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

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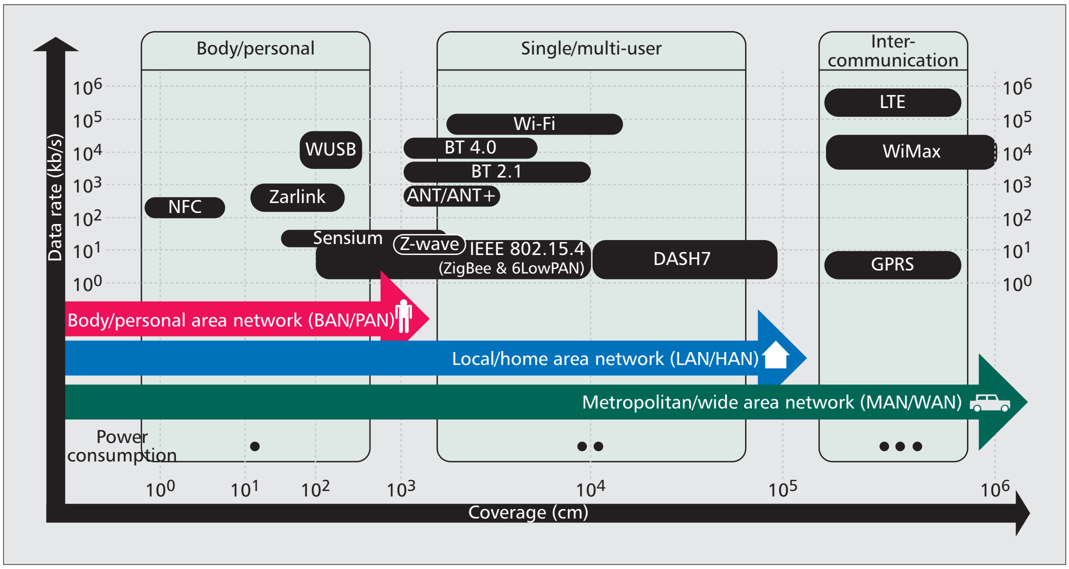

Figure 1. *Scheme of the patient end-to-end information flow illustrated with the most recently emerging transmission technologies in the context of their communication requirements.*

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.

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, three application domains are 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 Integrating 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 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.

	BT 2.1 +EDR	BT 4.0	ZigBee	NFC	Wireless USB 1.1	6LoW-PAN	DASH7	ANT	Sensi-um	Zarlink	Z-Wave	WiFi Direct
Freq. band (MHz)	2400	2400	2400, 868, 915	13.56	3100–10600	2400, 868, 915	433	2400	868–915	402–405, 433–434	900	2400, 5000
Modula-tion	GFSK	GFSK	O-QPSK	ASK	MB-OFDM	O-QPSK	FSK/ GFSK	GFSK	BFSK	2FSK/ 4FSK	GFSK	OFDM, DSSS
Distance (m)	1–100	60	1–100	< 0.2	3–10	1–100	1000	10–30	5–25	2 (body)	30	200
Radio layer	Bluetooth radio	Bluetooth radio	IEEE 802.15.4	ECMA-340 ISO/ IEC18092	UWB	IEEE 802.15.4	ISO/IEC 18000-7	Propri-etary	Propri-etary	Propri-etary	Propri-etary	802.11x
Data rate (kb/s)	3000 (max.)	25,000	20–250	106, 212, 424	53,000–480,000	20–250	28–200	1000	50	200–800	9.6–40	250,000
Topology	Piconet, scatternet	Piconet, scatternet	P2P, tree, star, mesh	P2P	P2P	Mesh	Mesh	P2P, mesh, tree, star	Star	P2P	Mesh	P2P
Alliance & Standards Bodies	Bluetooth SIG	Bluetooth SIG	ZB Alliance, IEEE	ISO/IEC, ECMA	Wireless USB Promoter Group, USB-IF	IETF 6LoW-PAN	DASH7 Alliance, ISO	ANT+ Alliance	None	None	Z-Wave Alliance	WiFi Alliance, IEEE

Table 1. *Comparative study of the main BAN/PAN and LAN/HAN technologies for e-Health applications.*

Emerging Technologies for e-Health Application Technology Domains

This section describes the most recent emerging technologies divided into the application domains introduced in the previous section. Their technical features and communication requirements are defined for each domain. Detailed technical information relating to the technologies is presented in Table 1.

BAN/PAN Technologies Domain

Within this domain, two groups can be defined. The first consists of standards such as Bluetooth Low Energy (BTLE), ZigBee, Near Field Communications (NFC), Wireless Universal Serial Bus (WUSB), IPv6 over Low-Power Wireless Personal Area Networks (6LoWPAN) and DASH7. BTLE is integrated into the latest version of BT (4.0) and features ultra-low-consumption idle operation mode, low latency, simple device discovery service, and point-to-point reliable transfer. BTLE also features two implementation modes: single-mode (which has low power consumption for integrated and compact devices) and dual-mode (which reuses BT classic hardware, sharing a single antenna and radio, and adds low-power features from the new protocol stack). It also features a native application layer for vital signs monitoring. ZigBee operates on the IEEE 802.15.4 standard, as this only defines the physical layer and medium access control (MAC). It is focused on applications that require low-data-rate transmission, long battery life, and data encryption. The hardware is considerably simpler than BT, achieving several years of battery life through minimal power consumption. NFC is a group of technologies featuring low coverage, fast data exchange, and a small frame payload. WUSB is the wireless USB standard extension, which is based on the emerging ultra wideband (UWB) radio technology, and introduces features such as extensive bandwidth, a proximity-based association mechanism, and security similar to wired communications. 6LoWPAN is defined by the Internet Engineering Task Force (IETF) and is oriented toward embedded devices (personal health, ambient monitoring). Its main features are IP connectivity with a simple header frame design and a hierarchical addressing model. DASH7, originally developed for military purposes and based on the ISO/International Electrotechnical Commission (IEC) 18000 standard, implements low-power technology and has one of the widest coverage ranges among technologies (redefined for BAN/PAN applications), while the data rate is considerably lower. 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 design, low latency, low power, and a variable transfer rate through adjusting power consumption. At the top of this technology model is ANT+, an interoperability layer ensuring compatibility between ANT devices from different manufacturers and distributors. The ANT+ device profiles define the network parameters and data structure so that products from different manufacturers can communicate seamlessly. Sensium is a wireless system for vital signs monitoring featuring low power consumption and based on a master-slave topology, where a slave device node periodically sends readings to the central node. 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., BTLE, ZigBee, and 6LoWPAN) 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 series 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 new emerging technologies such as *Gigabit WLAN*, also known as *WiGit*, which operates in the 60 GHz frequency band providing data rates on the order of gigabits per second. WiGit 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 WAN 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.

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Standards-Based Technological Initiatives for Interoperable e-Health Environments

Incorporating a new medical device into an e-health ecosystem is nowadays 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

To enhance homogeneity, the Bluetooth SIG created in 2006 a Medical Working Group to design a specific profile for PHD. The Bluetooth health device profile was published in June 2008 along with a new specific protocol called the Multi-Channel Adaptation Protocol, which manages the creation of a control channel and one or more data channels.

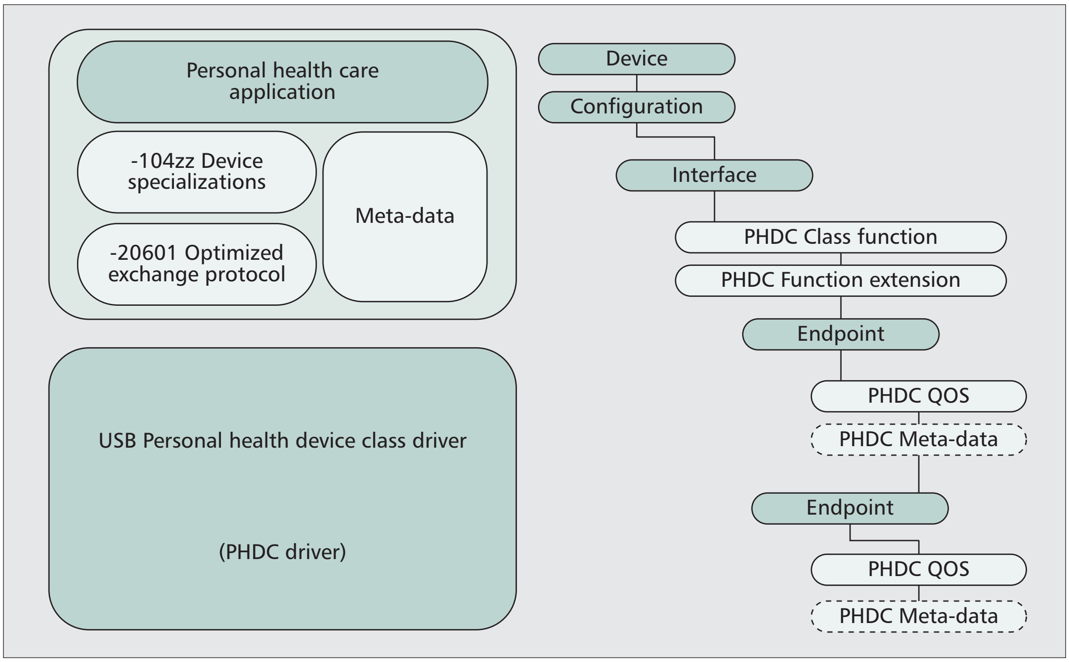

Figure 2. *USB PHDC technical features:X73PHD protocol stack over USB PHDC (left) and USB PHDC descriptor hierarchy (right).*

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.

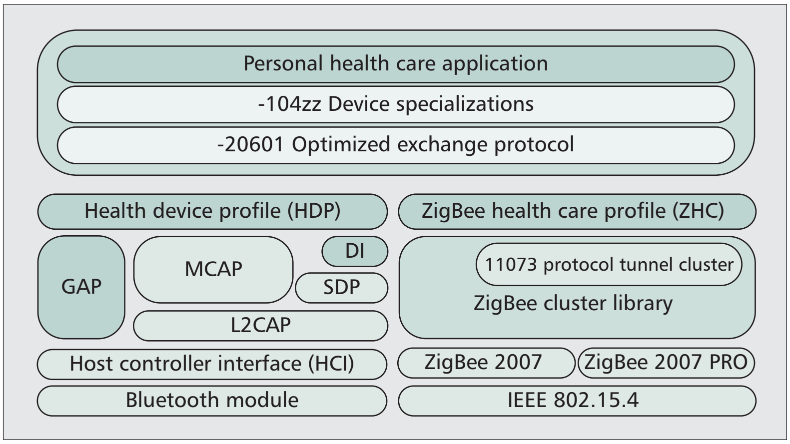

Figure 3. *X73PHD protocol stack over BT HDP (left) and ZHC (right).*

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 already selected the new BTLE specification, built-in Bluetooth 4.0, extending the configuration of the scenario while taking advantage of BT HDP features. In an attempt to enhance the integration process, stack implementations with BT HDP support were developed: JungoBTware, designed for low-power embedded systems; Stollmann BlueCode+, designed to be platform-independent; Toshiba Bluetooth Stack for Windows, certified by Continua Health Alliance; Ethermind Bluetooth Stack, developed by the Mindtree company for embedded systems and other architectures; and BlueZ, an open source implementation for Linux developed in collaboration with the Morfeo OpenHealth project [8].

Looking at other medical profiles, USB PHDC could easily evolve into WUSB. The function layer has undergone minor changes to increase efficiency and support sync, while the bus layer has been substantially adapted to the efficiency and security of wireless networks. Given the existence of a specific medical profile for USB, WUSB will probably be adopted as an X73PHD communication profile. In the case of ZHC, ZigBee shares the same radio standard with 6LoWPAN, which was created to try to resolve the problem of integration of different proprietary technologies in wider networks based on Internet services. Thus, 6LoWPAN is presented as an alternative to be integrated into X73PHD because of its open architecture based on standards, as well as its IP interconnection capacity which may enable Internet-based sensing services and ubiquitous computing [9]. In parallel, since 2010 the ZigBee Alliance, IETF and IP for Smart Objects (IPSO) Alliance have 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

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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 protocol 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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