Trends and Challenges of the Emerging Technologies toward Interoperability and Standardization in e-Health Communications

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ABSTRACT

Information exchange has experienced a paradigm shift due to the appearance of wireless transport technologies. A wide variety of technologies have been proposed recently with different characteristics for diverse application environments. Such emerging technologies can be applied — depending on their specific features — to different e-health use cases. Additionally, some of those technologies have already adopted a path to medical device interoperability, while others are on their way to enable that potential. Hence the need to perform an overview of such technologies, which can be useful when designing interoperable, wireless-enabled e-health solutions. This article therefore reviews the emerging technologies that can be incorporated into the complex e-health information communication ecosystem and details the transport technologies that have adopted a specialized medical profile for ISO/IEEE 11073 interoperability such as USB, Bluetooth, and ZigBee. Discussion is focused on the expected path of novel emerging technologies toward ISO/IEEE 11073-compliant medical device interoperability. As a result, this article provides an up-to-date guideline for designers of standard-compliant wireless-enabled e-health architectures, helping in the selection of the appropriate technology for their designs.

INTRODUCTION

Advances in new technologies have created an innovative background for patient e-health and wellness application development. Not only has the use case context evolved from hospital to home, and even mobile and personal services, but also the context information derived from the patient environment has been incorporated into the patient health status characterization model. As a result, other services and solutions such as ambient assisted living (AAL), ambient intelligence (AmI), and smart homes are becoming increasingly significant [1, 2]. These are combining with other more general solutions such as fitness and wellness, chronic disease management and diet or nutrition monitoring applications. The new initiatives tend to be integrated into the patient information ecosystem instead of being separated into monitoring and decision processes.

The availability of shared web-based applications and repositories has also contributed to this paradigm shift, as information related to the patient was previously supposed to be exclusively stored and managed in the electronic health record (EHR) inside the hospital. Nowadays, the information can be distributed through web interfaces so that every application can make use of a specific piece of data related to the user. Therefore, user monitoring related processes, which make use of collected physiological data, become bidirectional instead of unidirectional, distributed in an information network ranging from health professionals, relatives, and social networks to the actual patient. The most recent personal health devices (PHDs) have adopted many recent technical innovations related to electronics and information technology, leading to portable and implantable devices incorporating connectivity features as well as new measurement techniques made possible by advances in sensors (e.g. exhaled air glucose meter, advanced electrocardiographic [ECG] and electroencephalographic [EEG] signals, portable magnetic resonance imaging [MRI], implantable hearing aid) [3].

This scenario, together with increased device availability, patient–web interaction, and the tendency to follow the medical control processes has led to the development of a range of new e-health environments. The patient end-to-end information flow path can be described as having three segments: medical devices, gateway, and EHR remote server. These segments are integrated by means of
software applications and middleware technologies, offering the patient a personalized solution related to a specific use case. Every use case implies several requirements related to security, range, reliability, and operation time, and makes use of several medical devices and integrated communication technologies. In the context of the specific features of these e-health network setups, there are three application domains proposed: body/personal, single/multi-user, and intercommunication, as described in Fig. 1. Body/personal domains are built up with intelligent physiological small implantable devices (e.g., exhaled air glucose level monitors, ECG, EEG, image-based blood pressure meters, augmented reality, portable MRI). An external processing unit is located within the user motion range. The single/multi-user domain provides group logging capabilities from one to several users (rehabilitation, ICU, sports, military, training, and fitness-dedicated rooms) using generally non-implantable devices. The intercommunication domain covers both device to EHR remote server and gateway to EHR remote server connection paths, where real-time data like continuous monitoring (ECG holter) and event reporting application are mainly hosted.

For each of these domains, existing transmission technologies offer different technical features that satisfy the domain requirements. Some of them are more suitable than others, as they differ in power consumption, coverage, and data rate, among others [4]. Considering these requirements, Fig. 1 shows a classification of emerging communication technologies (detailed later).

Nevertheless, this spread of technology is at the same time complicating the interoperability among e-health applications in terms of protocol and semantic diversification. This is why the efforts of international initiatives and institutions like Continua Health Alliance, the Healthcare Information and Management Systems Society (HIMSS), the National Institute of Standards and Technology (NIST), and Inte-grating the Healthcare Enterprise (IHE) have been decisive to overcome the interoperability problem and promote a homogeneous e-health ecosystem. Regarding medical device communications, the special Working Group for Personal Health Devices (PHDWG) [5] has been working since 2006 to detect the connection requirements of devices while foreseeing their potential applications in a variety of use cases. As a result of collaborative work between several international institutions, an international family of norms has been developed to standardize communications between health devices, the International Organization for Standardization (ISO)/IEEE 11073 PHD (X73PHD) [6]. As a special feature of this standard, aware of the rapid development in transport technologies, X73PHD does not oblige devices to implement a specific technology, allowing the most suitable to be used according to the application context while meeting certain minimal requirements. In this way, an interoperable solution, supporting X73PHD, does not mean imposing technology restrictions but maintaining a range of selection, enabling a reasonable choice for each case. The result is the release of several profiles defined for health applications related to X73PHD, easing integration and improving their technical features.

Given this background, a detailed study as proposed in this work of available technologies is necessary. The most important characteristics and the potential contribution of such technologies to interoperability in the X73PHD ecosystem need to be analyzed. In this article the most recent emerging technologies in new e-health environments are summarized. The standards-based technological initiatives for interoperable e-health environments are detailed in an analysis of recently approved health profiles for transport technologies recommended by X73PHD. Future trends and challenges toward interoperability in e-health communications are discussed. Finally, the overall conclusions are presented.
Table 1. Comparative study of the main BAN/PAN and LAN/HAN technologies for e-Health applications.

| Frequency band (MHz) | Modulation | Distance (m) | Radio layer | Data rate (kb/s) | Topology | Alliance & Standards Bodies | Engineering Technology Force (IETF) and is oriented toward embedded devices (personal health, ambient monitoring). Its main features are low power consumption and small size. However, it also features low latency in object location, reduced protocol stack, encryption, and IPv6.

The second group comprises proprietary technologies such as ANT, Sensium Life Platform (Sensium), Zarlink, and Z-Wave. ANT is a general-purpose technology designed for wireless sensor networks (WSNs), which features a simple protocol stack, encryption, and IPv6. It also offers low latency in object location, reduced protocol stack, encryption, and IPv6.

The network is managed centrally, while all communications are single-hop via a bridge that can connect up to 16 nodes. These in turn are connected to a dedicated gateway for external access. To reduce energy consumption, all nodes are in idle state until the central node assigns a time slot. It integrates modules to represent devices oriented to medical applications such as heart rate (HR), ECG, temperature, and physical activity, and new ones can easily be added. Zarlink is an implantable radio frequency transmitter for ultra-low power consumption in accordance with the Medical Device Radio Communications Service (MedRadio). When the transmitter is configured as an implantable medical device (IMD), it
remains in a very low-power sleep state until it is awakened. Z-Wave is a proprietary protocol based on low consumption technology designed for communicating home electronic devices while providing remote control by simple commands (e.g., turn on-turn off or upload-download) with highly optimized headers with the ability to incorporate metadata. Its operating frequency range means that it is not affected by the interference of other short-range wireless protocols.

LAN/HAN TECHNOLOGIES DOMAIN

Some of the technologies described in the previous domain (e.g., Bluetooth, ZigBee, and LoWPAN) may also be included within this domain, depending on the distance to the signal receiver to which they are usually linked, and whether the type of scenario is individual or multi-user. In any case, it is clear that the most representative of wireless LAN (WLAN) technologies is the family of IEEE 802.11 standards (wireless Ethernet extension), because their market position is such that there is no other WLAN technology to rival them in this scenario. However, in this context, Wi-Fi Direct, which is a certification program developed by the Wi-Fi Alliance, should be highlighted. It consists of a variety of software protocols (Wi-Fi peer-to-peer specification) that allow Wi-Fi devices to communicate with each other directly without needing a wireless access point (AP). In terms of security, it uses the Wi-Fi protected setup to create connections (using WPA2) between devices. In addition, there are various new technologies such as Gigabit WLAN, also known as WiGig, which operates in the 60 GHz frequency band providing data rates on the order of gigabits per second. WiGig will not replace the existing Wi-Fi technology, but complement it, featuring higher data transfer speed over a shorter range.

MAN/WAN TECHNOLOGIES DOMAIN

The emergence of new technologies in this environment is strongly marked by the evolution of the telecommunications consumer market dominated by large companies, from device manufacturers (e.g., Ericsson and Huawei) to service providers (e.g., Vodafone or Verizon). Currently, the most extended wireless MAN technologies classified by their generation are: second generation (2G; Global System for Mobile Communications, GSM), 2G transitional (general packet radio service, GPRS; enhanced data rates for GSM evolution, EDGE, etc.), third generation (3G; Universal Mobile Telecommunications System, UMTS; code-division multiple access, CDMA2000, etc.) and 3G transitional (high-speed packet access, HSPA; evolved HSPA, HSPA+; Long Term Evolution, LTE; WiMAX, etc.). Some of the latest technologies, such as LTE and WiMAX, have become known as fourth generation (4G) technologies, but this definition only applies to the emerging technologies LTE Advanced (still in the process of standardization) and Mobile WiMAX Release 2 (also known as Wireless MAN-Advanced). To achieve this official 4G designation, both technologies meet the International Mobile Telecommunications (IMT) Advanced requirements including peak rates of 100 Mb/s–1 Gb/s in scenarios of high and low motion, respectively, being entirely based on IP packet switching and having the ability to switch between 4G, 3G, and Wi-Fi networks. The main difference between WiMAX and LTE is that while WiMAX takes advantage of earlier developments and deployments, LTE is being developed by companies and telecom operators, and, in the end, they choose which technology is finally deployed. However, given that the frequency allocation of the spectrum in many countries is specifically arranged for time-division duplex (TDD) or frequency-division duplex (FDD) transmission, the coexistence of both technologies seems to be appropriate to meet this market demand, given that LTE focuses more on the FDD spectrum and WiMAX on the TDD spectrum.

STANDARDS-BASED TECHNOLOGICAL INITIATIVES FOR INTEROPERABLE E-HEALTH ENVIRONMENTS

Incorporating a new medical device into an e-health ecosystem nowadays is a complicated task, especially if end-to-end integration is desired. While patient demographic and physiological information storage and classification can be solved by applications enabling Health Level 7 (HL7) and Clinical Document Architecture (CDA) or ISO/EN13606, gathering this information from the patient and managing the medical device functions and interactions with other systems involved in the process is a complicated goal. In this context, as mentioned above, X73PHD is considered to be the international standard that guarantees an interoperability framework for PHD [6] communications. The generic structure of the X73PHD protocol stack can be divided into two levels. The upper levels (layers 5–7 in the open system interconnection, OSI, model) include the personal health care applications (non-X73PHD-specific), all specific functionalities of X73PHD defined by the 11073-104zz specializations (which accommodate the specializations for each PHD) and the 11073-20601 Optimized Exchange Protocol. The lower levels (layers 1–4 in the OSI model) embrace the transport technologies that are outside the scope of X73PHD, although three of them have recently received a specialized medical profile for X73PHD: universal serial bus personal health device class (USB PHDC), Bluetooth personal health device (BT HDP), and ZigBee health care profile (ZHC).

UNIVERSAL SERIAL BUS PERSONAL HEALTH DEVICE CLASS

USB was the first technology to publish a X73PHD-compatible profile in April 2007. Before that, USB-based health devices were forced to implement their own proprietary protocols to exchange information. This USB PHDC specification describes the full architecture a health device and a host must support, as shown in Fig. 2a. It is composed of descriptors (data structures that contain information about the device) and commands to exchange medical data. The USB PHDC profile defines a hierarchy of descriptors which can be classified into standard, class specification, and
optional, as detailed in Fig. 2b. Within the hierarchy, endpoints are defined as logical entities within the device to establish a connection with the host by setting logical channels (pipes). Each one has its own quality of service (PHDC QoS) descriptor to describe latency and reliability (low good, medium good, medium better, medium best, high best, and very high best) and an optional meta-data descriptor (PHDC meta-data). In addition, USB PHDC defines a set of additional endpoints implementing the above-mentioned QoS requirements: control endpoint (mandatory, default bidirectional control pipe), bulk out endpoint (mandatory, path from the host to the device), bulk in endpoint (mandatory, path from the device to the host), and interrupt in endpoint (optional, path to the host when sending data in constant mode is necessary).

The communication procedure is as follows: When a device connects to the USB, the host initiates the enumeration process, reads the device descriptor, and assigns a unique number (from 0 to 127) to the device. If supported, the proper communication drivers are loaded depending on the class to which the device belongs. Exchanged frames can contain raw data and must not exceed 63 kbytes.

**Bluetooth Health Device Profile**

Typically, BT-based health devices used to be built using proprietary formats over the serial port profile (SPP). To enhance homogeneity, the Bluetooth Special Interest Group (SIG) created in 2006 a Medical Working Group (MedWG) to design a specific profile for PHD. As the result of this work, the Bluetooth health device profile (BT HDP) was published in June 2008 along with a new specific protocol called the Multi-Channel Adaptation Protocol (MCAP), which manages the creation of a control channel and one or more data channels. Moreover, the BT HDP includes other protocols enabling several functions, as shown on the left of Fig. 3. Logical Link Control and Adaptation Protocol (L2CAP) defines multiplexing of all higher protocols, flow control, QoS, retransmission, and segmentation and reassembly of all packages. Service Discovery Protocol (SDP) manages the discovery of other BT devices and services. The generic access profile (GAP) defines common processes to all profiles, such as authentication and encryption. The host controller interface (HCI) describes commands and events that are compatible with all hardware implementations of a BT module. In BT HDP, the X73PHD terms of agent and manager are replaced by source and sink, respectively. Noteworthy features are enhanced retransmission mode (ERTM), frame check sequence (FCS), reliable-type using L2CAP ERTM mode, stream-type using L2CAP streaming mode (SM), optimized reconnection (avoids redundancy), and an optional Clock Synchronization Protocol (CSP).

The communication procedure begins with one of the two devices (source or sink) establishing a control channel. This channel is used only for MCAP traffic, and both devices can use it to coordinate the creation of one or more data channels to carry X73PHD traffic. Finally, one end terminates the connection, by either first closing the data channels and then the control channel, or directly closing the control channel.

**ZigBee Health Care Profile**

The ZigBee Alliance Board of Directors approved the ZHC profile in 2010, which provides a description of the device clusters containing a set of attributes that represent the state of the device along with the communication commands. For instance, it specifies the location where a device is placed using a predefined set of codes (bathroom, kitchen, bedroom, etc.), allows manufacturers to
include non-standard features using specific clusters, and enables devices to send voice through the use of voice over ZigBee cluster. Within a ZigBee network there may be up to three types of devices: the ZigBee coordinator (ZC) controls the network and the paths to be followed by devices to connect with each other, the ZigBee router (ZR) interconnects separate devices on the network topology, and the ZigBee end device (ZED) can sleep most of the time, thus increasing the average battery life, and communicate with its parent node (the coordinator or a router) while not with other devices. To create a data tunnel compatible with X73PHD, a set of specific commands grouped in the so-called 11073 cluster tunnel protocol library have been developed. The entire protocol stack is shown on the right of Fig. 3.

The communication procedure begins when two X73PHD tunnels are established. In one, the manager behaves as a server and the agent as a client, while in the other, the roles are reciprocal. The manager then checks whether an agent has set an X73PHD profile and generates a connection request. The agent will respond with a connected status notification from which they can exchange X73PHD frames. The fact that all profiles are defined using clusters of the Zigbee cluster library (ZCL) allows reusing clusters used by multiple profiles.

TRENDS AND CHALLENGES TOWARD INTEROPERABILITY IN E-HEALTH COMMUNICATIONS

Having established the various technology initiatives (both proprietary and standards), the next challenges are oriented toward achieving harmonization in integrated solutions to ensure interoperability. This path leads to the need to develop a robust, standard, and efficient ecosystem for patient telemonitoring covering the main e-health environments. The development and implementation of new medical profiles could be the key to progress in this field. Nowadays, the adoption of such health profiles is promoted by Continua Health Alliance [7], which has included them in its recommended design guidelines. So far, two commercial devices already incorporate USB PHDC, and another five do so with BT HDP.

The work at Continua Health Alliance considers emerging technologies to have particular relevance in interoperability. In February 2011, Continua signed a collaboration agreement with the Wi-Fi Alliance for the promotion and adoption of Wi-Fi Direct technology. A specific medical profile is expected during 2011. By mid-2009, Continua Health Alliance along with ZigBee had partnered to drive HAN adoption and work on a Zigbee IP specification to integrate native IP support into the Zigbee stack. Combining the strengths of the Zigbee Smart Energy standard with the ubiquity of IP will trigger a rich new ecosystem of smart energy and smart grid devices that are seamlessly integrated. In March 2011, the ZigBee Alliance made available the latest round of revised Smart Energy 2.0 technical documents (still in draft status). Zigbee Smart Energy version 2.0 will be IP-based and offer a variety of new features to equate to 6LoWPAN.

At the same time, although DASH7 is designed as a burst communications protocol (BLAST type) with very reduced rates, it should be considered whether it is capable of supporting continuous telemonitoring applications or those requiring large data transfers such as images or video. Given the wide range of operation, a specific medical profile for DASH7 would open new scenarios of telemonitoring via X73PHD. On the other hand, NFC application in the context of e-health is still unknown because its minimum and quick information exchange. Therefore, ongoing research is evaluating its application to patient

Figure 3. X73PHD protocol stack over BT HDP (left) and ZHC (right).
identification, disease control, improving data quality and emergency response in developing countries, and so on [10].

Finally, proprietary initiatives such as ANT intended not only for biomedical environments but for multimedia applications in general must be evaluated. ANT provides efficient design and low consumption for long-battery-life devices. However, it is a proprietary protocol with a close architecture and therefore not directly compliant with X73PHD. This same situation of opacity and general purpose of the proprietary applies to other proprietary initiatives such as Sensium Life Platform, Zarlink, and Z-Wave, which makes them hard to translate to the X73PHD ecosystem.

CONCLUSION

This article provides a comprehensive overview of existing and emerging wireless transport technologies that can be used in the e-health context. An in-depth analysis of these technologies — according to the application domains presented — has been also performed. Moreover, it describes current trends and future challenges of the emerging technologies that are paving the way to the immediate future of interoperable and standardized exchange of medical measurements. More specifically, this article analyzes the existing technologies that have already embraced medical profiles for X73PHD compliance — USB PHDC, BT HDP, and ZHC — and identifies the possibilities of emerging wireless technologies to adopt such a strategy. This review therefore suggests these emerging technologies be integrated into e-health applications toward an interoperability framework, fulfilling specifically required technical features. As a result, this article provides an interesting start point for designers of standards-compliant, wireless-enabled e-health architectures, responsible for selecting the appropriate technology for their designs.

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