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Personal Health Records: Mobile Biosensors and Smartphones for Developing Countries

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Abstract. A target of telehealth is to maintain or improve the health of people outside the normal healthcare infrastructure. A modern paradigm in healthcare, and one which fits perfectly with telehealth, is "person self-monitoring", and this fits with the concept of "personal health record" (PHR). One factor in maintaining health is to monitor physiological parameters; this is of course especially important in people with chronic maladies such as diabetes or heart disease. Parameters to be monitored include blood pressure, pulse rate, temperature, weight, blood glucose, oxygen saturation, electrocardiogram (ECG), etc. So one task within telehealth would be to help monitor an individual's physiological parameters outside of healthcare institutions and store the results in a PHR in a way which is available, comprehensible and beneficial to the individual concerned and to healthcare providers. To date many approaches to this problem have been fragmented – emphasizing only part of the problem – or proprietary and not freely verifiable. We describe a framework to approach this task; it emphasizes the implementation of standards for data acquisition, storage and transmission in order to maximize the compatibility among disparate components, e.g. various PHR systems. Data from mobile biosensors is collected on a smartphone using the IEEE 11073 standard where possible; the data can be stored in a PHR on the phone (using standard formats) or can be converted in real-time into more useful information in the PHR, which is based on the International Classification for Primary Care (ICPC2e). The phone PHR data or information can be uploaded to a central online PHR using either the Wi-Fi or GSM transmission protocol together with the Continuity of Care Record message format (CCR, ASTM E2369).

Keywords. Personal health records, mobile health, biosensors, IEEE 11073, continuity of care record, ICPC

Introduction

'Telehealth' is for all people in all conditions; it is not just for medical personnel and their persons, and it is not just for cases of illness or injury. To be truly 'global', telehealth must also be for people who do not have 24/7 healthcare facilities or 24/7 broadband Internet connections. For such people 'mobile health' may be their interface to 'telehealth'.

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Information is critical for people to achieve or maintain their health, wherever they are. There are many sources of relevant health information— the individual himself or herself, healthcare providers, devices which measure health parameters and the rest of the individual's world. The "Personal Health Record" or PHR is a place for an individual to keep this information. Therefore, we are developing a PHR system which would always be available to the person, i.e. would be mobile (at least) and would contain the relevant information, for use by the individual himself / herself and by healthcare providers. Remember that a PHR is not an electronic medical record (EMR), so the data stored and the relevant standards may not be the same. Of course a PHR may be used by medical personnel, so the information should contribute to medical diagnosis and treatment, much like a person's health history.

Here we will discuss the information from biosensors— and we purposefully stress the word "information" rather than "data". We will emphasize the technical problems with the use of biosensors and point out solutions. There are several problems to overcome when trying to integrate device information into a PHR system. For example:

- Many biosensors do not follow standards for data formats. It is necessary to write device-specific "drivers" for most devices
- Biosensors use various or no standard connection protocols such as USB, Bluetooth, IEEE 11073, Zigbee 802.34, etc
- Most biosensor applications nowadays only deliver the raw data, but it is the information derived from that, which is relevant to the individual and his PHR.
- There are standards for healthcare message formats, such as HL7 (v2.x and v3.0) and the CCR (ASTM E2369-05), but few biosensor monitoring systems implement these
- There are various ways of dealing with binary data such as images. Again, there is no "standard" way.

Currently there are several medical sensor devices, standards and health record formats, which is confusing. Also, monitoring of physiological events in healthcare facilities has limitations: 1) failure to sample rare events 2) failure to measure physiological responses during normal periods of activity, rest, and sleep and 3) brief periods of monitoring cannot capture rhythmic variations in physiological signals.

The use of biosensors outside of healthcare facilities is growing and is useful [1]. To routinely implement systems including biosensors, standards should be a necessity. There are several standards organizations which have created numerous applicable or partially applicable standards. However, actual implementation is lagging behind. Numerous publications have described implementations of systems with mobile or static biosensors for personal use, home use, wellness monitoring, etc., but few of them have mentioned standards for data acquisition, storage or transmission [2-10]. One exception has been an 'OpenHealth' project in Spain [11]. OpenHealth is a research project in eHealth and mHealth, emphasizing the management of wireless biomedical devices in Body Area Networks (BAN); this project implements the main components of the ISO/IEEE 11073-20601 standard.

So there is still room for more development on standards-compliant frameworks, device customization, information derivation, etc. to be able to integrate mobile biosensors into mobile- or telehealth. We approach this via mobile personal health record (PHR) systems.

1. Overview of Biosensor and PHR Architecture and Standards

A generic health monitoring application with biosensors comprises at least two elements (Figure 1) – a Medical Device (MD) that records and sends the person's biomedical parameters, and a Host System (HS) that stores the collected information. The HS may be a PHR or Hospital Information System, among others. However, since there are usually several MDs in a relatively small area, most architectures include a third element, namely the Concentrator Device (CD)—a device (e.g. cellphone, personal computer, etc.) which gathers the data from the different MDs and forwards it to the HS, often via a Service Provider (SP). The HS may share information with others (Third-Party Host Systems –TPHS).

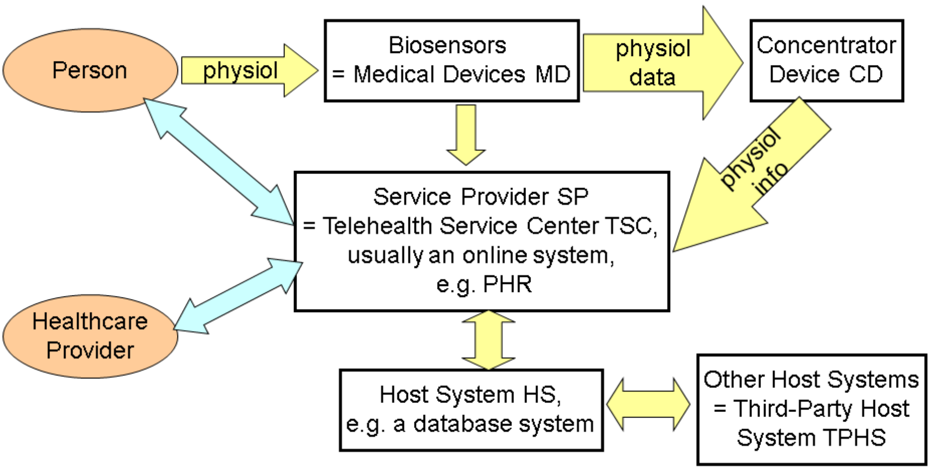

Figure 1. Overview of architecture of a biosensor system

1.1. From Standardization to Interoperability

Interoperability is both a prerequisite and an enabler for flexible and useful communication between MDs and HSs. Standardization of this communication flow is a crucial factor in achieving interoperability. Various standards, protocols and integration initiatives have emerged in recent years, including standards for medical device interoperability (i.e. MD-CD or MD-SP interface), standards for the interoperable exchange of EHRs (e.g. HS-TPHS interface), and integration initiatives for the coordinated use of these standards (i.e. MD-CD-SP-HS interface).

1.1.1. Medical Device Interoperability (MDI) (MD-CD or MD-SP interface)

Standards have been developed for medical device interoperability, including:

- Medical Information Bus (MIB) also called IEEE P11073 [12]
- INTERMED (ENV13735) [13]
- Vital Signs Information Representation (VSIR), usually called VITAL (ENV13734) [14]
- ISO/IEEE 11073 Point-of-Care (X73PoC) [15]
- Medical Device – Integrated Clinical Environment Manager (MD-ICEMAN) [16].

These attempts were not generally adopted, but they helped to establish the base in the medical device interoperability arena. Finally, the ISO/IEEE 11073 Personal Health Devices standard (X73PHD) [17] emerged in 2008. The X73 standards, originally intended for bedside monitoring in hospital environments, have been extended to wearable, multi-sensor monitoring systems designed for home healthcare.

1.1.2. Exchange of Electronic Health Records (HS-TPHS interface)

Personal Health Records (PHRs) have been steadily growing as an addition to "Electronic Health Records" (EHRs). The key distinction between a PHR and an EHR is that the individual who is the subject of the record is the key stakeholder determining content and possessing rights over that content. An example of a Web-based PHR is Microsoft Health Vault [18]. Standards also govern communications among EHRs and PHRs. Message format standards include

- ISO/EN13606 standard [19] represents the information in an EHR in an XML format
- Health Level 7 (HL7) [20, 21], version 2.x (the most widely used) represents information in a simple text structure of segments and fields
- Continuity of Care Record (CCR - ASTM E2369-05) [22].

1.1.3. Integration initiatives at the MD-CD-SP-HS interfaces

Referring again to Figure 1, several major players in the field, Continua [23], IHE [24], HITSP [25] and Microsoft have joined to suggest the following:

- MD-CD. This interface uses X73PHD
- CD-SP. This interface uses X73PHD nomenclature, the IHE Device to Enterprise Communication profile [24], and HL7 v2.6 for messaging purposes.
- SP-HS. This interface uses the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile [24] to establish communication and the HL7 Personal Health Monitoring (PHM) format [21] for data encoding, which in turn is based on the HL7 Clinical Document Architecture (CDA) [26].

The important question remains—which of the above can be applied or would be appropriate for a PHR system using cell phones or smartphones both as data collection (CD) devices and as PHR (HS) holders? Developing countries often do not have the requisite infrastructure to implement or even to use the standards listed above.

2. A Standards-based Architecture for Mobile Biosensors and Mobile PHRs

Because in developing countries cellphones are much more ubiquitous than Internet access, we adapt the framework in Figure 1 to a PHR system using cell phones or smartphones both as data collection (CD) devices and as PHR (HS) holders (Figure 2). The biosensor hardware consists of multiple, small, inexpensive battery-powered devices that lack much in the way of displays and data processing, including built-in smartphone cameras. As shown in Fig. 2, there are two categories of device specialization: x.73 (10404) sensors may include heart rate and SpO2 (for example the Nonin Onyx 9560), while x.73 (10406) may include ECG (for example the digiO2 CardioCare ECG) to measure serious heart conditions. The biosensors, including the camera, collect physiological data from the person, pre-process it and transmit it to the phone Concentrator Device.

Smartphone applications and the phone database are the CD and HS. The phone-based Manager includes a body sensor network management module to monitor the status of the sensors (Fig. 2); this is important especially for real-time data acquisition. The parameters of those sensors, including sampling rate, communication protocol parameters and even battery level, are monitored regularly through Bluetooth communication; warnings can be set for abnormal values. Another part of the Manager receives the data from external sensors via Bluetooth and data from the built-in camera, both via the data acquisition Agent. In collecting data from biosensors, we already encounter a problem—few if any devices comply directly with the IEEE 11073 standard, so the data acquisition 'agent' must be customized to individual devices.

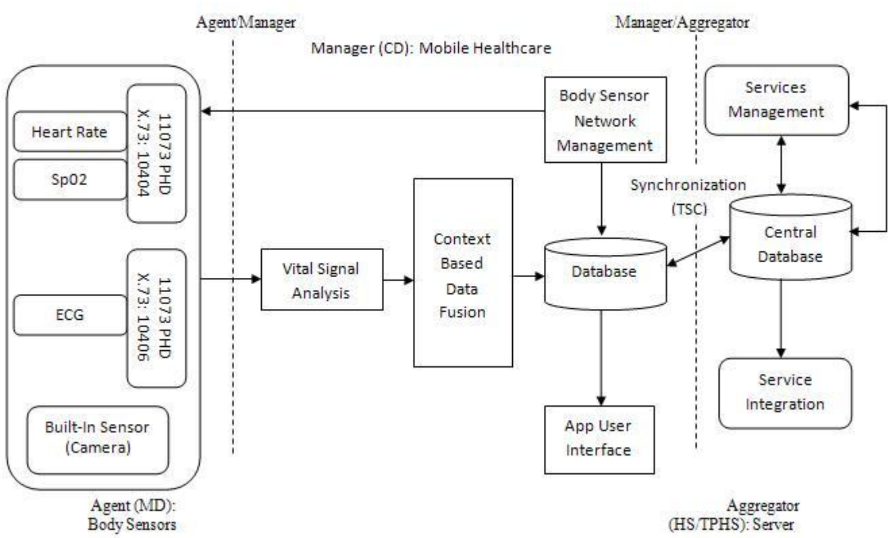

Figure 2. A phone-based framework for biosensor data collection, analysis and storage

After the person's physiological data has been acquired, we have another problem – deriving information from the sensor data. Body sensor data can be processed for 'vital signals' and optionally other phone sensor data, such as geographic location, can be processed as 'context' information. For example, heart rate information can be derived from the camera, an ECG recorder or a fingertip pulse oximeter. ECG data must be processed to reduce noise, smooth the baseline and identify and locate the QRS complexes and the R-R intervals. Camera video data must be processed to identify brightness peaks and their intervals. A pulse oximeter may send data packets of heart rate and SpO2 values calculated over a short time interval. To derive the most useful information from these we can find parameters for heart rate variability—mean, standard deviation, etc. These few parameters convey as much information as the original long data streams from the devices. In addition, the person's activity levels can be estimated from the phone accelerometer data. Context-based fusion of heart rate results and activity information will be able to estimate heart status. The on-phone processing also means that we avoid problems storing large amounts of raw data [27].
In health this data processing has considerable importance for individuals and health practitioners, who in most cases are not trained cardiologists and are not able to or in a position to interpret raw ECG or other pulse-rate data. Because heart rate changes with time, activity level, stress level, etc., it is more useful to derive parameters to describe the rate and its variations. Other biosensor parameters such as SpO2, blood glucose level, etc. are often presented as simple numbers and do not require extensive processing.

There is a local database (HS) in the smartphone and a central database (HS) in an online server. The local database stores the sensor data or processing results in a mobile (phone-based) PHR (acting as a HS). The local database also stores the personal profile of the individual, the system parameters of sensors (see above) and the settings of the smartphone app, for example, warning thresholds, warning event definitions, etc. Thus, detection of abnormalities can trigger warning messages at least to the phone user, and possibly to other designated people. In our implementation the phone PHR is built on the International Classification for Primary Care vocabulary ICPC 2e [28, 29].

To be part of a PHR 'system' the phone-based PHR information must be communicated to a more central database (or HS, right side of Fig. 2) [30]. This goes through a service provider (SP) or "Telehealth Service Centre" (TSC). Communication is through the available mobile or wireless networks – GSM, GPRS, Wi-Fi, etc. This also presents a problem—in many rural areas of developing countries, broadband networks simply do not exist or are very intermittent in their availability. This problem is at least partially solved by our ability to use the basic cell phone GSM network, i.e. to use SMSs for transmission. Looking back, the decision to process raw sensor data in the phone and store only useful parameters also contributes significantly to solving the transmission problem—we only need to transmit parameter values instead of huge quantities of raw data.

To be compatible with online PHR systems such as the Microsoft Health Vault [18], we return to the discussion of standards. The Continuity of Care Record or CCR [22] is a lightweight, easily implemented, person-oriented standard message format understood by Health Vault and other Web-based PHR systems; it describes the health status of an individual. Therefore, our phone-based PHR information, based on ICPC 2e, can be translated into the CCR format for transmission to an online HS (or TPHS); this is not difficult, as both systems have a similar structure.

3. Conclusion

We started by emphasizing the need for ‘global telehealth’ to adopt practices and systems, including biosensors, which can be used in developing countries. At the same time we emphasized the need for telehealth systems to finally adopt international standards for data acquisition, storage and transmission, in order to be compatible with existing (or future) health infrastructure. Our emphasis is on mobile health and mobile biosensors, and after reviewing various standards we have found the IEEE 11073 PHD standard to be the most appropriate for data acquisition, although to implement it we must still customize connections to individual sensor devices. Our decision to derive useful and comprehensible (to the normal user) parameter values from raw sensor data streams allows us to avoid the problems of storage and transmission of large quantities of data, especially important in developing countries. Our phone-based PHR uses the ICPC2e standard for its vocabulary and the CCR standard for communications with central, online PHR databases and systems. Thus, we hope to help people in rural, less developed regions benefit from health monitoring with biosensor systems which are available and affordable.

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