OpenECG: a European Project to Promote the SCP-ECG Standard, a Further Step towards Interoperability in Electrocardiography

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Abstract

Integrating the numerous available ECG devices to the citizen's electronic health record is a major challenge for the users of ECG interoperability standards, since most ECG devices implement protocols and file formats in ways that hinder the open interchange of ECGs and hamper ECG analysis, processing, and serial comparison.

The mission of the OpenECG portal is to foster the consistent implementation of interoperability standards in computerized electrocardiography. A help desk and a planned on-line validation and conformance testing service for the SCP-ECG standard assist manufacturers requesting feedback on their implementations. Additionally, tutorials, visualization tools, converters, and annotated ECG samples are expected to provide the framework for the systematic diffusion of standards in the everyday practice and pave the way towards interoperability in all ECG examinations.

1. Introduction

Nowadays cardiovascular diseases are the largest cause of mortality in western countries and ECG devices are an essential part in the process of acquiring, storing and communicating accurately the health status of a citizen. The electrocardiogram is the most common cardiology examination (0.3 ECG/capita/year in Europe alone) [1], but today the operation of most ECG devices is still based on proprietary protocols and file formats. As a result, unless recorded with the same device, electrocardiograms cannot be transferred and reused in different applications connected to the health information network.

ECG devices are currently used in many different settings including the patient's home, ambulance, GP offices, emergency wards, cardiology departments and intensive care units. Although they vary in form and size, most of the newer ones use digital recording, compression, interpretation, and communication. Embedded ECG devices usually have a keyboard and a screen to allow operators to enter patient data. Some companies provide an Application Programming Interface (API) that allows communication with the ECG device for data acquisition and patient data transfer. Typically, communication with the ECG management system of the same company facilitates the long-term storage of ECGs and associated diagnostic reports.

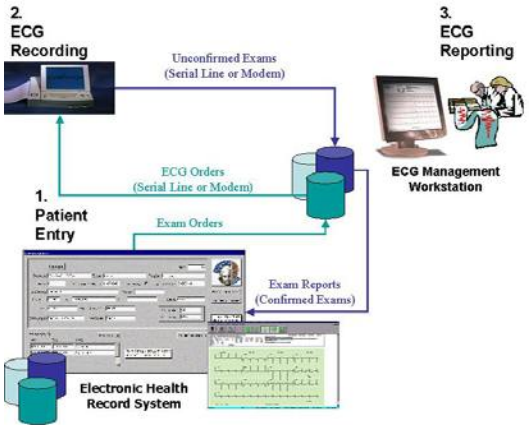

Figure 1. ECG workflow in a cardiology department [2].

The gradual adoption of the multimedia electronic health record demands seamless integration and interoperability of medical devices with 3rd party information systems. Achieving interoperability can be a very hard task, especially in the absence or inconsistent implementation of standards. Since integrating ECG devices into the clinical workflow to support work-list and avoid unnecessary data-entry requires customised development in close cooperation with the manufacturers (see figure 1). As noted in [2,6], it is only through high

expertise, availability of detailed protocol specifications, and committed cooperation of the manufacturers that ECG-related workflows can be automated.

The mission of the OpenECG project is to promote the consistent use of computerized ECG standards in resting ECGs and to pave the way towards emerging standards for stress ECG, Holter ECG, and real-time monitoring. OpenECG, coordinated by an interdisciplinary, highly motivated consortium, attracts membership from healthcare authorities, cardiologists, integrators, engineers, standardization bodies, manufacturers, and the public (see figure 2). Its specific goals with regard to computerized ECG standards are: a) to raise the level of awareness on ECG standards; b) to organize information days, workshops, and a programming contest; c) to consolidate expertise, assist integration and support correct implementations; d) to provide feedback to standardization bodies; e) to prepare the ground for interoperability in other ECG-related examinations. At the same time, OpenECG collaborates with other groups that are working to formulate and implement ECG-related integration profiles in cardiology and remote care.

The OpenECG portal will present news, reviews, and success stories. Registered members will have access to discussion groups, a help desk, and a collection of tools for handling SCP-ECG data (analyzers, converters, viewers, etc.). A database containing annotated samples of real SCP implementations will provide further help in the proper implementation of the SCP-ECG standard by manufacturers and integrators. Finally, analysis has already started for an on-line SCP-ECG certification and conformance testing service that will also be available to members of the OpenECG portal.

Section 2 discusses interoperability standards in computerized electrocardiography. Then, section 3 presents the structure of OpenECG portal and its planned services. Finally, section 4 discusses preliminary results and outlook from the first month in the life of the OpenECG portal. Section 5 concludes the paper.

Figure 2. Stakeholders in the adoption of ECG standards

2. Interoperability standards for ECGs

There are a number of health informatics standards that apply to the interoperability of ECG devices in various clinical settings. HL7 (http://www.hl7.org) has worked intensively over the years on an information model and messaging standards for the exchange of administrative and medical information including orders and results in the health care domain. Like other examination results, ECG data may be transferred in an HL7 message either as blob or as sequence of values. Some manufacturers have implemented versions of HL7 in their ECG management system for order and results communication.

The DICOM standard (http://www.nema.org) specifies an information model, a communication protocol and a file format. DICOM supplement 30 [3] defines a waveform interchange format, which can be used in the exchange of any waveform not just ECGs. In the context of the IHE initiative DICOM related standardization efforts focus on the specification and implementation of integration profiles throughout the health enterprise.

There is also a recent FDA initiative to use XML as the record format to communication waveform data including ECGs [5]. Their motion is driven by the need for a general format to acquire ECG and other time series data recorded in clinical trials.

The SCP-ECG standard [4] was developed to allow full interoperability between ECG devices and a generic host system, standardizing both the communication and the data format. The SCP Standard is the result of a EU supported project that European, American and Japanese Manufacturers and Users have jointly worked and agreed on (1989-1990). In 1993 it became a European ENV, later positively balloted within the American Association for the Advancement of Medical Instrumentation (AAMI EC71), and is currently a new work item proposal to the International Electrotechnical Commission - IEC TC/SC 62 WG1 and ISO TC215. Unfortunately, only a few manufacturers have adopted this standard so far, while the majority still use proprietary solutions that impede the seamless integration of ECG devices for health management and continuity of care [6].

The HL7 standard originating from the health administration world and the DICOM standard from diagnostic radiology, attempt to address interoperability in the whole enterprise. FDA efforts address ECG data formatting in general and although XML is popular and portable, the FDA effort needs more time to complete. Radiological Society of North America (RSNA) convenes annual interoperability demonstrations involving IHE & the DICOM standard in the RSNA conference, while HL7 holds annual interoperability demonstrations in the HIMSS conference. All these efforts, however, are general purpose and concentrate on interoperability issues after the ECG has been acquired successfully and stored in the ECG management system. Only the SCP-ECG standard addresses specifically communication with the electrocardiograph, ECG compression, and storage.

The SCP-ECG standard has been developed specifically for compression and communication of

resting ECGs and if extended appropriately it could address the needs of Holter or Exercise ECGs or real-time monitoring. The SCP standard has been around for some time now. The first SCP-ECG Conference occurred in 1989 and addressed issues of device communication, data storage, and compression [7]. The small size of an ECG file formatted according to the SCP-ECG standard allows fast and reliable exchange under different settings possibly as part of an HL7 message in XML. OpenECG sets out to promote the use of cooperative use of standards by introducing the OpenECG portal as a link between the theory of standards and the practice of interoperability.

3. OpenECG portal

OpenECG seeks to involve all the stakeholders in the adoption of computerised ECG standards and engage in activities that will promote the consistent implementation of standards (see figure 2). The OpenECG consortium has found enthusiastic support among representatives from health professional societies, hospital managers, ECG equipment manufacturers and resellers, IT specialists, service providers, health authorities and patient associations. In the OpenECG thematic network they will join their efforts to realize effective open solutions for the home, the ambulance, the clinic and the hospital. In this way, electrocardiograms recorded with different ECG device models will be archived and communicated in high precision allowing the effective serial comparison with previous electrocardiograms of the same person.

Figure 3. Announcement of the 1st OpenECG Workshop.

The OpenECG portal supports the virtual community of those interested in the application of Computerized ECG standards and SCP-ECG in particular. The portal will provide general information on computerized ECG standards including historical facts, specifications, news, links to relevant initiatives and success stories. It will also provide a selection of member services. These services will include:

- Moderated newsgroup and discussion groups on ECG interoperability standards.
- On-line discussion groups on standardization of Stress ECG, Holter and vital signs monitoring and other cardiology examinations.
- Member pages with links to own organization.
- On-line services for members including a Help desk assisting the application of the standards
- Repository for computerized ECG tools
- Collection of annotated ECG samples from different manufacturers.

The members enjoy a help desk that provides them with information on how to correctly implement the standard. They also gain access to an open source repository for Computerized ECG tools for visualization and conversion among different ECG file formats. In addition, a planned series of on-line courses and tutorials address the needs of different groups such as integrators, health professionals, and administrators.

Members will also have the opportunity to bring their own view in the network by contributing their own material in member pages. Except for the content available in the member that specifically expresses the viewpoint of the creator, thematic committees that will be nominated by the network, will be editors responsible for the specific content.

A bimonthly electronic newsletter, will report on the activities of the network, and interesting events worldwide.

3.1. Certification & conformance testing

Interoperability requires that the manufacturer either implements the standard directly in their equipment or at least provide drivers for the conversion of existing databases and ECG files, from their proprietary format to the standard.

OpenECG plans to develop a pilot on-line conformance testing and certification service for the use of the SPC-ECG standard in cooperation with CEN and integrators involved in the development of multi-vendor solutions. This is a first step in the development of validation conformance testing procedures for e-health services that employ ECG devices.

The specification of the guidelines for conformance testing and certification will start in the 1st OpenECG workshop (Figure 3), in cooperation with members of the OpenECG network. This activity will address:

- Identification of the certification criteria
- Conformance testing levels for the SCP-ECG standard file format.
- A mechanism for on-line automatic certification procedures
- Integration profiles for Computerized Electro-cardiography.
- Links to conformance testing and certification

procedures for other interoperability standards for computerized ECGs and related methods.

This on-line service will be the first European on-line certification and conformance testing for computerized ECG standards and is expected to have a major impact on the correct implementation of the SCP-ECG standard and integration profiles in general.

3.2. Tools for computerized ECGs

One of the reasons for the limited deployment of the acquisition, storage, and communication of computerized electrocardiograms in the SCP-ECG file format is the lack of freely available visualization tools.

OpenECG will maintain an annotated collection of electrocardiogram samples from different manufacturers and an Open Source Repository of tools for visualization, processing, and translation of computerized electrocardiograms using the SPC-ECG standard. The OpenECG community will be responsible for the selection, evaluation and construction of the tools.

The OpenECG portal will also run a contest for the development Open Source ECG tools starting in the 1st OpenECG workshop. These tools should enable the visualization of ECG files in different setting and the conversion among different computerized ECG standards. The winners will be nominated and prizes will be given out in the follow-up conference.

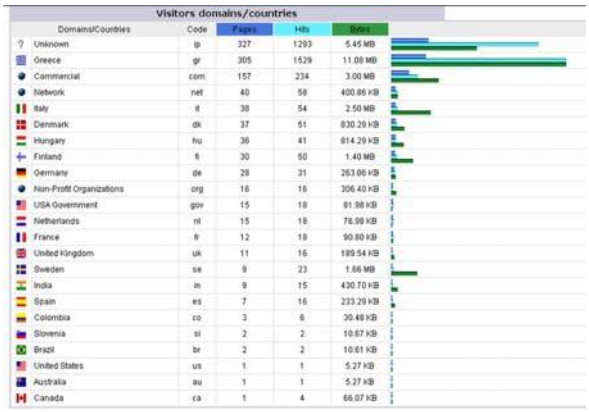

Figure 4. Visit patterns in the OpenECG Portal

4. Preliminary results and outlook

The OpenECG portal aired in August 1 for internal evaluation by the consortium. Since September 1 2002, the portal is officially operational accepting requests at the help desk. The pattern of visits in the September 2002 appears in Figure 3.

In preparation for the 1st OpenECG Workshop, the OpenECG consortium gained the support and active participation of stakeholders who have realized the benefits from interoperability of computerised ECGs. The OpenECG site has received visitors from many countries including Brazil and Australia (Figure 4) and the traffic has been rising steadily in September.

5. Conclusions

The mission of OpenECG is to raise public awareness on ECG interoperability standards, promote the use of Computerized ECGs, foster interoperability among different implementations, and pave the path towards the consistent use of standards in other cardiology examinations. OpenECG plans to pursue these goals through the OpenECG portal providing for those interested in ECG interoperability standards a help desk, an on-line certification and validation service, a repository of visualization and conversion tools, information days and a programming contest.

We expect that the creation of a network building on the experience and vision of the early adopters will facilitate the open exchange of high quality computerized ECGs, making lack of interoperability an obscure problem of the past and setting an example for other diagnostic examinations in the domain of cardiology.

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