OpenECG: Medical Device Interoperability as a Quality Label for eHealth Services

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Abstract

Personal medical devices proliferate as emerging eHealth consumers -chronic patients and health conscious citizens- use them regularly to monitor their health. In the quest for quality and performance, plug-interoperability of medical devices is a quality label for Electronic Health Records (EHRs) and eHealth systems that effectively collect, process, and analyze medical data. However implementing standards typically involves additional costs, and unless widely implemented, standards do not guarantee interoperability.

The OpenECG network aims to bridge the gap between standards on paper and their implementations promoting the practice of interoperability in electrocardiography. This paper reports on recent developments in ECG interoperability that involve OpenECG, focusing on SCP-ECG conformance testing, the pending amendment to the SCP-ECG standard, and harmonization efforts between HL7v3 aECG and SCP-ECG. The expert network of OpenECG combined with its open-source tools and free services, support ECG manufacturers and integrators in realizing ECG interoperability standards and creating robust peer-reviewed eHealth systems.

1. Introduction

Advances in medical device technology deliver a proliferation of diagnostic devices ranging from blood pressure and ECG monitors to implantable pacemakers and defibrillators. As the barriers between health and healthcare fade away, novel eHealth services incorporate affordable portable and wearable medical devices promising empowered consumers the ability to monitor their health. Plug-interoperability of electrocardiographs and other health monitoring devices in the context of personal EHRs ensures effective self-care and wellness management for our active, mobile, and aging society. Moreover, seamless integration of electrocardiographs in clinical procedures is considered the key to reducing inefficiencies resulting in suboptimal care and avoidable medical errors.

The OpenECG network was created in 2002 when the need for universal access to high quality care, reduction of medical errors, and containment of health care costs, renewed interest in interoperability standards. However, standards alone do not guarantee interoperability. First, standardization efforts barely keep up with the time-to-market constraints of the innovation driven medical device industry. Second, implementing standards is costly and time-consuming. Finally, testing conformance to interoperability standards frequently involves diverse software components from different medical device manufacturers, integrators, and eHealth providers [1,2]. OpenECG supports the consistent implementation of standards in digital electrocardiography upholding interoperability as a quality label for eHealth systems [3]. Since 2002, the OpenECG network has been steadily growing to reach 682 members from 56 countries in September 2006, bringing together people from diverse cultures and disciplines in a network where knowledge, experience, and efforts are shared (see Figure 1).

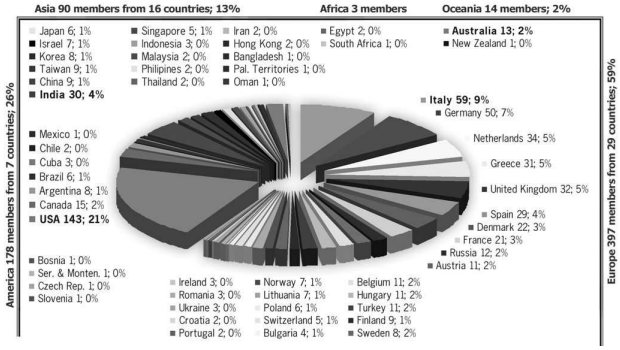

Figure 1. The OpenECG network in September 2006.

In section 2 (Methods), first the activities of the OpenECG network are placed in the context of relevant eHealth scenarios and other interoperability initiatives. Then, we report on developments in SCP-ECG conformance testing, the SCP-ECG standard, and other harmonization efforts. Section 3 (Results) reports on the SCP-ECG conformance testing that has been used by members in 20 countries and 40 organizations. Section 4

(Discussion) places OpenECG activities in the context of the new EU medical device directive and section 5 (Conclusion) summarizes the paper.

2. Methods

OpenECG activities complement those of CEN, HL7, IHE, and other interoperability initiatives on patient identification and EHR summaries, upholding interoperability as a quality label for integrated consumer-oriented eHealth services, cultivating trust and assisting continuity of care. This role of OpenECG can be attributed to the special synthesis of its members. Members of the OpenECG network are primarily ECG device manufactures (25.1%) and biomedical engineers (16%). Almost 20% of the OpenECG members are engaged in EHRs, eHealth and remote care (see Figure 2).

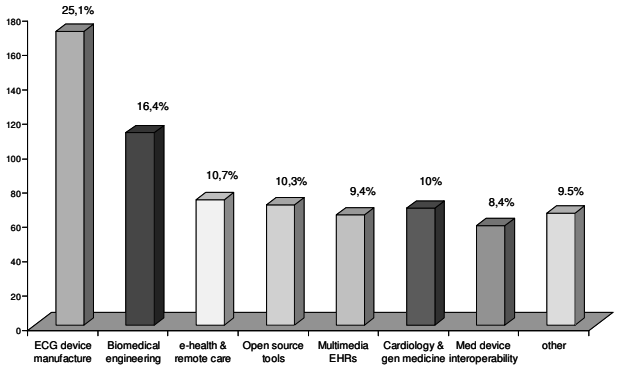

Figure 2. Background of OpenECG members.

The Integrating the Health Enterprise initiative (IHE) started at the end of the 90's to provide an implementation framework for so called integration profiles in the health enterprise. An integration profile leverages health informatics standards to facilitate integration of heterogeneous systems in clinical workflows. The use of specific standards is documented in an integration statement that declares the capability of a specific product to support an IHE integration profile. The IHE Cardiology technical framework (IHE CARD-TF): "*defines specific implementations of established standards to achieve integration in cardiology*" [4]. Over the years, IHE CARD-TF has developed integration profiles for several cardiology workflows including those for cardiac catheterization, echocardiography, and retrieval of ECGs for display. In the integration statements of IHE, conformance claims are made in direct reference to standards.

SCP-ECG is a "de jure" open standard format for the transmission and subsequent display of ECGs. Thus, the work of OpenECG on assisting its consistent implementation is clearly complementary to that of IHE. In different workflows, conformance testing applies to the ECG record generated by the medical device. It also applies to the ECG file received and maintained by an ECG management system in the hospital or the EHR system in a primary care clinic. The ECG to be tested may also be submitted as part of a second opinion request or a referral to an eHealth service. Moreover, software modules may update the ECG with demographic and clinical information such as patient id, blood pressure, etc. Then, dedicated modules may analyze or process the ECG and/or compare it to earlier ECGs of the same person. In all cases, however, it is necessary to attest that the ECG file is well-formed and of adequate diagnostic quality.

2.1. SCP-ECG conformance testing

SCP-ECG (CEN/EN 1064:2005) [5], the European standard for ECG interoperability, refers to four compliance levels (see Figure 3). Compliance levels II and IV require the inclusion of rhythm data that is considered important by cardiologists and enable automatic serial analysis and comparative study of ECGs. When rhythm data is included, implementation of the SCP-ECG high compression method can significantly reduce the file size. High compression in SCP-ECG is quite complex to implement. Software engineers creating vendor-independent tools need to implement all options to ensure support of manufacturer design choices. Luckily, peer support by the OpenECG community, the OpenECG helpdesk, conformance testing services and tutorials at the OpenECG portal clarify the standard and reduce the risk of error. Conformance testing can be performed at the ECG record and at the ECG device levels. Testing a device requires its physical availability. Testing ECG files is a service offered on the OpenECG portal. OpenECG conformance testing does not provide formal certification. Nonetheless it assists developers in implementing SCP-ECG, providing access to SCP-ECG testing tools through a web-page on the Internet and as web service that can be integrated in any product [6].

Category	Data Sections Required	Content Description
I	0,1,7,8	Demographics, global measurements, and interpretation
II	0,1,2,3,6,(7),(8)	Demographics and ECG rhythm data
III	0,1,2,3,5,(7),(8)	Demographics and reference beats
IV	0,1,2,3,4,5,6,(7),(8)	Demographics, ECG rhythm data, and reference beats

Figure 3. Compliance categories in CEN/EN1064:2005.

Dedicated validation tools for SCP-ECG conformance testing comprise a format checker, a content checker, and a sample ECG data set. The sample ECG data set includes records with and without compression [7,8]. For OpenECG-validated ECG records and devices, OpenECG certificates can be issued.

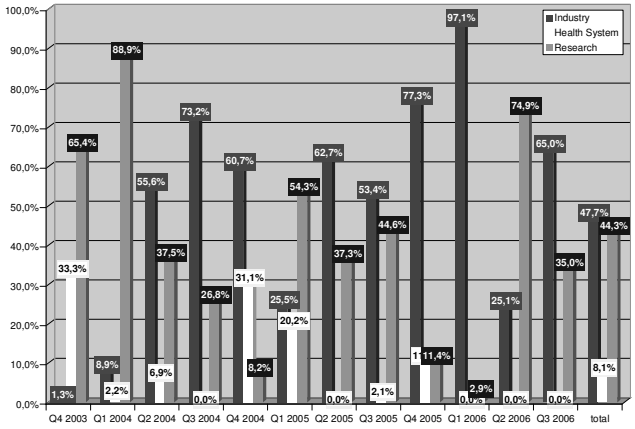

Figure 4. Use of the SCP-ECG conformance testing by OpenECG members (online and as a web service).

OpenECG launched the 1st online conformance testing service for SCP-ECG in September 2003 based on tools developed by Zywietz et al. [7]. The first experimental format/content checker dates back to July 1, 2003 and applies to SCP-ECG files version 1.0 or 1.3 (service version was 1.0). After two months of experimental operation, the service was released in the members' section of the OpenECG portal. Constructive comments from OpenECG members led to the first revision of the tools that was released in June 2004 (version 1.03a). Since then, the tools are regularly updated based on input from OpenECG members and developments in the standard itself.

After the publication of CEN/EN1064:2005 in February 2005, conformance testing was released also as a web service. The option of the web service enables OpenECG members to integrate the conformance testing functionality in third party software and test the validity of ECG files that arrive from different sources. All ECG files submitted for testing were re-tested with the new version of the tools in the standard and web service version [6]. There were occasions where non-conforming files caused the testing tools to fail. This problem was fixed in the interim version 1.13A, which was released on June 7, 2005.

The next major update of the testing tools occurred on March 29, 2006. Conformance tests were extended to all sections of an SCP-ECG file, while some cross-sectional checks were also added. Both the SCP-ECG content (2.0) and format checker libraries (1.13B) were changed. However, version 1.13B created very large reports that could not be easily stored in the ECG database and reduced availability of the conformance testing service. The issue was addressed in the next (current) version of the content checker (version 1.13C) and format checker (version 2.10), which were released on June 21, 2006. In case of too many errors, reports are truncated. The current version allows computerized checking of matching SCP-ECG format specifications for SCP-ECG file version 1.0, 1.3 (AAMI), 2.0 and 2.1 [8]. So far, service maintenance occurs transparently and does not disrupt the availability of the service.

2.2. Technical amendment to SCP-ECG

OpenECG is active in providing feedback from implementation to standard developments organizations (SDOs). Besides providing feedback to the IHE CARD-TF, members were particularly active in a technical amendment to SCP-ECG that is currently under ballot [9]. This amendment proposes reduction of the conformance levels in SCP-ECG. It also includes a comparison and harmonization of ECG lead definitions as well as recommendations regarding calculated, reconstructed, or derived leads; the result of joint work among working groups of leading international SDOs.

2.3. Harmonization with HL7v3 aECG

An OpenECG working group managed by Alois Schloegl in the frame of the BIOSIG project, currently develops a harmonized normative two-way converter between aECG and SCP-ECG in open source with support by IEEE 1073 and CEN [10].

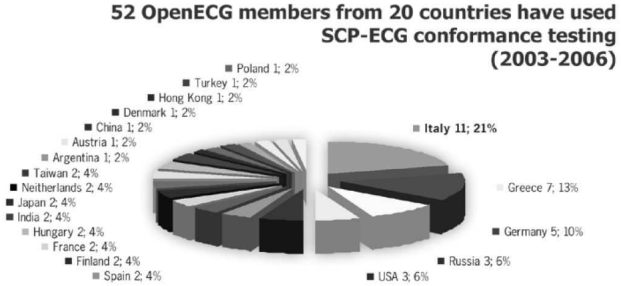

Figure 5. Users of SCP-ECG conformance testing.

3. Results

Over the years, conformance testing sustains the interest of the community and particularly the ECG industry: almost half the tests have been submitted by members affiliated with the ECG industry (Figure 4). Overall, 25% of the members using the conformance testing service are involved in ECG manufacturing, 16% biomedical engineering and ECG research, and 10% in

clinical practice. 10% are interested in open source tools and a combined 20.1% in eHealth, remote care, and EHRs.

Use of conformance testing by members in different countries is shown in Figure 5. Leading is Italy with 11 members, who have submitted 37.3% of the tests. After Italy, most ECGs have been submitted by Greece (17.74%) and Hungary (11.89%). As SCP-ECG is a European standard, 92% of the ECGs were submitted by Europe, 4% by Asia (Japan, Taiwan, China, India, Hong Kong), and just 3% by USA. ECG devices and eHealth services have been tested, improved, and validated using online tools and support from the OpenECG helpdesk. In addition, based on member feedback and analysis of more than 1700 tests registered online, the robustness of the service is constantly improving.

4. Discussion and conclusions

The medical device sector in Europe is covered by three Directives specifying the essential requirements for medical devices sold in the European market: the 1990 directive on active implantable medical devices (90/385/EEC), the 1998 directive on in vitro diagnostics (98/79/EC), and the 1993 directive on medical devices (93/42/EEC). Medical devices are subject to a risk management process and risk/benefit analysis relevant to their safe operation and their achieving the intended performance. In the proposed amendment of 93/42/EEC, the emphasis is on deregulation and fostering competitiveness of the medical device industry. Targeting simplicity, clarity, and transparency, the proposed amendment does not include references to EHRs beyond "what the device manufacturer considers relevant" and raises the question whether an "eHealth directive" is necessary to set up the framework for the safe provision of eHealth services.

OpenECG through voluntary contributions from its members links expertise in implementation with worldwide standardization efforts. However, similar initiatives need to be established for personal medical devices in the wider scope of ISO/IEEE 11073 standards for functional and semantic interoperability. Similar initiatives, if associated with the development of open reference multi-parametric biosignal databases endorsed by professional organizations, will no doubt pave the way for pervasive and ubiquitous eHealth. In that regard, the work of the National Institute for Standards and Testing (NIST) in the USA is also of interest as they provide open-source validation tools for a range of health-related software standards including ISO/IEEE 11073 in a national setting. That, in view of the pending revision of the EU medical device directive will hopefully assist coordinated efforts in the technical assessment of eHealth services and further promote the vision of plug-n-play medical device interoperability as a patient safety issue and a quality label for eHealth.

5. Conclusions

High quality eHealth services require access to the ever-expanding medical knowledge and seamless integration of medical devices to an active EHR capable of managing personal wellness profiles. OpenECG promotes plug-interoperability of medical devices as a quality label for eHealth systems to advance quality of service and cultivate consumer trust in the next generation of ambient intelligent working and living environments.

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