

Towards a Network of Interoperability Testing Centers: an OpenECG Perspective

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Keywords: Interoperability, Conformance Testing, eHealth, Standards, ECG data formats, waveforms, certification, quality assurance, telemedicine

1. Introduction

As OpenECG gains momentum offering concrete services to its members, its role as a bridge between standardization organizations, ECG vendors, the scientific community, and end users becomes more prominent. Indeed, there is a renewed interest in interoperability: standardization bodies seek to define successful eHealth standards, citizens maintain personal electronic health records and use home care services, general practitioners increasingly use electronic health record systems with digital ECG support, and ECG vendors view OpenECG as a quality label [1].

Electronic health records, the aspiration and dream of Florence Nightingale is now tangible due to technological advances in information and telecommunication technologies. Establishment and maintenance of personalized wellness pathways are feasible due to advanced diagnostic methods, clinical protocols and guidelines. Beyond that, the integrated electronic health record concept promotes recording of comprehensive health data from conception to death and affordable personalized medical devices allow citizens to play a key role in managing their own health and the health of their loved ones. However, there are obstacles; and one of them is lack of interoperability.

The vision of the OpenECG consortium is to establish a network of interoperability testing centers and in cooperation with national standardization bodies, to promote interoperability and patient safety, while maintaining cohesion at the European level. Through coordinated actions, OpenECG will be able to further reinforce integration of digital Electrocardiography in daily health care practices, promote consistent implementation of standards, and assure interoperability of ECG devices used in the context of electronic health records and eHealth in general. At the same time, the cost of implementing standards will decrease, contributing to the competitiveness of SMEs marketing small devices for personal health management.

2. Methods

The high market penetration of low cost wearable and portable ECG devices used in home care, telemedicine, and personal health management is expected to play a key role in the evolution of eHealth and mobile health services. This tendency pronounces the need for substantial testing of quality and safety issues, an aspect of which is interoperability. eHealth in the information society is recognized as “an integrated intelligent person-centered health care delivery system that contributes to the improvement of quality, access, and efficiency of healthcare.” Unfortunately, the eHealth sector in Europe demonstrates tardiness when compared to other sectors. User acceptance is a critical factor in the recognition of eHealth as part of the health care delivery process. Despite advances in technology, in the eve of the “Knowledge society,” most ECGs are recorded, reported and archived on paper, a limiting factor for broad access to quality care. Lack of documented benefits, slow adoption of electronic health records and limited interoperability are among the contributing factors.

The resting ECG is the most frequent non-invasive cardiology examination affecting a large part of the population in the western world including people diagnosed with heart disease or prone to it due to lifestyle. The fact that the cost of ECG recorders is low when compared to radiology equipment is no excuse for ECG vendors who choose to use proprietary protocols and data formats in an attempt to save time and protect their market. In the knowledge society, there should be a mandate for conformance to interoperability standards. Furthermore, work on standard ECG layouts that look as good on the screen as on paper and consistent terminology should be disseminated to become a driving force towards the acceptance of digital ECGs, eliminating the “digital divide” and increasing cohesion around Europe.

Interestingly enough user associations and national health boards of the European member states actively pursue integration of medical devices to electronic health records and clinical information systems. The OpenECG Industrial Advisory Board (IAB) comprises seven core members, mostly representatives of national health boards and professional associations. There is also an associated board of ECG manufacturers. The

OpenECG IAB acts in advisory capacity identifying trends, raising awareness, and promoting OpenECG objectives. Growing pressure is also applied on manufacturers by ad-hoc user groups like the ECG user group in Denmark, the MUSE user group in the Netherlands, and others. Conformance to standards is now present as a requirement in procurements for ECG devices. Overall, users groups take the lead and interoperability starts to be recognised as an aspect of patient safety. In this setting, the role of OpenECG as a neutral body, is to provide specifications and verify that interoperability requirements are met.

In the beginning of the OpenECG project, almost two years ago, there were fewer data formats for ECGs than today [2]. This calls for harmonization of alternative data formats, since standardization efforts for medical data formats suitable for electronic health records, telemedicine, and ambulatory care present a lot of fragmentation. In USA, FDA demanded disclosure of waveform data recorded in clinical trials and after 2.5 years specifications, samples, and an ECG viewer are freely available. The 'Annotated ECG format' is now part of the HL7 family of standards. In Japan, a consortium of manufacturers is working on MFER, another standard for the storage of waveform data. Advance specifications, samples, and free viewers for SCP-ECG, MFER and the Annotated ECG formats are available at the OpenECG site. In Europe, the German IMEX project of VDE is developing MSD, a new micro-system data format (based on SCP-ECG section 1), to address the needs of wearable devices [3]. Unfortunately, the effectiveness of interoperability standards is limited by the lack of harmonization and their narrow or too generic scope, especially in the context of the electronic health record.

OpenECG can help in linking theory to practice. It provides a forum for sharing experience on the deployment of pre-standards, the promotion of best practice, and the dissemination of open-source components. The expert members of the OpenECG community collaboratively review the technical material, test data sets, and specifications. Thus, the validity of claims is verified and the quality of the tools & services continually improves. The helpdesk and the members' list provide a forum for discussion of important issues and furthering of interoperability for electrocardiographs and other ECG devices. In this way, the cost of implementing standards for integrators and small manufacturers is no longer prohibitive.

Nowadays, developing interoperability standards is an extremely slow process and implementing them unreasonably costly. Furthermore, the integration of legacy ECG devices frequently requires establishing contact and signing non-disclosure agreements with various manufacturers, a tedious and time-consuming task. This lack of information drives people towards ad-hoc solutions, sacrificing interoperability, quality of care, and eventually patient safety. SCP-ECG as an interchange format is compact, comprehensive, and provides a small electronic health record in each ECG record. More importantly, SCP-ECG addresses resting ECG quality and accuracy, and supports domain dependent compression that makes it suitable for storage in the European health card (~8kb). There have also been extensions of SCP-ECG for Holter, stress ECG, even for spirometry examinations based on the principles of the SCP-ECG standard [4,5]. Overall, the availability of best practice in implementation, specifications, and tools within the OpenECG community would significantly lower the cost of interoperability.

3. Results

OpenECG has succeeded in establishing a worldwide community and international recognition (about 200 members in March 2003). The 1st online service for conformance testing of ECG records to SCP-ECG, the European standard for ECG interoperability, opened in September 2003. Since then, it has been used more than 200 times by 25 members. Also, four manufacturers and several integrators have received assistance by the helpdesk in implementing the SCP-ECG standard. The online service for conformance testing of ECG records and the offline process for testing ECG devices establish the foundations for interoperability testing centers and certification services in collaboration with national standardization bodies. Such services provide confidence to users that ECG interoperability requirements as they apply to ECG-related services and systems have been met.

Furthermore, recent international standards for the performance of ECG devices aiming to protect patient safety, suggest the development of regional ECG databases of common pathologies to serve as a reference point for testing ECG equipment in specific geographical areas. OpenECG plans to extend its activities to cover other standards focusing on promoting interoperability as an aspect of patient safety.

4. Conclusions

OpenECG's envisioned role as the link among national testing centers is to serve the community in technology assessment of ECG devices, promote harmonization among alternative ECG data formats and reduce the risks involved in the use of eHealth services. In the long term, establishing consumer confidence will contribute to an increase in the market acceptance of ECG and eHealth products, while contributing to the realization of comprehensive electronic health records.

Acknowledgements

The work reported here has been supported by the European Commission under contract 2001-IST37711.

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