Grid-enabled medical devices, Innovation in eHealth, and the OpenECG network paradigm

C.E. Chronaki, F. Chiarugi, and M. Reynolds

***Abstract*— Nowadays, empowered chronic patients pursue a prolonged, active, and productive life. Their independence is supported by disease management plans, sophisticated medical devices, and Information & Communication Technologies (ICT) that emerge as a major utility next to electricity and water. Meanwhile, the next generation Grids promise resilient, pervasive, and knowledge-driven services delivering ambient unobtrusive care, anytime and anywhere. Such services, however, depend on plug-interoperability of medical devices and integration with Electronic Health Records (EHR).**

Building on the OpenECG network paradigm that promotes interoperability in electrocardiography, this paper discusses the challenge faced by eHealth as medical devices are treated separately from EHRs in an uneven hardware-software separation. This separation leads to fragmented clinical knowledge, avoidable medical errors, and suboptimal care. Medical device data should be seamlessly acquired, processed, interpreted, and archived. Medical devices should be also quality-controlled and integrated with EHRs to maintain health pathways and adjust alert levels. Starting from OpenECG services, risk management and conformance testing for Grid-enabled medical devices are presented as key performance factors and patient safety issues for eHealth. While regulation typically discourages innovation, regulated Grid services to safeguard security and interoperability are proposed to support personalized care and gradually weave eHealth into the fabric of life.

I. Introduction

After electricity and water, ICT is perceived as the next major utility service delivering secure and trusted on-demand eHealth services to our aging society. Cardiovascular disease, diabetes, cancer, and musculoskeletal conditions are key health challenges we face at home, on the move, and in the workplace. According to the silver book on chronic disease and medical innovation [1], 40% of adults 45-65 and 67% of seniors over 65 suffer from at least two chronic conditions, which limit their ability to perform daily living activities. Indeed, advances in ICT, micro- & nano-technologies, and biomedical research guide developments in a robust medical device sector characterized by a yearly growth factor of about 7.8%, in Europe alone. With more than 10,000 medical device models in circulation, the impact of medical devices on the costs and effectiveness of care is rapidly increasing, in some cases surpassing pharmaceuticals, the main pillar of health care [2].

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C.E. Chronaki and F. Chiarugi are with the Institute of Computer Science, FORTH, Heraklion, Crete, Greece (phone: +30-2810-391691,58; fax: +30-2810-391428; e-mail: {chronaki, chiarugi}@ics.forth.gr).

M. Reynolds is with AMS Consulting in the UK.

Indeed, medical device innovation can lead to significant quality of life improvements, but plug-interoperability of medical devices and integration with EHRs is a prerequisite. Up-to-now EHRs have been treated differently from medical devices in an uneven hardware-software separation leading to fragmented medical knowledge, avoidable medical errors, and suboptimal patient care. Seamlessly acquiring, processing, interpreting, and archiving medical device data in standard formats would clearly contribute to maintenance of health pathways and alert levels as part of personal EHRs. However, security concerns regarding medical devices connected to the Internet seem to hinder interoperability, placing responsibility on the manufacturers [3]. Moreover, integration with EHRs based on interoperability standards is not well-established and narrow availability of quality-assured multi-parametric biosignal databases and associated knowledge tools limits acceptance of personalized health monitoring by clinicians and the public. Recognizing this gap, standardization bodies attempt to accelerate their time-consuming procedures and eHealth interoperability initiatives emerge. Among them, the Integrating the Health Enterprise initiative (http://www.ihe.net) engages health professionals' organizations and the industry in establishing integration profiles in a number of diagnostic areas including Cardiology. A complementary activity, the OpenECG network (http://www.openecg.net), consolidates world-wide expertise to advance interoperability in electrocardiography (see Fig. 1).

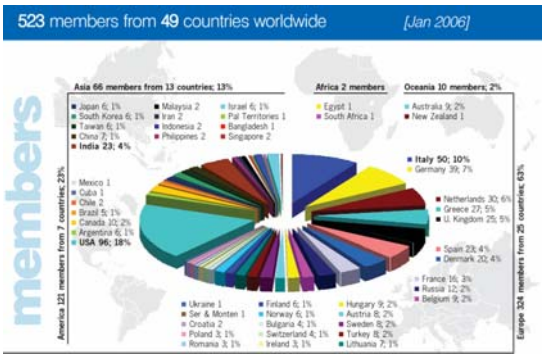

Fig. 1: OpenECG exceeds 650 members from 52 nations in June 2006.

This paper uses the example of the OpenECG network to discuss a major challenge for eHealth, namely risk management and interoperability of Grid-enabled medical devices.

Traditionally, the Grid is perceived as an integration platform for data and computing resources as determined by its

definite characteristics: *"coordination of resources that are not subject to centralized control"*, *"use of standard open and general-purpose protocols and interfaces*", and "*delivery of non-trivial qualities of service"* [4]. Beyond that, the European vision for the next-generation Grids as conveyed by Service-Oriented Knowledge Utilities (SOKU) is that of a major ICT commodity that provides pervasive and knowledge-driven services in a resilient to failure, autonomous, and self-healing framework that is dependable, trustworthy, and secure [5]. Grid-enabled medical devices as part of ambient eHealth services may interact with SOKUs not only for risk management and interoperability, but also for quality assurance and background medical knowledge.

The remainder of the paper is organized as follows: Section II (Materials and methods) firstly addresses Grid innovation in eHealth, focusing on Grid-enabled medical devices and standardization efforts for plug-n-play medical device interoperability. Then, the focus moves to OpenECG member services and conformance testing for SCP-ECG (CEN/EN1064:2005) [6], the European standard for ECG interoperability. Section III (Results) reports on the use of conformance testing on the Internet and as a web service, and proposes similar services on the Grid. Section IV (Discussion) places the prospects, challenges, and potential impact of health monitoring on the Grid in the context of the pending revision of the European medical device directive and developments concerning risk management, security threats, and patient safety.

II. Materials and methods

A. Grid innovation for eHealth

General practitioners are increasingly using EHR systems and medical devices to support their gatekeeping role in primary care. More and more, active, health conscious, aging citizens acquire personal medical devices to monitor their health at home or in the workplace; in some cases at the suggestion of health professionals, in some cases under prescription, but often on their own initiative. Medical devices can also be used with EHR systems and health journals and communicate health monitoring data and alarms to call centers. Considering the clinical value of medical devices and their potential impact on shared care and wellness management, a pressing need arises. It is the need for uniform recording of health data to address flexible care protocols, risk management, and overall technology assessment. Plug-interoperability of medical devices and support of vendor-neutral formats are features that reduce the risk of medical errors and enable automatic value checking and alert management; patient safety and quality indicator issues for eHealth [7-9].

However, medical devices increasingly incorporate off-the-self (OTS) software components, and network connectivity increases security and privacy risks as it makes medical devices susceptible to virus, worms, and other malware. The Food and Drug Administration (FDA) in the USA, issued a warning raising concerns on the potential vulnerabilities of OTS software that could permit an attacker to gain unauthorized access to a medical device and reduce its safety and effectiveness [3,10]. Such concerns and the underlying shared responsibility for network security can hinder interoperability efforts towards provision of integrated care.

The Grid is an opportunity for innovation in eHealth. In biomedicine, the Grid provides access to vast distributed resources via a uniform interface and supports biomedical research for individualized disease management. Gradually, however, with service and knowledge Grids, business models of a global Grid infrastructure entailing a mobile end-user perspective, emerge. They address pervasive and ubiquitous application scenarios where machines and devices dissolve in the ambient invisible Grid [11-15]. In that direction, Grid research projects that focus on the health needs of aging citizens add value to a Grid fabric that provides for resilience, security, and trust. They pave the way towards Grid-enabled eHealth services that facilitate collaboration across organizations and assure that the right information is at the right place at the right time [16-19].

In this context, Grid-enabled medical devices should be able to interact with the global Grid infrastructure: (a) making medical data available on the Grid as part of EHRs residing on the Grid, (b) using regulated Grid services for interoperability, quality assurance, risk management, security and trust, (c) interacting with knowledge repository, interpretation, and analysis services that operate on the Grid. Thus, Grid-enabled medical devices may provide scientific data on the Grid to further biomedical research and at the same time use the dependable and secure Grid infrastructure to alleviate risks and enable pervasive health care. Already, health monitoring on the Grid using proxies to mitigate the issue of intermittent connectivity and asynchronous operation has been demonstrated in the frame of e-Science in the UK for a wearable jacket monitoring heart rate and a glucose sensor archiving the acquired health data on the Grid [18].

Next generation Grids promise a secure and trusted environment for comprehensive EHRs at individual and population level. Grid-enabled medical devices can contribute to multi-parametric biosignal databases, while analysis and interpretation of health trends, epidemiological surveillance, and alarm detection are performed in real-time though appropriate SOKUs. SOKUs capture the key notions of service orientation (i.e. dynamic assembly and adaptive run-time behaviour), knowledge (i.e. semantically-assisted automated functionality), and utility (i.e. services that are directly usable with established functionality, performance, and dependability) [5]. However, a prerequisite of the larger SOKU vision is settling issues associated with risk management and interoperability. Data format, identification, semantics and terminology, configuration, and quality con-

trol are only some of these issues.

In the OpenECG network, collaboration among members, open source tools, and online services provide early feedback from implementation to standardization bodies and facilitate harmonization efforts. A number of OpenECG member services already available as web services can be readily transferred to the Grid, promoting interoperability of ECG devices and linking ECG records to EHR systems in vendor-independent formats. Grid services for quality assurance covering the full lifetime of a device can also be provided to reduce time-to-market and facilitate vigilance and post-market surveillance (see Fig. 2). Achieving interoperability of medical devices is central to the creation of cooperative research databases that can help record, analyze, and interpret personalized health pathways. Additionally, the cost of conforming to standards, ensuring safety and essential performance, can be mitigated by establishing virtual organizations that collaborate and share information, taking advantage of the security and dependability of the Grid. Review of relevant standardization efforts in the international community and the achievements of the OpenECG network, provide insights into the role of world-wide collaboration on interoperability and quality assurance.

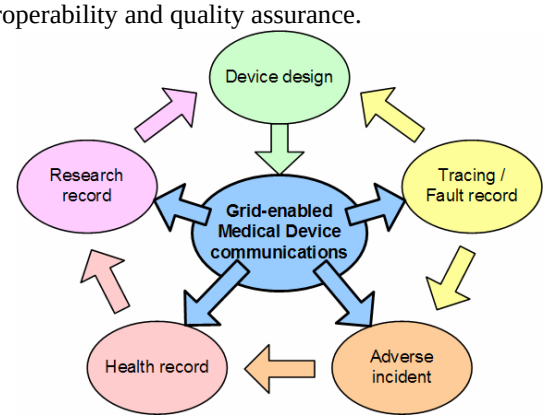

Fig. 2: Grid-enabled medical devices and their quality assurance workflow.

B. OpenECG: promoting medical device interoperability

The development of open standards for medical device interoperability has a long history. Table 1 shows only some of its highlights. In a ten year project (1980-90), the Common Standards for quantitative Electrocardiography (CSE Study) established the principles of quantitative electrocardiography and the framework for the development of interoperability and performance standards. Work on a resting ECG standard, Standard Communication Protocol - computer-assisted electrocardiography (SCP-ECG), started in 1990, the European pre-standard (prENV1064) was available in 1994, and the official standard was released by CEN, in 2005 (EN1064:2005) [6]. In contrast, European work on point of care standards (VITAL) started in 1993 and collaboration between IEEE, ISO, and CEN led to the publication of the official standards (CEN/ISO/IEEE 11073) in 2004/5. File Exchange Format (FEF) is a data format based on VITAL that addresses presentation and storage of time-synchronized biosignal data. FEF was released as a pre-standard in 2002 (ENV14271:2002) [20], but its adoption is still limited.

Worldwide, there is a proliferation of 'standard' formats specifically for ECGs and other medical waveforms. The annotated ECG format commissioned by FDA in 2002 for clinical trials and adopted by HL7v3 in 2004, has formed the basis for XML formats promoted by large ECG vendors. Other open ECG formats are the DICOM waveform standard (Supplement 30) and MFER, a Japanese storage format for waveform data. A recent workshop on guidelines for exchange of polysomnography data reiterated that the proliferation of data formats has negative impact on the effective collaboration of research groups world-wide [21].

TABLE 1: TIMELINE OF MEDICAL DEVICE INTEROPERABILITY AND STANDARDIZATION EFFORTS

1980-90	Common Standards for Quantitative Electrocardiography (CSE Study); IEEE1073 started work on the so-called Medical Information Bus
1989-90	European, American, and Japanese vendors and users start work on SCP-ECG
1993	SCP-ECG standard for trial use published as ENV1064:1993; CEN TC251 VITAL project: representation of biomedical signals, measurements, events, and alarms with IEEE1073 input
1994-96	OEDIPE Project to promote the exchange of ECG in SCP-ECG format
1997	CEN TC251 INTERMED project: medical device interoperability with IEEE1073 input; CEN TC251 FEF: VITAL-based file exchange format
2000	VITAL standard for trial use published as ENV13734:2000; INTERMED standard for trial use published as ENV13735:2000; CEN TC251/ IEEE1073/ISO TC215 co-operation on medical device interoperability
2001	HL7/IEEE 1073/ISO TC215 co-operation on medical device interoperability; SCP-ECG proposed as ISO 11073 standard (failed due to IEC WI)
2002	FEF standard for trial use published as ENV14271:2002; OpenECG project IST2001-37711; SCP-ECG proposed as IEC standard 60601-1-53; Epimedics project for self-care of people at cardiac risk
2003	HL7 RCRIM project adopted 11073 as basis for annotated ECG (-10102) for regulatory approval of clinical trials
2004	First five harmonized ISO/IEEE 11073 series standards (Point-of-Care Medical Device Com) published; HL7 IDC project adopted 11073 as basis for standardised terms (-10103) for implantable cardiac devices
2005	ASA-APSF-IOTA project adopted 11073 as basis for standardized terms for medical devices in SNOMED-CT and CDA reports; SCP-ECG published as European standard EN1064; Harmonized ISO/IEEE 11073 series standards (Point-of-Care Medical Device Com) published as ENs
2006	CEN/ISO/IEEE 11073 family of standards selected as the basis for the work of Bluetooth SIG and related Continua Alliance, for interoperability of personal health devices.

The 12-lead ECG is the most frequent non-invasive diagnostic examination for cardiac patients and with recent belt-like electrodes can be performed virtually anywhere with considerable accuracy for active and passive monitoring of cardiac problems [22]. In digital form, it is possible to serially compare ECGs, control the quality of the recordings, and manage alerts [23]. SCP-ECG is the European standard for communicating digital ECGs that ensures interoperability, and, to some degree, quality of digital ECG recordings [6]. SCP-ECG covers an interchange format and a limited number of messages for the acquisition, compression, transfer, and storage of 12-lead ECGs. With SCP-ECG, compatible systems can transmit, store, and receive ECGs with full waveform fidelity. However, despite the proliferation of ECG devices and the fact that the ECG in its digital form is a critical part of the EHR, standard data formats like SCP-ECG are not widely adopted.

The OpenECG network was formed in 2002 bringing together the stakeholders of ECG device interoperability and approached interoperability as an issue of patient safety and quality for eHealth [7]. The mission of OpenECG is to advance interoperability in electrocardiography through the promotion and consistent implementation of standards. It brings together people with different cultures and background in a network where knowledge, experience, and effort can be shared (see Fig. 1). Approximately 25% of the OpenECG members are ECG device manufacturers or system integrators and the OpenECG portal supports them with vital information and tools on the practical aspects of ECG interoperability. OpenECG advocates open data formats for ECGs facilitating the creation of vendor- and device-independent ECG databases and stimulates the development of open source processing, analysis, and visualization tools. Interoperability tools available to OpenECG members include a converter from SCP-ECG to the DICOM waveform standard as well as several open source viewers and parsers. However, a milestone for OpenECG was the first online conformance testing service for SCP-ECG.

C. Interoperability testing: the case of SCP-ECG

In most developed nations, safety, conformance testing, and device approval require testing of a medical device by a notified body officially recognised by the local regulatory agency. All these institutions require that the device is physically provided and all tests are performed by inspection and by respective measurements. Testing for safe interoperability in ECG devices would involve an additional cost since current SCP-ECG implementations differ significantly and, in some cases, are erroneous. Even though conformance testing and interoperability certification from the OpenECG network do not constitute official certification as provided by international/ national notified bodies, they provide substantial support to developers and integrators and are considered a major breakthrough for ECG device interoperability.

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

Fig. 3: Compliance categories of SCP-ECG (CEN/EN1064:2005) standard.

In SCP-ECG, there is provision for four compliance levels (see Fig. 3). Compliance levels II, IV require the inclusion of rhythm data, which is considered important by cardiologists and enable automatic serial analysis and comparative study of ECGs. When rhythm data is included, a proper implementation of the high compression method can significantly reduce the file size. However, high compression is quite complex and peer support by the OpenECG community or tutorials like the ones at the OpenECG portal can help reduce the risks of introducing errors. Furthermore, software engineers creating vendor-independent tools need to implement all options to ensure support of several manufacturer formats.

Conformance testing applies not only to the ECG record generated by the medical device, but also to the ECG file received and maintained by an EHR system or an eHealth service, which may feed to it demographic and clinical information such as patient id or blood pressure. Dedicated validation tools for conformance testing (a format checker, a content checker, and a sample ECG data set including records with and without compression) have been developed. Testing can be performed at the ECG record and at the ECG device levels. For OpenECG-validated ECG records and devices, an OpenECG certificate is provided upon request.

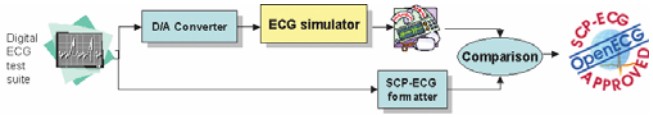

Fig. 4: Testing conformance of electrocardiographs to SCP-ECG.

ECG record level testing is available automatically through the OpenECG portal, but also as a web service [24]. Any authenticated OpenECG member may submit an ECG record for interoperability testing. The results provide insight on the content and format of the ECG record. The 'content report' accounts for parsing the ECG record according to the SCP-ECG specification. The 'format report' lists warnings and errors resulting from a basic format checking of the ECG record. ECG device level testing is available offline. The device has to be physically available and be accompanied by appropriate documentation of the communication protocol and software drivers for interconnectivity. An analog ECG test data set is submitted to the device and the output is compared with the original input data (see Fig. 4).

The web service version of the conformance testing service can be integrated to third-party software and provides access to the content and format testing tools through a programming interface. Four parameters, namely the web server and port offering the service together with the username and password of the OpenECG member, can be configured. Using the web service, a program submits the ECG file for testing. The client software provides a response with the testing results including the number of errors and warnings, the URL to retrieve the posted ECG file, as well as URLs to retrieve the full content and format reports. The WSDL description of the web service can be registered in a UDDI registry to allow real-time discovery and invocation. In a similar way, a Grid port can offer the same functionality in the frame of the Open Grid Service Architecture (OGSA).

Ensuring ECG interoperability involves not only implementation of SCP-ECG, but also its harmonization with

other ECG data standards. Recently, an OpenECG working group endorsed by IEEE1073 and CEN TC251 WGIV was formed to develop a normative converter between the HL7v3 annotated ECG format and SCP-ECG. The results will be available in open source as part of the BIOSIG project [25].

III. Results

Online conformance testing was created by OpenECG to drive interoperability of SCP-ECG implementations by ECG device manufacturers and software vendors. It is based on a general methodology for validating the conformance of ECG devices and ECG records to the SCP-ECG standard. So far, several members have used interoperability testing on the OpenECG portal, and in some cases also received assistance from the OpenECG help desk, to consistently implement SCP-ECG in ECG devices and enable integrated scenarios of health care provision. The web service is a further step towards robust user-accepted vendor-neutral software systems with SCP-ECG support, advancing interoperability and quality control. It supports the practical set-up of EHRs with digital ECGs and the adoption ECG analysis procedures such as serial comparison, promoting personalized health care.

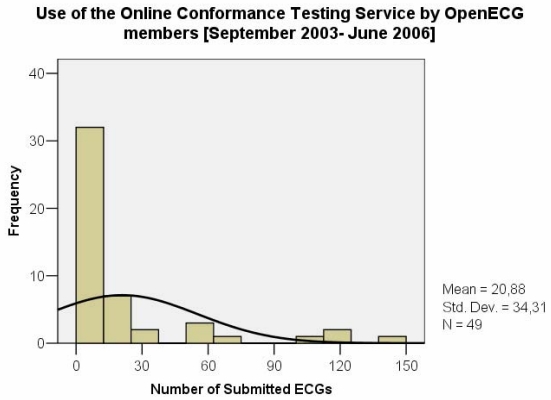

Fig. 5: Online conformance testing service of ECGs at the OpenECG portal.

Conformance testing has been available since September 2003. In June 2006, the online service has been used by 49 (8%) OpenECG members. The largest number of ECGs submitted for online conformance testing by an individual OpenECG member is 143 (m=20, s=34) as shown in Fig. 5. 50% of the OpenECG members that used the service submitted 5 ECGs or less. The web service version of conformance testing has been used by 6 OpenECG members, between 1 and 53 times, since its June 2005 release. So far, to our knowledge, at least two ECG vendors and two integrators have implemented correctly the SCP-ECG standard using the online conformance testing service of OpenECG.

Conformance testing assists integrators and manufacturers, who consider endorsement by OpenECG a quality label for their products. Before OpenECG, the only option available was auto-certification, i.e., self-declaration of conformance to standards or interoperability with equipment of certain vendors. Using the web service, integrators can combine different dialects of SCP-ECG into robust vendor-independent viewers. Two viewers were adapted to incorporate the web service: a multi-vendor ECG viewer developed at FORTH/ICS [26] and an open source ECG viewer available at the OpenECG repository [27]. The web service option enhanced the functionality and increased the overall quality of both viewers [24].

All submitted ECG files are stored in a database together with conformance testing results. Currently this database has grown to include more than 1500 ECG records some conforming (others not) to the SCP-ECG standard. The database of tested ECGs submitted for conformance testing can be made available within the Grid. The main organizational requirement is that a virtual organization pairing to the OpenECG network is established to promote the use of Grid services for interoperability, security, and conformance testing of medical devices.

IV. Discussion and Outlook

A. *Grid-enabled medical devices for health monitoring*

Individualized health monitoring involves measuring multiple physiological parameters and setting up personal health profiles based on normal trends and individual health performance, actively or passively [22,23]. Health monitoring requires knowledge about what is normal, extreme, and alarming based on the personal EHR and available knowledge databases, which so far have been isolated “islands” confined to large companies or research centers. It entails increasingly biomedical devices and biosensors, which are frequently sold over the counter. Finally, it involves biosignal analysis algorithms, which in some cases are provided on payment of a fee to manufacturers of ECG devices. Such services could add-value to the Grid economy. Clearly the Grid presents an opportunity for SMEs working in this niche market to collaborate effectively by sharing databases but also offering/using interpretation services possibly on pay per use business models.

As far as OpenECG is concerned, porting currently available web-services under the Globus Toolkit (GT3) is certainly a vital step towards realizing Grid-enabled medical devices. Naturally, it is only a first step towards supporting the workflow processes in Fig. 2, but with user awareness and wider availability of the Grid infrastructure, the demand for Grid-enabled medical devices and eHealth services will rise. Adopting ISO/IEEE 11073 standards for functional and semantic interoperability of Grid-enabled medical devices as well as establishing a virtual organization along the lines of OpenECG, focusing on developing multi-parametric biosignal databases and promoting medical device interoperability on the Grid, would prepare the ground for pervasive and ubiquitous health care. 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 their national context.

B. The new European Medical Device Directive

The medical device sector in Europe is covered by three Directives affecting more than 10,000 products [2]: the 1990 directive on active implantable medical devices (90/385/EEC), the 1998 directive of in vitro diagnostics (98/79/EC), and the 1993 directive on medical devices (93/42/EEC). These directives specify the essential requirements that have to be met when medical device products are sold on the European market. Medical devices are subject to a risk management process and risk/benefit analysis relevant to their safe operation and their achieving the intended performance. The most important areas addressed by the proposal for a revised 93/42/EEC directive are conformity assessment, adequacy of clinical data on investigations, and increased transparency to the general public in relation to approval of devices by notified bodies. In the proposed amendment 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. That raises questions about the need for an "eHealth directive" that would provide a framework for the safe provision of eHealth services.

Meanwhile in the USA, concerns have been raised by FDA regarding the security of networked medical devices containing OTS components. In response, HIMSS presented a disclosure statement for manufacturers reporting on the handling of patient data on the medical device [3]. Although the fact that medical devices can be affected by computer viruses is of considerable concern, the route to safer integration lays in achieving a better understanding of the shared roles and associated responsibilities that manufacturers, regulators, users (and/or their support staff) should play.

The way forward, in an integrated approach to health improvement, should not block interoperability as a way of reducing a single point risk, whilst simultaneously increasing other risks. Grid-enabled medical devices and virtual organization along the lines of OpenECG that can cooperatively test and timely disclose problems with medical devices can promote interoperability in eHealth and contribute to quality care, fostering quality control and cultivating consumer trust.

V. Conclusions

OpenECG promotes best practice for interoperability in electrocardiography and offers interoperability services for SCP-ECG. Establishing a similar but wider initiative for Grid-enabled medical devices and offering Grid services for risk management, quality assurance, and interoperability would build consumer trust, support personalized care, and gradually weave eHealth into the fabric of life.

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