Development of an Android App in Compliance with the Continua Health Alliance Design Guidelines for Medical Device Connectivity in mHealth

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Abstract

Due to the demographic change and rising amount of people suffering from lifestyle induced chronic diseases, developed countries face a remarkable cost explosion in the health care sector. Additionally a lack of nursing workforce has been predicted [1]. mHealth solutions are seen as a chance for individuals to keep track of their health condition, to take more responsibility for their lifestyle and to improve the efficiency of care by providing high quality data to formal and informal careers and health professionals. In order to implement these mHealth solutions a high level of standardization is necessary for easy and quick integration of personal health devices (e.g. blood pressure monitor, blood glucose meter) with gateway devices (e.g. smart-phones) and electronic health record (EHR) systems. The Continua Health Alliance Design Guidelines describe a set of internationally established standards and frameworks for this purpose. This paper describes the experience gained during the development of an Android application which is capable of communicating via Bluetooth using the Health Device Profile and the ISO/IEEE 11073-20601 Optimized Exchange Protocol. The WAN interface uses the IHE DEC and XUA profiles in order to securely forward health data to health professionals. Building on existing modules from earlier project phases a Continua Health Alliance compliant Android app using commercially available components was implemented within one month by a team of two developers. Therefore it seems feasible for SMEs to build mHealth applications for these purposes from a technical point of view. Additional effort for regulatory purposes needs to be considered.

1 Introduction

The demographic change in developed countries towards an elderly population and the increasing prevalence of chronic diseases lead to rising costs in the health care sector [2]. Chronic diseases like COPD, cardiological pathologies or diabetes cause direct costs as well as a high amount of indirect costs [3,4]. A major cause of these diseases is the individuals’ lifestyle. Low personal fitness and a low level of activity paired with mostly unhealthy nutrition are the main reasons for lifestyle caused diseases [5]. One approach to face these challenges may be the reinforcement of primary and secondary prevention and the empowerment of the individuals to take responsibility for their own well-being. This could be achieved by increasing the persons’ self-awareness by providing mHealth solutions for remote monitoring of health & fitness data and integration of social networks for assistance and motivation.

This work is part of the Healthy Interoperability research project. Since 2009 a profound knowledge base in the field of telemetry of personal health data has been gained by developing several applications for secure and standardized transport of vital parameters [6]. One major achievement was the implementation of the Continua Health Alliance Design Guidelines [7] which describe a set of internationally established standards and frameworks for mHealth. Since joining the Continua Health Alliance in 2009 the group contributed to the progress of this community. The improvements and refinements for chosen standards and frameworks have been observed and implemented.

This paper reports the development of an Android app compliant to the Continua Design Guidelines and addresses the challenges that vendors face during implementation.

2 Methods

Security of investments, usability and interoperability can be ensured using international standards for data communication [8]. The Continua Health Alliance uses the ISO/IEEE 11073-20601 standard [9] as the exchange protocol for communicating data in Personal Area Networks (PANs) and Local Area Networks (LANs). This standard defines generic data structures for personal health data, common services available during communication and an optimized transfer syntax and protocol for the exchange of control and data messages. Semantic interoperability is gained through the usage of the ISO/IEEE 11073-10101 nomenclature standard and by the introduction of “Device Specializations” defining a set of basic capabilities and data definitions for each device class, e.g. the device class specific standard configuration.
Further capabilities have been implemented due to the constraints defined by the current version of the Continua Design Guidelines. The Continua Health Alliance demands using a secure connection on the transport layer level, i.e. providing TLS. Therefore the authentication between the IHE-Agents on a software component level is implemented using certificates and as an appropriate cipher suite TLS_RSA_WITH_AES_128_CBC_SHA is used by the Android app. In order to conform to the Continua Health Alliance Design Guidelines in respect to security requirements for WAN-communication, OASIS SAML (Security Assertion Markup Language) [13] shall be supported for Entity Identity Assertion. Therefore the IHE ITI Profile XUA (Cross-Enterprise User Assertion) is used as a basis for integrating SAML-Tokens into existing Web service messages, like the PCD-01 Communicate PCD Data transaction (CommunicatePCDData request) used within the DEC-Profile. There are two options for generating this SAML-Assertion: It can be built within the Android app or requested from an appropriate external Secure Token Service (STS) as specified in WS-Trust [14]. In Java on JSE or J2EE platforms 3rd part libraries are available for either option. As a step to implementation these libraries were therefore evaluated and it was attempted to port them to the Android platform.

The Android app was designed for mobile devices running Android 4.0 [15] or above as these versions implement the Bluetooth Health Device Profile (HDP). The Galaxy Nexus smartphone, Samsung Electronics Austria Gmbh [16], one of the first phones implementing Android 4.0, was used as a development platform for the Android app. As a development environment Eclipse Indigo version 3.7.2 [17] with the appropriate Android-Plug-in supported by Google was used.

Integration tests were performed with existing commercial personal health devices by single stepping through the configuration and data transmission procedures as they are defined in the Continua Design Guidelines for the PAN and WAN interfaces. The resulting data messages were manually reviewed.

### 3 Results

The developed Android 4.0 application was implemented and tested successfully with the blood pressure monitor UA-767PBT-C, A&D Company Ltd. [18], the weighting scale UC-321PBT-C, A&D Company Ltd. [19], and the pulse oximeter PureSAT 9560BT, Nonin Medical Inc.[18].

The SAML libraries could not be ported from JSE/J2EE to the Android platform without modifying the operating system. Therefore a SAML Web service client including appropriate SAML-processing were implemented within the Android app. The SAML-Assertions were claimed from an appropriate Secure Token Service and added into the SOAP-Header of the PCD-01 SOAP request.

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**Image 1** Architecture of the Android HIO-AHD app

On top of the transport layer, the Android app incorporates an ISO/IEEE 11073 coding engine (X73 Manager depicted in Image 1), which allows encoding/decoding of byte arrays coded compliant to the Medical Device Encoding Rules in order to provide capabilities to exchange messages according to the Optimized Exchange Protocol. In this first version, the coding engine supports the standard configurations found in the corresponding ISO/IEEE device specialization documents of the weighting scale, pulse oximeter and blood pressure monitor.

The measured values from the personal health devices (measurement parameter, measurement value, physical unit and time stamp as well as information on the PHD itself) are decoded from the received byte streams and mapped to a data structure called HIO DataContainer. By using this generic data container, which was developed for the HIO Software-Framework [10], the app is prepared for further expansions and future functionalities.

Integrating the Healthcare Enterprises (IHE) technical frameworks (TF) [11,12] are referenced by the Continua Health Alliance Design Guidelines for transmitting data further over Wide Area Networks (WANs) as well as to Health Reporting Networks (HRNs) for storage in form of CDA documents. For point-to-point communication between the application hosting device (AHD, e.g. smartphone) and a WAN-Device, the IHE DEC (Device Enterprise Communication) profile defined in the IHE PCD (Patient Care Device) technical framework serves as a basis for the Continua Health Alliance Design Guidelines. Apart from the specification by the DEC-Profile in the IHE PCD technical framework, there are additional restrictions which need to be fulfilled to be Continua compliant.

From the HIO DataContainer the data is passed to the Device Observation Reporter (DOR)-Instance, which includes the HL7 V2.6 processor. The HL7 processor generates appropriate HL7 V2.6 messages according the Continua Health Alliance Design Guidelines, using the information held within the HIO DataContainer. Subsequently the prepared message is transmitted to the WAN-Receiver described by the Continua Health Alliance Design Guidelines.

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The development and testing of the Android app lasted one month. 20 developer days were invested. Two individual developers with specific areas of expertise were involved using code and experience from earlier project stages.

4 Conclusion

The mHealth application was successfully implemented and tested on the Android platform, within a time-frame of one month. This shows that an implementation of the Continua Design Guidelines, including their underlying standards and frameworks, for Android platforms, OS Version 4.0 or greater, is feasible with a reasonable effort. Therefore it can be concluded that not only large vendors but also SMEs may substantially contribute to the progress in this market area. In the near future larger health care providers should be able to implement care services using this technologies and eventually even smaller health care providers can be expected to join the overall work flows. However, regulatory issues need to be addressed whenever health data is processed and transmitted. This generates additional obstacles for implementers. The Android philosophy of an open source operating system has resulted in multiple vendor specific flavors of the operating system. This may increase the complexity of establishing secure and reliable implementations and systems.

A further issue is the number of available Continua certified personal health devices on the market. At this time 48 products (including software components) are available. Although the number of certified devices increases steadily not all necessary requirements of specific user groups can be fulfilled. This may be addressed by also using alternative transport protocols like ANT+ and Near-Field Communication (NFC).

This work was based on the Android platform. There are other widely used mobile platforms. Most of them do not provide Bluetooth HDP. In addition it is hard for developers to provide applications for all platforms simultaneously. Taking those challenges into account, it can be expected that further time is needed for wider adoption and availability of mHealth applications for care.

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5 References


