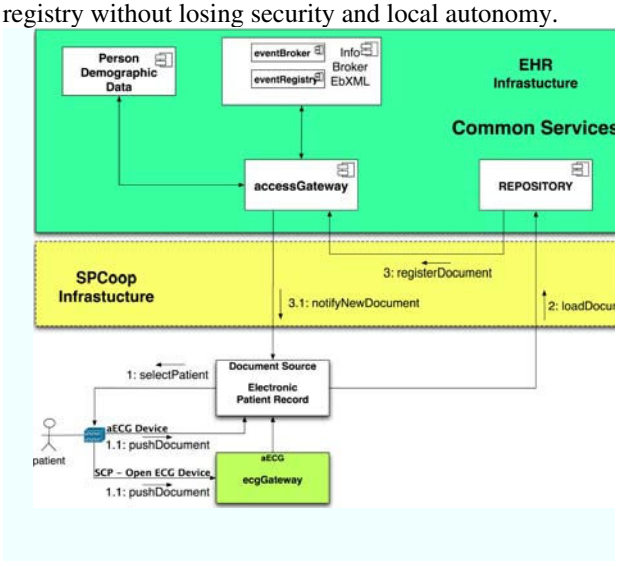


Figure 1. Document Source

The general structure of this system can be divided

into three sub-systems: the common services, the SPCoop and the client infrastructure.

Common services are the core of the Italian infrastructure based on ebxml model with the idea of a registry and a repository. The registry is the system indexing documents and the repository is the real archive of documents indexed in the registry.

SPCoop is the acronym of Sistema Pubblico di Cooperazione, Public cooperation system infrastructure, and this is the network services infrastructure created for Italy e-Government projects.

The client side shows a generic Document Source, and a Document Consumer, the first is the source for aECG Documents and is able to communicate through the SPCoop infrastructure with the Registry/Repository Level.

The second is a client that is able to consult the EHR registry and download an HL7 CDA Document filled with aECG documents.

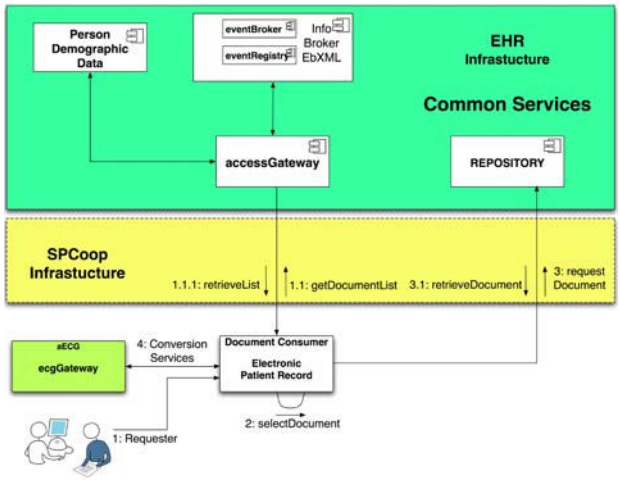


Figure 2. Document Consumer

## 4. ECG conversion service

The core of the system is a simple but useful component made in web-service technology, able to convert and interpret an ECG file from native format to annotated ECG format and vice versa. This service should have the capability to send the produced files, along with meta data in a HL7 CDA header, to a central EHR repository, or to convert the aECG format in simple visualization formats, like Jpeg, PNG, or in vectorial formats like PDF and SVG.

The following piece of xml code represent the HL7 annotated ECG document showing the patient demographic of trial subject.

```
<trialSubject>
        <id root="2.16.840.1.113883.3.400"
        extension="123"/>
        <code code="ENROLLED"
        codeSystem="2.16.840.1.113883.5.111"
        codeSystemName="ResearchSubjectRoleBasis"
        displayName="Enrolled in trial"/>
  <subjectDemographicPerson>

  <name>
        <given>Paolo</given>
        <family>Rossi</family>
  </name>

   <administrativeGenderCode code="M"
        codeSystem="2.16.840.1.113883.5.1"/>
        <birthTime value="19530508"/>
        </subjectDemographicPerson>
  </trialSubject>
```

HL7 annotated ECG inherits the HL7 V3 Reference Information Model, hence the way to write XML code resembles the CDA R2 XML code. Even if the aECG is made for trial purposes, it can easily contains real demographic data. The code system used, to specify codes is LOINC [7] (Logical Observation Identifiers Names and Codes) that is a database and universal standard for identifying laboratory observations. Other standards for classification and coding can be used, and must be identified by an OID as a code system. For example to code the ECG leads is necessary to use the OID 2.16.840.1.113883.6.24 that represent the IEEE 1073 Standard for Medical Device Communications (MDC).

## 5. Discussion and conclusions

This approach can be useful to integrate legacy ECG acquisition systems in an effective simple and low cost way, opening the possibility to create a central node for distribution and archiving biomedical signals.

One of the issues that is present, is the conversion and managing of great amount of ECG data, in fact certain kind of continuous recording signal can occupy over 1 GB of space if converted in XML data format.

In this case the service has to be more complex, in order to extract only a region of the waveform, instead the whole XML file that could be too heavy for transmission or visualization, and must be able to compress or decompress XML files using various compression techniques (i.e. Gzip, bzip, zip). However this kind of problem can be addressed by pre-fetching the document in a client local cache. In the case of the need for fast access to an electronic patient record in an emergency scenarios, where is necessary a synthetic view of the cardiology state of the patient, only a subset of the signal, prepared by a specialist MD, is enough to fulfil emergency need.

We hope that this approach will help to solve the compatibility problems present today with ECG and also with other instrumental file formats.

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