

Review of Interoperability techniques in data acquisition of wireless ECG devices

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Abstract: *Wireless medical devices with enhanced capability operating within Body Area Network (BAN) are key elements in: telehealth, and remote health monitoring systems. They help to capture process and store vital signs acquired through sensors and transfer them through communication protocols such as ZigBee and Bluetooth to aggregators. However, due to the heterogeneity of devices and manufacturers' proprietary applications, the devices lack adequate interoperability between each other and Health Information Systems (HIS), thus making it difficult to sort data and/ or make it usable to medical team. In this study we reviewed the various approaches employed to facilitate interoperability in wearable wireless Electrocardiogram (ECG) devices ranging from model driven interoperability (Information model, data models etc.); ECG format; ontology; standards and mapping of physiological data, available in literature in the last five years with respect to advancement in telecommunication. The findings indicate that wearable wireless ECG needs both retrospective and anticipatory interoperability mechanisms due to advancement in telecommunication technology especially with the promising fifth generation (5G) technology, to facilitate the transmission of the right information from the patient to the healthcare provider.*

Keywords: *Data exchange, Information model, Information Interoperability, standards, Wireless ECG*

I. Introduction

Currently with the advancement and rapid adoption of sensors in monitoring, measuring, capturing and processing patients' physiological signals such as: blood pressure; heart signals, sugar level etc., medical sensors provide promising application in health monitoring either remotely or otherwise: this has led to the development of wireless wearable devices that operates within the Wireless Body Area Network (WBAN).

Electrocardiography (ECG) is one of the most important physiological signals that wireless wearable sensors has proved valuable in capturing[1]–[3], it provides evidence for early detection of heart diseases in non-invasive and accurate way[4]. However, due to manufacturers' proprietary applications, heterogeneity of sensors' design and medical information systems variations, data captured differs in format and contents creating poor data which may not be useable for the purpose for which it was capture due to poor interoperability of systems.

Interoperability is defined as “the ability of two or more systems or components to exchange information and use the information that has been exchanged”[5]. Therefore in Personal Health Devices (PHD) for data exchange to be possible, standards were developed such as ISO/IEEE 11073[6]–[8] and IEEE 21451 with different solutions proposed for connecting the medical devices (MD) with medical health systems standards such as Health Level 7 standard (version 3 been the most recent)[9] to facilitate seamless exchange of data between devices in the system BAN and medical information systems (MIS).

In the work of [10] three levels of interoperability were identified in information : semantic, structural, and syntactic interoperability, the data representation or formatting is of great relevance to syntactic heterogeneity, and mapping mechanism directly and easily solve this type of difference amidst systems; representational interoperability involves data modeling constructs which is of relevance to structural heterogeneity while DTD or Extensible Markup Language (XML) schema can solve the structural conflicts [11], semantic heterogeneity remains elusive and more complicated.

Smartphones and wireless technology is the trending development in the mHealth and its part of the segments, that is worth more consideration as interoperability between them is a major problem, smartphones are devices with powerful computing capabilities running operating systems such as iOS, Androids, Windows etc. These smartphones are enhanced with data capturing abilities through air interfaces for voice, video, and data communication such as UMTS, Bluetooth (BT), WiFi, and several internal sensors such as gyroscope, accelerometer, and Global Positioning Systems (GPS) receiver which contribute additional useful data to the ECG data acquired from the sensors.

In other to allow seamless transfer and useable data from a wireless wearable ECG sensor various standards are considered, however, semantic interoperability of clinical information with the growth and convergence of sensors, information and communication technology remains a challenge in collecting and using

data from wearable wireless devices such as ECG sensor systems for remote monitoring of ECG signals due to heterogeneity and compositions of the system and types of data been collected. The purpose of this review is to establish: the trend in interoperability of wearable wireless ECG monitoring or diagnostics devices; to establish the core information required for wireless ECG devices to capture as useful information for its medical purpose and finally to find out if they are sufficient to enhance interoperability.

This paper is organized as follows: section two the methodology is described; section three detailed description of studies in last five years (2010 – 2015) that worked on medical devices interoperability with respect to ECG; section four gives a brief description of the various standards developed to facilitates seamless data exchange, section five discusses the various solutions that have been proposed in the literature to solve the problem and finally a comparative analysis is done with a proposed future study.

II. Methodology

Five steps as proposed by [12] was used: identifying terms to typically use in literature search; locating literature; reading and checking the relevance of the literature; organizing the literature selected; and writing the literature review. This is “to present results of similar studies, to relate to the ongoing dialogue in the literature and to provide a framework for comparing the result of a study with other studies”[13]. The following steps were followed: determination of the study topic; filtering literature through the extraction and inclusion criteria; evaluation of the quality of studies; analysis of the data and report of the results.

The main focus of this review is the interoperability of wearable wireless ECG monitoring and capturing devices and medical information systems. Academic databases (IEEE Xplore ,ScienceDirect, ACM Digital Library, Google Scholar and Springer Link) were searched through a bottom-up approach by narrowing the search from a broader term- Interoperability to Electrocardiogram. The initial inclusion criteria were based on any studies within five years i.e. 2010 – 2015 and wireless wearable ECG but most of the studies failed to address wireless wearable ECG instead they focused on ECG so after double reading the abstracts a total of twenty five articles was finally accepted.

III. Results

Various studies have researched into the area of standards and interoperability of wireless medical devices with focus on the various standards involved in the operationalization of eHealth systems, in other to enable them work seamless with other medical information systems e.g. Health Information Systems (HIS), Laboratory Information Systems (LIS), Remote Monitoring systems (RMS), Electronic Health Record (EHR) etc.

In the works of [14] ECG formats was proposed to enhance interoperability between ECG systems and information systems in the healthcare domain, which broadly in nature could either be binary or XML-based: the Standard Communications Protocol for computer assisted electrocardiography (SCP-ECG, initially developed as European standard EN1064); HL7 annotated ECG (HL7 aECG, American standard from the American National Standards Institute— ANSI); Digital Imaging and Communication in Medicine (DICOM) Waveform Supplement 30, or Medical waveform Format Encoding Rules (MFER, Japanese standard). The interoperability between remote ECG machine and remote diagnostic center was investigated and interoperability was enhanced through the analyses of information requirements need and interaction flow using transactions and workflow design with Web Service to realize the interaction which they proposed could be applied to portable devices [4], the works of [15] argues that standards such as HL7 and IEEE 11073 that are responsible for messaging within HIS and integration between medical devices respectively, promise full interoperability between medical devices and external software systems but their work shows that in order to integrate telemedicine system prototype for clinical research , the full implementation of these standard is not necessary, however, their study did not identify which biomedical signals (and signal qualities) are actually necessary for specific telemedicine procedure in the domain of focus (EMS). The works of [16] , ECG data were converted from the originating data capturing devices to HL7 messaging and could be transmitted to the HIS through the internet thereby causing seamless interoperability between the mobile platform and the different health information systems based on HL7 standards, the challenges here is that associated with data conversion, moreover, [17] focused on data and different devices working and exchanging data smoothly for u-healthcare systems by providing a framework for it, while [18] through ontology encoded in XML and mapping of ECG waveform data interoperability is improved and data exchange between any digital ECG device mapping the ECG data enable such to be viewed via internet browser display and supports both representation of ECG waveforms and automated diagnosis.

Wearable ECG recorder for a mobile point-of- care (POC) using the third generation (3G) connectivity, the focus was on information model [19] where plug –and- play interoperability was consider for mobile POC applications, the study was based on Bluetooth® Health Device Profile (HDP) using ISO / IEEE 11073 standards especially the domain information model (DIM) which is responsible for: medical device

system (MDS) object; ECG Waveform object; Device Status; and Persistent Metrics object (PM). Authors in [20] examined the inconsistencies in coordinated use of two standards – ISO/IEEE 11073 and SCP-ECG (EN1064:2005 + A1:2007) mapped the mandatory attributes defined in ISO/IEEE 11073- 10406-d02 and the minimum SCP-ECG fields to enhance interoperability but did not implement this for a tele cardiology systems though , are both x73-PHD and SCP-ECG compliant. Furthermore, other standards such as the SNOMED-CT formed the conceptual basis for ontology proposed for cardiovascular risk stratification (CVRS) [21].

Heterogeneous data from different sources with mixed form of data type such as multimedia and efficient management of data was the focus of study [22] who proposed a framework for multimedia content management to identify features and generate identifiers for the multimedia resources in other to facilitate efficient data query processing. The revision of HL7 v2 to HL v3 leads to using bilateral mapping from ISO/ IEEE 11073 domain information model (DIM) to specific message or document standards to facilitate interoperability between clinical applications and medical devices in [23] the ISO / IEEE 11073 DIM was used to derive an HL7 v3 Refined Message Information Model (RMIM) of the medical device domain to improve data backtrack or trace.

IV. Standards for Wearable Sensors Systems

The general systems architecture for a wearable wireless medical device is shown in fig. 1.

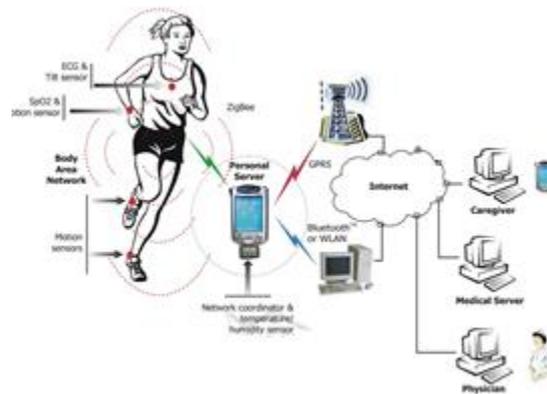


Figure 1

Source: [14]

The various levels in the architecture are: integrated circuits, wireless communication; sensors; personal server (smart-phones); medical database server; the internet, and remote monitoring system. The data flow around these systems is shown in fig. 2

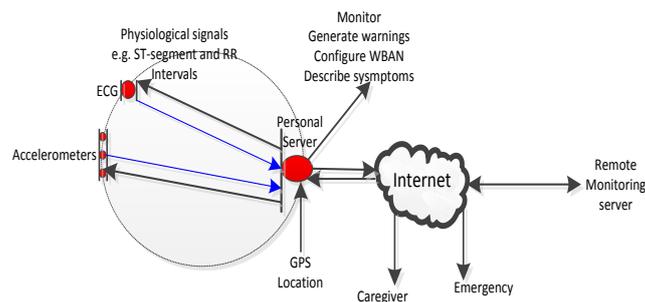


Figure 2: Data flow in integrated

In other to ensure excellent data flow in fig. 1 several standards were developed and will be discussed below;

4.1 ISO / IEEE 11703 (x73):

The ISO / IEEE11703 standards enable communication between medical, and wellness devices and with external computer systems. They provide automatic and detailed electronic data captured that are client-related, vital signs information physiological data and device’s operational data. This standard is often referred to as x73, it is basically concerned with the interface between the medical devices (agent) and concentrator

device (manager)[15]. The latest version been x73-Personal Health Devices [6], [7], [8], it is based on the optimized Exchange Protocol (ISO/IEEE 11703- 20601) which defines the framework for making an abstract model of available personal health data in the transport-independent transfers syntax required to establish logical connections between systems and to provide the presentation capabilities and services needed to perform communication tasks. The x73-PHD Standard also defines device specializations for different MDs (such as pulse oximeter, blood pressure, thermometer or weighing scale), but excluded the ECG device specialization[16] until [17] which specified a normative definition of the communication between personal basic electrocardiography (ECG) devices and managers (e.g. cell phones, personal computers, personal health appliances ,and set top boxes) in a way that enables plug and play interoperability is established in ISO/ IEEE 110703-10406:2012.

This standard consists of term codes, formats and behaviors in tele-health environments restricting optionality in base frameworks in favor of interoperability with the definition of the common core of communication functionality for personal tele-health basic ECG using 1 – to 3- lead ECG) devices. The ECG devices were further distinguished from diagnostic ECG equipment with respect to support for wearable ECG devices, limiting the number of leads supported by the equipment to three, and not requiring the capability of annotating or analyzing the detected electrical activity to determine known cardiac phenomena.

ISO/IEEE 11073-10406:2012 is consistent with the base framework and allows multifunction implementations by following multiple device specializations (e.g. ECG and respiration rate) while an amendment ISO/IEEE 11073-10406a is on underway[18]

4.2 IEEE 21451-x (previously known as IEEE 1451.x)

The 21451-x: 2010 focuses on a network-neutral interface for connecting processors to communication networks, sensors and actuators, it allows smart transducers and sensors designers to have reference to protocols, extensible messaging and presence protocol (XMPP), transducer electronic data sheets (TEDS), signal treatment, networks, web services, radio frequency identification etc.[19] The object model contains blocks, services, and components; it specifies interactions with sensors and actuators and forms the basis for implementing application code executing in the processor.

TEDS identifies everything about the transducer including the following: manufacturer, model number, revision code, serial number, device type and date code for transducers; timestamp on the unit calibration, the variable, type, and limits of use; calibration constants; signal conversion data model, model length, and number of significant bits; channel timing read / write setup time, sampling period, warm-up time, and update time; power supply requirements (voltage and current) and overhead: TEDS length and number of channels.

4.3 Health Level Seven International (HL7)

HL7 is a standard developing organization that is not-for-profit, accredited by American National Standards Institute (ANSI), dedicated to providing comprehensive framework and related standard for exchange, integration, sharing and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services [20].

HL7 is a health information protocol developed most widely used - a messaging standard that enables different healthcare application to exchange important sets of clinical and administrative data, it is a complex electronic business extensible markup language (eXML) code format used to transmit information within HIS. A shared reference model of the healthcare and technical domains helps to unify the HL7 specification [21], [22].

These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems. HL7 standards support clinical practice and management, delivery, and evaluation of health services, that are recognized as the most commonly used in the world[23]. It helps define how information is packaged and communicated form one party to another; set the language, structure, and data types that are required to provide a seamless integration between systems; it provides support for the following – clinical practice of health services; management of health services; delivery of health services and evaluation of health services. This standard provides a broad set of standards creating domain specific protocols to achieve interoperability among healthcare service providers. It provides some specific codified language protocols that are widely accepted and used globally by many health care organizations also there is a highly specified standard used for medical imaging that has developed.

4.3.1 HL7 Information Model

The HL7 information models comprises of three types of models which are based on UML, which differs in the concrete notation, they are also different in terms of information content, scope , and intended use.

The models types based on information are: reference information model (RIM); domain message information model (D-MIM) and refined message information model (R-MIM) [9]

4.3.2 Reference Information Model (RIM)

This is the information model that encompasses the HL7 domain of interest in its totality. The RIM is the source of the data content of HL7 interoperability artefacts (V2.x messages and XML clinical documents CDA R2) [24] - is coherent, and shared. This reference model is used as the basis for deriving ebXML message documents use in standardized information exchange protocol (TCP /IP). RIM is a pictorial object model representing data domains and the life cycle of message or a group of messages follow [25], [26]

4.3.3 Domain Message Information Model (D-MIM)

A D-MIM is a refined MIM is subset of the RIM that includes a set of classes, attributes and relationships that can be used to create messages and structured clinical documents for a particular domain (a particular area of interest in healthcare). There are predefined D-MIMs for a set of over 15 universal domains, such as Accounting and Billing, Care Provision, Claims and Reimbursement, and so on.

4.3.4 Refined Message Information Model (R-MIM)

The RMIM is a subset of a D-MIM that is used to express the information content for a message/document or set of messages/documents with annotations and refinements that are message/document specific. The content of an R-MIM is drawn from the D-MIM for the specific domain in which the R-MIM is used.

V. Discussion

In the analyzed solutions detailed in section 2 we establish the common trends within literature employed to facilitate interoperability among wireless wearable devices, the aggregator network and medical information systems, in last five to six years it has been addressed basically within three broad categories with respect to medical devices in wireless devices category using wireless ECG devices as case study:

1.1 Technical Interoperability or System Interoperability

Various studies approached the issue on this level as it deals with machine level communication and thus makes heterogeneous systems in wearable wireless systems; communications technology and health information systems a reality, this addresses the hardware / software components and systems platforms. The trend in addressing this type of interoperability is the use of standards such as ISO/IEEE 1451.x and IEEE 11073 (x73) in the works of [6][7][8] focused on machine –to – machine communication protocols and infrastructure for exchanging data between participating systems [27]. The technical scope of this type of operability is limited as it only concern with technicalities associated with connecting devices for the purpose of exchanging information.

1.2 Structural Interoperability or Conceptual Interoperability

At this level various studies tackles heterogeneity using models for data representation. Conceptual models were proposed to bridge the gap between technical and conceptual design, the works of [28]. At this level the focus is agreement on data format and each data strings which were well reviewed in the works of [28] and is achieved through data models and information models for specifying semantic schemes in a way that enables it to be shared. Available formats includes but not limited to DICOM, ecgAware, mECGml (for mobile devices), XML-ECG etc. each of these format had their own shortcomings in that some are implemented in Binary while others were implemented in XML, the binary implemented ones though use a smaller space for storage is not readable to humans, while the XML formats are readable to humans and are not the best when compressed[28] but there exist various techniques for compressing it [29].

1.3 Semantic Interoperability or Information Interoperability

The approach used to address this type of interoperability problem in the literatures as reviewed in section 3 are the mechanism that deals with terms and expression, hence it has the ability to help interpret the information exchanged meaningfully and accurately automatically. It helps to provides useful results as defined by the end users at the users end and the healthcare center. The mechanism used majorly is ontology [18], [21] – this serves as support to semantic interoperability which involves how information is used differently by other organizations, this helps to carry knowledge and helps serve as the reference model of entities and interactions in the domain and knowledge.

1.4 Core Information for wireless wearable ECG devices

The main aim of standards are to “provide real-time plug-and-play interoperability for patient’s connected medical devices and facilitate the efficient exchange of vital signs required at the point-of-care, in all healthcare environments”[30], therefore the information collected must have useable information, the reviewed carried out showed that there exist specific information that are captured from the patient and the details features of the signal that is been captured, therefore for this review we looked at the information from the information requirement and entities classification base, information that are relevant to both the patient, the medical personnel and the hospital.

The following were the various sources of information needed or supplied through the wireless ECG devices; information about the medical devices [15],[31]; information about the patient [15]; information about the location of the patient and Information about the physiological signal that is been captured from the patient [15]. This information contains entities that are of great concern to both the patients and the healthcare provider, these information needs to be delivered to HIS.

VI. Conclusion

The review has looked closely into the various methods and approaches that have been employed to facilitate information exchange and usability between wireless medical devices and HIS, the use of interoperability standards promotes the information contents captured to be uniform and relevant for the purpose for which it was captured either monitoring or diagnostic or for both reasons.

In this study an interoperable wireless ECG sensor needs different interoperability standards from IEEE 11073, IEEE 1451 and HL7 using different mechanism such as ontology, mapping of data, reference models and data models.

It is therefore necessary to approach the interoperability of this kind of medical devices from the perspective of basic requirement of the information contents, required by the medical personnel supplied by the patient’s device based on the manufacturers design for the device. What now? In order for an interoperable wireless wearable ECG device there needs to be consensus in terms the basic requirement in term of identification of the users as a variable or a constant e.g., will the device be used by a single individual or by several persons, can the device capture all the type of signals that will help the medical team diagnose a cardiac condition or it will only help to monitor the ECG, since HL7 already cares for the exchange of data at the HIS, therefore focus should be on the device, the network and the healthcare providers to enable synergy in the manufacturing and use of the wireless ECG sensors.

We therefore propose further study in the interoperability of the wireless ECG devices with respect to the fifth general telecommunication technology.

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