

A Closer Look on Standards Based Personal Health Device Communication: A Résumé over Four Years Implementing Telemonitoring Solutions

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Abstract

Background: For years telemedical systems have been presented as potential contribution for tackling the increasing incrimination on healthcare systems due to related costs of chronic diseases. Especially interoperable personal health devices (PHDs) are expected to facilitate the successful implementation of telemedical systems. Continua Health Alliance has published implementation guidelines for end-to-end device communication chains based on existing international standards and frameworks (IEEE, HL7, OASIS, IHE). **Objectives:** Based on the experience of multiple projects implementing the Continua guidelines and the Continua architecture this paper identifies, examines and discusses the open issues that have to be solved for an effective, efficient and broad use of PHD communication. **Methods:** The developed Continua conform software components were tested with Continua certified devices, open source IHE software components and within a simulated environment using Continua's test tools. Exchanged messages were manually reviewed and security observations were recorded. Regulatory and management questions were addressed by researching available literature, observing discussions among stakeholders and recording opinions of individuals within the project partner institutions. **Results:** The software components were successfully tested for conformance according to the Continua guidelines including their underlying standards and security requirements. Issues concerning security requirements, patient identification, regulatory aspects, market integration and EHR integration were identified. **Conclusions:** The Continua guidelines and tools enable technically complete implementations of telemedical solutions especially for most chronic diseases, but a number of issues still remain open. Technical obstacles are likely to be solved on international and standardized bases whereas regulatory issues and local regulation might result in locally limited solution biotopes.

Keywords

Interoperability, Continua Health Alliance, HL7, IHE, IEEE 11073, eHealth, PHD.

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1 Introduction

In their article about the global burden of chronic diseases Yach et al. state “Despite growing evidence of epidemiological and economic impact, the global response to the problem remains inadequate” [1]. Therefore it seems inevitable to study possible solutions for this burden. Telemedical systems have been found to be useful in

decreasing healthcare costs, simultaneously increasing the well-being of the monitored patients [2]. This potential triggered the “Healthy Interoperability” (HIO) project at the University of Applied Sciences Technikum Wien. HIO and its sub-projects focus on the development of interoperable solutions in the field of eHealth by implementing widely harmonized and evaluated standards as well as standards recently under development. The goal is to pro-

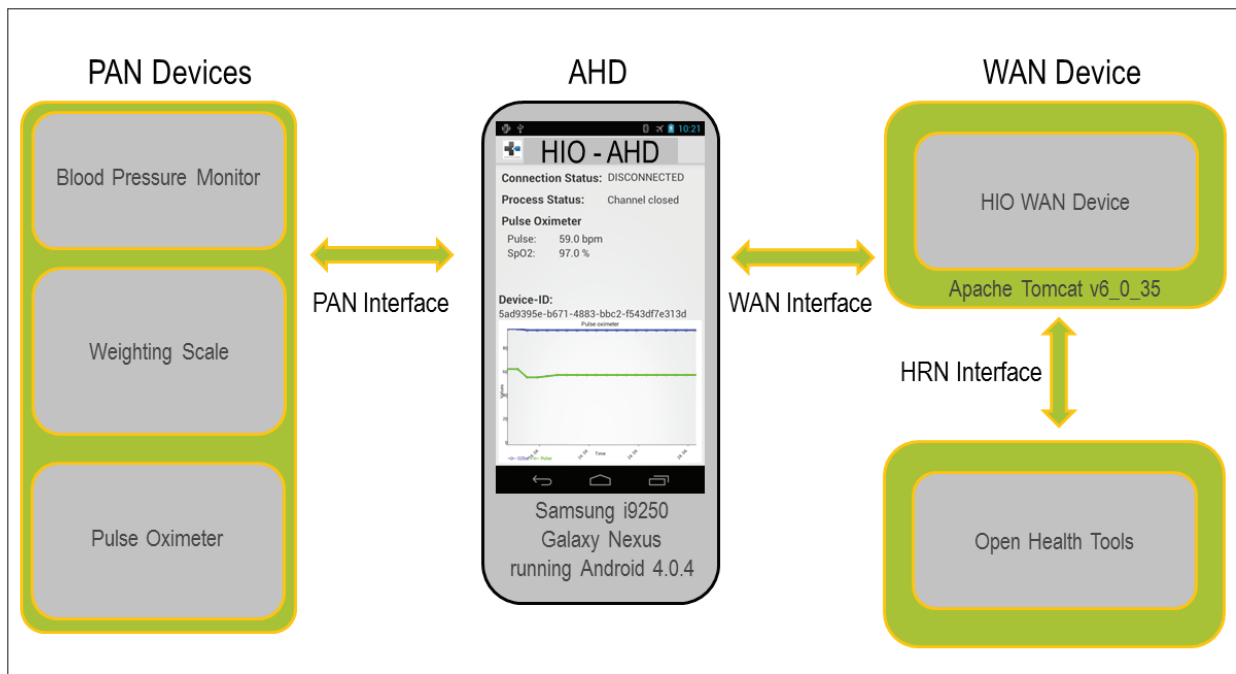


Figure 1: Healthy Interoperability architecture, conforming to the Continua Health Alliance architecture.

vide means for medical devices to be easily implemented in the daily routine of chronically diseased people, one of the largest potential user groups of telemedical solutions. Regarding the benefit of such solutions Bodenheimer et al. have found that “18 of 27 studies concerned with 3 examples of chronic conditions (congestive heart failure, asthma, and diabetes) demonstrated reduced healthcare costs or lower use of health care services” [3].

Once standardized systems are available, implementations can be expected to be cheaper and more flexible. In addition to improve care for chronic disease patients, this will also enable applying telemedical systems for prevention in early stages of chronic diseases. This includes lifestyle oriented approaches, for example to control the increasing prevalence of obesity, in order to control the exploding healthcare costs. “Despite the massive health impact we are witnessing today, adequate prediction and/or prevention mechanisms remain grossly underdeveloped” [4] Other potential use cases have been identified: The integration of telemedical systems into the environment of elderly people is becoming increasingly important due to the demographic development of the society. These potential fields of application for telemedicine have been identified, but “while using technology and HIT (health IT) for the expressed purpose of advancing better health care, we have neglected to optimize the use of technology to advance better health” [4].

As already mentioned the standardized communication is seen as the core element to provide widely deployable, cost saving PHDs in order to decrease the economic burden of chronic diseases and their related effects. “Personal health care and sports applications often require the integration of different devices and communication chan-

nels. A core problem in these areas is the variety of existing data transfer formats resulting in a complex development process which often does not facilitate the adaptability and integration of additional devices” [5]. In the “Continua Health Alliance” industry, healthcare providers and technology companies cooperate to improve the quality of personal healthcare by promoting and applying communication standards [6]. Based on well defined use cases Continua defines requirements and the architecture for end-to-end communication of medical device data. The alliance uses standards, which are already in use and provided by organizations like IEEE, HL7 and OASIS. Continua also provide supportive material like documents, reference source code, test tools and a certification scheme. Certified devices may easily be deployed within applications in the mentioned use cases and sectors of health and care.

Current and past projects show that not only the industry companies, but also research groups from different countries focusing on the areas around the Continua Health Alliance. The projects around Martinez et al. focus on the development, implementation and promotion of the ISO/IEEE 11073 (X73) standard family, which is a core component within the Continua guidelines [7, 8].

Clarke et al. are focusing on home care monitoring using smart meter infrastructure [9]. By using ZigBee [10] components in correlation with X73 messages and IHE-PCD (WAN-Interface) components, they are addressing a Continua domain. These are only some few examples for current research projects in the area of the Continua Alliance and further projects will come up.

The purpose of this paper is to discuss the, within the HIO-Projects, identified and experienced open issues that

have to be solved for an effective, efficient and broad use of personal health device (PHD) communication.

2 Methods

The basis for this paper's analysis has been assembled in several projects over the last four years. International standards like the X73 family [11], HL7 v2 and v3 (CDA) and also profiles from the IHE technical frameworks [12, 13] have been studied and applied.

2.1 Software Development and Security

Starting in 2008 the first steps have been taken by implementing X73 within first console based prototypes for transmitting temperature values via TCP/IP [5]. This standard was still under development at that time. In 2009 a first version of a standard based framework for integrating PHD data into medical information systems was developed [14, 15]. It extended the capability of exchanging measurement data between an agent and a manager via X73, by introducing additional device specializations and capabilities (PM-Store Segments). Further extensions of the software framework in 2010 [16, 17] implemented parts of the IHE profiles XDS, ATNA, PIX/PDQ and DEC as well as an HL7-CDA document generator (PHM-Report). This completed a consistent communication chain which complies with the Continua guidelines.

Technikum Wien joined Continua in 2009 and started the development of an Android App, which acts as an Application Hosting Device (AHD) in Continua terms. The HIO-AHD on one hand receives data from PHDs via the Personal Area Network (PAN)-Interface and on the other hand transmits the data further on via the Wide Area Network (WAN)-Interface to first instances of medical server infrastructure as shown in Figure 1. The following components have been used:

- AHD (HIO-AHD App) on a Samsung i9250 Galaxy Nexus (Android v4.0.4)
- WAN-Device (HIO-WAN-Device) running on an Apache Tomcat v6.0.35
- Continua certified PAN-Devices: blood pressure monitor, weighting scale, pulse oximeter
- HRN Software Components: Open Health Tools: Open-XDS, -ATNA, -PIX/PDQ [18]

The developed HIO-AHD, as shown in Figure 1, has been tested using two approaches. On the one hand the HIO-AHD was tested with different Continua certified products of the mentioned PAN device classes. The measured data was sent to the HIO-AHD via the X73 protocol and then transferred to the HIO-WAN-Device via HL7 v2.6 messages. Finally a Personal Health Monitoring (PHM) -Report was transmitted to a locally installed IHE infrastructure based on the Open Health Tools [18].

On the other hand the HIO-AHD has been checked in a simulated environment set up with testing tools provided by Continua. The HL7 and X73 messages were tested according to the stated device specializations, by the test tools.

Additionally in each approach a manual review of the exchanged messages was performed in order to assess the conformance to the relevant standards.

Security issues were a main focus. The data chain to be developed must assure that only qualified individuals and devices generate and access sensitive patient data. Observations made during software development were therefore recorded.

2.2 Regulatory and Management Issues

Beside the correct transmission of the measurements from the device to any kind of archive, there are a lot of additional requirements to be fulfilled and that have turned out to be challenges because they are beyond any of the current technical specifications. Some of them are crucial to be solved for a successful implementation.

Telemonitoring of vital signs and health parameters from patients in their home environment will influence the future treatment and medication of a patient. Therefore reliability is a core requirement. Beside the correct transmission of the measurement results the medical data must be unambiguously linked with the person whose reading had been taken. Patient identification across the complete data transmission chain is therefore crucial so that values of one patient do not end up in the record of another.

The development of software for medical purposes involves other regulatory aspects. This also applies to personal health applications like the HIO-AHD Android App. Therefore the European Medical Device Directives [19] as well as the Austrian "Medizinproduktegesetz" [20] have to be taken into account in order to address patient safety issues sufficiently.

Technical specifications and other types of regulations are essential contributions to improve healthcare by using the available technology. On the other side success depends on devices and products available on the market at reasonable cost and effort.

This work addressed regulatory and management questions by researching available literature, observing discussions among stakeholders and recording opinions of individuals within the project partner institutions.

3 Results and Discussion

3.1 Software Development and Security

The HIO-AHD software was developed and tested as described in the methods. Blood pressure, weighting scale and pulse oximetry readings were successfully transferred from Continua certified devices to the HIO-AHD via a Bluetooth link. They were further successfully transmit-

ted to the HIO-WAN-Device via HL7 v2.6 messages as required by the guidelines. Of the received HL7 messages a PHM-Report was generated and transmitted to the IHE-XDS infrastructure provided by the Open Health Tools [18]. All messages were manually reviewed for conformance to the necessary standards as described in the methods. Conformance to the Continua PAN, WAN and HRN -Interfaces was successfully established.

On the security side the Continua architecture includes provisions only on the Interface level. The PAN-Interface from PHD to AHD for example relies on the security of the transport channel itself. BT HDP for example provides sufficient security.

From the AHD onwards the Continua WAN-Interface is mainly based on the IHE-PCD Technical Framework. Similar to the HRN-Interface, the WAN-Interface uses proven and stable standards. Data interoperability as such is therefore easily achievable with reasonable effort. In general the security measures of the Continua WAN-Interface are built upon the IHE-XUA Profile for integration of entity identity assertion. The Design Guidelines require integrating a SAML-Token within the PCD-01 message sent by the WAN-Device, but leave it optional to either request the SAML-Token from a foreign STS or build it up within the WAN -Device software itself. The fact that Continua only requests the presence of a SAML-Token but does not provide clear specifications on how to generate the token and the necessary attributes introduces a security issue. Implementers will not use a consistent set of attributes to generate SAML-Tokens. The resulting applications will therefore not provide fully interoperable communication with server sided access control regulation.

The new IHE profile XUA++ [21] tries to address this problem but it is in a very early stage yet, available for trial implementation only. Further cooperative work has to be done to define specific attributes by Continua but also by IHE and others.

3.2 Regulatory and Management Issues

3.2.1 Patient Identification

The Continua guidelines provide for a patient identifier to be sent with the measurement values. However Continua does not suggest how this identification should take place.

Identification might be performed at the PHD itself, e.g. by a fingerprint reader. The identification on the PHD itself puts additional demands on the device manufacturer as it requires integrating technologies into the PHD which allow a user to identify himself/herself.

Alternatively data identification can be performed elsewhere by mapping the unique system-id of the PHD to a single person according to a predefined mapping table. The latter is more comfortable to the user because apart from taking the measurement as usual no other effort is necessary. The PHD will for example pass the read values,

together with its system-id, to the AHD. The AHD will match the PHD system-id to the patient id and pass the data on via the WAN-Interface to a WAN-Device. Alternatively a WAN-Device might implement a mapping table and perform the data identification. This approach faces the drawback that every device may only be used by one user exclusively.

Another strategy also identifies the data on AHDs. This is possible if the AHD is only used by one individual. NFC based systems for example enable the usage of mobile phones for collecting data from PHDs and for identification of the measured values as demonstrated by Morak et al. and Kumpusch et al. [22, 23].

The ISO/IEEE 11073-20601 protocol and the underlying device specializations also introduce issues concerning identification of users. The device specializations define for each device class a standard configuration describing required attributes which both communication partners need to implement for conformance. Not every standard configuration does support the handling of multiple-person event reports, i.e. a Continua certified device might not even be able to transmit user identity related information in their default and permitted setting.

3.2.2 Regulatory Aspects

There are a number of issues related to software for mobile AHDs, like an application running on a smartphone that add complexity to meet regulatory requirements: Distribution most properly occurs over an online market where customers will typically not receive advice and training. Software for a wide variety of different hardware platforms and different versions of operating systems needs to be developed, tested and supported. The effort to establish the regulations that an application needs to conform to is considerable, especially if multiple regional legislations are concerned.

The “Application of risk management for IT-networks incorporating medical devices 80001-1” standard defines a “medical IT network” as “an IT network that incorporates at least one medical device [24]. It provides guidance on performing risk management for medical IT networks. The telemedicine applications studied here, fit into this definition. It can therefore be assumed that 80001-1 may help to provide safe and reliable services. However practical experience from applications is still rare.

One strategy to lower the burden is to generate information packages in the PHD and to transport them across the AHD and all other relay stations without data manipulation or interpretation to the package destination in the EHR. This enables a clear split of responsibilities: The PHD generates the data, the transport chain assures that it passes through unchanged. This replaces the requirements on the transport chain, especially if the packages are encrypted. This strategy might increase the dissemination of Continua compliant devices and software applications in this special area.

General solutions for regulatory aspects are not avail-

able. As of today, each telemedicine service needs to be analyzed on an individual basis.

3.2.3 Market Integration

Continua has selected three transport technologies for the communication between PHD and AHD: Bluetooth [25], ZigBee [10] and USB [26]. The basic transport protocol is common on all three: the ISO/IEEE 11073-20601 standard. PHDs have to conform to the respective ISO/IEEE 11073-104xx device specialization standard.

The Bluetooth “Health Device Profile” (BT HDP) has been introduced by the Bluetooth Special Interest Group (SIG) in order to overcome interoperability and security concerns of the Bluetooth Serial Port Profile. BT HDP is already implemented in some PHDs available on the market. On the AHD side most devices still do not support the BT HDP. Additionally work is proceeding on the “Bluetooth Low Energy” profile, as an element of the Bluetooth Core Version 4.0. Devices implementing other low power wireless protocols like ANT [27], which has wide acceptance in applications already today, can be integrated into Continua conformant systems.

By June 2012 a total amount of 48 (44 in 2011 and before) Continua - certified devices were available. Nevertheless it is difficult or even impossible for end-users to purchase devices and often even for large scale healthcare providers on the European market.

3.3 EHR Integration

The Continua HRN-Interface connects AHDs with EHRs. It is based on IHE-IT Infrastructure technical framework and underlying standards, especially on the profiles XDS, XDR, XDM, ATNA, PIX and on the HL7 CDA R2 standard (profiling the PHMR implementation guide). Many vendors have already adopted those IHE profiles and a large number of products is available on the market and installed in operative systems. Therefore it can be assumed that the HRN-Interface is sufficiently stable, complete, but also well tested. A lot of experience is available from operative systems. Continua offer certification of the HRN-Interface, however only for the WAN-Device side that delivers the data to the EHR. HRN-Devices are excluded from Continua certification.

The data guidelines for the HRN-Interface specify that the Continua HRN-Interface on the WAN-Device shall use SNOMED-CT coding for device data, for example the coding of the observation types. This could most probably lead to problems for countries, which have no license agreement for SNOMED-CT coding, for example Austria. In order to enable common telemedicine activities solutions to this problem need to be found for example by choosing an alternative way for coding device data within the HRN-Interface.

4 Conclusion

Based on the implementation experience reported here it is concluded that the Continua Design Guidelines and the tools provided by Continua enable technically complete implementations of telemedical products and solutions especially for telemonitoring of the most important chronic diseases. The major harmonization effort has also kick-started a global community of engineers who are now able to disseminate the knowledge and provide useful systems.

A number of issues that reach out of the engineering domain still remain open: Although technical and interoperability solutions for patient identification are available, these still need to be included into devices that are available and generally used. Today the number of available device types does not address all requirements from quite a few telemonitoring use cases.

On the regulatory and security side we are missing complete sets of rules for responsibilities, roles, data access and transport that then need to be implemented into IT systems. Although some countries do have laws for telemedicine it is still prohibitively hard for vendors to provide products for a global market. Integrating the regional local regulatory and market islands is a remaining challenge.

In parallel to the engineering effort we see users engage in the process, using the technology and generating valuable reference data. This data will support the open discussion on the impact of these new developments to the healthcare system.

Continua addresses the technical as well as the regulatory and management issues in its respective working groups. Other groups jointly contribute to the effort. The process will continue on the sides of vendors and users. Extrapolating from the number of productive results and from the speed at which they occur, we can expect to see more issues solved and more systems in practice in the near future.

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