Interoperability in Digital Electrocardiography after the OpenECG Project

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Abstract

At a time of rising demands for interoperability in eHealth, OpenECG was funded by the EU to promote standards & open data formats in digital electrocardiography. Driving forces for OpenECG are patient mobility, regional networks, continuity of care, and the vision of the life-long EHR. The number of OpenECG members is steadily increasing, to reach 281 (203 from Europe) in 42 counties in October 2004. A programming contest, a members' mailing list, data sets, specifications, and tutorials combined with online services such as the help desk, converters, content & format validation, etc., bring users, manufacturers, and integrators to the portal.

In this paper, a recent questionnaire distributed to OpenECG members gives the opportunity to discuss OpenECG-related activities and prospects, in the frame of global trends & challenges in eHealth standardization, interoperability testing, technology assessment, and quality labeling for medical devices and EHR systems.

1. Introduction

Nowadays, the high market penetration of low-cost wearable and portable ECG devices for telemedicine and personal health management plays a key role in the evolution of eHealth and mobile health services. Furthermore, health cards, and in particular the European health insurance card presents an opportunity for instant access to emergency health data including a reference ECG. Thus, interoperability becomes increasingly important, as it is deemed a quality and patient safety issue not only for medical devices that record ECGs, but also for EHR systems responsible for long-term storage of health data. The unreasonable cost of integrating ECG devices led to the OpenECG project aiming:

- to encourage and promote the use of computerized ECG standards, raising awareness among users
- to consolidate expertise and use best practice to assist users, integrators & manufacturers in the consistent implementation of ECG standards
- to maintain a strong liaison to standardization bodies & professional organizations worldwide and to provide feedback regarding pitfalls & limitations in existing standards
- to support emerging standards for stress ECG, Holter, portable and wearable health monitoring.

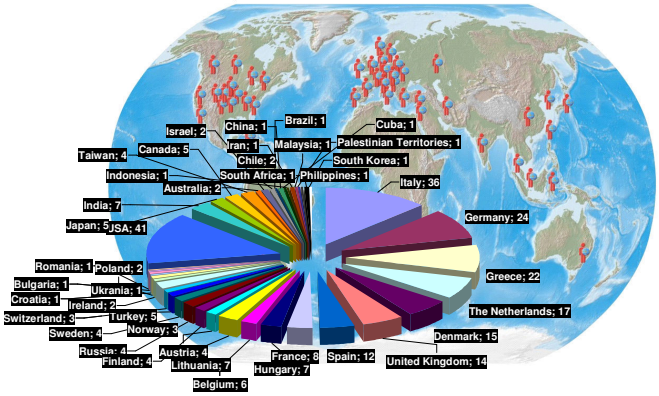

Figure 1: OpenECG has 281 members from 42 countries.

In August 2002, the OpenECG network and the www.openecg.net portal, linked to an advisory board of national health boards & industry representatives were established. Since then, several manufacturers and integrators have received assistance by the OpenECG help desk in implementing the SCP-ECG standard. The online conformance testing of ECG records and the offline process for testing ECG devices have established the foundations for interoperability testing centers in collaboration with standardization bodies [1]. This novel service is used regularly by about 10% of the OpenECG members, to ensure that their implementations of the SCP-ECG standard are consistent and interoperable [2].

Before OpenECG, there was a notable lack of public training material for ECG standards. The OpenECG

portal has bridged this gap with tutorials on how to implement the SCP-ECG standard, as well as specifications and data sets for SCP-ECG, HL7v3 annotated ECG, MFER, DICOM waveform suppl. 30, and the Philips XML format. The collection of these tutorials, specifications, and data sets in the portal enables harmonization and interaction among stakeholders and facilitates peer review of tools and contents.

OpenECG has also contributed to open source development through its programming contest. Members and contestants contributed tools for ECG record parsing and display. The best ones are now part of the repository.

Numerous presentations, national information days and two conferences have also contributed to the overall impact of the OpenECG initiative. The most important were the 1st OpenECG workshop "Bridging the interoperability gap in ECG devices" (Crete 2002), the Information day "Certification for interoperability" (Thessaloniki 2003), and the 2nd OpenECG workshop "Integration of ECGs into the EHR & Interoperability of ECG Device Systems, where we are - where we are going..." (Berlin 2004). Proceedings of these events are available at www.openecg.net. Besides organizing events, OpenECG participated in several meetings of Standards Developing Organizations (SDO), delivered about 40 presentations in relevant conferences, has joined forces with pre-existing user groups like the Muse user group in the Netherlands, and established new ones like the ECG group in Denmark. The impact of OpenECG can be also traced in Google where 1200 hits were recorded (September 2004).

Nevertheless, one of the key observations at the 2nd OpenECG workshop was that there are more ECG standards around now, than when OpenECG started! [3] Notably, standardization efforts worldwide have intensified. Also, there is a lot of pressure for reform as standardization procedures are considered slow and ineffective. The only -relatively- successful standards for 'ICT for health' are those led by vendor and user communities e.g. HL7, DICOM, IEEE; all SDOs that operate outside the formal standardization bodies. So what should the next steps for OpenECG be? How should we proceed to alleviate interoperability problems?

In pursuit of solutions, ideas, and answers, a questionnaire was prepared to request feedback from the OpenECG community and set up a roadmap for the future of the OpenECG network. Section 2 introduces the questionnaire. Section 3 presents the results of the questionnaire and places them in the context of new challenges for OpenECG. Section 4, further discusses the role of OpenECG in the context of global developments in standardization, quality assurance, and quality labeling. Finally, section 5 presents our conclusions.

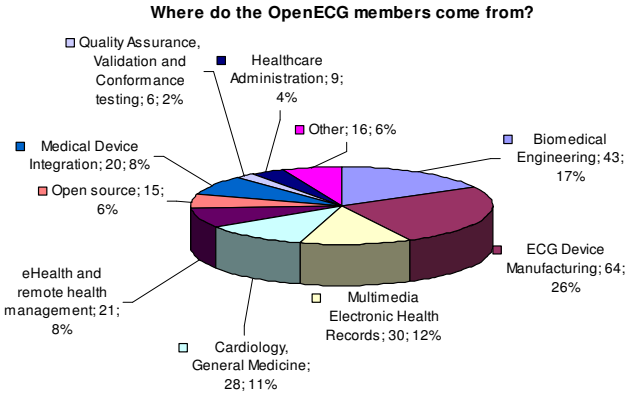

Figure 2: Main area of work for OpenECG members.

2. Methods

The composition of the OpenECG community as reflected at the time of the questionnaire, is multidisciplinary: ECG manufacturers (24%), medical informatics (24%), biomedical engineers (22%), academic (10%), health care professionals (6%), developers and integrators (5%), IT managers (3%), standardization (2%), etc. Their areas of interest is manufacturing (26%), biomedical engineering (17%), electronic health records (12%), healthcare (11%), medical device Integration (8%), eHealth services (8%), etc. (Fig. 2).

The questionnaire was short and comprised 14 multiple choice questions. Free text allowed members to develop their viewpoint. The average time to complete was estimated to 5 minutes. It was distributed to the 258 members of the OpenECG network in the last week of August 2004. After two weeks, 65 (25%) of the 258 members had responded.

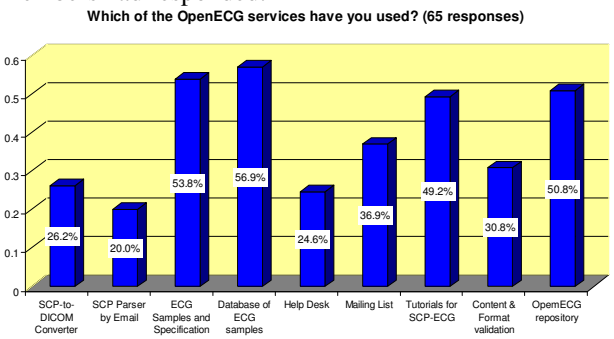

Figure 3: Popularity of member services at the portal.

3. Results

One of the first questions investigated member expectations when joining OpenECG. Top choices were integration services (62%), conformance testing (59%), helpdesk and code samples (56%), and news (40%). Other responses were "meeting people with similar

interests", "public domain viewers and converters", "format specifications and open source readers", "communication with ECG experts", etc.

Another question asked members which services and tools they had used at the members' section of the OpenECG portal and how they rate them. ECG samples (57%), specifications (54%) and the repository (51%) in Fig. 3, were the most widely used services in the portal. The conformance testing (30%), the Help Desk (25%), and email service for ECG parsing (20%) were used less frequently. This can be attributed to the specificity of the services since they relate to the SCP-ECG standard.

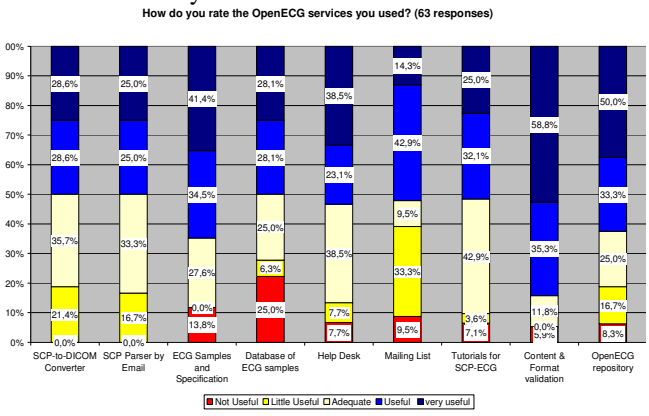

Figure 4: Most services were considered at least adequate.

The quality of all member services was considered at least adequate (80%) (Fig. 4). The highest ratings among member services were received by content and format checking for SCP-ECG records (95%), the help desk (86%), data sets & specifications (86%), and the open source repository (75%) [4].

Even though the format and content validation tools were used only by 30% of the responders, conformance testing received a warm response as shown in Fig. 5.

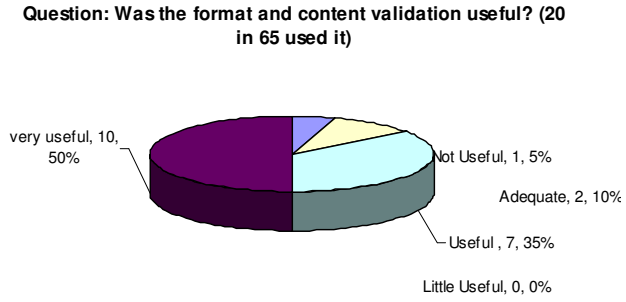

Figure 5: Conformance testing has received the highest rating.

The conformance testing service of OpenECG is a major step away from auto-certification and towards technology assessment and quality labeling. The service is available for free to the OpenECG members and has been updated several times based on expert feedback. Each submitted record goes through about 400 tests, and if successful, an OpenECG certificate can be provided.

The OpenECG repository was rated 4th, when half the responders had actually used its content. At this stage, the repository is still at its infancy and leaves much more to be wished for. Nevertheless, through peer review and community contributions, we anticipate enrichment of the OpenECG repository with the addition of reference implementations for standards and open-source ECG viewers endorsed by professional associations.

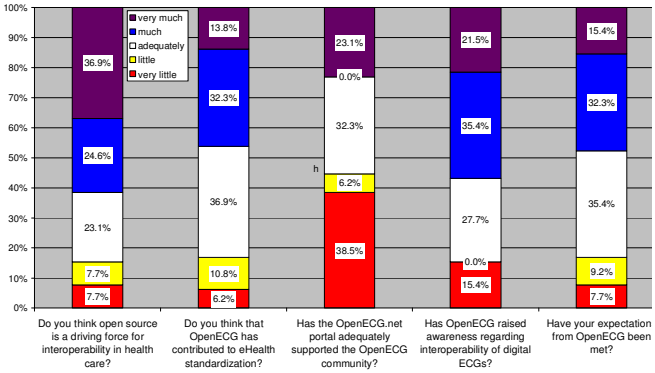

Figure 6: Members' opinion on the impact of OpenECG on ECG interoperability.

Another question investigated the impact of OpenECG on interoperability by: (a) promoting open-source development, (b) contributing to eHealth standardization, (c) addressing the needs of the community by means of using the portal, (d) raising awareness on ECG device interoperability, (e) meeting the expectations of members (Fig. 6). Based on responses, OpenECG did manage to raise awareness for ECG interoperability (85%) and to contribute to eHealth standardization (83%). Furthermore, its open-source activities can significantly contribute to interoperability in healthcare (85%). Overall, OpenECG met the expectations of its members (83%). However, there is more to be done. Almost half the responses (45%), suggested that the www.openecg.net portal has not reached its full potential. Indeed, so far the portal has addressed mainly the needs of integrators and manufacturers and emphasis has been mostly on content rather than on structure and presentation. New sections need to be prepared and maintained in different languages to address the localized needs of doctors, IT managers, and technical personnel.

In response to the question "what additional services they would like to see in the portal?", members requested more samples, viewers and converters (71%), implementation guides (62%), tables on "which device supports which format" (58%), conformance reports (46%), and procurement specifications (26%). It was also suggested to create ECG viewers as activeX components, build an SCP-ECG converter for the GE Muse format, and provide access to ECG analysis programs.

In the question "how should OpenECG keep its momentum?" yearly workshops (55%) and newsletters (52%) were suggested to keep the OpenECG spirit alive. Other useful proposals were to translate OpenECG to other languages, to provide best practice guidelines, to place OpenECG under EU framework, and to link to IHE activities in cardiology.

Regarding membership fees for OpenECG, 48% would prefer an open free-access portal (Fig. 7). However, 38% of the responders were willing to pay a membership fee of about 100 Euro for the services of the portal.

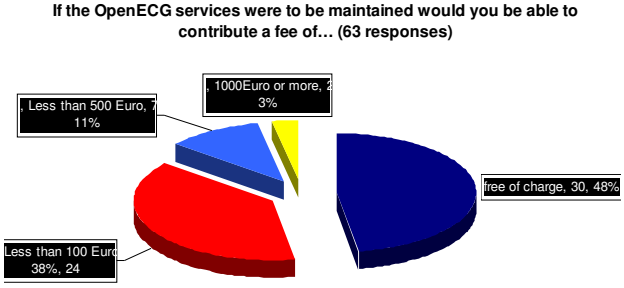

Figure 7: 38% of the responders would pay 100 Euro membership fee for OpenECG.

4. Discussion

Current initiatives in Europe and USA show the renewed interest of policy makers in interoperability and standards. The CEN/ISSS eHealth focus group, in its report on current and future eHealth standardization, notes the lack of public awareness regarding standards, complete profiles of standards, and reference implementation that can serve as best practice [5].

In the meantime, as the OpenECG network gains momentum, its role as a bridge between standardization organizations, ECG vendors, the scientific community, and the end-users, becomes more prominent: OpenECG is recognized by ECG vendors as a quality label.

However, responses to the questionnaire suggest that OpenECG should intensify its efforts, reaching out more towards the users and widening its scope. Firstly, the existence of multiple formats calls for harmonization and quality assurance. In USA, there is the Annotated ECG format, now part of HL7v3. In Japan, there is MFER, a standard for the storage of waveform data. In Europe, the IMEX project is developing MSD, a new micro-system data format (based on SCP-ECG), to meet the requirements of wearable devices. Secondly, although ECG viewers and converters exist for some ECG formats, terminology issues are not adequately resolved and there is a lack of consensus on ECG presentation & reporting guidelines. Thirdly, OpenECG advocates that data format and protocol specifications should be freely available to reduce the cost of device integration. However, achieving interoperability is still very costly, since a non-disclosure agreement is usually required to integrate each ECG device model.

Finally, there are many issues that OpenECG has not addressed so far. There are no widely accepted open standards for examinations like Holter, stress ECG, and monitoring of physiological parameters. Interoperability in the area of wearable ECG systems would facilitate the creation of reference databases of physiological signals including ECCs, and the generation of personalized health alerts. Furthermore, so far only IHE has addressed collaborative use of standards as integration profiles. The establishment of interoperability testing centers possibly in collaboration with ETSI or CEN could help in promoting the effective use of standards, while at the same time providing best practice paradigms. Work with professional organizations possibly within the auspices of IHE in Cardiology, Cardiology Societies, and EuroREC could help OpenECG reach this goal.

5. Conclusions

At the end of the OpenECG project, the struggle for ECG interoperability has just begun. The OpenECG network has to persist and establish closer ties with relevant initiatives to create a network of collaborating interoperability testing centers in Europe. Only in this way citizens can ripe the benefits of truly integrated care.

Acknowledgements

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References

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