Expert Perspective

Standards and Interoperability in Digital Electrocardiography. The OpenECG Project

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Nowadays, when we buy a new printer for our computer, we expect that after plugging it in (and perhaps running a short setup program from a CD-ROM) we will be able to print out pages from a word processor, a spreadsheet program, or whatever, and we expect that they will look basically the same as they did on the old printer that has just been replaced.

We expect all this regardless of the type of computer we are using, or the brand of printer. These things, at least during the last five to ten years, have become irrelevant for most of the so-called "peripheral" devices. This idea, the concept of "plug and play", is perhaps the most advanced illustration of what is often called "device interoperability".

Interoperability is best achieved through the use of standards. Standards may dictate the entire range of function of a device or they may define just a minimum subset of functionalities. To return to our printer example, a multicolour pen plotter designed principally for drawing graphs will obviously have different capabilities than a monochrome laser printer—however, certain actions they share, such as ejecting a sheet of paper and moving to a new page, can be initiated via a standard communication interface. Functions that only apply to a particular model can be dealt with using specific driver software provided by the manufacturer.

Another example of standards is the hypertext mark-up language (HTML) used in Internet World Wide Web pages. Regardless of what kind of computer you are using, if you have a standard "browser" program you can access the Web to look up bibliographical references through Medline, submit your abstracts to the European Society of Cardiology's annual Congress, subscribe to and even read a variety of medical journals, and so on.

Anyone who uses a computer with any regularity has become so used to this situation that it is easy to forget that things were not always so easy. Sadly, in the realm of medical devices progress in this direction has lagged far behind developments in the general computer peripheral world. In the case of electrocardiograph (ECG) devices in particular, we find hardly a trace of interoperability in the current marketplace. In practice, this means that the choice of ECG device can involve a commitment to specific associated database software, with the result that it may be difficult, if not impossible, to store ECG recordings from different manufacturers in a single database that can be shared within your departmental, hospital or regional health information structure.

The two above examples (printers and Web pages) represent different kinds of standardisation: standards for communication and standards for data format. Both are necessary for true, full interoperability: both are notably absent from the technical descriptions of most ECG devices.

Interoperability and the cardiac patient

To put this in a practical context, let us consider the following clinical scenario. A forty-year-old man comes to your outpatients' department complaining of intermittent chest pain and dyspnoea on effort. His ECG is consistent with a picture of coronary artery disease, but the signs are not clear enough to be conclusive. Communication is difficult because the patient has only recently moved to your country and does not speak either your native language or English very well. However, you manage to determine that he had similar symptoms about one year before and was prescribed some medication by a cardiologist in his country of birth. Unfortunately, the patient is unable to tell you either the earlier diagnosis or the kind of medication he was taking. If only you could see the ECG recording from a year ago ...

Let's ramp up the technology a little and modify the scenario. You are using a state of the art electrocardiograph that transmits ECG recordings to your computer in digital form, automatically stores them in a database, and displays its output on the computer screen. This time, the patient's previous examination was in your own hospital, so you call up the electronic record from the computer database and try to view the previous ECG. No luck! In the meantime your department has bought new ECG devices and the software that comes with them is unable to recognise the format of the old recordings. Muttering to yourself about this so-called advanced technology, you call for the patient's paper record, hoping that the old ECG printout will be inside and has not faded too badly.

You have an interest in technology and you are aware that in other areas this kind of problem has already been largely overcome, through the establishment of the two kinds of standards mentioned above: communication and data storage. The development and promotion of interoperability in ECG devices, through addressing and drawing attention to these and other relevant issues, is the goal of the OpenECG project which was started in July 2002 and was funded by the European Union.

OpenECG

The OpenECG initiative was originated in western Europe by partners from Denmark, Germany, Greece, Italy and Spain, with interests ranging from device manufacture to telemedicine (Table 1). Since the first OpenECG Workshop, which was held in Crete in October 2002, membership of the OpenECG network has increased almost fivefold, while the OpenECG Web portal[1] has attracted a steadily increasing number of visitors from all around the globe (Figure 1).

We were particularly pleased to receive support from the European Society of Cardiology, as represented by the Working Group on Computers in Cardiology. Also, the response from manufacturers has been encouraging (64 members as of August 2004). There appears to be a general shift in attitude taking place away from closed, proprietary solutions and towards the use of open standards. Some companies are already beginning to view OpenECG certification as a valuable quality mark, and this and other major results of the OpenECG project were summarised during the second OpenECG workshop held in Berlin, Germany in April 2004.

An important function of OpenECG is the provision of information and software facilities designed to aid developers and users of ECG devices. One standard to which OpenECG has devoted particular attention is an already existing European standard for the digital storage and transmission of ECG data: the name of that standard is SCP-ECG.

SCP-ECG

Brief history

The "SCP-ECG Standard Communication Protocol for Computer-Assisted Electrocardiography", or

Table 1. The OpenECG consortium.

Organisation	Country	
ICS-FORTH (Project leaders)	Greece	Catherine Chronaki Franco Chiarugi Philip Lees
FUNEN	Denmark	Ib Johansen Henning Voss Lisbeth Jorgensen
BIOSIGNA	Germany	Christoph Zywietz
IFC-CNR	Italy	Alberto Macerata Fabrizio Conforti
RGB Medical Devices	Spain	Ricardo Ruiz Fernandez

A

B

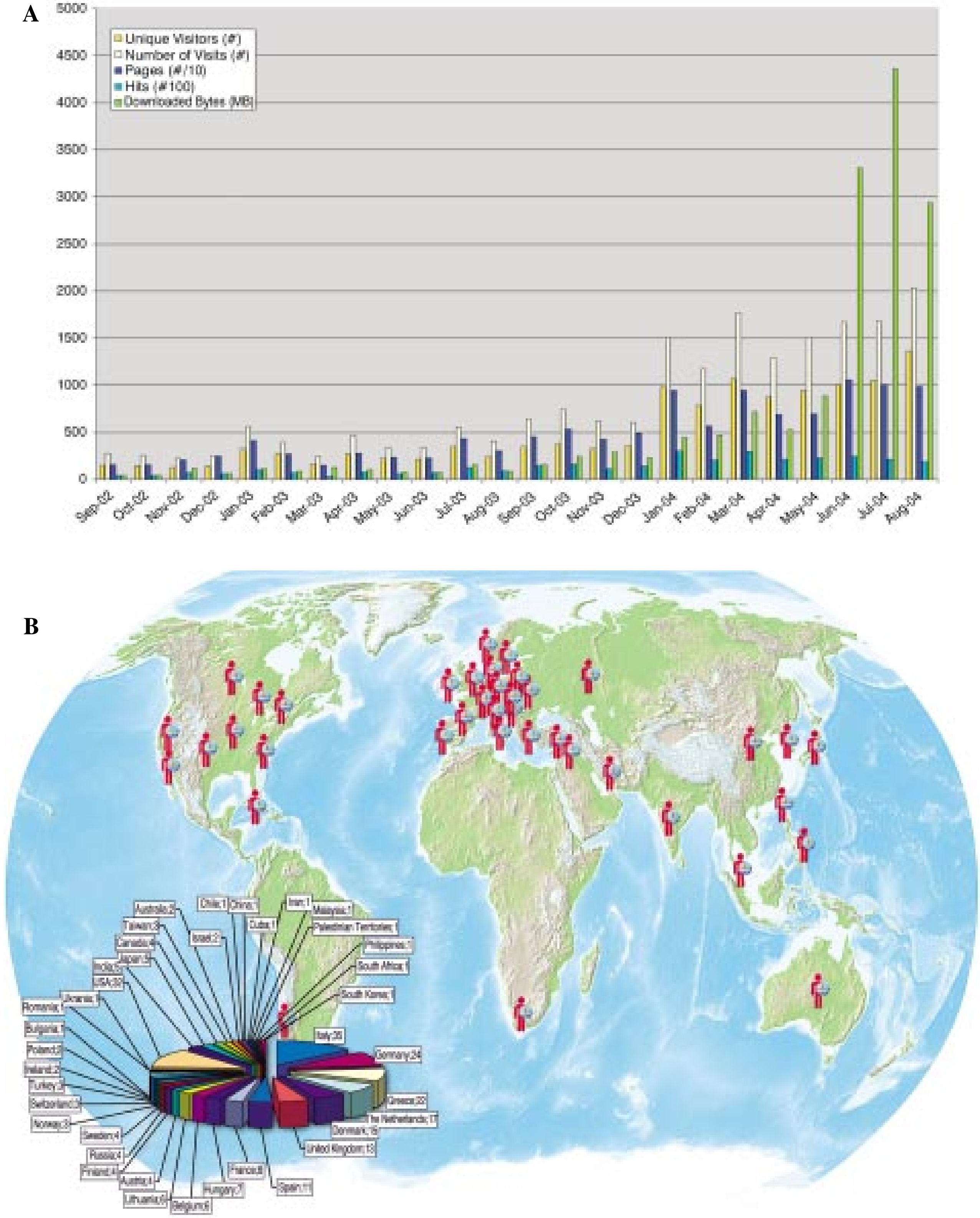

Figure 1. A.Web traffic on the OpenECG portal since the 1st OpenECG Workshop (September 2002 - August 2004). The dramatic increase in downloads towards the end of the period displayed (green bars) shows the importance of the OpenECG portal as an emerging resource for software, sample data and technical documentation. B. Distribution of open ECG members from around the world. As of August 2004 OpenECG had 258 members from 39 countries.

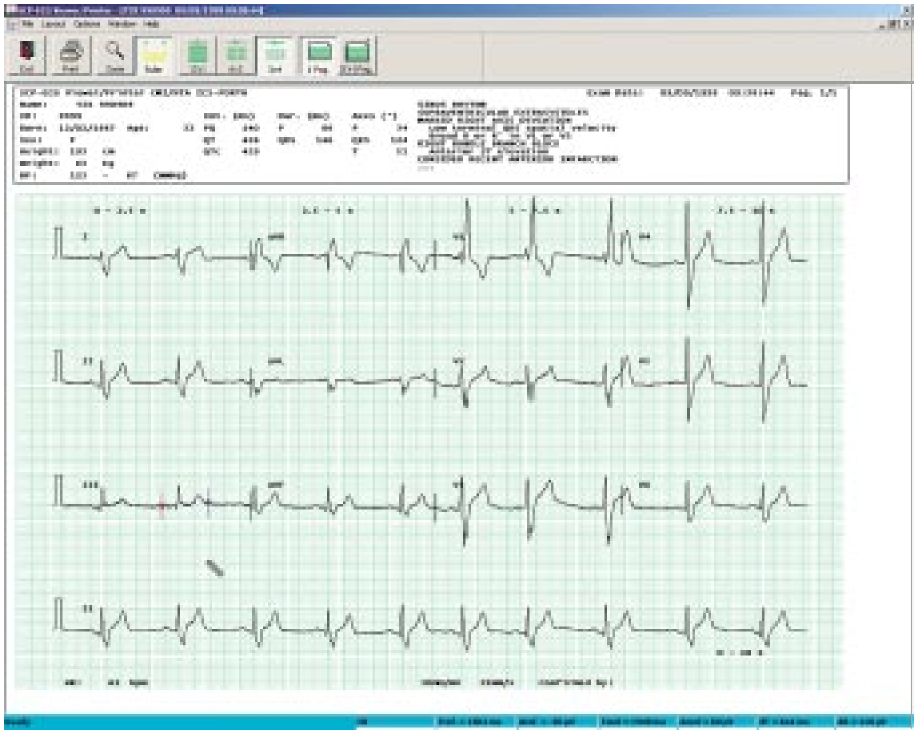

Figure 2. Screenshot of an SCP-ECG viewer printer developed by one of the OpenECG partners. This program is capable of displaying digitally stored ECG files from 7 different manufacturers.

SCP-ECG for short, was approved by CEN in 1993 as a pre-Standard ENV 1064. SCP-ECG is a standard that specifies the interchange format and a messaging procedure for standardized transmission of ECGs between various computer systems and electrocardiographs.

This standard was implemented by some European and American manufacturers. Practical experience during implementation and in the field confirmed its usability for telemetric applications as well as for data volume effective storage and retrieval (as demonstrated, for example, in the OEDIPE project[2,3]). However, the originally desired high flexibility, with many manufacturer specific implementation options and a few ambiguities within the text, resulted in insufficient interoperability between devices of different manufacturers. As a consequence, this document was reviewed by an AAMI committee (now with participants from Europe) and the revised version was then balloted positively and became in 2000 the AAMI Standard EC71.

Contents of an SCP-ECG file

Apart from the ECG recording itself (digital ECG data may be compressed for easier storage and transmission), the SCP-ECG file contains a header section with specific information about the patient and the examination (patient ID, patient name, date and time of acquisition, etc.).

The file may also contain additional information, such as computed parameters (heart rate, intervals, wave durations and amplitudes, axes, etc.), diagnosis and so on. All this may be displayed on a computer screen using an appropriate viewer (Figure 2).

Current status and future prospects

Although a lot of work was put into the development of the SCP-ECG standard, it has not been adopted as widely as its creators would like. The fact is that so far only a few ECG manufacturers offer support for SCP-ECG. The OpenECG project is currently making a determined effort to promote this European standard by offering a variety of services. These are described in detail on the OpenECG Web portal and will be summarised below.

Help desk

The OpenECG help desk (helpdesk@openecg.net) has been offering general advice on digital ECG interoperability in general and the SCP-ECG standard in particular for more than two years.

Device and/or ECG record conformance testing

OpenECG members involved in ECG device manufacture have access to a testing and certification service to verify the SCP-ECG compliance of their products. Also, digital ECG records may be analysed in order to examine to what degree they comply with the SCP-ECG data format.

SCP-ECG databases

Sample SCP-ECG files may be downloaded from the OpenECG portal for inspection and analysis. OpenECG has also provided samples of digital ECG data in other relevant formats.

Tools and converters

Other tools are available: 1) a converter of SCP-ECG records to DICOM Waveform format available through on-line submission via the OpenECG portal; 2) an e-mail based ECG record parsing service for testing SCP-ECG files, which returns a textual report containing all the information that the parser was able to extract, as well as an image file with a printout of the 12 leads of the submitted ECG record; 3) programs released as open source code contributed by participants to the OpenECG programming contest.

It is the hope of the OpenECG consortium that, by making these facilities freely available to interested parties, device manufacturers will be more stimulated to comply with relevant standards. Furthermore, by promoting the development and use of tools for analysis and conversion we aim to contribute to the greater harmonisation of digital ECG data and to improve quality assurance.

Discussion

Almost all newly developed electrocardiographs with medium or high capabilities offer features for digital recording and interpretation and the possibility to transfer a digitally stored ECG to a data management system.

Digitisation allows the application of various computerised algorithms to the ECGs, not only interpretation programs, and in recent years new diagnostic techniques have been applied, such as RR variability, late potential analysis and QT dispersion analysis. Moreover, the collection of digital ECGs in a data management system can allow their access through the World Wide Web,[4] their easy sharing for secondary consultation, and further capabilities, such as comparison with previous ECGs of the same patient or with similar ECGs from a reference database.

Serial ECG analysis can be helpful, not only in the diagnosis of chest pain,[5] but also in prognosis and risk stratification,[6] the evaluation of medication[7] and clinical follow up.[8] A cumulative approach to risk stratification in non-ST elevation coronary syndromes can improve predictive accuracy.[9]

The advent of digital electrocardiography means that the serial comparison of ECGs is much easier than before—provided that the ECG recordings being compared share the same format. For this reason, it is important that the cardiological community become aware of the importance of supporting international standards for the storage and transmission of digital ECGs.

Although it is possible to integrate manufacturer-specific software into a more generic computer information system,[10] from the point of view of the cardiologist the advantage of standardisation is obvious. Regardless of whether the digital ECG recording comes from your own local database, is sent to you as an e-mail attachment, or is downloaded from a Web page, as long as it uses a standard format, such as SCP-ECG, the same viewer can be used to display it and compare it with other recordings from different sources.

Therefore, in your own department, when you replace your SCP-ECG electrocardiograph you need only ensure that the new one is capable of generating SCP-ECG compliant data too, and then there will be no need to change your viewer and analysis software—everything will work just as it did before. As for your foreign patient, his previous ECG can now be transferred through the Web to your computer and can be displayed in the same viewer you use for your own ECG recordings.

The broad adoption of an international standard for digital ECG archiving and transmission would be a major step towards a "plug and play" model that would realise the ideal of a universal, integrated, electronic health record for cardiac patients.

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