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Usage of international standards for integrating extramural monitoring and personal health device data into medical information infrastructure

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Abstract

Integrating extramural measured devices data into medical information systems is becoming more and more attractive for integrated medical care. A lot of devices already have the ability to transfer measured data to mobile devices or computers and a few systems offer submitting data to a centralized information database or information system. Unfortunately, all of these devices use proprietary protocols and processes which makes integration into other systems a major problem. To address this problem the Healthy Interoperability project has been created with the objective of creating a framework for transferring health data based on international standards. The paper outlines how the framework architecture takes full advantage from the definitions of the international standards ISO 11073, HL7, IHE and CEN 13606. Even the definition of the user profiles and the security framework is based on standards from ETSI, ISO and CEN. By using these standards the framework can also perfectly be used for intramural communication.

Keywords:

e-Health, Medical device, Device communication, Personal health, PHD, ISO 11073, HL7, IHE, CEN

Introduction

Integrating extramural measured devices data into medical information systems is becoming more and more attractive for integrated medical care. Existing and new upcoming devices offer a big variety of possible use cases ranging from monitoring and alerting up to observing the own health status by using personal health devices. Using such device data is as useful for observing chronic disease parameters as for prevention. A lot of these devices have the ability to transfer measured data to mobile devices, mobile phones or personal computers and it would be very valuable to submit the data to health provider information systems or to integrate it into an electronic health record or a personal health record. At the moment there are only a few companies and systems that offer transmission of data to a centralized information database or information system. Unfortunately, device connectivity to enterprise services is however currently very proprietary and all of these systems use proprietary protocols and processes which makes integration into other systems a major problem. To address this problem the Healthy Interoperability project has been started in January 2009 with the objective to overcome the problem of non interoperable interfaces by designing and developing a communication framework that is solely based on international standards and thus enables technical and semantic interoperability. This framework shall also facilitate access to the many different types of available data and provides this data to intelligent personal services.

Materials and Methods

System Architecture

In addition to the main goals of the project some further requirements were defined to be considered in the first phase of the project.

- Sensors and devices should be capable of being integrated into the framework on a plug & play basis which means, that no specific setup has to be done be the user to start communication.
- The framework shall be very flexible and allow easy extension of functionality by integrating new software modules with a plugin concept.

Figure 1 outlines the systems components and architecture.

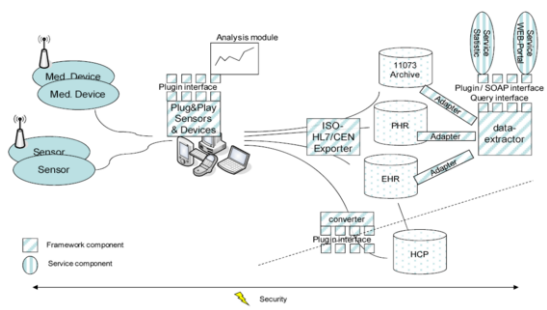

Figure 1- System overview

The framework has a modular architecture that enables a lot of different configurations and therefore the functionality of the system depend on the modules used in a specific configuration.

International standards and standard based framework

During the first six month of the project a lot of international standards have been evaluated to be used in the framework. The following standards have been chosen to be implemented in the framework modules:

- ISO/IEEE 11073 [4]: defines device communication and information exchange on a plug & play basis. Core part of the concept is an agent – manager communication where the device is the agent.
- HL7: the HL7 definitions of both message based standards are used in the project. The Version 2 messaging as part of the IHE profile definitions and the CDA specification (part of V3) for generating medical documents on a XML basis. The HL7 "Personal Healthcare Monitoring Report (PHMR)" implementation guide is used to convert device data to a CDA document.
- IHE: To integrate patient care devices into medical data flows IHE defined the "Patient Care Device Technical Framework" [6] with the DEC profile. In principle this definition fits well to the requirements of the "Healthy Interoperability" project but it had been developed for intramural processes. Nevertheless the profiles are implemented and the upcoming problems will be dealt with. But using the DEC profile means a lot of other profiles get involved – Figure 2 gives an overview of needed IHE profiles.

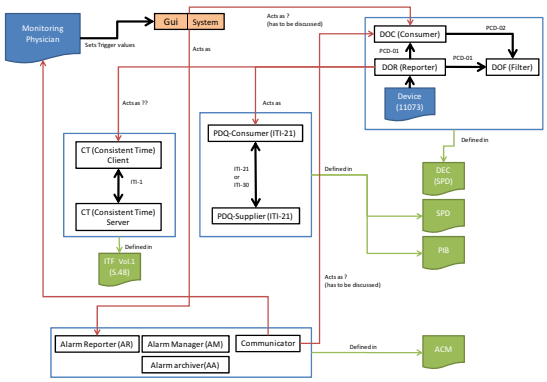

Figure 2- IHE profiles needed (without XDS)

Furthermore, the XDS profile definition of the IT Technical Framework is used to implement a document consumer module for the framework to integrate data into an IHE based EHR.

- CEN 13606 [3]: has been evaluated for defining domain models and flexible data structures. This standard really has high potential but as it is not part of the definitions of any other international framework (e.g. IHE) the usage in the project has to be further evaluated.
- Continua Alliance: the open industry coalition focuses their work to personal health (fitness, wellness), chronic diseases and solutions for aging population. They published the "Continua Design Guideline" which defines the basic conditions for device data communication (the guideline is based on ISO/IEEE 11073 and PHMR). They also offer a certification process for devices and systems.

Results

Device communication

Based on the ISO/IEEE 11073 basic and profile definitions device communications for three different devices has been set up and tested so far: a pulse oximeter (Nonin, USB based), a data logger (Bluetooth based) and a clinical thermometer (see next paragraph). Overall five device profiles for different device classes and the central 11073 manager module were implemented. The manager is already being able to integrate devices and start communication on a plug&play basis. At the moment the manager runs on mobile devices with Windows Mobile operating systems but because of the Java implementation it can be easily ported to any other system.

Clinical thermometer device

For testing purposes and to demonstrate the usage of the framework for intramural setups a hardware prototype for a clinical thermometer was developed (Figure 3) and the software for ISO 11073 conformant communications was implemented on the used microprocessor. The device has a RFID module to identify a patient via a RFID wrist band and it communicated with the manager via Bluetooth. At a further project stage the RFID identifier will be used to query demographic data from the HIS or any other system and the device displays the name of the patient the device display.

Figure 3- prototype of a clinical thermometer

Module architecture

After conception phase the module structure for the framework was defined and the basic modules to be implemented first were selected - Figure 4 shows the architecture and the modules. The core of the system is called "controller" a module which manages all the other modules and applications that are plugged into the framework.

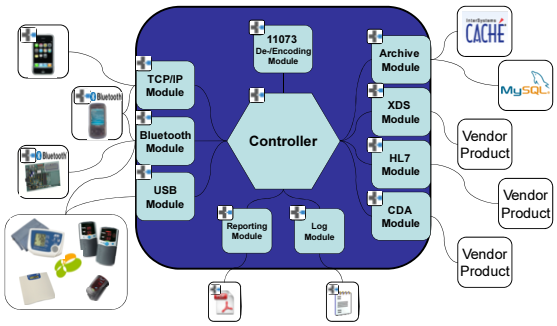

Figure 4-Module architecture

A module can be added easily by simply providing a java library file at a specific location. The controller mentions the new application and integrates it into the framework. At a second step each module has to register itself at the controller and as a part of the negotiation process the new module defines the type of data it can provide (write) or it wants to have (read). The controller administrates all the modules and manages a common data container. This container can be filled by different modules and can be accessed by others. The controller takes care of the data request done by all modules and notifies a module as soon as all requested data is available by releasing an event. This means that for instance a module needs data that can only be served by two other modules (e.g. a CDA Module needs data from the device and from a demographic query). Using this plug and play interface also third party modules can easily be integrated without any change of the framework.

All of the 11073 based modules (on the left side of Figure 4) have already been implemented. Also development of the log and archive modules was finished. The archive model writes the data into the object oriented Cache database. The HL7 and IHE modules are currently under development.

Standard based controller data container

The controller holds one or more data container, which are used for data exchange of the modules. The design of this container is also based on the selected standards. The container can hold ISO 11073 structured data (also raw data is provided for compatibility issues), HL7 data, a CEN 13606 EHR-Extract or any other data structure. The demographic data is currently designed to be stored in the HL7 RIM model. Figure 5 shows an UML overview of the container. Access to data is controlled by the controller.

Use case analysis

In parallel to the technical development the analysis of possible use cases and the related processes, which started at the beginning of the project, is continued. Among others this includes scenarios for patient to doctor communication, chronic diseases but also intramural use cases (see clinical thermometer). The results of this analysis project and the documentation will be published by ISO as part of an official ISO.

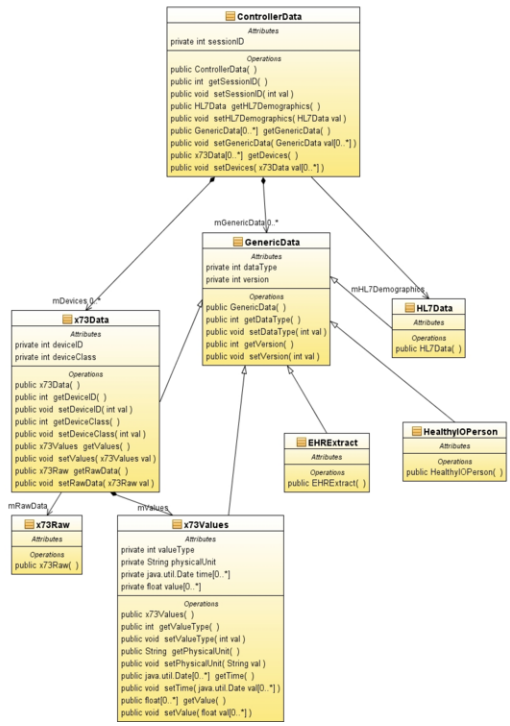

Figure 5-UML Model of the data container

Discussion

Continua Alliance

The Continua Alliance, their definitions and their certification process gets more and more attention as the interest in devices, which support data transmission to mobiles or PCs, grows.
Especially the market for consumer devices and devices supporting ambient assistant living (AAL) is growing. Especially for AAL the communication based on an international standard is a very important issue because it enabled interoperable systems and that massively reduces costs. But therefore the availability of Continue certified devices gets more and more into the focus. At the moment there are only a few certified device classes on the market, but according to Continua in January 2010 a lot of compatible devices should come to the market.

ISO 11073 reverse channel

At the moment the ISO 11073 agent – manager communication is mainly unidirectional, which means the device is sending data. The only exemption is that some devices can get configuration parameters from the manager. In some cases (e.g. the clinical thermometer) this seems to be too limiting, because sometimes the reverse channel should be usable for data transfer (e.g. clinical thermometer: questioning the patients name to be displayed on the device).

Remote configuration

It seems to make sense that a doctor who is monitoring a patient's data should be able to change the configuration of the monitoring device. But this raises a lot of problems especially in regard to security because it has to be ensured that a specific configuration really was entered by a doctor and that it is not a fake. This also has a lot of legal aspects. Therefore at the moment the communication is only unidirectional.

Security

As the Healthy Interoperability frameworks handles medical data special security and data protection definition has to be applied and sufficiently addressed. End to end encryption would be nice to have but fails because of current technical limitations, such as key distribution or using electronic certificates on medical devices. Hence also the security requirement of non repudiation is still vacant.

For securing the communication route from the mobile to the health provider information system currently the ISO/TR 11636:2008 about "On-Demand VPN" is evaluated.

Also the process for assigning a device to a patient is still not satisfactorily solved. The assignment still requires manual interaction. To optimize the assignment process or find a automated reliable solution will be part of future work in the next month.

Profiles

The behavior of such a system depends on the situation when and where it is used. So the system has to provide different profiles. Profiles can have different categories, for example "communication profiles" which control the data transmission channel or "situation profiles" like "at home" or "at restaurant" which for example controls the audio response of the systems. Profiles can be active or not and usually more than one profile is active.

Pilots

For the next year two pilot installations are planned to demonstrate the operation of the system. First pilot will be patient monitoring in the home care area. The pilot addresses older people at the age of 70+ who are currently served by a care organization. The pilot aims to monitor health parameter online and on a second step implement a kind of alarm management for abnormal data.

The second pilot will address self management of oral coagulation. Concerned people get a device for home and self measured device data is transferred to a server where a medical attendant periodically validates the values.

Acknowledgments

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References

[1] Behr, M., Lyssy, C., Kabakci, M., Mense, A. Sauermann, S. Archivierung von standardisierten IEEE 11073 Informationsobjekten in einer Datenbank für den Personal Healthcare. Tagungsband, 3. Forschungsforum der österreichi-schen Fachhochschulen - Villach, Österreich, 15.-16. April 2009

[2] Bicer V. et al: Archetype-Based Semantic Interoperability of Web Service Messages in the Health Care Domain; International Journal on Semantic Web & Information Systems, 1(4), 1-22, October-December 2005

[3] CEN 13606-1 European Standard – European Committee for Standardization; Health informatics - Electronic Healthcare communication - Part 1: Extended architecture. Central Secretariat: Rue de Stassart, 36 B- 1050 Brussels, 2006

[4] IEEE P11073-20601 Draft Standard for Health informatics - Personal; health device communication - Application profile - Optimized exchange protocol

[5] Nee Oliver et al.: SAPHIRE: Intelligent Healthcare Monitoring based on Semantic Interoperability Platform - Pilot Applications, IEE Proceedings Communications Special Issue on Telemedicine and e-Health Communication Systems. 2008

[6] Integrating the Healthcare Enterprise: IHE Patient Care Device Technical Framework; Rev. 1.1, 2006, www.ihe.net

[7] Integrating the Healthcare Enterprise: IHE IT Infrastructure (ITI) Technical Framework; Rev. 5.0, 2008, www.ihe.net

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