Quality Criteria and Concepts for the Development of Mobile Health Applications

Por

Matthias Frohner

Orientador: Stefan Sauermann

Co-orientador: João Agostinho Batista Lacerda Pavão

Tese submetida à
UNIVERSIDADE DE TRÁS-OS-MONTES E ALTO DOURO
para obtenção do Grau de
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em Engenharia Electrotécnica e de Computadores, de acordo com o disposto no
DR – I série – Nº 151, Decreto-Lei n.º 115/2013 de 7 de agosto e no
Regulamento Geral dos Ciclos de Estudo Conducentes ao Grau de Doutor
DR, 2.ª série - Nº 133 de 13 de julho de 2016

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"He had found a Nutri-Matic machine which had provided him with a plastic cup filled with a liquid that was almost, but not quite, entirely unlike tea."

The Hitchhiker's Guide to the Galaxy, Douglas Adams (1952 - 2001)

UNIVERSIDADE DE TRÁS-OS-MONTES E ALTO DOURO

Doutor em Engenharia Electrotécnica e de Computadores

Os membros do Júri recomendam à Universidade de Trás-os-Montes e Alto Douro a aceitação da dissertação intitulada "**Quality Criteria and Concepts for the Development of Mobile Health Applications**" realizada por **Matthias Frohner** para satisfação parcial dos requisitos do grau de **Doutor**.

Dezembro 2018

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Critérios de Qualidade e Conceitos para o Desenvolvimento de Aplicações Móveis para a Saúde

Matthias Frohner

Submetido na Universidade de Trás-os-Montes e Alto Douro
para o preenchimento dos requisitos parciais para obtenção do grau de
Doutor em Engenharia Electrotécnica e de Computadores

Resumo — A qualidade é uma medida do desempenho de um sistema ou *software* com base nas expectativas do utilizador. Para aplicativos móveis, os aspetos de qualidade também são importantes, se não ainda mais importantes, em comparação com aplicativos de *desktop*, já que a grande quantidade de aplicativos móveis disponíveis permite que um utilizador alterne para outra solução que atenda ao mesmo propósito. Este trabalho investiga a aplicabilidade de modelos de qualidade de *software* estabelecidos e descreve as características de qualidade mais importantes para aplicações móveis de saúde (*mHealth*), as quais foram identificadas através de entrevistas com especialistas. O trabalho mostrou que a "interoperabilidade" é de suma importância e coloca em evidência os recursos do sistema/*software* para trocar dados com outros sistemas. Primeiro, os casos de uso foram identificados e especificados usando um modelo desenvolvido para o efeito. O primeiro caso de uso lida com a aquisição de dados usando dispositivos pessoais de saúde em combinação com *smartphones*, e o segundo caso de uso descreve a comunicação de dados entre um dispositivo móvel e um provedor de saúde, usando interfaces padronizadas e formatação de documentos. Esses casos de uso foram implementados como protótipos *Android* e foram validados com base num conjunto de critérios derivados de diferentes diretrizes e especificações disponíveis para comunicação de dados de saúde. É também fornecida informação acerca de desafios de interoperabilidade envolvidos no campo de sistemas de energia, uma vez que a experiência reunida nesta área para testes de conformidade e interoperabilidade, também pode ser aplicada a sistemas de IT e aplicativos móveis da área da saúde. Os esforços de padronização e harmonização atuais são discutidos ao nível técnico

e regulatório. A interoperabilidade é apenas um dos critérios de qualidade que precisa de ser abordado, uma vez que, se os dados forem trocados usando protocolos de comunicação proprietários e terminologia não harmonizada, essas informações não poderão ser usadas facilmente para processamento posterior

Palavras Chave: eHealth, mHealth, Qualidade, Telemonitorização, Normas de Comunicação, Validação, Testes.

Quality Criteria and Concepts for the Development of Mobile Health Applications

Matthias Frohner

Submitted to the University of Trás-os-Montes and Alto Douro
in partial fulfillment of the requirements for the degree of
Doctor of Philosophy in Electrical Engineering and Computers

Abstract — Quality is a measure of how well a system or software performs based on its user's expectations. For mobile applications, quality aspects are important as well, if not even more important compared to desktop applications, since the multitude of available mobile applications enables a user to switch to another solution that fulfills the same purpose. This work investigates the applicability of established software quality models and depicts the most important quality characteristics for mHealth applications that were identified in expert interviews. It showed that "interoperability" is of paramount importance and denotes the system/software features to exchange data with other systems. First, use cases were identified and specified using a developed use case template structure. The first use case deals with the data acquisition using personal health devices in combination with smartphones, and the second use case describes the communication of health data from a mobile device to a health care provider using, standardized interfaces and document formats. These use cases were implemented as Android prototype applications and were validated against a set of criteria derived from different guidelines and specifications available for health data communication. Insights from interoperability challenges in the field of energy systems are provided, since experience has been gathered for conformance and interoperability testing that can be applied to health IT systems and mobile application, as well. Ongoing standardization and harmonization efforts are discussed on a technical and on a regulatory level. Interoperability is only one of the quality criteria that need to be addressed, but once data is exchanged using proprietary communication protocols and non-harmonized terminology, a further use of the data is aggravated,

independent of the fact if the data use is sooner or later.

Key Words: eHealth, mHealth, Quality, Telemonitoring, Communication Standards, Validation, Testing

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Many thanks to Stefan Sauermann, who, as a role model, has always inspired me with his exceptional knowledge in the various fields that are connected to the term *eHealth* he always managed to point out the relevance and the connections between the single areas. His experience with interoperability of health care systems acted as the giant's shoulder enabling me to participate in the world of standardization. Furthermore, I can consider myself very lucky to have got in touch with the colleagues and friends that I found at UTAD in Portugal. Especially João Pavão, Luis Pereira, Rute Bastardo, and Victor Costa for their hospitality and the efforts they took to introduce me to the Portuguese culture and making me feel very welcome every single time I visited this beautiful country.

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Glossary, Acronyms and Abbreviations

Glossary

App –short for Application

Downstream Data Exchange –Data exchange between a mobile phone and devices that are used in the context of eHealth as an external data source (e.g. blood pressure device) and are connected to the mobile device via short range transport channels

eHealth –use of IT technologies for health applications

mHealth –eHealth application for the mobile devices

Mobile Application –Applications that are supposed to run on a mobile device. Mobile applications are available on market platforms and can get installed by the mobile device's user

Mobile Device –Device that is wearable and is personalized by its (mostly) single user. These devices are smartphones, tablets, or wearables, where the latter

might have reduced capabilities to be personalized by the user in terms of installing applications

ANT –wireless technology for data communication in the field of sports- and wellness monitoring

ANT+ –profile based specification for ANT communication

Data at Rest –State of data when it is stored on the phone

Gazelle –Test framework developed and used by IHE for interoperability and conformance testing

IHE –Integrating the Healthcare Enterprise. A consortia promoting the use of already existing standards by profiling the identified standards to be applied for a certain use case. IHE provides test events for interoperability and conformance test.

LOINC –Logical Observation Identifiers Names and Codes, terminology that is used mainly - but not exclusively - for coding laboratory parameters

PCHAlliance –founded based on the Continua Health Alliance. Providing interface specification to communicate data from the patients' home towards an electronic health record system

SNOMET-CT –Systematized Nomenclature of Medicine - Clinical Terms; Taxonomy of clinical vocabulary

Upstream Data Exchange –Data exchange between a mobile phone and a remote service, where data is mainly sent from the phone to the service (e.g. sending vital data from the users phone to a health professional) via wide range transport channels

Wearables –short for wearable computers. Wearables are supposed to be worn on the body or mounted to clothing during usage

ZigBee –wireless technology introduced overcoming the shortcomings of classic Bluetooth regarding the energy consumption

List of Acronyms

Initials	Expanded
ASN.1	*Abstract Syntax Notation One*
API	*Application Programming Interface*
App	*Application*
BAN	*Body Area Network*
BER	*Basic Encoding Rules*
BT	*Bluetooth*
BLE	*Bluetooth Low Energy*
CDA	*Clinical Document Architecture*
CDG	*Continua Design Guidelines*
CMHAFF	*HL7 Consumer Mobile Health Application Functional Framework*
DEC	*Device Enterprise Communication*
DFDL	*Data Format Description Language*
EDR	*Enhanced Data Rate*
EHR	*Electronic Health Record*
GPS	*Global Positioning System*
HCP	*Healthcare Provider*
HDP	*Health Device Profile*
HIPAA	*Health Insurance Portability and Accountability Act*
IEC	*International Electrotechnical Commission*
IEEE	*Institute of Electrical and Electronics Engineers*
IHE	*Integrating the Healthcare Enterprise*
ISO	*International Standard Organization*
IT	*Information Technology*
LAN	*Local Area Network*

Initials	Expanded
MDER	*Medical Device Encoding Rules*
NHS	*National Health Service*
OID	*Object Identifier*
PAN	*Personal Area Network*
PCD	*Patient Care Device*
PCHAlliance	*Personal Connected Health Alliance*
PHD	*Personal Health Device*
RCAP	*Record Control Access Point*
SCADA	*Supervisory Control and Data Acquisition*
SIG	*Special Interest Group*
SOAP	*Simple Object Access Protocol*
TCP/IP	*Transmission Control Protocol / Internet Protocol*
UML	*Unified Modeling Language*
UUID	*Universally Unique Identifier*
WAN	*Wide Area Network*
WHO	*World Health Organization*
XML	*eXtensible Markup Language*

List of Abbreviations

Abbreviation	Significance
e.g.	exempli gratia, for example
et al.	et aliae, and the other people
etc.	et cetera, and so on

(continued on the next page)

(continued)

Abbreviations	**Significance**
i.e.	id est, that means

Introduction

Mobile devices like smartphones or tablets seem to be the most personalized digital devices that accompany us during our days. No matter if the users of the smartphones are digital natives or digital immigrants, more and more features of these devices are used in our daily lives. Staying in contact with family and friends, doing the banking, keeping track of schedules, proving identity (two way authentication), navigation, or accessing the Internet; for various reasons daily routines where changed due to technological advances and mobile phones. These devices changed our daily lives on multiple levels, since they enabled users to access information more or less all over the planet and be (virtually) available 24/7.

One can categorize the vast amount of devices on the market nowadays based on the platform they run. On the one hand, there is Apple, the pioneer that introduced smartphones in form of the iPhone for the broader public, and on the other hand, Google with its Android operating system. The strategies of these "big players" on the mobile market are very different since Apple provides and manages the whole ecosystem of hardware and software on its own. Google is mainly the provider of the operating system and its services. The needed hardware is developed and sold by different companies that bring their devices onto the market with a more or less

adapted version of Google's Android operating system. Nonetheless, both share the principle of a market platform for distributing mobile applications (apps) that users can install conveniently in order to fulfill their individual needs. Hence, one smartphone in use will differ from the next based on its personalizations, such as different wallpapers, the distribution of icons on the home screen, the applications installed on the device, and, last but not least, the device itself. Due to the success of smartphones, the next step was the introduction of tablets. Those new devices use the smartphone technology but offer larger screens that ease their use, but (often) lack - compared to smartphones - direct connection capabilities to mobile networks. Furthermore, they are at a disadvantage when it comes to size and weight. They run the same operating systems like smartphones and therefore also enable users to customize their tablets based on different applications downloaded from the marketplaces.

Recent numbers of the US market, presented by ComScore (2017) for the year 2017, state that 50% of all digital media is consumed using smartphone applications, and only 34% on the classical desktop computer. The remaining 16% are divided by tablet applications, tablet web, and smartphone web. In total, 87% of the time users spend with their devices is by using applications, and only 14% on mobile web. (ComScore, 2017)

Statista, Inc., presents on their webpage that with March 2017, Google's Play store hosted 2.8 million applications and Apple's App Store provided 2.2 million applications for download (Statista, 2017a). Statista also states that the number of mobile applications downloaded worldwide in 2016 reached almost 150 billions and Statista estimated approximately 200 billions and 350 billions in the years 2017 and 2021, respectively (Statista, 2017b).

The number of new applications that try to catch the users' attention and canvass to be used is increasing day by day and makes it difficult for users to choose between multiple different applications fulfilling the same, or very similar, demands. The majority of the applications available in the application stores can be purchased for free. Current numbers for the Google Play store show that almost 95% of the

offered applications are for free (Statista Ltd., 2018). But *for free* is not always *free free*, since developers and publishers of applications depend on revenues and earn money indirectly, either by placing advertisements in the free to use versions or by offering only a reduced set of features. For both cases, normally an upgrade to the *pro-version* will free the applications from ads and reveal the whole set of features. Guidelines on how to price an application, see for example the article *How to Price Your App: Free or Paid* by Ryan Chang (2014), describe that users are more and more unwilling to pay for an application, but by considering advertisements and in-app purchases the vendors can shift cash flows. Apart from the purpose of earning money directly with an application, whether by putting a price on the application, using advertisement, or providing in-app purchases, another means to *earn* money is by collecting large amounts of data from the user population. The utterance

> if you are not paying for it, you're not the customer; you're the product being sold,

which seems to date back to a post by a user called *blue_beetle* in an online forum back in 2010 (Blue_beetle, 2010) seems to illustrate exactly this idea. Making users aware that *there is no such thing as a free lunch* might enable them to reflect on what data they are willing to share and what *price* they are willing to pay for that. This circumstance will influence the experience a user will gather with a certain application and will result in the overall personal quality rating of the application. Article 13 of the European General Data Protection Regulation (GDPR) (European Union, 2016), which has been enforced since the 25$^{\text{th}}$ of May 2018, regulates - beside other items - that the *data subject* must be informed about what kind of personal data is collected, the purpose for processing these data and the legal basis to do so. Besides, Article 13 defining the responsibilities of the *controller* in cases when data is directly collected by the data subject, Article 14 continues to define the controllers' responsibilities when personal data is not directly acquired by the data subject but by third parties.

Especially Article 13 is of interest concerning telemonitoring programs including

applications that are run on the users'/patients' smartphones. Data describing the physical condition of a patient by measuring vital parameters, blood glucose levels, or psychological conditions by asking the patients to answer questionnaires are considered sensitive information and are addressed as personal data in the context of the GDPR. The patient, as the data owner, is entitled to administrate the collected data, even if he or she takes part in a professional telemonitoring program. These facts are addressed, for example, in the recent HL7 (Health Level 7) technical report describing a functional framework for consumer mobile health applications released as a draft in January 2018 (Health Level Seven International, 2018).

Frey et al. (2017) empirically investigated if the stages of life of users can be predicted based on the applications they have installed. Part of their work was to collect information concerning installed applications from the 1425 participants who took part in the survey. One finding was that the average user decided to have 44 applications installed. These applications can be assigned to different categories, like games, business, education, or travel. Another category on the markets is *health & fitness*. Health and fitness applications encompass a wide area of health and fitness topics, from tracking and sharing fitness data, or keeping a diary with vital parameters or nutrition, to tele-medical solutions.

The Greenpaper on mobile health published by the European Commision (2014) uses the definition for mHealth from the World Health Organization (2011). They state that mHealth covers "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices", and extends this definition by including lifestyle and wellbeing applications.

The World Health Organization further stresses that mHealth implements the use of mobile data services, voice and text services, Bluetooth technologies, as well as data gained from a mobile phone's GPS receiver. This WHO report gives an overview of the implemented and to-be-implemented mHealth initiatives on a global scale (based on WHO countries). The most often reported applications include health call centers and helplines, emergency telephone services, and applications for emergencies and

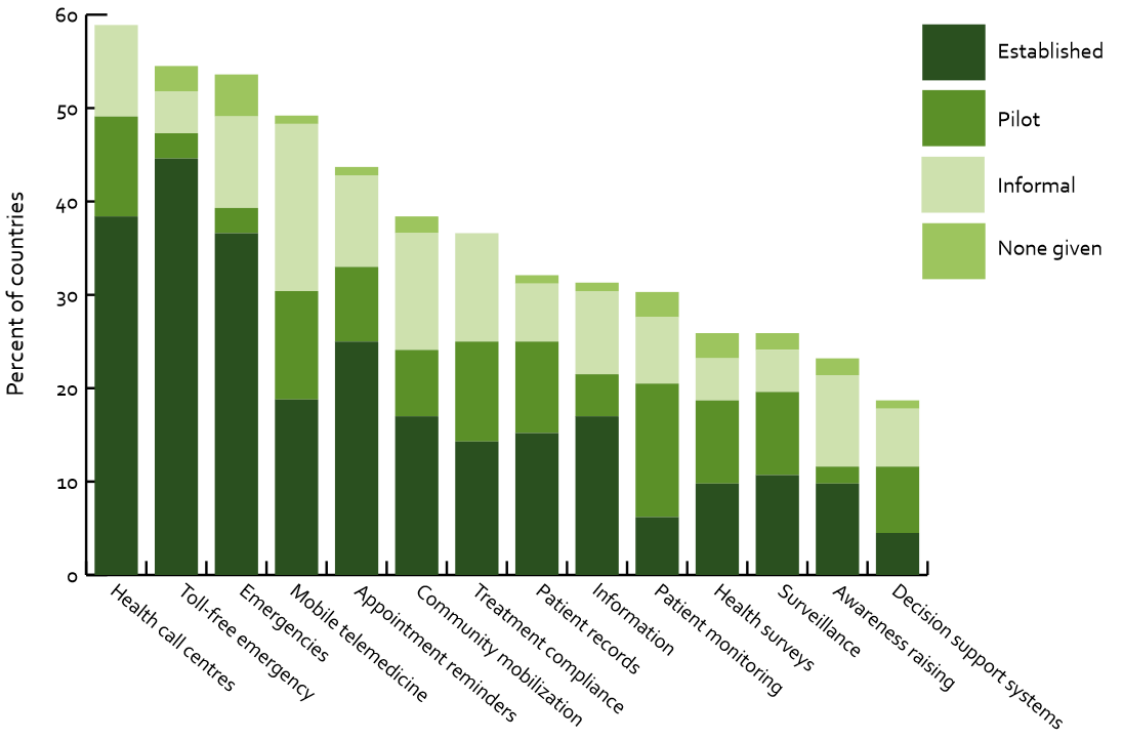


Figure 1.1 – mHealth Initiatives, globally (taken from World Health Organization (2011))

mobile telemedicine (Figure 1.1). (World Health Organization, 2011)

Facilitation of mHealth applications can a be a tool for detecting diseases, especially chronic diseases, at an early stage, since patients are stronger engaged in their own health by assessing conditions using medical devices at home on a regular basis and are enabled by mobile technologies to share the gathered information with health professionals easily. The patient will likely develop a healthy lifestyle if feedback from health professionals arrive on a regular basis and fast. Extrapolated to a larger population, it can be expected that a healthier society has positive effects on the overall financial cost of the stressed healthcare systems within the European member countries. (European Commision, 2014)

A report on "Patient Adoption of mHealth" by the IMS Institute for Healthcare Informatics (2015) summarizes that in the year 2015, 50% of mHealth applications offered only limited functionality, as they only informed, instructed, recorded, or

displayed health related information and did not offer additional features. Hence, their role in healthcare was rather limited. An interaction or form of communication with healthcare providers is not possible with such applications. Since health professionals are not involved in the design of this kind of applications, plenty of applications are available to be used by the end-users. These users have no guidance in the decision which application might be best suited for them. Hence, the end-users can only rely on ratings available in the application store (or elsewhere on the Internet), and they might have to try multiple application before they find an appropriate application. This circumstance unveils the fact that "mechanisms to rate, certify and select apps" are needed. The report from IMS continues by stating that 10% of the investigated mHealth applications implement the possibility to connect to an external sensor or device. While most of these applications can be categorized as fitness applications, the number of applications that can connect to medical devices, e.g. blood pressure monitor devices, is rising. Consumers are interested in connecting their phones with external sensory devices and they embrace this feature fast. Healthcare providers or organizations are not that fast to include these technologies in their care paths. (IMS Institute for Healthcare Informatics, 2015)

A common issue of software development and usage, including mobile applications, is a certain concern about quality. Multiple definitions for quality exist in literature, stating a common concept, but it might still depend on different points of view. Quality can be a measure for (not exclusively) the stability, the performance, or the usability of a software system. It might also be a measure representing security, safety or privacy issues. However, maybe simplified, quality can describe the extent to which a software solution suits the needs of the users. Quality is only achievable if the users' needs are known during the development phases of the software product. For standard software, or off-the-shelf software, programmers have an idea about the intended customers, but might not be able to know specific needs of all the addressed customers in detail. Since this potential group is very heterogeneous, and the distribution via application markets reaches all mobile users to the same extent, it is difficult to satisfy the requirements/demands of all users equally.

1.1 Motivation

In our daily routine, digital mobile devices and software solutions are accompanying components and the increasing number of mobile and affordable devices cement their importance in our lives. New fields of applications have been introduced in order to assist a user in various tasks. Especially in the area of mobile applications, single software solutions collect enormous amounts of data that a single user - with or without knowing - generates. A lot of these data are of sensitive character (Gilbert et al., 2011), and the use of these data is mostly not obvious to the user (McAllister, 2014). The gathered information is mainly used for commercial purposes and user profiling, but could also be used for open data applications. Apart from the implementation based aspects of modern applications, social and cognitive factors also play a more and more important role.

Mobile applications are mainly distributed via the device specific online application stores. Developers can sign up for a distribution license and can offer their software products to users globally (Holzer and Ondrus, 2011). This easy to use form of distribution channel - almost without any entry barriers - has led to an increasing number of companies and implementers offering their products. Nonetheless, in many cases, the quality of new implementations cannot keep up with the increasing speed and shortened time periods of the software development cycle. A lack of a classification system (Nickerson et al., 2007), missing quality criteria and missing functional and especially non-functional requirements (like data security, data privacy and usability) make it difficult to compare and validate these applications. These problems become tangible whenever a person, a company or a public body has the task to choose, to select or to recommend applications.

1.2 Structure of this Work

In the Chapter *Background*, this work introduces different scenarios where mHealth applications are used and introduces different types of applications, based on their capabilities to connect and interact with external devices and/or server applications. This chapter continues with different aspects of requirement engineering, since the set of features to be implemented in a mobile application needs to fit the requirements that are stated by the users and/or can be derived from regulatory frameworks. Based on requirements and the users' needs, quality criteria can be derived and different software quality models are described. Relevant stakeholders, like HL7, for standardizing communication interfaces are presented and their relevance is discussed. To clarify the field of interoperability, interoperability challenges that effect the communication of data from an external sensor device (e.g. *Personal Health Device* (PHD)) to the mobile application, and interoperability challenges that effect the communication of data from the mobile application to server based systems are described separately. The first, the communication with external sensor devices, deals with the availability of wireless interfaces and communication standards, where the latter, the communication with remote services, deals with communication protocols and formats following HL7 specifications. Furthermore, profiles from *Integrating the Healthcare Enterprise* (IHE) that are relevant for mHealth scenarios are described. The chapter ends with security requirements and disease management programs where the implemented prototype application described in this work, can be applied.

The Chapter *Materials and Methods* defines the approach that was used to validate the applicability of quality models for mHealth applications and give a prioritization of the quality characteristics and quality sub-characteristics introduced in the quality models. In addition, a *user/mobile-application engagement model* from a user's viewpoint is introduced. Based on existing use case methodologies, a condensed use case template is developed. This work was continued by identifying relevant frameworks that target to provide guidance on how to implement the

requirements stated in the use cases. Conditions and techniques are stated for the development of the prototype mHealth applications and a criteria catalog is defined for validation purposes. This criteria catalog considers the defined use cases and the frameworks and guidelines that were identified. This chapter ends with the transfer of gained knowledge from the medical IT domain and introduces synergistic aspects of interoperability in the field of energy.

In the *Results* section, the outcomes of the conducted expert reviews for validating the applicability of quality models and quality characteristics for mHealth applications are presented. This survey also contains the validation of the user/mobile-application engagement model. Using the introduced use case template, two use cases in the field of mHealth are presented, and the prototype implementation for these use cases is described. The prototypes are validated using the defined set of criteria and the outcome of this validation is stated in this work. Furthermore, the outcomes of an Android application simulating PHDs is addressed. Finally, experiences from interoperability testing in the field of energy, using IHE's testing framework *Gazelle* are reflected.

The *Discussion* interprets the presented results and provides the big picture and the strategies to develop mHealth applications. Insights from the work of standardization of CDA (Clinical Document Architecture) documents are provided and the connections to other relevant fields of standardization and harmonization are presented.

1.3 Genesis of this Work

The results presented in this work reflect the research activities of the author from the last years. Parts of the results were published and presented at national and international scientific conferences. The following list states only the publications with lead authorship of the author of this thesis:

- Frohner, M., Urbauer, P., Forjan, M., Pohn, B., Gerbovics, F., Sauermann,

S., and Mense, A. (2012). Development of an android app in compliance with the continua health alliance design guidelines for medical device connectivity in mhealth. *Biomedizinische Technik*, 57(SUPPL. 1 TRACK-N).

- Frohner, M., Urbauer, P., and Sauermann, S. (2017). Bluetooth Low Energy Peripheral Android Health App for Educational and Interoperability Testing Purposes. *Studies in health technology and informatics*, 236:336-342.

- Frohner, M., Meyer, M., Donsa, K., Urbauer, P., David, V., and Sauermann, S. (2018b). Telemonitoring of Blood Glucose - A Prototype Android Application Enhancing the Patient / Health Professional Experience Using Health IT Communication Standards. *In DSAI 2018: 8th International Conference on Software Development and Technologies for Enhancing Accessibility and Fighting Info-exclusion.* in Press.

- Frohner, M., Gottschalk, M., Franzl, G., Pasteka, R., Uslar, M., and Sauermann, S. (2018a). Smart grid interoperability profiles development. *2017 IEEE International Conference on Smart Grid Communications, SmartGridComm 2017*, 2018-Januar(October):189-194.

Besides this scientific publications the author of this thesis was leading author for the following HL7 Austria standard documents, written for the Austrian electronic health record system ELGA and the Austrian federal ministry of health and women:

- ELGA GmbH (2017a). ELGA CDA Implementierungsleitfaden - HL7 Implementation Guide for CDA (R) R2: Laborbefund - Version 2.06.2 - 31.01.2017

  translates to: ELGA CDA Implementation Guide for Laboratory Reports

- BMGF (2017). Implementierungsleitfaden Meldung an das Epidemiologische Meldesystem (EMS) - Labor- und Arztmeldung - Version 2.00

  translates to: Federal Ministry of Health and Women. Implementation Guide for Reporting to the Epidemiological Vigilance System

Currently, normative specifications are developed for the *Pensionsversicherung* (public pension insurance), Statistic Austria, and the Austrian Medical Chamber and will be publicly released on a Wiki page.

2 Background

This work investigates different quality models for software and system development and their applicability for mHealth applications. Based on a survey showing the relevance of different quality characteristics stated in the quality models, especially the need for interoperability capabilities of systems and software, quality criteria are defined for mHealth applications. These criteria address aspects of use, as well as existing frameworks and guidelines for standardized communication interfaces. Prototype implementations are introduced in this work based on a developed use case template and two identified and specified use cases in the field of data acquisition using personal healthcare devices, and the standardized communication of clinical documents. Software test methodologies for conformance and interoperability tests are described, implemented in a prototype application simulating personal healthcare devices, and a report on ongoing test efforts in the different, but related, field of interoperability in energy systems are introduced. The work also develops a user/mobile-application engagement model, describing the user engagement with a certain application. Hence, this chapter provides an insight into ongoing efforts of the above mentioned topics that are covered within this work.

2.1 Quality Requirements for Software Development

Quality, in the context of software development, is a concept to describe how well a software product fulfills the demanded requirements. These requirements can be stated by the customer, be established based on a business context, they can be derived from statutory provisions, they can be deducted from standards that are in place for certain fields of application, or existing guidelines and best practices. Different quality models are available that define various dimensions of quality consisting of single quality characteristics. Some of the characteristics can be used to describe if the software product accomplishes the pre-defined tasks (*functional requirements*) where other characteristics are used to describe how well the task is performed (*non-functional requirements*). The different flavors of characteristics demand different approaches how to validate to which degree the requirements are fulfilled. Hence, there is no common methodology to test the quality of a product in terms of the system's performance, its security measures, or its usability. In addition, the perspective of how the system is evaluated can change from a more technological perspective to a perspective of an end-user. Where the first is dealing with quality characteristics and properties that are assigned to the software system itself, the latter deals with characteristics that the user of the system perceives.

The ISO/IEC standard 9126-1, *Information technology - Software product quality*, define the "Quality Model" in its part 1. This model is depicted in Figure 2.1 and it shows the relevant quality characteristics for *external and internal quality*. Apart from the other characteristics stated in this figure, the functionality of the software product is of major importance, since a system might be very efficient and very stable, but if the intended purpose of the software is not fulfilled, the system cannot be used. The standard describes functionality as follows:

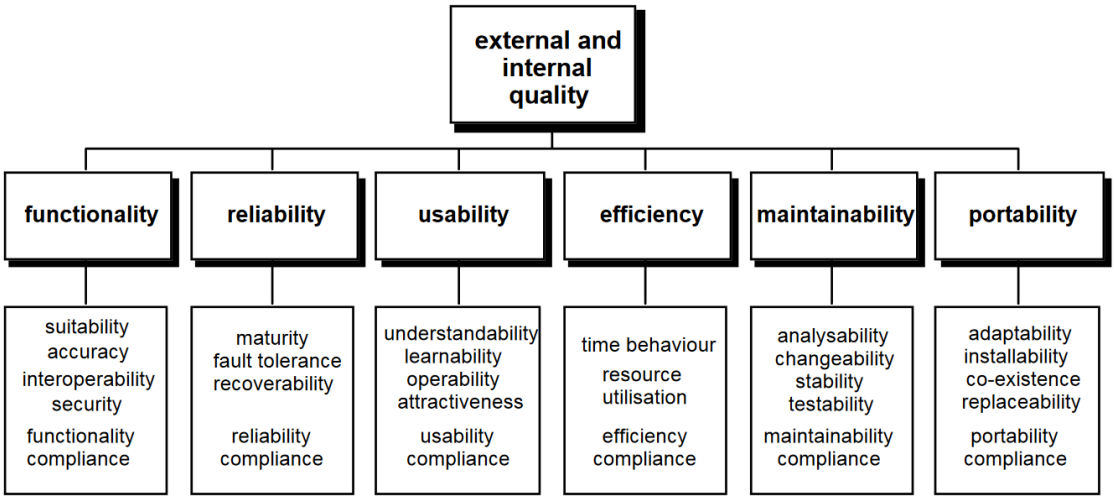


Figure 2.1 – External and internal quality criteria of software according to ISO 9126 (2000)

> This characteristic is concerned with what the software does to fulfil needs, whereas the other characteristics are mainly concerned with when and how it fulfils needs. (ISO 9126, 2000)

Based on this basic requirement of *functionality*, the subcharacteristics *interoperability* and *security* seem to be of major importance, since they are not directly connected to solving a specific task. Their purpose is to ensure connection features with other software/systems and to ensure data privacy and security.

Bøegh (2008) describes that for software requirement engineering and software quality requirements, an isolated view on the upcoming software product is not sufficient. A broader approach is necessary to take the whole system into consideration, which combines the computer system itself, including its hardware, its software and data, mechanical parts, and human processes. Each of the stated parts of this holistic approach can be reflected in a quality model and needs to be considered for a software product.

There are multiple definitions for the term *quality* in place. Prominent definitions are available from standard developing organizations, one example being from the ISO/IEC/IEEE system and software engineering vocabulary (ISO/IEC/IEEE

24765, 2010) referencing to other standards like IEEE 829, a standard for software and system test documentation (IEEE Computer Society, 2008) where quality is defined as "the degree to which a system, component, or process meets specified requirements" (ISO/IEC/IEEE 24765, 2010) or "the degree to which a system, component, or process meets customer or user needs or expectations" (IEEE Computer Society, 2008). The first definition clearly states that validation can result in a metric, showing to which extend quality has been achieved. Based on a set of specific requirements, someone is able to check what criteria have been achieved and where quality is lacking. The second definition is more critical since quality is defined partially on "soft"-criteria. For a customized software solution, the chance to clarify the specific needs with the customers and to discuss the targeted solutions is given, however, it is not an easy task. For off-the-shelf solutions targeting a broad cohort, the collection of criteria to satisfy the need and expectations is more difficult. Each individual of this cohort is going to grade the quality of the application when it is used in the individuals' specific context. Therefore, a more detailed look at this type of quality has been defined in ISO/IEC 9126-1 (ISO 9126, 2000) and it has now been taken over in the newer ISO/IEC 25010 standard (ISO/IEC 25010, 2011).

These standards take existing definitions of quality into consideration (focused on product quality) and define a more complete quality model. This quality model introduces (1) internal and (2) external quality attributes, and (3) quality in use attributes. Internal quality attributes address techniques and approaches for software, or document validation and might consider internal instructions for e.g. reusability. External quality attributes summarize requirements the software's capabilities to satisfy needs when the system is used under specified conditions. The concept of quality in use stresses the characteristics of the software when used by the end-users within their environment and in the users' specific context. ISO/IEC 25010 extends the former model from ISO/IEC 9126-1 so that quality in use is no longer a product but a system quality parameter. It includes additional sub-characteristics for satisfaction and "freedom from risk" (formerly called "safety") and introduces the "context coverage" characteristic. Those three quality characterizations are dependent on each other, i.e. internal quality attributes

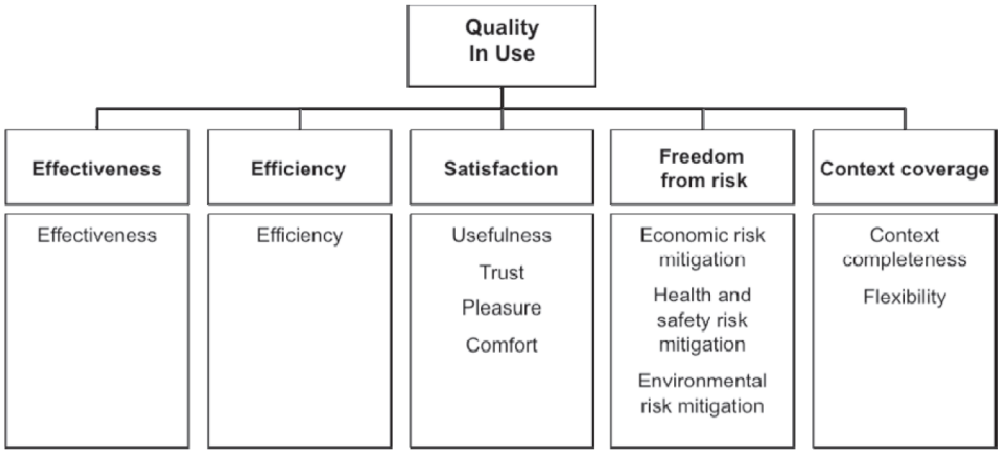


Figure 2.2 – Quality in use: this model represents the quality characteristics of a product from a user's perspective (figure taken from ISO/IEC 25010 (2011))

influence the external quality attributes and those influence the quality in use attributes. Internal and external quality attributes are modeled based on classical functional (suitability, accuracy, interoperability, security, functional compliance) and non-functional (reliability, usability, efficiency, maintainability, and portability) characterizations of a product.

The quality in use model, as depicted in Figure 2.2, shows the quality characteristics and sub-characteristics that are relevant from an end-user's perspective.

Whenever an application meets the quality in use criteria for a certain user or user group, the chances of getting better ratings or reviews on the application market rise and result in "ratings and reviews are benchmarks of app quality" (Google, 2018). Based on an application's ranking and reviews, the emotional perception of potential users is influenced (Huang and Korfiatis, 2015). Kim et al. (2013) write about a model describing the connection between the users' engagement in mobile applications, the perceived value, the users' satisfaction, and the continued engagement intention of the users. These findings have been used to formulate the hypothesis that "increased engagement has a positive impact on a consumer's continued intention to use mobile applications" and supported this by a survey.

Stressing the different views on quality (internal, external and in use) once more, it can be stated that the first two are more attached to the development phases of an application, i.e. criteria for reaching a certain level of internal and external quality can be reached before the application is brought to a market. The latter - the quality in use - is perceived by the users - therefore after the launch of a product - and it reflects the potential difference between the user requirements engineering phase and the actual user behavior and the user perception of the application. Poor quality in use might be the result of the gap between the user's expectations (pre-install or pre-use of the application) and the user's experiences with the application (after installing or after using it). One reason for this variance are functional capabilities that do not work the way the user had expected. Furthermore, a mismatch between certain expectations and perceptions is likely to occur when the user is not able to find or interpret the described features of the application and finds them missing during usage. The latter will result in the fact that the user might consider not to use the application any longer and substitute this application for another.

Vagrani et al. describe the "smaller life cycle" of applications and developed and tested a model stating the reasons for uninstalling applications. They cluster the different reasons for the smaller application life cycle into four categories; (1) Unsupported Telecom Infrastructure, (2) Post Adoption Performance, (3) Mobile Equipment Hardware Concerns/issues, and (4) Data Privacy and Security Issues. They found that high data consumption, higher GPS usage, and higher resource consumption increase the possibility of uninstalling an application. Furthermore, as data security concerns, where they stress that the latter "comes up as a new significant factor". (Vagrani et al., 2017)

A report from the British Standard Institution (BSI), named *Health and wellness apps - Quality criteria across the life cycle - Code of practice (PAS 277:2015)* (BSI, 2015), starts with highlighting the term *Fitness for purpose*, meaning that an application should meet all technical requirements and quality criteria in order to be accepted by the involved parties (users and application publisher). Moreover, fitness for purpose is aligned with the intended use that should be considered during all

project phases and within the application's documentation. The report continues with the definition of the application life cycle from the developer's perspective and introduces the quality criteria based on ISO/IEC 25010. This report maps identified criteria for health and wellness application to the *Health on the Net (HoN)* quality criteria that have been introduced for medical and health websites. The HoN foundation state as their mission

> to promote the effective and reliable use of the new technologies for telemedicine in healthcare around the world (Health on the Net Foundation, 2018)

and provides a certification program for health websites. This certification includes an assessment of the eight *HONcode principles*, which include *Authoritative, Complementary, Privacy, Attribution, Justifiability, Transparency, Financial disclosure* and *Advertising policy* principles. (Health on the Net Foundation, 2018)

Another document dealing with mobile applications and their quality aspects and requirements was drafted by HL7. The *HL7 Consumer Mobile Health Application Functional Framework, Release 1* (CMHAFF) (Health Level Seven International, 2018) was released by HL7 in the beginning of the year 2018 and is currently available as a standard for trial use and is, at the time being, balloted by the community. The intended audience for this document are mainly developers and vendors of mobile health applications. This document should provide a guideline for the development and the placement on the market for mobile health applications that are not intended to be used and operated by health professionals. Saying that, it also excludes certain clinical and health application functionalities as well as "general" device security requirements and infrastructure requirements. It should be a guide for general requirements that can be found in mobile health applications on the consumer market and enables the audience to further start profiling. Based on a *mobile application life cycle* (see Figure 2.3) the single corresponding chapters provide recommendations concerning the implementation.

Further clustering within this HL7 report is achieved by three different use cases.

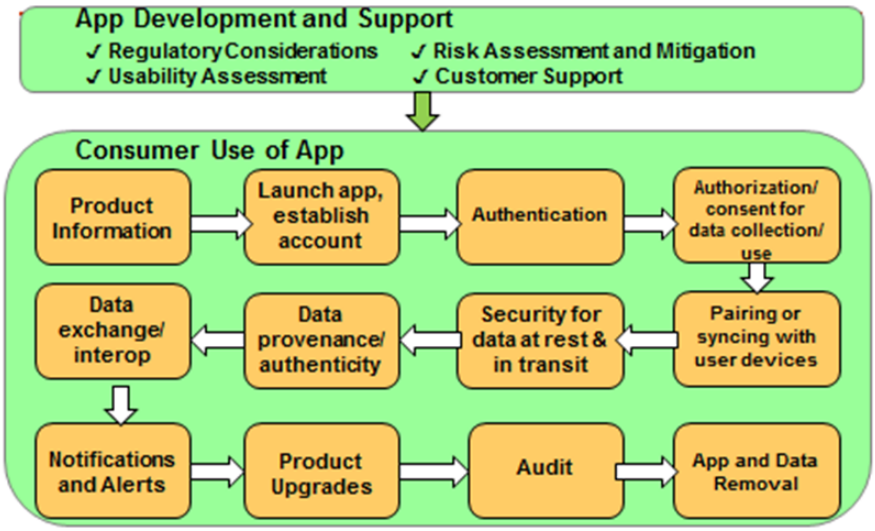


Figure 2.3 – Application Life Cycle stated by HL7 Consumer Mobile Health Application Functional Framework, taken from Health Level Seven International (2018)

The first deals with a standalone application in the context of wellbeing, e.g. an application recording the walked distances using the GPS sensors of mobile phones. The second use case describes a wellness application connected with a back-end service that hosts information. A weight management application can be considered as an example. The last use case describes a disease management application, characterized by a connection to an electronic health record system. Based on these use cases, different categorizations are further depicted and shown in Table 2.1. The matrix that is described in this table shows on the one hand that different categories of mHealth applications can be considered: wellness applications or medical applications. On the other hand, the matrix discusses topics of interoperability (data collection and data transmission) and the possibility to use either unregulated or regulated (medical) devices. Finally, this table discusses security and safety aspects by stating the importance of data integrity for mobile applications that are part of medical scenarios. As an example of legal requirements that need to be considered for medical devices, the matrix contains references to the *Health Insurance Portability and Accountability Act* (HIPAA) (Pub. L. No. 104-191, 1996). This United States act defines privacy and security regulations for medical

Table 2.1 – Categorization of the Use Cases stated in HL7 Consumer Mobile Health Application Functional Framework, taken from Health Level Seven International (2018).

	Simple	Device Integrated	EHR Integrated
Medical Device App Categorization	wellness	wellness or medical	medical
Device Data Collection	none	unregulated or regulated device	regulated device
PHI Data Collection	smartphone	smartphone/PHR	cloud/EHR
Data transmission by App	none	device-app-PHR	device-app-cloud-EHR
Importance of Data Integrity	low	mid	high
(USA) HIPAA covered?	no	no, only if white-labeled	yes

information exchange and management. Concerning use cases where devices (PHDs) are integrated to communicate with mobile devices, HIPAA provisions must only be considered if the product is provided by a HIPAA regulated organization (even if the product is not distributed under the organization's name but as a white-labeled product).

2.2 Software Engineering Requirements Methodologies

The first step in a product life cycle is the definition and clarification of the needed functions that the customer states. The artifacts that arise from this phase are the basis for further development. Both parties need to ensure that the desired goal is very clear from the beginning of the project. Abran and Moore (2004) describe different topics that are affected and included in the overall term *Software Requirement*, besides the software requirement fundamentals and the process itself. Those are:

- Requirements Elicitation: defining the origin of the software requirements and how those can be collected by the software engineer
- Requirements Analysis: investigation of the collected requirements for conflicts between the individual requirements and how they can be solved, how the requirements are reflected by the future environment, and the derivation of software requirements based on the system requirements
- Requirements Specification: the generation of a document stating the requirements that can be used for review or evaluation purposes
- Requirement Validation: the requirements may be reviewed to ensure that their specification is understood and conforms to standards used in the company

ISO/IEC/IEEE 29148 (ISO/IEC/IEEE 29148, 2011), the international standard for life cycle processes of system and software engineering, defines *requirements engineering* as

> interdisciplinary function that mediates between the domains of the acquirer and supplier to establish and maintain the requirements to be met by the system, software or service of interest.

This standard then describes requirement engineering as an iterative process where the suppliers' requirement definition process, the requirements analysis process, and the architectural design process all include feedback loops. The overall process is stated to be recursive, i.e. outcomes from one process act as the input for the next, more detailed, process.

The different levels of abstraction - from requirement engineering from a system perspective to requirement engineering on a software level - are also depicted by the *Architecture Development Method* (ADM) from the *The Open Group Architecture Framework* (TOGAF), but with a higher focus on management layers (The Open

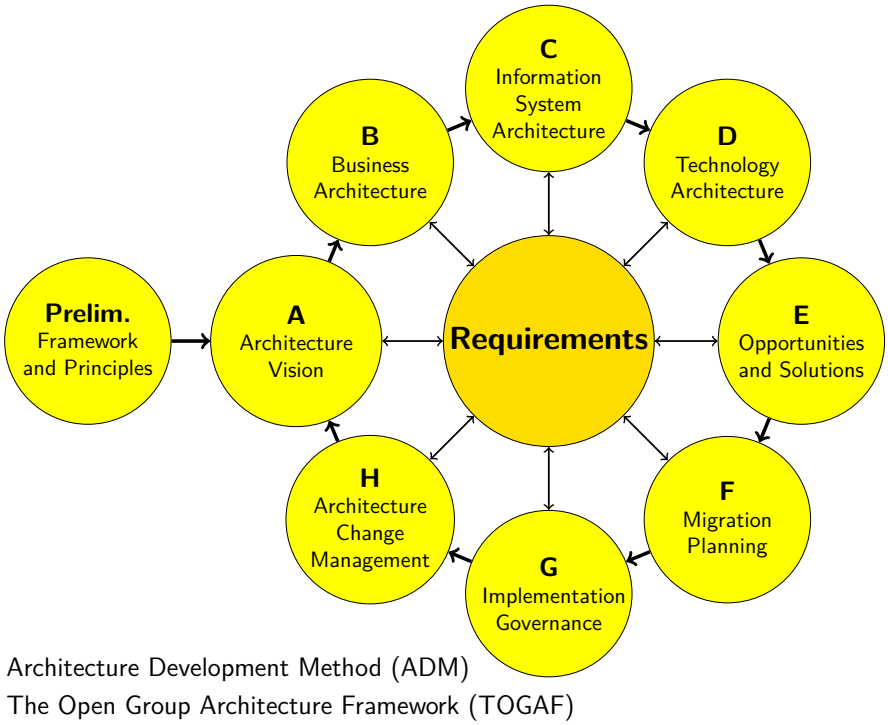


Figure 2.4 – Architecture Development Method (ADM) defined by The Open Group Architecture Framework (adapted and based on (The Open Group, 2009))

Group, 2009). The process is described in eight subprocesses that depend on each other and are all part of the overall requirements management process (Figure 2.4).

Defining the requirements is dependent on the users' and/or acquirers' needs. In order to formulate the needs, the definition of the intended use case or use cases is desirable. Based on these use cases, the first iterative requirements engineering processes can start to provide a formal representation of the use cases. The IEC standard 62559-2 (IEC 62559, 2015) specifies templates for use cases, actors and requirements lists.

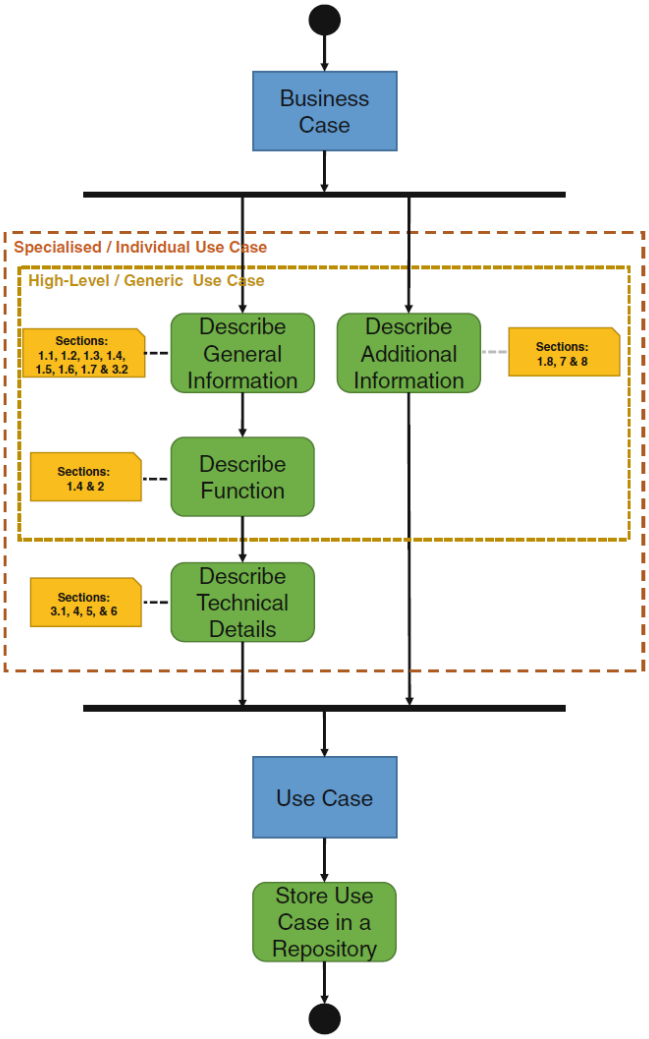


Figure 2.5 – Use case methodology according to Gottschalk et al. (2017). The reference to the sections (orange boxes) are based on the IEC 62559-2 standard (IEC 62559, 2015)

Gottschalk et al. (2017) explain how the IEC 62559-2 standard can be applied and included in the conceptional approach of IHE for profile definitions. This work shows how the generic use case methodology can be implemented and aligned with already existing processes and methodologies used in different fields. Furthermore, it elaborates the available templates from the IEC standard. The whole process of the use case methodology is depicted in Figure 2.5.

2.3 Interoperability Challenges of Software Systems in eHealth

According to Healthcare Information and Management Systems Society (2013) (HIMSS), interoperability is the capability of healthcare IT systems and software applications to exchange and share information with each other. HIMSS stresses that besides the exchange and sharing of information, the receiver should be enabled to *use* the data. Especially this point is of most importance whenever data should be interpreted, managed and analyzed automatically using IT systems. This society takes over the definition of three different levels of interoperability that are stated in a report on *Uniform Data Standards for Patient Medical Records Information* by the National Committee on Vital and Health Statistics (NCVHS) (2000). These three levels are:

- Basic: meaning that information can be exchanged between two computer based systems but the receiver might not be able to interpret the data.
- Functional: meaning that information that is exchanged can be interpreted by the receiving system at least on a data field level, i.e. the syntax of the message needs to be defined. However, the receiving system might not be able to interpret the information that can be found in the single data fields.
- Semantic: meaning that the receiver is able to interpret the received information. This requires the use of a harmonized set of terminologies both communication partner are able to understand. Hence, further processing of the receiver data can be achieved.

Beside these levels of interoperability, other definitions of levels are available and extend these levels. These extensions might include interoperability of processes, interoperability on an organizational level, or aspects of legal interoperability.

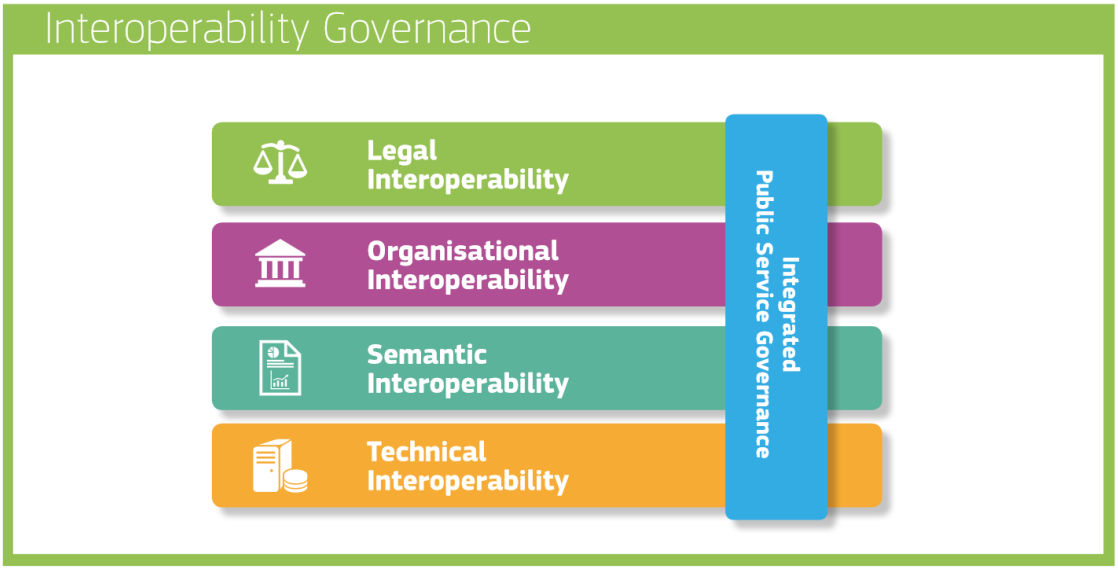


Figure 2.6 – Interoperability model of the European Interoperability Framework. Taken from European Union (2017)

2.3.1 European Interoperability Framework

Interoperability of systems is also one challenge that is recognized and addressed by the European Union. The European Interoperability Framework (EIF) (European Union, 2017) defines interoperability as the ability of organizations to "interact towards mutually beneficial goals". This includes the sharing of data using IT systems. This definition suggests that EIF is not only focusing on technical challenges but approaches the issue of interoperability on a more holistic level. EIF is not addressing the healthcare sector specifically but describes the mean to exchange information between public administration bodies. Figure 2.6 depicts the different levels of interoperability as stated by the EIF. The first two align with the three levels stated by HIMSS, being *Technical Interoperability* and *Semantic Interoperability*, and the last two address issues on *Organisational Interoperability* and *Legal Interoperability*.

EIF tries to overcome administrative burdens that are the results of the historical development of isolated systems that are used by the single member countries.

Interoperability is an enabling technology enabling European member countries to exchange information for the sake of the citizens. The report presents a set of common models, recommendations, and principles in order to contribute to a digital single market. The 47 recommendations are assigned to the 12 principles. These principles cover topics from Subsidiarity and proportionality, Reusability, Security and Privacy, to Assessment of Effectiveness and Efficiency. In the context of this work, recommendation number 21 is of specific interest. This recommendation state:

> Put in place processes to select relevant standards and specifications, evaluate them, monitor their implementation, check compliance and test their interoperability. (European Union, 2017)

It has been recognized by the European Commission that interoperability is a basic requirement, also for public administration purposes within the member countries. EIF is used by the *European Interoperability Architecture* (EIA) where single building blocks are defined and can be reused for multiple purposes. Both of these efforts are part of the *Interoperability solutions for public administrations, businesses and citizens* (ISA^2) (European Commission, 2018).

In the world of medical IT, organizations are already in place that use methodologies which are aligned with this recommendation 21. Organizations like *Integrating the Healthcare Enterprise* (IHE) and the *Personal Connected Health Alliance* (PCHAlliance) promote the use of standardized interfaces to be used for exchanging health data. Both parties identify applicable communication standards, specify those standards in terms of profiling, provide specifications that are publically available, and provide software test tools to validate the conformity of tested software systems.

2.3.2 Organizations Addressing Interoperability Challenges in Medical IT Systems

In architectural designs, intended to bring the different sources of information together and linking the different software solutions of the systems' stakeholders, interoperability capabilities of the systems involved become a crucial factor. Whenever data is needed to be shared between IT based systems, the implemented interfaces need to be designed based on prior defined specification. These specifications are described in communication standards, but often lack very restricted requirements in order to satisfy the involved parties with a certain level of flexibility. In terms of interoperability, this flexibility has contra-productive effects, since the solutions of different vendors might implement the requirements stated in the standards differently. Hence, the intended information exchange is no longer possible, although all vendors state that they have implemented their software in accordance with the standard.

This mismatch of implementations was observed in the field of medical IT, where the first implementations of radiology systems claim to implement the *Digital Imaging and Communications in Medicine* (DICOM) standards from The Association of Electrical Equipment and Medical Imaging Manufacturers (2018). Based on these experiences, the *Integrating the Healthcare Enterprise* (IHE) (IHE International Inc., 2018c) initiative was founded.

Integrating the Healthcare Enterprise (IHE)

Integrating the Healthcare Enterprise promotes the use of existing communication standards to ease the orchestration of decentralized services to achieve a common goal: sharing medical information. Based on single use cases, the IHE develops *integration profiles* that specify how the use case's demands can be solved technically. Profiles are connected to a specific medical domain (e.g. cardiology, pathology, laboratory medicine, etc.) or to overarching domains, like the IT infrastructure.

For each domain, IHE defined technical frameworks where profiles and underlying use cases can be found. The technical frameworks came in different volumes with a continuously rising level of technical detail specification. Volume I documents introduce the profiles, the needed software entities involved (IHE actors) and their interaction capabilities in form of IHE transactions. Volume II specifies transactions, i.e. which communication standards need to be implemented and further restrictions based on the standard. An example of a profile that is relevant within this work tries to specify how measured parameters can be communicated from a device to an enterprise. This *Patient Care Device* profile (IHE International, 2015) solves the use case when data should be transmitted from a device that is located outside the boundaries of the healthcare facility. The IHE actor on the side of the data source can be implemented on a smartphone or tablet.

When it comes to professional health IT systems, IHE is the leading organization for addressing and solving interoperability issues. Concerning telemonitoring issues, another organization, beside IHE is available that also has the intention of promoting already existing standards, and not defining new ones: the Personal Connected Health Alliance (2018d) (PCHAlliance).

Personal Connected Health Alliance (PCHAlliance)

The *Personal Connected Health Alliance*, formerly known as Continua Health Alliance, is an organization that introduces *Continua Design Guidelines* (CDG) for software implementations focusing on interoperability. The design guidelines define the Personal Healthcare Device (PHD) interface, for the communication of data from the PHD to IT health infrastructure (Personal Connected Health Alliance, 2016). PCHAlliance relies on the *Device Enterprise Communication* (DEC) profile from IHE. Therefore it is not a competitor of IHE, but adds to their specification and focuses on "the first mile" of the data to be transmitted. Figure 2.7 shows the communication steps and the interfaces of the CDG. This steps describe how health data can be communicated from a PHD (the left side of the architecture shown in Figure 2.7) to an *Healthcare Information Service* (depicted on the right side of

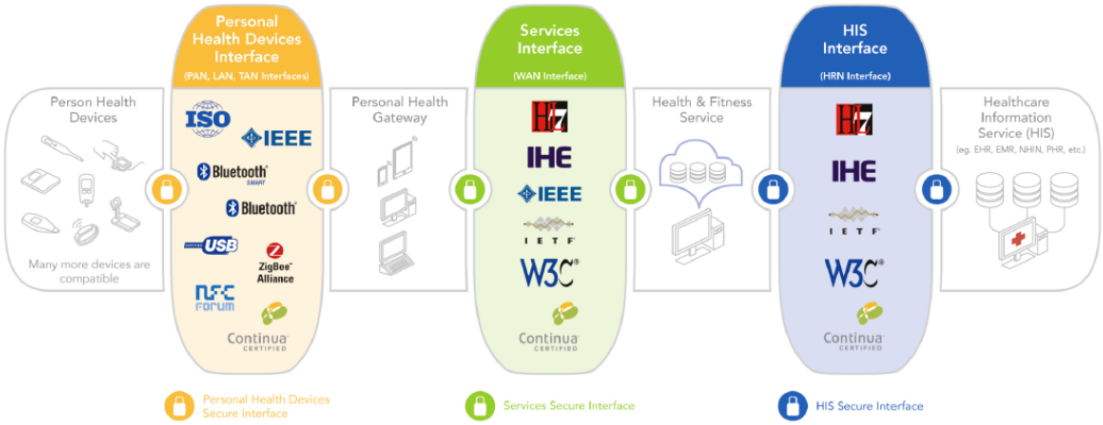


Figure 2.7 – High level architecture as stated by the Personal Connected Health Alliance (2017c)

the architecture shown in Figure 2.7). The process of standardized communication defines the

- *Personal Health Device Interface* between the PHD and a *Personal Health Gateway* (e.g. the mobile device of the patient/person), the
- *Service Interface* between the Personal Health Gateway and a *Health & Fitness Service* (e.g. a telecare provider), and the
- *HIS Interface* between the Health & Fitness Service and a *Healthcare Information Service (HIS)* (e.g. an electronic health record system).

Depending on the use case to be implemented the needed interfaces can be selected based on the design guidelines.

2.3.3 Testing and Certification

In the year 1982 Adrion et al. (1982) discussed how software quality can be improved using testing, validation and verification methods throughout the whole software development cycle. This paper contains the definitions for the three terms used and state that testing is

> the examination of the behavior of a program by executing the program on sample data sets.

Nowadays this term is further clustered along different axis. It can be distinguished, among other things, between *static* and *dynamic* software testing, where the first is conducted without executing the software, e.g. code analysis, analysis of (requirement) documents. The latter is more related to the definition as stated above.

Adrion et al. (1982) further defines *validation* as the "determination of the correctness of the final program or software product", and *verification* as the "demonstration of consistency, completeness, and correctness" in the single software development stages. These definitions, as they were stated in 1982, have varied as well, since both - validation and verification - should be applied in all software development phases. This is also applicable for mobile application development and testing.

Concerning interoperability testing and conformance testing of medical data that is exchanged, IHE and PCHAlliance organize test events where different vendors can test their implementations with software products from other vendors. IHE hosts this test event, called *Connectathon*, on an annual basis. Once a year a Connectathon is organized for Asia, Europe, and North America using the *Gazelle* test management system (IHE International Inc., 2018a). During a Connectathon, the vendors are asked to fulfill the test cases that are based on the requirements from the IHE profiles a vendor claims to have implemented. A single test needs to be conducted three times with a different consortium of test partners. If all of these tests are passed successfully, the vendor is entitled to ask for a *Integration Statement*, proving that requirements for a profile are met. This statement can be published by the vendor showing what software components were tested.

The PCHAlliance offer a similar test event. Those events are called *PCHAlliance Plugfest* and offers vendors the possibility to test their mobile software solutions or PHD interfaces with other vendors. Vendors who test their products on conformance

with the Continua Design Guidelines won't get any form of certification or statement unlike the participants of the IHE Connetathons. However, taking part at the plugfest is an opportunity to get in touch with other manufacturers and can be used as pre-testing for planned certification testing. These certification tests are conducted at a PCHAlliance test lab, where the conformity is tested against simulators and the interoperability is tested using available devices. In order to prepare for the certification test, members of PCHAlliance can download the *Continua Enabling Software Library*, providing test cases, simulators, and reference code to be used by the vendors offline. Personal Connected Health Alliance (2017d)

2.3.4 Interoperability for Mobile Applications

Interoperability is an issue for almost all mobile applications. Independent of receiving data from PHDs, forwarding information to health service providers, or providing information for an electronic health record system, interoperability guarantees that exchanged data can be interpreted and used. Even if data is only stored locally, interoperability might be considered to enable the use of locally stored data by another application or a subsiding application running on the same device. This section defines different prototype scenarios that can be found in mHealth applications. From simple stand-alone applications to applications that are part of a professional health record system.

Different Scenarios of Use for mHealth Applications

This section contains information about different use cases for telemonitoring and telehealth applications and describes the requirements the IT architecture must fulfill. It will be emphasized that standardization is of major importance in order to provide sustainable and maintainable solutions. Beside technological issues, the different kinds of *quality* and what characteristics are involved are described. Keeping in mind that mobile applications in the field of health deal with sensitive data, the definition of quality is stressed to meet the requirements for secure handling

of these kinds of data.

Mobile devices nowadays offer plenty of calculation power and storage space. Smartphones and tablets, as very user-centric devices, can play an important role when it comes to the management of personal data. They feature interfaces to communicate with devices in their proximity, like Bluetooth or WiFi, and over long distances using mobile networks. Based on these capabilities, use cases and scenarios can be studied where the primary role of the mobile device is the routing of information from local area networks (LAN) or personal/body area networks (PAN/BAN) to wide area networks (WAN). Services can be developed and hosted that offer the collection of, for example, personal vital data, to get monitored and analyzed by trained personnel. Those professionals can react if the transmitted values exceed given thresholds and contact the monitored people faster than it would be done in aperiodic visits or check-ups. Other scenarios might not focus on such communication infrastructures and describe simpler tasks, like a health diary on a person's phone without any features to share data. Besides the separation of applications into medical and non-medical applications, the following categorization of meta-types of mHealth applications was developed:

- stand-alone applications: The mHealth applications run on the users' phones and do not provide any interface outside the boundaries of the phones.
- stand-alone application connected to the Internet: The mHealth applications on the users' phones do not provide any interface outside the boundaries of the phone with the exception of loading, transmitting, sharing and/or visualizing content from or to the Internet in an unspecified way.
- application able to communicate with devices over LAN/PAN/BAN: The mobile applications on the users' phones are able to communicate with medical, health or fitness devices that are operated by the users themselves.
- application with interfaces dedicated to health care services: The mobile applications on the users' phones provide interfaces to load, transmit, share

and visualize data based on formats and communication protocols used for web based services in health care setups.

Another means to differentiate mHealth applications can be based on the intended user group. An application might be designed and be used by lay people, enabling the self-management of health and fitness parameters, or including centralized data storage capabilities in form of a personal health record. In contrast to that, an application can be intended for the use by health professionals to help with their daily business. Health professionals might use the application to access medical records within a hospital environment or might use the application for decision support. Based on the targeted user group, the application's layout and language might differ a lot. Whereas for lay people easy-to-use features and appropriate language need to be considered, for professional health applications, legislative conformance, performance, and robustness are of higher importance. Additionally, it can be assumed that lay people install and use their applications based on their own decisions, whereas health professionals might be "forced" to use mHealth applications as tools in their daily routines.

Certain mHealth applications might not always be considered to be dedicated to one of the above introduced types, but they might include features that belong to multiple meta-types. Many other characterization criteria are available as well, like professionals versus lay people, diaries or reminders versus decision support. The categories concerning their interfacing capabilities will be used in this work to underpin the importance of communication standards and system architectures.

Stand-Alone mHealth Applications Stand-alone mobile health or fitness applications are not connected to any kind of device and are not connected to services offered on WAN connections (e.g. Internet). The applications might use features implemented on the smartphone, tablet or wearables, starting from the real-time clock and calendar for reminder services, over acceleration sensors for activity tracking to geo-location services to track covered distances. Simple diary applications also fall in this group of applications, whether the body mass or the

blood glucose level is monitored. The applications might implement export or import routines to read or write files to the file system.

Stand-Alone mHealth Applications with Internet connection This type of application implements an interface to communicate with services available on the Internet. Various kinds of information can be queried and visualized for the users. Data with a non-medical or non-fitness characteristic might enrich the user's experience, e.g. if a smartphone's location data is used to find the nearest pharmacies. Another big group of applications that share user specifics with peers can be linked to this group of mHealth applications and enable virtual competitions.

Applications Communicating with Fitness and Medical Devices The usage of the smartphones' or tablets' interfaces for short range communication enables users to record data from external devices. These devices are either fitness monitoring devices and activity meters, or medical devices. These may record parameters from outside the body or parameters that the human body generates. They use the - mainly wireless - communication channels of the device to receive data, enabling seamless, digital, and automatic transfer. The most common interface technologies used are the different versions of Bluetooth, ANT, and ZigBee.

Applications with Interfaces to Healthcare Services This type of mHealth application is part of a larger IT architecture with well-defined interfaces and communication standards. Since these systems are merely used in professional domains, requirements concerning user identification and security are crucial. Those applications enable to access and view health related information in larger contexts, like data from an electronic health record system.

The four different use case scenarios are depicted in Figure 2.8. From the perspective of the mobile device data exchange can be differentiated whether data is gathered from devices (PHDs) in the proximity of the mobile device, or data that is exchanged with remote services using wide area transport technologies. The first is referenced

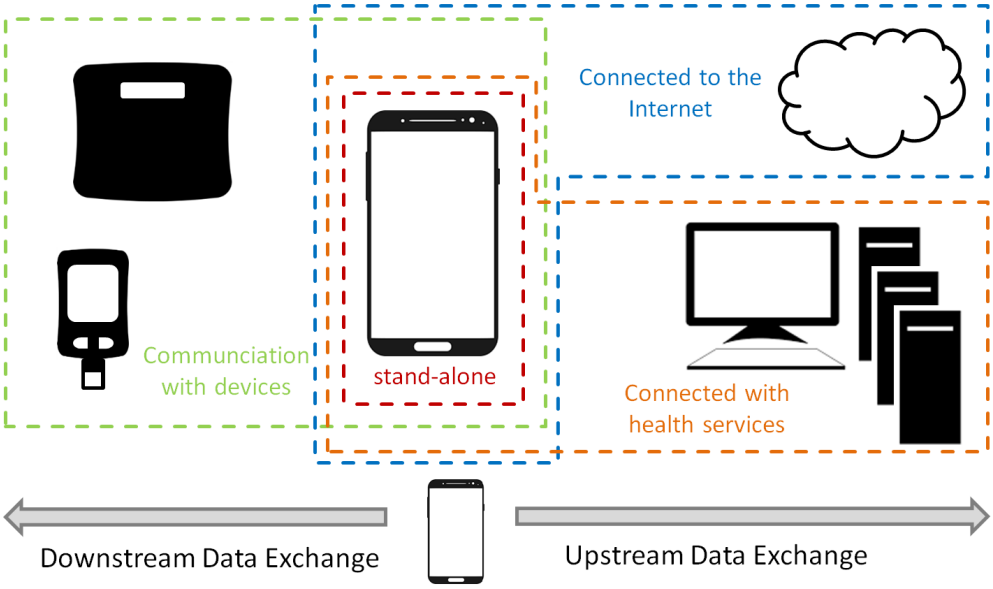


Figure 2.8 – The four scenarios of mHealth applications. Downstream data exchange over short range transport channels and upstream data exchange using wide area transport channels.

as *Downstream Data Exchange*, where the mobile application is mainly the receiver of data, where the second is referenced as *Upstream Data Exchange*. For upstream data exchange, the mobile application might be primarily the sender (forwarding data to healthcare provider services, PHR, EHR, etc.), or the receiver (gathering information from services available on the Internet).

2.3.5 Interoperability of mHealth Applications with Personal Health Devices - Downstream Data Exchange

Personal health devices, like blood pressure monitors, body weight scales, or blood glucose meters, and fitness/wellness devices, like pedometers and external tracking devices, are available for end users in an increasing number. Such electronic devices are more and more capable of digitally communicating the gained data to remote devices like mobile phones. Since the number of vendors of mobile phones, as well as the number of manufactures of PHDs and fitness devices, have been increasing

as well, end users benefit from a common interface. Such interfaces combine the transport technology (e.g. wired vs. wireless), the used communication protocol, and the semantic concepts that are used for transporting information. On the consumer market, the most popular interface for such cases - at the time being - is Bluetooth Low Energy. Nonetheless, other technologies are still available. From an end user's perspective, an interface that the mobile device supports out-of-the-box is most preferable. Using adapters that are connected to the mobile devices of the users, can increase the number of supported interfaces, but limit usability. When it comes to available transport technologies found on mobile platforms, the following list shows interfaces that are suited for personal area networks and can be used to gather information from external devices.

- Bluetooth classic and Bluetooth enhanced data rate (EDR)
- Bluetooth Low Energy
- WiFi
- ANT
- ZigBee
- USB

The above mentioned technologies - with the exception of Bluetooth Low Energy and ZigBee - are transport protocol agnostic, i.e. the transport channel does not restrict the protocol that shall be used for the communication. Hence, only the knowledge that a device supports classic Bluetooth is not sufficient when it comes to plug-and-play interoperability. Those transport channels fulfill the stated requirements for "basic" interoperability, i.e. two devices can connect with each other, but lack interoperability on the syntactic and semantical level. Hence, further restrictions need to be elaborated. For ANT, specific profiles have been designed, specifying the structure and the semantic content for specific use cases. This effort is labeled ANT+. For the other, above mentioned, technologies the ISO/IEEE 11073 family

of standards specifies the requirements concerning the protocol and the semantics to be used. The following sections give an overview of which interface technologies are used by consumer available PHDs and describe the most prominent and widest used technologies to ensure semantic interoperability for mHealth applications.

Interface Technologies Used for Personal Health Devices

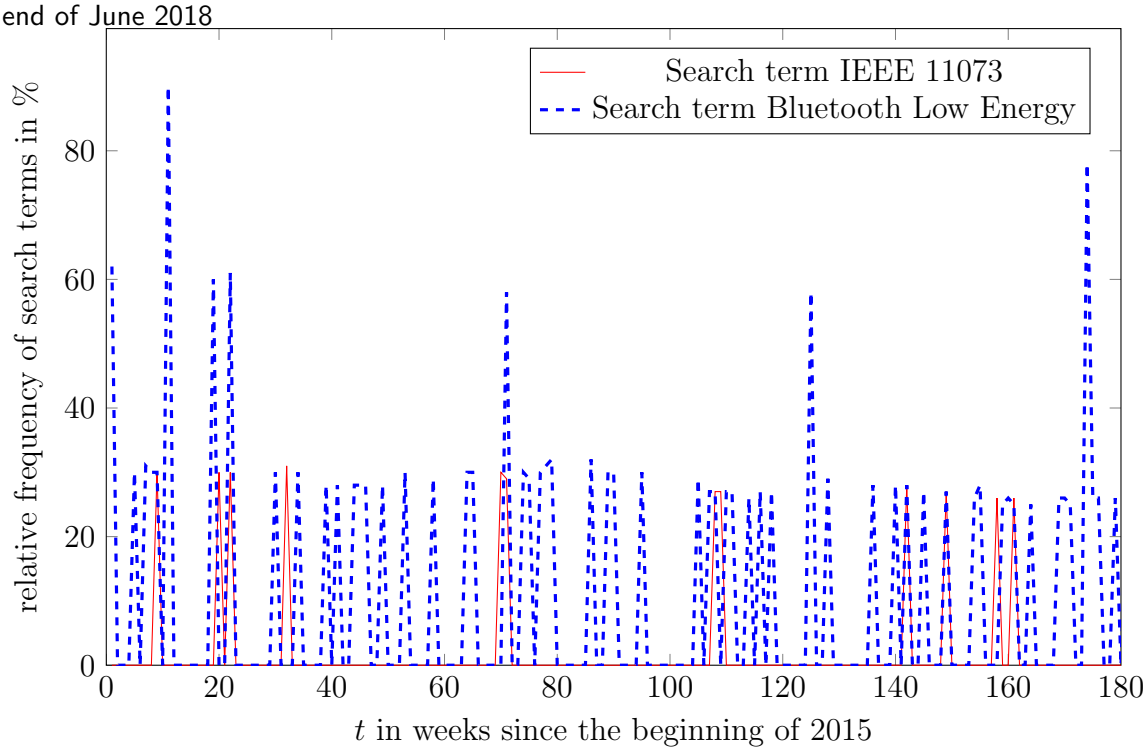
Based on the example of blood glucose meters, Google was used to search for glucose meters available on the consumer market in order to identify the interfaces used by these devices. This example is chosen since diabetes is one of the four *priority noncommunicable diseases* as identifies by the *2011 Political Declaration on the Prevention and Control of noncommunicable diseases* (World Health Organization, 2014). The identified glucose meters were grouped, based on the stated interface technologies used, i.e. categorized in Bluetooth, ZigBee, USB, and NFC. Beside the interface technology used, the devices were validated if they promote to be *Continua Certified*. Table 2.2 presents the results of this research conducted on the consumer market. (Meyer et al., 2018)

Table 2.2 – Comparison of identified blood glucose meters, data transport, and standardization statuses taken from Meyer et al. (2018)

Glucose Meter	*Data Transport*	*Continua Certified*
Accu-Chek® Guide	Bluetooth/USB	YES
Accu-Chek® Instant	Bluetooth/USB	YES
Contour® Next/Plus ONE	Bluetooth/USB	YES
FORA® D40	Bluetooth/USB	YES
Accu-Chek® Active	USB	YES
Accu-Chek® Mobile	USB	YES
Accu-Chek® Aviva/Performa Insight	USB	YES
Abbott FreeStyle Libre	NFC	NO
Accu-Chek® Aviva/Performa Connect	Bluetooth/USB	NO
AgaMatrix Jazz Wireless 2	Bluetooth	NO
Beurer GL 50 evo	Bluetooth/USB	NO
BodyTel® GlucoTel	Bluetooth	NO
Dexom G5	Bluetooth	NO
FORA® TN'G / TN'G Voice	Bluetooth	NO
GlucoMen Areo / Areo 2K	Bluetooth/USB/NFC	NO
MediTouch® 2 connect	Bluetooth/USB	NO
Medtronic Enlite® Sensor	Bluetooth	NO
OneTouch Verio Flex®	Bluetooth/USB	NO

Table 2.2 only depicts the transport technology but lacks detailed information about the implemented communication protocol. This information is rarely provided by the vendors in the online description of the products. This is not only the case for blood glucose meters but also for other PHDs. The communication protocols that can be considered are *ISO/IEEE 11073-20601* and *Bluetooth Low Energy*, since the first is transport agnostig, i.e. this protocol can be implemented for serial Bluetooth profiles and USB, where the latter is of interest since many devices - PHDs, fitness gadgets and devices for other use - implemented Bluetooth Low Energy in the past years. Therefore a Google Trend analysis was performed in June 2018. The used search keywords *IEEE 11073* and *Bluetooth Low Energy* were used to investigate the relevance of these terms in the last 5 years. An additional filter was set for

Figure 2.9 – Google Trend Analysis of the frequency of the search terms *IEEE 11073* and *Bluetooth Low Energy*, respectively with the filter *health* from the beginning of 2015 till the end of June 2018



health. The search resulted in normalized hits for both terms, on a weekly basis. The normalization was based on the week with the most hits in August 2014, for the term Bluetooth Low Energy. The timespan was manually reduced to only show results from the beginning of 2015 to the end of June 2018, and those numbers are depicted in Figure 2.9 (and therefore do not include the 100% from August 2014). This figure shows that the term *Bluetooth Low Energy* was searched more frequently and stable compared to the term *IEEE 11073*.

The ISO/IEEE 11073 Family of Standards

The ISO/IEEE 11073 family of standards origins from the point-of-care domain within the intramural sector. A substandard for PHDs has been developed since those device classes have, compared to point-of-care devices like bed-side-monitors,

limited capabilities. This ISO/IEEE 11073-20601 standard IEEE Engineering in Medicine and Biology Society (2011b) defines an optimized exchange protocol for PHDs. Based on an information model from the ISO/IEEE 11073-10201 standard (IEEE Engineering in Medicine and Biology Society, 2011a) defining a domain information model for point-of-care devices, the information model was adapted. The ISO/IEEE 11073-20601 standard further specifies how remote systems can interact with a PHD implementing this standard, and this is depicted in the service model. In addition, a communication model specifies a state machine for the session based communication between a PHD and the server. To ease the integration of this standard further, specific device profiles are stated in single substandards. From an implementer's perspective, this means that if a blood pressure monitor is implemented, a closer look into the device specialization for blood pressure monitors, ISO/IEEE 11073-10407 (IEEE Engineering in Medicine and Biology Society, 2008) should be considered. In this document all the relevant information is condensed in order to be implemented in a blood pressure monitor. Figure 2.10 shows the domain information model for the blood pressure monitor, specifying the information model that shall be implemented. This model defines the MDS (Medical Device System) having one class holding the systolic, diastolic and the mean arterial pressure (MAP), and might have one class holding the pulse.

In order to ensure semantic interoperability, the concepts are coded based on the ISO/IEEE 11073-10101 (IEEE Engineering in Medicine and Biology Society, 2002). This standard defines a common terminology. From this group, the Rosetta-Terminology-Mapping project has emerged, giving a vendor instructions on how to get from a proprietary and unharmonized coding of concepts into the world of ISO/IEEE 11073-10101 and semantic interoperability.

Besides the specification of the information model in terms of the domain information model for the different device classes, and the specification of the terminology to be used, the ISO/IEEE 11073-20601 standard specifies the transfer syntax. For this specification, the standard uses ASN.1 (Abstract Syntax Notation One) definitions of the data models. This syntax notation defines and specifies the

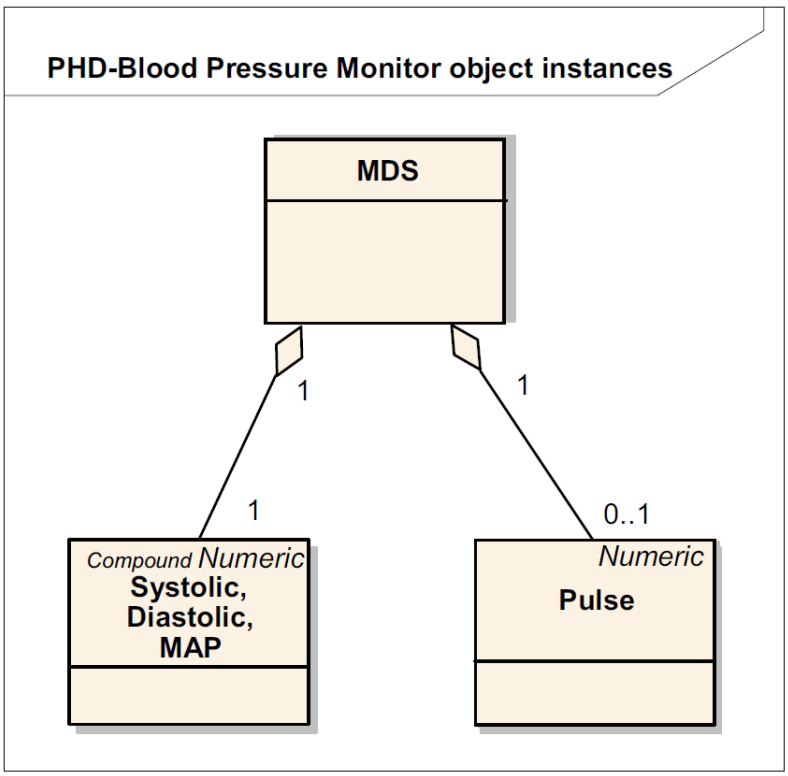


Figure 2.10 – Domain Information Model According to and taken from IEEE Engineering in Medicine and Biology Society (2008).

basic data types and the higher data types in a markup language that is independent of the programming language used for the implementation of ISO/IEEE 11073-20601 compliant systems.

Listing 2.1: ASN.1 specification for the ApduType taken from the ISO/IEEE 11073-20601 (IEEE Engineering in Medicine and Biology Society, 2011b).

```
ApduType ::= CHOICE {
aarq [57856] AarqApdu,    -- Association Request [0xE200]
aare [58112] AareApdu,    -- Association Response [0xE300]
rlrq [58368] RlrqApdu,    -- Association Release Request
-- [0xE400]
rlre [58624] RlreApdu,    -- Association Release Response
-- [0xE500]
abrt [58880] AbrtApdu,    -- Association Abort [0xE600]
prst [59136] PrstApdu     -- Presentation APDU [0xE700]
}
```

Listing 2.1 shows an example of the ASN.1 specifications. It states that an APDU (Application Protocol Data Unit) shall include one of the higher data types defined within the *CHOICE* list. The numbers in the squared brackets indicate the unique identifier of the chosen choice element and will be used within the message that is going to be transferred between the systems. In order to derive the intended transfer syntax from the ASN.1 specifications, encoding rules are needed. For systems that state compliance with ISO/IEEE 11073-20601, the *Medical Device Encoding Rules* (MDER) shall be applied. This set of encoding rules are based on the *Basic Encoding Rules*, with some features to decrease the size of the transferred data. Using the MDER, a byte array will result providing the information in a binary coded format. The receiver can decode the binary coded information applying the MDER once more. The binary format has the advantage that the data that is sent over the transport channel is more condensed than for example using *string* coded data. Frohner et al. (2013) compare the estimated size of the data packages for sending five physical readings using the ISO/IEEE 11073-20601 with the text based HL7 Version 2.x messaging and found that by using the binary format, the size of the payload is reduced by the factor of 9.

Since ISO/IEEE 11073-20601 defines the protocol on the application layer, no restrictions concerning the transport channel to be used, are in place, i.e. this protocol can be implemented on top of TCP/IP to be used in LAN, or to be used on top of serial interfaces like USB or Bluetooth. Restrictions concerning the latter are formulated by the Personal Connected Health Alliance in their Design Guidelines, stating that for classic Bluetooth transmissions, the *Health Device Interface* (HDI) profile shall be used, whereas the use for more generic profiles, like Bluetooth's serial interface profile, is prohibited by these guidelines (Personal Connected Health Alliance, 2016). From an implementer's perspective, this requirement decreases the number of platforms for implementations, since the HDP is not available on a larger number of platforms. Frohner et al. (2012) demonstrate an Android implementation that conforms the Continua Design Guidelines.

Bluetooth Low Energy

Bluetooth Low Energy (BLE) has been introduced on the market to overcome the high power consumption of classic Bluetooth, and to provide additional network topologies for BLE devices. Compared to classic Bluetooth, the power consumption of BLE decreases (ideally) to the 1% (Bluetooth SIG Inc., 2018d).

The Bluetooth Special Interest Group (SIG) specifies *profiles* and *services* to be implemented in BLE enabled devices. Such profiles contain one or more *Generic Attributes* services in order to harmonize the feature list of BLE devices. The services include single characteristics and the characteristics may include descriptors. All instances of services, profiles, characteristics and descriptors are identified by a uniquely assigned number, a UUID. Figure 2.11 shows the hierarchical setup of the above mentioned artifacts. Concerning the services in general, there are mainly four different ways how interactions between devices can occur. These procedures include:

- Read: a pull mechanism that enables the receiver to query information from the sensor device
- Write: a mechanism to write information from the receiver on the sensor device
- Notification: a push mechanism for sending information from the sensor device to the receiver
- Indication: a push mechanism for sending information from the sensor device to the receiver, including an acknowledgment from the receiver on the application level

This specification of common profiles has been introduced with BLE, i.e. it was/is not an integral component of classic Bluetooth and therefore ensures interoperability for BLE devices. This fact was acknowledged by the Personal Connected Health Alliance, since it specifies the use of BLE for Personal Health Device Interfaces

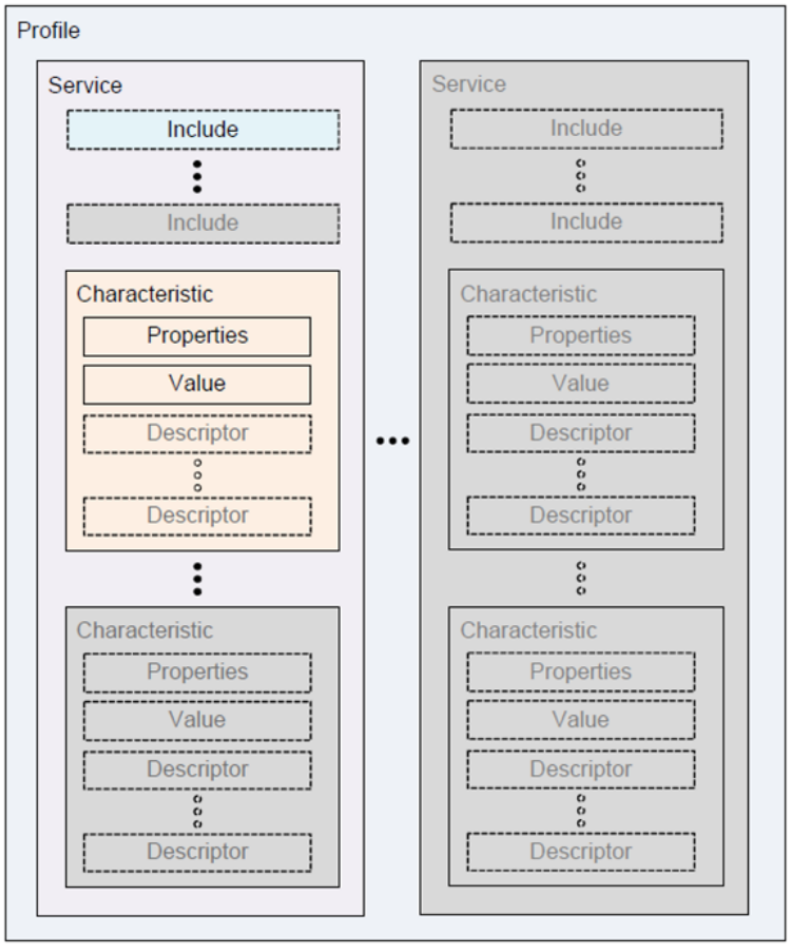


Figure 2.11 – Overview of the Generic Attributes and the hierarchical structure as defined for BLE (Bluetooth SIG Inc., 2018a).

without additional restrictions. In the example of a blood pressure monitor, the Bluetooth SIG specifies that the blood pressure service needs to implement the following characteristics (Bluetooth SIG Inc., 2018b):

- Blood Pressure Measurement: characteristic that is used to send blood pressure measurements using the *indicate* mechanism. The implementation of this characteristic is mandatory for all blood pressure devices.

- Intermediate Cuff Pressure: characteristic that is used to send interim pressure values of the blood pressure cuff to get visualized on the receiving device

using the notification mechanism. The implementation of this characteristic is mandatory if the characteristic is supported, otherwise this implementation is excluded.

- Blood Pressure Feature: characteristic that is used to send supported features of the blood pressure sensor device, e.g. body movement detection supported, or irregular pulse detection supported, using the read mechanism. The implementation of this service is mandatory for all blood pressure devices.

2.3.6 Interoperability of mHealth Application with Health Services - Upstream Data Exchange

Data that is available on a mobile device is often shared with peers or health professionals in order to get feedback on the sent data. Such use cases include a telemonitoring scenario where a patient is asked to transmit the gained vital readings to a health service on a regular basis. The health service operator is expected to monitor the vital signs and provide feedback for the patient. In such scenarios, a common interface is very helpful, since the setup and maintenance of a single interface is cheaper, compared to a multitude of different interfaces. In this area, specifications from the PCHAlliance and from the IHE are valuable. The specifications from the PCHAlliance refer to those from IHE, i.e. in the end, IHE provides the needed documentations to implement interfaces between a mobile phone and a health service provider. The architecture sketched by the PCHAlliance (see Figure 2.7) depicts possibilities how data can be transferred from a mobile phone to WAN services. The first possibility describes the interactions with a Health & Fitness service where the mobile phone sends single messages that contain the vital signs information. Those messages are supposed to be triggered by the information received from the PHD on the mobile phone, i.e. whenever the mHealth application receives information from a connected PHD, the mHealth application will transform the content and sent a message to the remote service provider. The second approach, not directly derivable from the PCHAlliance's architecture, describes the generation

and transfer of a medical report document. The document is generated using the mHealth application, where the trigger for this procedure is most probably the user himself/herself. The document is then packed into a SOAP message and forwarded to a Health Information service (e.g. electronic healthcare record system) where it will get stored and made accessible for an authorized audience.

HL7 Messages

HL7 is one of the key standardization bodies in the field of medical IT. The main area of standardization, as the *7* in HL7 indicates, is on the application layer (referencing the ISO certified model of *Open System Integration* (OSI) where the 7^{th} layer represents the application layer). Therefore, HL7 does not define network topologies or sessions management of network communication, but focus on the syntax and semantics of messages and documents. All the different versions of HL7 messages are summarized under the name *HL7 messages Version 2.x* (the latest version at the time when this thesis was written was 2.7). HL7 refers to these message standards as the *workhorse* of data exchange within intra-mural environments, as well as in more distributed environments.

The messages consist of multiple segments, identified by the first three characters, separated by line breaks. The segments contain multiple fields, and the content of a single field is defined by its position within the segment. Furthermore, fields can contain sub-fields in order to separate data into a finer granularity (e.g. the patient's name will be separated into first name, second name, last name). The Listing 2.2 shows an example of the transmission of vital parameters. The first segment is the *message header*, defined by the three characters *MSH*. This segment is the beginning of all HL7 version 2.x messages, since it defines - among other things - the special characters for segmentation (^ ~ \ &), the intended recipient, the sender, and the trigger event for the message. The second segment in the example is the *patient identification* segment, where a unique patient identifier, the patient's name, his/her date of birth, and the administrative gender is located. The subsequent segment is the *observation request (OBR)* segment and then multiple *observation*

(OBX) segments follow. Each of the OBX contains information on the type of observation, using SNOMED-CT terminology, the read value, the physical unit, a reference range and the timestamp of the observation. From a semantical point of view, especially the coded concept of the measurand is of interest, since the code (located in the first sub-field of the 3rd OBX field) is a unique representation of a SNOMED-CT concept. The second sub-field represents the display-name of the concept (also defined in SNOMED-CT) and the third sub-field holds the information that the code has been taken from SNOMED-CT in the first place.

Listing 2.2: HL7 Version 2.x example for the communication of vital parameters

```
MSH|^~\&|VSM001|MIRTH_CONNECT|HIS001|MIRTH_CONNECT
   |20100511220525||ORU^R01|MSG0000001|P|2.5|||NE|NE|CO
   |8859/1|ES-CO
PID||6537077|6537077^^^^CC||ANDRES FELIPE^FERNANDEZ CORTES
   ||19860705|M
OBR|1||VS12340000|28562-7^Vital Signs^LN
OBX|1|NM|271649006^Systolic blood pressure^SNOMED-CT||132|mm[
   Hg]|90-120|H|||F|||20100511220525
OBX|2|NM|271650006^Diastolic blood pressure^SNOMED-CT||86|mm[
   Hg]|60-80|H|||F|||20100511220525
OBX|3|NM|6797001^Mean blood pressure^SNOMED-CT||94|mm[Hg
   ]|92-96|N|||F|||20100511220525
OBX|4|NM|386725007^Body temperature^SNOMED-CT||37|C|37|N|||F
   |||20100511220525
OBX|5|NM|78564009^Pulse rate^SNOMED-CT||80|bpm|60-100|N|||F
   |||20100511220525
OBX|6|NM|431314004^SpO2^SNOMED-CT||90|
   |94-100|L|||F|||20100511220525
```

HL7 Clinical Document Architecture

Although HL7 message standards are widely used all over the world, these standards have some drawbacks concerning interoperability. From the syntactical point of view, the single fields specify what content they should code, but the *how* is often not very clearly defined. Therefore, HL7 started to improve this shortcoming and

it resulted in Version 3 of HL7 standards. HL7's Version 3 standards are based on three pillars:

- a reference information model
- a definition of common data types
- the usage of a well defined vocabulary

HL7's Clinical Document Architecture became an ANSI standard in 2005 and an ISO standard in 2008.

HL7 Reference Information Model In the communication of two parties, messages are being exchanged. The sender formulates and sends the message, whereas the recipient receives and reads the message. Sending and receiving are core requirements when it comes to interoperability. The HIMSS (Healthcare Information and Management Systems Society, 2013) would call this interoperability on a foundational level. Nevertheless, the content of a message needs to be interpreted by the receiving end in order to achieve the overall goal of data communication. However, this interpretation step, as the name suggests, means that the coded information will be analyzed in order to derive valuable content from it. This step of interpretation is solely done by the receiver, without any influence by the sender who formulated the content in the first place, i.e. the understanding of communicated concepts might vary between the sender and the receiver and might therefore lead to a miss-interpretation of the received data. From a receiver's point of view, the receiver needs to know *how* the sender has formulated the message and this does not only concern the used vocabulary and the coding technique. It also includes the context and the intention of the sender at the point in time when the message has been sent. In order to overcome these issues, HL7 has started to formulate and specify the reference information model, enabling all stakeholders to share the common perspective of the context and the intentions. This reference information model (RIM), is independent of any specific implementation of any

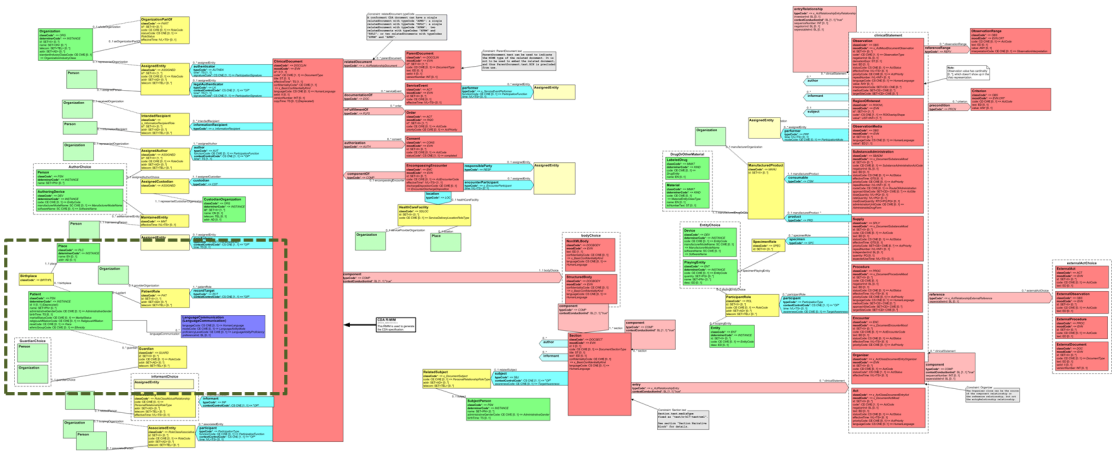


Figure 2.12 – Refined Message Information Model from Health Level Seven International (2005), defining the atomic building blocks of a HL7 CDA document. Elements within the green dashed line are depicted in Figure 2.14 for demonstration reasons.

specific use case, but it specifies the entities and artifacts (and their combination and interaction possibilities) in the health domain normatively. Using the RIM as a basis, one of the widest used standards has been derived: *HL7 Version 3 CDA Release 2*. This standard specifies a document structure for clinical documents that are intended to be exchanged between the different stakeholders in the health sector. The specifications of the single atomic components that can be used within a CDA document are represented in the CDA RMIM (Refined Message Information Model) as depicted in Figure 2.12.

The CDA-elements within the RMIM are color coded based on the definitions of the CDA RIM. Six different elements are defined (see Figure 2.13) to be used for coding medical content in accordance with the HL7 CDA standard. Those elements can be separated into four main classes: *Entity, Role, Participation*, and *Act*. The remaining two classes are used to link roles or acts with classes of the same kind, using the *Role Relationship* or *Act Relationship* class, respectively.

Figure 2.14 shows the classes that are defined by HL7 CDA to hold information about the patient. Using the *Participation* class *recordTarget* the *PatientRole*-element is linked with the *ClinicalDocument* XML-root-element (the pink colored coded class).

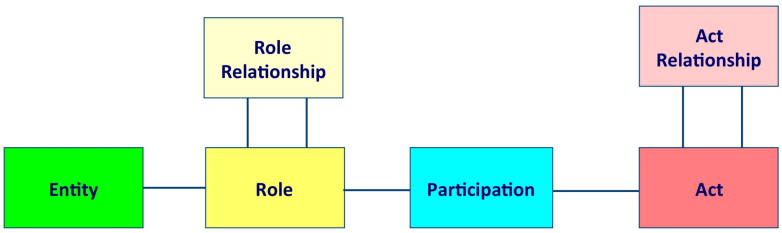


Figure 2.13 – The six classes of the HL7 CDA RIM, taken from HL7 Deutschland e.V. (2018).

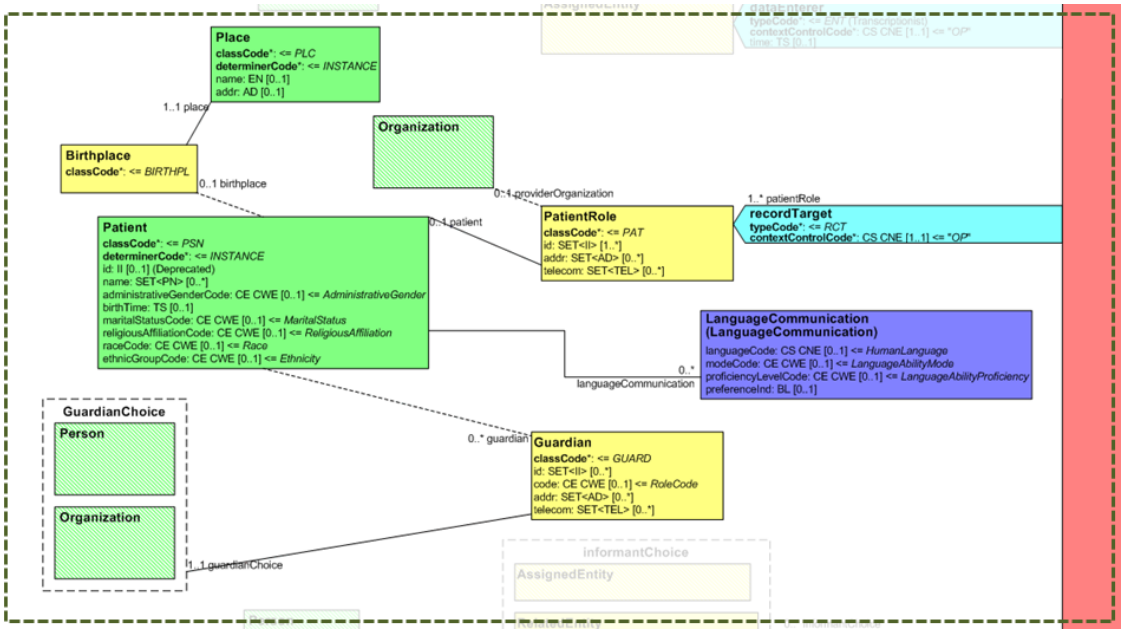


Figure 2.14 – Extract of the refined Message Information Model from Health Level Seven International (2005), specifying how the patient is modeled.

The PatientRole element contains information about the patient like the unique patient identifier and the address(es) of the patient. The green *Patient* element is linked with the PatientRole and code, beside the name of the patient, other demographic information, like the administrative gender of the patient.

Structure of the CDA document A CDA document consists of a *header* and a *body*. The first holds the administrative and meta information that is needed for the clinical documents. Content, such as information about the patient, the authors

of the document, the custodian, or further participants, can be found in the header. The body of the CDA holds the clinical information. In general, the body can be implemented in two different ways. A CDA might have a *structuredBody* or it might have a *nonXMLBody*. The first is the more common one, since it enforces interoperability, whereas the latter might contain any kind of (non-structured and specified) information (as long as it is not an XML-structure). NonXMLBodies might just contain an embedded picture, a word-document or a PDF. As this is not desirable when it comes to interoperability due to the fact that the data is neither structured nor does it follow semantical rules, it will not be discussed any further within this work. For the *structuredBody*, the clinical content is further clustered into one or more sections. The basic XML-structure of a CDA section can be found in Listing 2.3.

Listing 2.3: Basic structure of a CDA section (neither elements nor attributes contain data in this example; only the structure of a *section* is described)

```
<section>
  <templateId root=""/>
  <code code="" codeSystem=""/>
  <title/>
  <text/>
</section>
```

The *templateId* element is an important element when it comes to interoperability. As the name suggests, this element holds the identifier for a template. A template restricts the elements that have to be used according to the HL7 R-MIM (see Figure 2.12) for a certain block within the XML document and, moreover it can also be used to specify the content and values the XML elements shall have. Basically, the identifier is a *Universal Unique Identifier* (UUID), but it is mostly implemented as an *Object Identifier*, in the context of CDAs.

According to the example stated in the Listing 2.3, the value of the *root* attribute of the templateId element might restrict the section into having a *code* element, as well as a *title* and a *text* element. Above that, the stated templateId can further demand that the *code* attribute within the code element shall hold a defined value

as well as a *codeSystem* attribute.

The *code* element contains the information of what the section is about in a machine readable form, i.e it is more or less a coded representation of the *title* element that holds the title of the section in a string format. For the *code* element, besides the code itself, the information about the code system hosting the code is necessary. This information goes into the *codeSystem* attribute. Furthermore, the *code* element might also hold - among others - attributes such as the clear text representation of the used code systems, the display name of the code, and the version of the code system used in a machine readable form. The last two elements stated in the Listing 2.3 are human readable information in form of the title and the text of the section. For the text, structural elements like listings, paragraphs, or tables might be used to encode the information that is communicated within the document.

Human vs. Machine Readable Content CDA has become a relevant standard for medical reporting, since it enables the transfer of human readable and machine readable information within one document. HL7 specifies structural XML-elements that are either human readable or machine readable texts. Therefore, the human recipient of a document is enabled to display the contained information and the computer system used can extract structured and coded information from the document as well. Especially the latter is of interest for storing received patient information into a patient's record.

In order to visualize the content of the CDA document for human inspectors, a transformation step is needed to render the data contained within the XML document. This transformation is facilitated using an XSLT processor (*XSLT* stands for *Extensible Stylesheet Language Transformations*). The input for this processing step is, on the one hand, the XML document that shall be transformed, and, on the other hand, the set of transformation rules stated within an XSLT stylesheet. Following this rule, the XSLT-processor generates a result tree, i.e. another representation of the XML content out of the content of the XML file. This process is depicted in Figure 2.15).

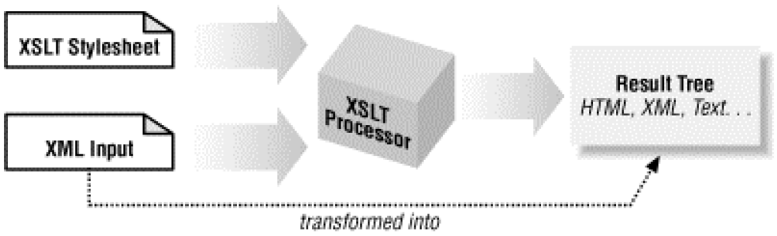


Figure 2.15 – The XSLT transformation process, picture taken from Burke (2001).

For clinical documents in form of a CDA document, the XSLT processor generates an HTML representation that can be viewed in off-the-shelf browsers. The XSLT processor is part of these browsers and together with the clinical document the stylesheets need to be shared. However, since the representation of the document depends solely on the stylesheet, the stylesheet can be exchanged if a different visual representation is needed (that still holds the same content).

For the machine readable content, multiple elements within the XML document are defined. When it comes to interoperability, these machine readable parts are of major interest, since those enable the receiving system to interpret and make use of the data. Having a CDA document that is fully "interoperable" is a challenge hard to meet in certain applications. HL7 respects this and defines different CDA *Levels*. These levels make it possible to reach defined stages of interoperability. The most often used levels are (Boone, 2011):

- *CDA Level One*: This is the minimum level of interoperability. Machine readable information can only be found in the CDA header. The intended use of such CDA documents is, to be exchanged between different healthcare providers over time and organizational boundaries. Therefore, information about the document needs to be known to the systems in place. Therefore, this level describes that the CDA header needs to be in place holding the administrative information and meta data of the document itself. This enables the document's author to store the document within an XDS environment, since the meta data is needed for the registering process, and later for the query for documents.

- *CDA Level Two*: This level expands the requirements from level one and enforces the use of coded information on the section level. This means that machine readable information needs to be provided in order to determine what a section is about. In order to follow this requirement, the *code* element (see Listing 2.3) of each section needs to be present and filled with a valid code describing the section.

- *CDA Level Three*: Level three demands of the creator of the document to provide coded information on the lowest level possible, i.e. the *entry* level. This CDA level represents all human readable information, also in a machine readable way. However, it is hard to reach, especially in cases where human information is not structured. Coding the information that is contained in a narrative text is significantly harder than coding information that is already structured in form of a table.

An analogy for the CDA levels and the level of machine readability can be found in a library setup. If somebody is interested in borrowing a book, he or she can use the library's register to find basic information about the book. The book's title, its author, the publisher and further information can be found in the register, including information on which shelf the book is to be found. This level of information maps to the CDA Level One, where general information about the clinical document is available. If a person accesses the bookshelf, finds the book and opens it to its table of content, he or she can have a look at the chapters that are available within the book. This can be compared to the CDA Level Two, where machine readable information about the sections within the document is coded. Finally, when the library visitor reads the content's of the single book chapters, this is then the CDA Level Three, where the machine can "read" the content found in the entries. Based on the R-MIM (see Figure 2.12) these three levels can be easily identified and are illustrated in Figure 2.16. CDA Level One includes all classes that are contained within the CDA Header, i.e. the administrative information and meta information to describe the context of the clinical observations. CDA Level Two extends CDA Level One with the coded information on the *section* level, and CDA Level Three

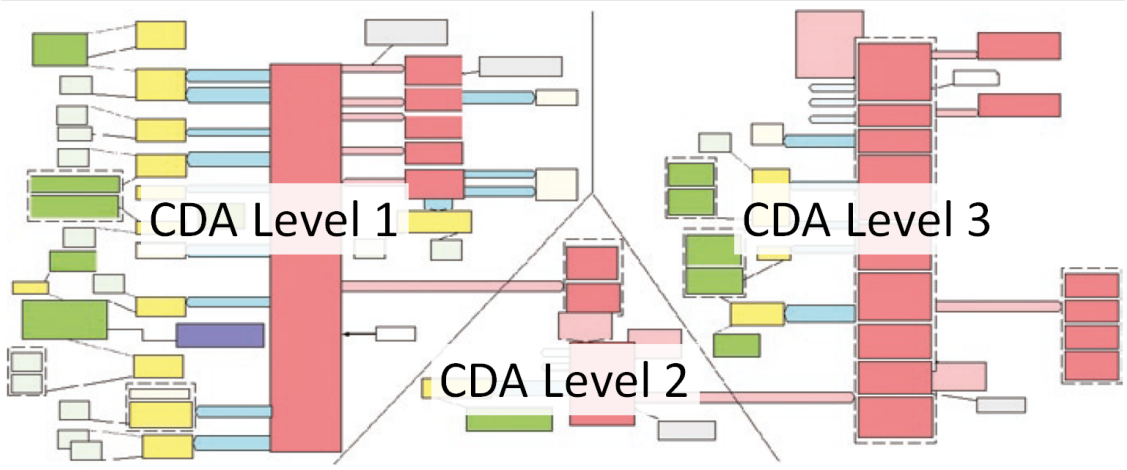


Figure 2.16 – The three CDA Levels based on the structure of the CDA R-MIM. Figure taken from Boone (2011) with adaptations.

includes machine readable information on the single clinical statements, like an observation or a substance administration.

Other sources, such as (HL7 Deutschland e.V., 2013), agree with the basic concept of those three levels but also argue that the granularity is insufficient. They define nine levels. HL7 Deutschland's definition of CDA levels can be found in Table 2.3. These levels can be aligned with those defined by HL7 based on the number used for the level. However, HL7 Deutschland introduces a fourth level when the clinical document contains links to external documents, but they also state that these levels are used internally and are not officially harmonized.

Table 2.3 – CDA Levels according to (HL7 Deutschland e.V., 2013)

Levels	*Description*
1A	The body contains a PDF file and the header is used for coding the meta data.
1B	The body uses XML elements for providing the content, but does not code the information in a machine readable format.
2A	Some of the sections contain machine readable information about the section, but not all of the sections have this information.
2B	All sections contain machine readable information about the section.
2C	Beside the machine readable codes, all sections contain a valid template identifier.
3A	Some of the *text* elements contain structured, human readable data.
3B	All of the *text* elements contain structured, human readable data.
3C	All the *entry* elements contain a valid template identifier.
4	Links to external documents are available.

Validation of CDA Documents The HL7 CDA standard defines a document structure that is based on XML, i.e. a CDA document is a valid XML document. It contains the needed elements and follows the structural requirements as stated in the HL7 CDA XML schema file. Having this schema file in place, a generated CDA document can be validated against this schema as one of the three validation steps for XMLs. An XML, and therefore also a CDA document, can be tested in three steps:

1. well-formed: an XML document shall comply to the general rules that are defined in W3C (2008). This includes, among other things, the correct nesting of the single XML-elements, the right use of opening and closing tags and the correctly encoded characters.

2. valid: an XML document shall comply to the requirements defined in the XML-schema file. This file defines the XML-elements that are entitled to be used in an XML document. On top of the definition of the W3C, the schema files define the name and data type of the XML elements, if their use

is mandatory or not, and define the cardinality of the single elements.

3. conforms to business rules: an XML document shall comply to the business rules as described in the specification documents. Those rules can be formulated as assertions within a Schematron file. Using Schematron test engines, the CDA document to be validated can be tested.

The three above mentioned test steps are conducted in the sequence as stated above, i.e. first the CDA document is checked if it is well-formed, then it is checked if it is valid and lastly the Schematron test is applied. For this purpose, Health Level Seven International (2005) provides the CDA schema files that can be applied for all schema tests of all kinds of CDA files. Business rules are defined for specific purposes within well-defined domains in form of *Implementation Guides*. For example, the IHE defines in its content profile for laboratory reporting (Integrating the Healthcare Enterprise, 2017) the needed structure and - partially - the required content for laboratory reports from an IHE perspective. Another example is the Austrian health record system *ELGA* defining the requirements for laboratory reports in Austria in the HL7 Austria accredited implementation guideline for laboratory reports (ELGA GmbH, 2017b). Since the specifications might differ between IHE and ELGA, the business rules also differ and, hence, the Schematron files differ as well. ELGA has published the most recent version of the Schematron files on their webpage (ELGA GmbH, 2017a) and they can be download for offline validation purposes. Moreover, CDA documents can be validated (against XML, schema and Schematron) online via (ELGA GmbH, 2018).

IHE Profiles

Although communication standards are available to be implemented in software solutions, it has shown that solutions from different vendors are not able to exchange data even if both products state compliance with a common standard. Hence, IHE provides *Profiles* specifying how a certain standard shall be used for a given use case. These profiles are collected in *Technical Frameworks* based on the domain

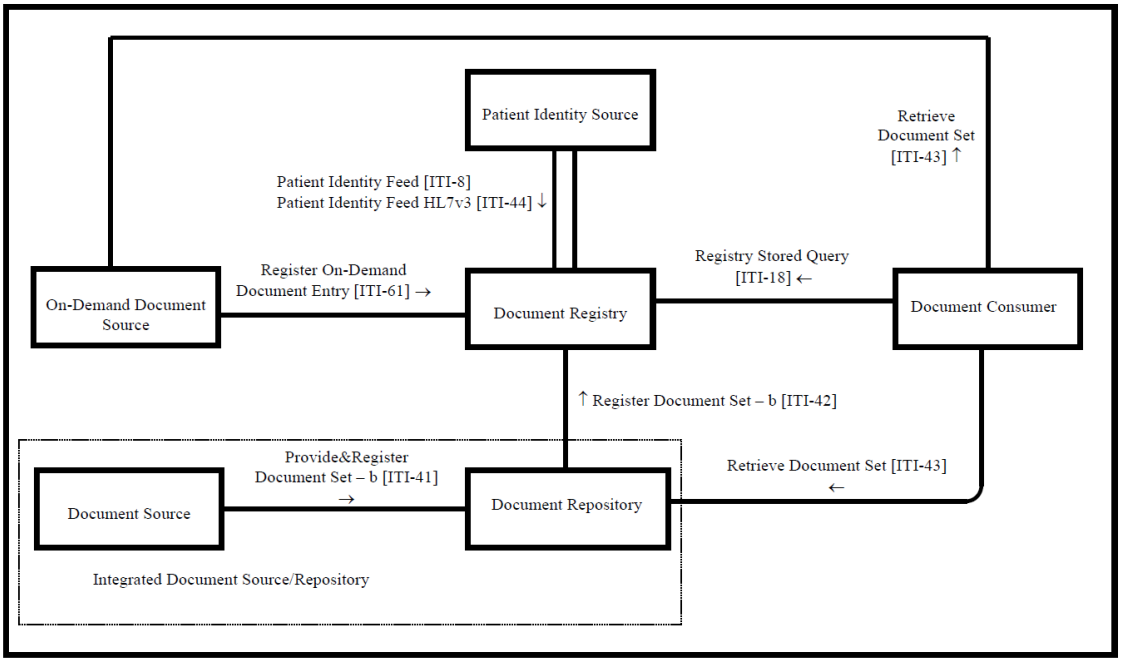


Figure 2.17 – Actors/Transaction Diagram of IHE's Cross-Enterprise Document Sharing (XDS) profile (IHE International Inc., 2018b)

where the use case can be found. One of the most prominent profiles is IHE's *Cross-Enterprise Document Sharing* (XDS). This prominent IHE profile specifies how clinical documents can be exchanged between different stakeholders and XDS requires a complex IT infrastructure. This infrastructure enables the provision of documents that other parties can download. The software components that are required for this task are introduced in IHE's actors/transaction diagram (see 2.17). This diagram depicts the software actors and the transactions between each other. In contrast to this implementation, IHE's *Cross-Enterprise Document Reliable Interchange* (XDR) specifies direct communication between partner, i.e. the sender of the document forwards the content to a dedicated receiver. Beside these profiles, *Cross-Enterprise Document Media Interchange* (XDM), enables the exchange of information bound to a physical medium.

2.3.7 Interoperability Challenges in the Energy Domain

Interoperability challenges are not only a topic for systems used in the health sector. In the energy domain interoperability became a prominent topic, since the transition towards *renewable energies* demands the use of smaller and distributed energy producing components. Large power plants that produce energy based on fossil fuels will be replaced by wind parks, photo-voltaic farms or other assets where the generation of energy cannot be controlled as easy since they depend on environmental factors. Hence, a large number of different devices needs to be managed and controlled in order to keep up a constant power grid supply. This control needs to implement standardized communication interfaces. The research project *Integrating the Energy System* (IES) investigates to which extend the harmonization processes and the conducted interoperability tests from the health sector can be applied to the energy domain.

2.4 Privacy and Security Considerations of Software Systems

Since the information mHealth applications deal with contain sensitive data, some protection measures need to be placed against unauthorized access from people and systems. This is a requirement, no matter if the data is only stored on the device or if the data is communicated using technologies over mobile applications boundaries to other applications running on the same mobile device, or to other services.

The *Health Insurance Portability and Accountability Act* (HIPAA), enacted by the United States Congress, specifies in Title II, subtitle F-Administrative Simplification Part C, Section 1171 (6) the following

> Individually Identifiable Health Information. - The term 'individually identifiable health information' means any information, including demographic information collected from an individual, that-

- is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
- relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and

  (i) identifies the individual; or

  (ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

Pub. L. No. 104-191 (1996).

The HIPPA concerns with individually identifiable health information mainly, whereas a broader definition of the term *personal data* can be found in the European *General Data Protection Regulation* (GDPR) (European Union, 2016) that has been enforced in May 2018. Article 4 defines personal the following

> 'personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person; (European Union, 2016)

Already in the year 2009, an article titled *Four Billion Little Brothers* by Shilton (2009) stressed that mobile phones have the potential to become the "the most widespread embedded surveillance tools in history". Due to the multitude of embedded sensor systems within a mobile device, personal habits can be observed and - in the worse cases - shared with third parties without the knowledge and the permission of the mobile device user. The article further explains different

applications of *participatory sensing*, where data is collected by individuals using their phones. An investigation of the collected data could unveil new data that was invisible before. Examples mentioned include applications that can be used to calculate the individual's carbon footprint based on location changes and the estimated means of transport (e.g. walking, riding the bike, taking the bus), or a health diary logging eating and exercising. In order to ensure the privacy of every individual's data, the solution is not only a technical exercise, but the individuals need to be trained and informed what data is collected and what will be done with it. Especially the users should be aware that "traces are easily to mine and difficult or impossible to retract once shared". (Shilton, 2009)

Taking up the topic of participatory sensing, Christin et al. (2011) defines privacy in participatory sensing system as the

> guarantee that participants maintain control over the release of their sensitive information. This includes the protection of information that can be inferred from both the sensor readings themselves as well from the interaction of the users with the participatory sensing system.

This definition is used to evaluate around 30 sensing application available if the data that is collected is appropriate. This data includes time, location, pictures taken, sound, acceleration, pollution, biometric data, and barometric data. Christin et al. (2011) found that almost all application track the tuple of location and time, enabling the potential disclosure of the people's home and/or workplace. Furthermore, habits and routines can be derived (e.g. frequent hospital visits) and therefore reveal information that - if not protected from access - can be valuable for third parties (e.g. employers). The paper continues by presenting and discussing countermeasures. One user-centric solution can be to implement different levels of granularity of the shared data (e.g. information of the city and not the exact location), or that the location data is sent in less-frequent intervals, disabling a too detailed location tracking. Other technical solutions, besides pseudonymization, can be *spartial cloaking* where a collective of users is grouped based on a common

attribute (e.g. located in the same district) and their data only shows this common identifier, not individual information. The paper concludes that participants need to contribute for their very own sakes. (Christin et al., 2011)

Kotz (2011) suggests a taxonomy for privacy threads in mHealth applications in his work. The paper starts by pointing out that in mobile setting not only health related data is collected and shared, but also information about the patients' lifestyles and activities can be tracked easily. Also from the patient's perspective, mHealth applications offer means, not only to share the data with health professionals, but also with coaches, family or friends, and therefore the term *privacy* becomes a "complex issue". As a consequence, the paper tries to define a taxonomy for privacy threads with the categories *mis-use of patient identities, unauthorized access to Personal Health Information (PHI) or Personal Health Records (PHR)* and *unauthorized disclosure of Personal Identifiable information (PII) and PHI* on the top level. On the next level of the taxonomy, single categories for different user groups are inspected where a privacy breach is expected to happen. Those groups consist of the patient himself/herself, insiders (staff of the provided health service), and outsiders (unauthorized third parties). (Kotz, 2011)

A systematic review of mobile applications for diabetes self-management published by El-Gayar et al. (2013) shows that out of 71 investigated applications only one states compliance with HIPAA. Another five applications restrict the access using a password mechanism and only two applications use a secure channel for data transmission. The authors of this article discuss that patients acknowledge that automated data entry can increase the usability of such diabetes applications and report that non-functional requirements like security are implemented poorly.

2.5 Chronic Disease Management

The report on *Diet, nutrition, and the prevention of chronic diseases* from the World Health Organization (1990) that was published in the 1990ies, already stressed the

connection between the change in diet and the prevalence of chronic diseases. The WHO study group collected the knowledge on the change towards an "affluent" diet and reports the effects on the health of larger populations throughout all age groups. The report states that energy-dense food, the shift from complex carbohydrates to free sugar, and the high level of fat, is the most common cause of death in developed countries (cardiovascular diseases and cancer). Therefore they suggest nutrition policies for developed, as well as for developing countries, to counter this rising issue of "affluent" diet and the resulting increasing cost of the health care systems and the overall social cost.

In the HALE project, more than 2300 men and women have been observed for 12 years in order to detect what potential effects of the Mediterranean diet, activity, and smoking and drinking habits have on chronic diseases. The findings are reported in Knoops et al. (2004). Although the study discusses the limitations of the outcomes in terms of low numbers of participants with unhealthy diets or other lifestyle associated factors, it shows that a Mediterranean diet, a higher physical activity level, moderate alcohol consumption and nonsmoking can be associated with lower rates of chronic heart diseases, cardiovascular diseases, and cancer.

In 2006, the *American Heart Association Nutrition Committee* released recommendations how changes in lifestyle and nutrition have repercussions for chronic diseases, especially cardiovascular diseases, for the general population (Lichtenstein et al., 2006). According to Lichtenstein et al. (2006), guidelines for reducing the risks of cardiovascular diseases include:

- consume an overall healthy diet
- aim for a healthy body weight
- aim for recommended levels of low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (DHL) cholesterol, and triglycerides
- aim for a normal/healthy blood pressure
- aim for a normal/healthy blood glucose level

- be physically active
- avoid use of and exposure to tobacco products

At the time being, some of the goals stated in the list above can be measured easily on a regular basis by oneself. Modern day health devices or personal health devices can be used by lay people, since the atomized digital equipment is available. This includes the measurement of body weight, blood pressure, blood glucose level, as well as physical activity. Data can be gathered digitally at the user's place, e.g. using a smartphone, a tablet, or a smartwatch, interfacing personal health or fitness devices. Once available on a mobile device, the data can be used for viewing or analyzing purposes, health diaries can be established and last, but not least, data can be shared with other parties. These parties might include friends, relatives, peers, formal and informal caregivers, and health professionals. The report concludes with

> the current challenge to healthcare providers, researchers, and government officials is to develop and implement effective clinical and public health strategies that lead to sustained lifestyle changes among individuals and, more broadly, among populations (Lichtenstein et al., 2006).

Telemonitoring programs can be one means to enable effective health strategies, where a mobile application is (at the moment) one important actor enabling the sharing of data. As an example for the system architecture, the setup of the Austrian IT infrastructure is depicted in Figure 2.18. However, this quote also shows that those challenges can only be tackled by involving all the stakeholders (Lichtenstein et al., 2006).

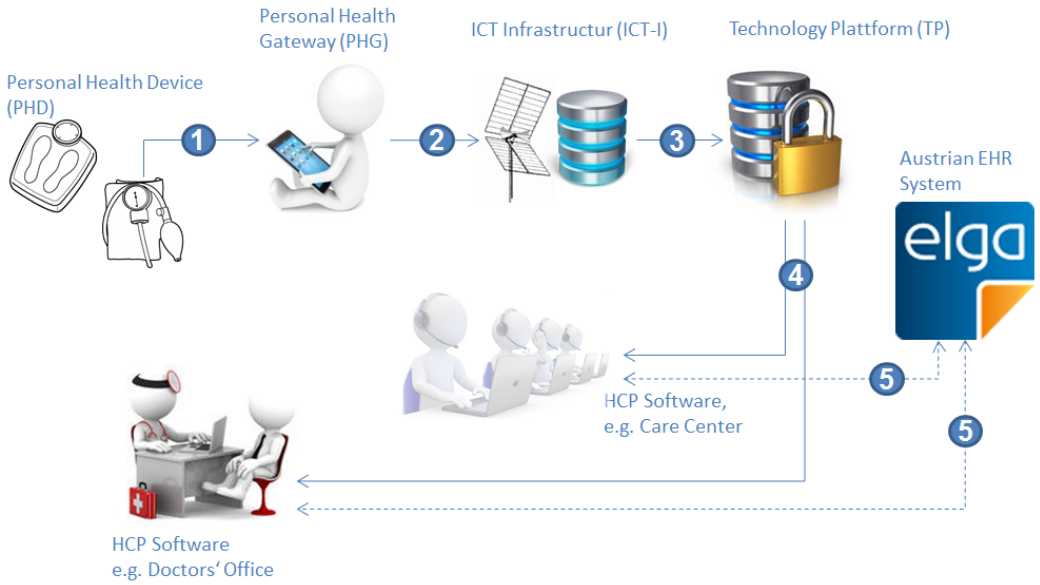


Figure 2.18 – Austrian framework guideline for IT infrastructure for telemonitoring purposes. Taken and adapted from Austrian Ministry of Health and Women (2017).

3 Materials and Methods

In order to define criteria for the implementation of mHealth applications in form of a guideline, the following methodology was used:

- User/Mobile-Application Engagement Model: The first step designs a model for the "application life cycle" from a user's perspective. This model depicts the engagement level of the mobile application user with a specific application over time with the motivation of software implementers and software vendors to focus on the users' needs and expectations. The model was validated in expert interviews based on a standardized questionnaire.

- Use Case Design and Definition: Interoperability issues are often characterized by the fact that multiple different manufacturers (from different domains) need to provide software interfaces that facilitate the communication of data over the vendors' product boundaries. Hence, the vendors need to harmonize this interface together. Experience shows and standards demand that a structured way is favorable to define the use case. This structuring improves the common understanding of the targeted use case and enables software test engineers to derive software test cases out of the use cases. In addition to the use case template available in IEC 62559 *Use case methodology - Part 2: Definition of*

the Templates for Use Cases, Actors List and Requirements List (IEC 62559, 2015), a simplified use case structure is introduced, condensing the key content of the structured approach as described by the IEC standard. Two use cases for mHealth applications were then specified based on the developed use case structure.

- Software Quality Characteristics: This step first reviewed available software quality models and software quality characteristics. These models and characteristics have been defined for general software development purposes. Hence, an expert review was conducted to assess these models and characteristics for their relevance in mobile eHealth environments. The experts were asked to state their opinions on the different characteristics and sub-characteristics and their relevance for mobile health applications. Their answers should also reflect the relevance of the characteristics for different user groups (primary users, secondary users, and indirect users) that are part of various scenarios in the eHealth domains.

- Frameworks and Criteria Catalog: In this step, available frameworks were identified and selected. Since the expert review of the relevant software quality characteristics showed that *Compatibility* was rated the most relevant software product quality characteristic, especially frameworks focusing on interoperability issues were considered. Criteria and requirements addressing compatibility were collected which are listed in the selected frameworks, and result in a checklist-like criteria catalog for (mainly, but not exclusively) implementors of mobile health applications. Using these criteria, an implementer can find the most relevant features that need to be implemented in a mobile application. Interoperability challenges were one main focus for this criteria catalog.

- Prototype Implementation: Based on the use cases defined, two Android application were developed. These applications deal with not only the interoperability issues of communicating data from a PHD to a mobile device, but also with the generation and forwarding of clinical documents to health

professionals.

- Validation of Prototype Implementations: Based on the criteria catalog, the developed applications were validated. For this validation, the application for communicating with PHDs was tested with a set of different devices from different manufacturers (one blood glucose meter and four weighing scales). The clinical document that was generated by the second prototype application, and was validated against the specifications for clinical documents by using XML-validators.

- Interoperability Testing for Mobile Applications: Testing the communication capabilities with PHDs can be a burdensome task. Taking measurements need to be repeated for multiple times in order to validate if the mobile application receives these measurement values correctly. Hence, this work introduces a simulator for PHDs, implemented as an Android prototype. This applications simulates various PHDs for interoperability testing and provides an XML based test case configuration file. Based on the configured tests the simulator application provides different measurement values over Bluetooth Low Energy services.

- Transfer of Gained Knowledge to other Domains: Interoperability challenges can be observed in other domains than eHealth as well, since the author of this work is engaged in a project that transfers the methodology of IHE to solve interoperability challenges in the energy domain. Based on the efforts made for the transition of energy supply towards renewable energy sources, multiple smaller energy devices (consumer photo-voltaic panels, smaller wind farms, etc.) are foreseen to be installed in so-called *Smart Grids*. Therefore, the need for communication between the assets and *Supervisory Control and Data Acquisition* (SCADA) systems will increase. The project demonstrates that the transfer of the methodology, including interface testing strategies, is doable. Similar to this transfer, the number of mobile endpoints might increase over time, enabling the energy consumers (households) to interact with their energy devices more easily.

3.1 User/Mobile-Application Engagement Model

Quality characteristics can manifest themselves to be present or not in different stages of the software life cycle from an end-user perspective. For example, the initial set-up might be complex, but the use of the application is easy. Establishing a secure connection to web-servers, or external sensor devices, which might be a task during the initial setup, can daunt users or, in worse cases, can make users resign from this application. Especially in cases where the benefit of the needed configuration is not obvious, users might tend to give up and search for alternatives.

From an implementer and sales perspective, the way mobile applications are distributed and sold is different from classic software applications. It is the marketplace of Google or Apple that are pre-setup when a mobile device is purchased. Users can easily browse through apps provided on *Google Play* or in Apple's *App Store* and select applications they want to install on their devices. There is no need for the user to go to other (online) shops since the platforms' app stores are the "single point of shopping" for the standard user group. Holzer and Ondrus (2011) cite the *The Long Tail*, by Chris Anderson, explaining that the market platforms can leverage the long tail of selling applications. This is due to the fact that once an application is released on the platform, no storage cost arises and therefore the application can stay on these platforms for a long time and might - even if not best selling - create revenue. However, Zhong and Michahelles (2013) doubt the relevance of the long tail, since their study showed that Google Play is largely dominated by a very few number of good selling apps. Those apps also receive better user ratings which in the end increase their position within the search result and attract more users.

From an end user's perspective, the application life cycle of mobile applications is of interest. Finally, the users decide if an application will become a bestseller or digital shelf warmers. Figure 3.1 depicts the user/mobile-application engagement model from a user's perspective and the engagement with *one* application, i.e. this model shows the "relationship" between a user and one single application. This

model covers the phases starting from a *demand phase*, where the user's attention rises in order to solve a certain problem by using an application and ends either in the *usage phase* or with the un-installation of the application. The phases show the level of user engagement within a certain phase. The following subsections describe the different phases in detail.

3.1.1 Phases in the User/Mobile-Application Engagement Model

Demand: Users in this phase possess a mobile device and start to think about a certain issue they want to solve by using a mobile application. This phase can be rather short when, for example, a user is asked by a third party (friend, relative) to install a certain application. Another scenario of a very short demand phase is when a user takes part in a care program and the program demands the use of a certain application. Longer phases might occur when a user's needs are not too distinct and no timely constraints require immediate action.

Pre-install: The starting point of this phase is characterized by the first time the user enters the application market on his/her mobile device in order to search for a specific application that is targeted to satisfy the identified demand from the previous phase. The users are expected to search, based on key words, for applications available within the market, or enter the name of the targeted application directly if the application to be installed has already been chosen. This can be the case when a third party recommends a specific application to be used, or the user becomes aware of a certain application via, for example, advertisements. The time span of this phase might also vary considerably, based on the before mentioned different approaches for searching. Users might find different applications that are suitable to solve the needs, and compare the results based on ratings, comments, costs, needed permissions, displayed screenshots, and the applications' description. Filtering the hits for system requirements is of minor importance since the found applications have already been pre-filtered by the market, since the devices parameters (e.g.

OS version, screen size, screen resolution, etc.) were automatically included in the search in the first place.

Post-install: This phase is entered, when the user starts the installation routine of the application. Within this phase, the initial setup of the application is done by the user. He/She might be asked to agree to *terms and conditions*, *privacy regulations*, and *permissions* that need to be granted, enabling the application to work as intended. Furthermore, the user might need to configure connections to additional hardware that is required or can be used with the installed application. Examples of that are Bluetooth connections to portable Bluetooth speakers, fitness gadgets, or medical devices. Another characteristic of this phase is to create a user account or provide login information for single sign one services provided by identity providers such as Google, Apple, or Facebook.

Usage: This phase describes the time after the user has installed the application on the mobile device. All necessary steps for the initial setup are completed and the application can be used by the user as intended by the application. This phase does not distinguish between active use of the application or if the application was installed but rarely used.

Uninstall: This phase terminates the usage phase, since the user actively decides to uninstall the application for some reason.

3.1.2 Different User Types

Based on Figure 3.1 and the way a single user might engage with a single application, different user types are suggested for further use in this work. The introduced user types do not characterize an individual to belong to a single type alone, since the user types are applications specific, i.e. a person can belong for a certain application to one user type, but to another type for a second application. These user types are identified by the letters A to D.

User Type A: This type of user installed and set up an application and are considered

to remain in the *Usage* phase. After an initial usage time, they continue to use the application on a regular basis, i.e. the user's engagement with the application is high.

User Type B: This user type completed the initial setup and started with a high user engagement. In contrast to user type A, this engagement drops rather fast at a point in time e. Reasons for this can be that the user found that the application does not fit the (latent) needs after a period of usage. Another possible scenario is that the user becomes aware of an alternative application that is more preferable. This user group can be accounted to the *Usage* phase, but with a decreasing engagement with the applications, and might even end with the transition into the *Uninstall* phase.

User Type C: User type C is characterized by the circumstance that he/she will lose his/her user engagement level in the phase *Post-install*. This can be triggered, by difficulties of the single steps needed for the initial setup of the application, like connecting with external devices. Another scenario might be that the user does not agree with the stated terms and conditions, is not willing to accept the needed permissions of the installed application, or is not able or does not want to sign up for a mandatory user account. The user will not use the application actively although keep it on the phone, i.e. transfers into the *Usage* phase but has a negligible engagement level with this application, or the user will uninstall the application directly after the uncompleted setup or at another future point in time.

User Type D: These users start investigating the application store searching for different applications that seem to be applicable to solve the personal demand. From the perspective of a user and a single application, the user might decide not to use a specific application and therefore the engagement with this application drops to zero. Scenarios, when such things happen, include a user not installing this application based on the application's description, the rating of the application and the comments from other users. Other scenarios include that the potential user is not satisfied with the required permissions, the terms and conditions of use, or the privacy terms that are stated.

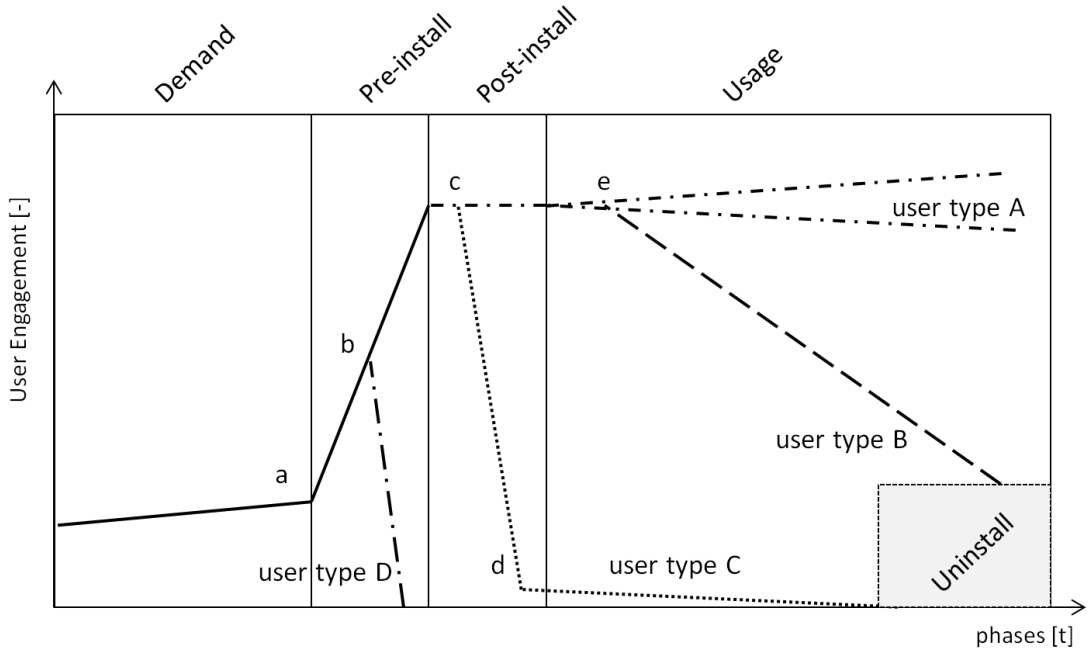


Figure 3.1 – The user/mobile-application engagement model

3.2 Use Case Design and Definition

The definition and harmonization of use cases, especially those including interoperability challenges, is an adequate way to bring all stakeholders to a common understanding. Based on more generic business use cases, technical use cases can be derived specifying the actors that are needed, the information that should be exchanged and the trigger events for these communications. In IHE use cases are solved by the specification of *Profiles* that depict the interfaces and communication standards that need to be implemented and the message content in terms of the structural requirements and the semantic restrictions to be used. Therefore, a profile in the context of interoperability, as described on the IHE webpage (IHE, 2016), seeks to "provide a common language" with which all involved stakeholders in the healthcare sector can discuss their needs. The profiles provide the implementation details for the communications standards used in a certain use case. Hence, an IHE profile defines the technical implementation strategy in order to solve interoperability

issues is real-world use cases. The ISO technical report 28380-1 describes the IHE standards adoption process and further defines and distinguishes *content profiles* that specify the content that shall be transmitted, and *integration profiles* that specify the information exchange itself in terms of interactions which are needed between different software solutions (ISO TR 28380-1, 2013).

One standardized approach to start with the definition of use cases is described by IEC 62559 *Use case methodology - Part 2: Definition of the Templates for Use Cases, Actor List and Requirement List* (IEC 62559, 2015). This standard provides a structured template to address and cross-reference all the criteria that are included in one use case. Although a structured and documented approach is relevant, recent use of this standard shows that the work needed for writing and maintaining this artifact is burdensome. Based on the experiences with this approach, a condensed use case template is introduced (see Section 3.2) and will be used for this work. Annex A.2 shows one example of a use case that is similar to the use cases introduced in this work, using the templates from the IEC standard. The focus of the condensed use case template lies, apart from the clarification of used nomenclature, on the interoperability issues that should be addressed. That approach aligns with the definition of the term *use case* from IHE, which has been published as a technical report (ISO TR 28380-1, 2013), as a "textual and graphical depiction of the actors and operations that address information exchange". Considering this narrow definition from the IHE perspective and the wider view on use cases as stated by IEC 62559 the introduced use case template considers both approaches. Hence, it does not only contain information relevant for the implementation of the interfaces but also considers the origin of the data to be exchanged and the data format that might be decoupled from the used transport channel when generic transport channels are specified.

1. Name, Identifier, Version Management, Nomenclature and Narrative of the Use Case

Table 3.2 contains the name, the unique identifier, and the narrative description of the addressed use case. Besides this template includes the needed meta-data for controlling the version and status. Terminology that is relevant to understand the description and graphics needs to be included as well.

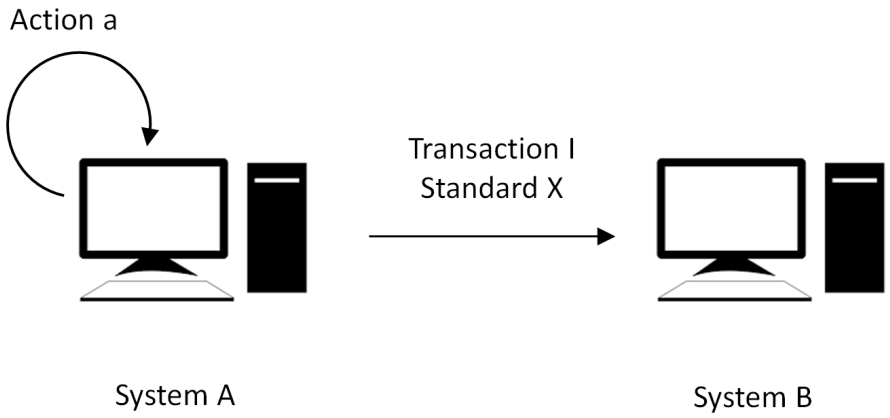
Table 3.1 – Template for Use Case Identifiers and Short Narrative of the Use Case

Name of the Use Case		*Identifier*	
Version	*Author:* *Status:* *Last Modified:*		
Nomenclature			
Action –an action represents a process that is not directly involved in a communication with another system, but is a precondition for the transaction. An example for an action is the generation of the content that will be transfered to another system. **Transaction** –a set of messages that is exchanged for a certain purpose.			
Narrative of the Use Case			

2. Architecture and Information Exchange

The use case template depicted in Table 3.2 contains the graphical representation of the use case including the definition of the systems involved, the definition of the actions and the definition of the transactions. Beside the definition of the systems, actions, and transactions in the graphic, those artifacts need to be described in the corresponding table elements.

Table 3.2 – Template for Use Case Architecture and Information Exchange

Architecture

Systems
Description of the systems involved
Actions
Description of the actions. e.g. fetching of data
Transactions
Description of the transactions

3.3 Software Quality Characteristics

In order to identify issues that influence the perception of quality in the context of mobile applications, an expert questionnaire was designed (the questionnaire can be found in Appendix A.1). This questionnaire is titled *Survey Concerning* ***Quality Criteria*** *and Concepts for* ***mHealth*** *Applications* and starts with the definition of stakeholders. It's based on ISO/IEC 25010:2011 (ISO/IEC 25010, 2011) and has been applied for mHealth applications. The following stakeholders were defined:

- *primary user*: a person who installs an application from the app-market and uses the application voluntarily, and/or who has been instructed by a third party to use a certain application.

- *secondary user*: a person who provides support (e.g. by providing content) or maintains and manages the use of a mobile applications.
- *indirect user*: a person who receives output from the application (e.g. health professionals for tele-health)

After the definitions, five questions were formulated. The first three target the applicability of quality characteristics as defined by ISO/IEC 25010:2011 for mHealth applications, the fourth question asks for needed certifications programs in order to validate and certify the proper implementation of the quality characteristics (independent of whether certification in the addressed field already exists or not), and the last question asks for assessment for the user/mobile-application engagement model as introduced in Section 3.1.

The survey was conducted in form of individual interviews at Austria's biggest national eHealth conference 2018 (AIT Austrian Institue of Technology GmbH, 2018). The intention of the survey was to get feedback from experts in different fields, i.e. researchers, implementers, and disease management program providers. The questionnaire was handed out in English, the interviews were conducted in German.

3.4 Frameworks and Criteria Catalog Addressing Interoperability

The Food and Drug Administration (FDA) published a report stating recommendations for designing interoperable medical devices in 2017 (U.S. Department of Health and Human Services - Food and Drug Administration, 2017). This document stresses the requirement that manufacturers must conduct a risk management including the risks that result from the implemented electronic interfaces. The following points need to be considered according to this report:

- Purpose of the electronic interface

- The anticipated user
- Risk management
- Verification and validation
- Labeling considerations
- Use of consensus standards

U.S. Department of Health and Human Services - Food and Drug Administration (2017) concerns that the manufacturer should have a clear picture concerning the purpose of the interface to be implemented. Interfaces and capabilities include sending and/or receiving of information, as well as command and control features that are controlled via the implemented interface. Beside these basic interface requirements, the manufacturer should consider the different types of users of the system as well as the mitigation factors that can reduce the risk when the manufacturer's system is connected to other devices/system via the implemented interface. The report also stresses that suitable validation and verification means need to be in place, not only for the development phases but also maintenance and release of new updates. Additionally the manufacturer should provide sufficient information, so that users can connect and use the system/software implementing the interface. The last recommendation states that harmonized communication standards should be considered for implementation of interfaces. (U.S. Department of Health and Human Services - Food and Drug Administration, 2017)

More detailed recommendations concerning the data exchange and interoperability can be found in HL7's draft standard *HL7 Consumer Mobile Health Application Functional Framework, Release 1* (Health Level Seven International, 2018), where five conformance criteria are stated. The first four of these criteria deal with the exchange of information across the system boundaries of the mobile device, i.e. data that is received from a device (e.g. PHD) or data that is sent to remote services (e.g. electronic health record). The conformance criteria demand the use of standard terminology and standard data formats whenever the mobile applications

send data to remote services. HL7 states the use of SNOMED CT or LOINC for the terminology and HL7 Consolidated CDA or HL7 FHIR as standard formats as an example. For a communication of either unstructured data with remote services or the communication with devices, this document suggests using HL7 CDA or IEEE 11073. The fifth criteria should be applied when an application collects personal health information and states that an import and export of data should be enabled.

3.4.1 Downstream Data Exchange

Data exchange between mobile health applications running on mobile devices and personal health devices and fitness monitoring devices is mainly achieved over wireless transport channels. Keeping in mind that both endpoints of this communication must implement a common interface, manufacturers of personal health and fitness devices need to respect the available technologies on the broad variety of mobile devices. Since Bluetooth and WiFi interfaces are available on almost all mobile devices, the PHD manufacturers will implement this interfaces most often. Otherwise, additional hardware in form of adapters must be used by the end-user in order to communicate with PHDs. Based on available products on the consumer market it seems that Bluetooth, especially Bluetooth Low Energy, is the driver for data communication. WiFi - at the time being - provides higher bandwidth but lacks in energy efficiency. The same can be said for classic Bluetooth and Bluetooth *Enhanced Data Rate* (EDR). Other technologies like ANT or ZigBee seem to loose market since Bluetooth has accomplished to overcome past shortcomings by the introduction of Bluetooth Low Energy. In short, concerning the user's experience of interfacing external sensor devices in general, the users would favor a common interface that is available on all the users' devices. Otherwise, the users need to investigate if a certain device is compatible with the user's mobile device every time a new device is connected to the phone in order to transfer data.

The PCHAlliance is a major player in the field of enhancing interoperability

between PHDs and mobile devices. The architecture showing the communication interfaces (see Figure 2.7) includes various standards that are relevant for the communication of data and semantic interoperability. In PCHAlliance's *Personal Health Device Interface Design Guidelines* (Personal Connected Health Alliance, 2016), the conformance criteria are listed for the different types of interfaces the PCHAlliance supports. In general, the different types can be boiled down to basic types of interface implementations. The first type is based on the specifications from the ISO/IEEE 11073-20601 family of standards and the support of either NFC, classic Bluetooth, USB, or ZigBee as transport technologies. PCHAlliance uses the term *X73-IF* for identification. The second type is only defined by Bluetooth Low Energy. Generic X73-IF capabilities, i.e. independent from transport technologies, are defined for the PHD (service device) and the mobile device (client device). Based on the underlying ISO/IEEE 11073-20601 family of standards further restrictions are stated in the interface design guideline document. Concerning the Bluetooth Low Energy interface guideline, PCHAlliance introduces the supported device-specific specifications that are taken from the Bluetooth SIG. Beside those device-specific specifications, general requirements are stated.

HL7 is well known for specifications in the field of medical IT that are relevant for large IT architectures within the professional domains. Recently, HL7 drafted the *HL7 Consumer Mobile Health Application Functional Framework* (Health Level Seven International, 2018) where one of the addressed issues was interoperability of exchanged data. In this draft, HL7 suggested a set of conformance criteria addressing the communication of data to and from a mobile device. In addition, this document specifies that data communication shall be encrypted.

In order to support the application development process and for testing purposes, PCHAlliance provides the *Continua Enabling Software Library* (CESL) (Personal Connected Health Alliance, 2018c). This kit should enable implementers to design their codes and to test their implementation against code compliant to Continua specifications. Software products that are implemented following the requirements stated by Continua guidelines can show their compliance in two ways. First, the

organization can request a statement that their product is *Continua Compliant*. In order to reach this level, the organization needs to run software tests provided in the *Continua Test Tool* (CTT) (Personal Connected Health Alliance, 2018b) and providing Continua with a self-declaration that all the required tests have been passed. The alternative is the *Continua Certification*, a certification that is for Continua member only, enabling the organizations to show their compliance by using the Continua Certified logo. For the certification the device or the application is tested in certified test laboratories for conformance with the requirements stated in the Continua Design Guidelines and tested for interoperability with devices/applications that are already available. In both cases - for the compliant as well as the certified devices - Continua will publish the devices on their web pages. The first compliant devices and software products listed on the Continua web pages show a declaration date from March 1st, 2018(Personal Connected Health Alliance, 2018a). In total, there are six devices listed that come from a single manufacturer. This shows that the schema is rather new. The list of Continua certified devices holds entries that are dating back to the year 2009 and about 120 devices and software products can be found (Personal Connected Health Alliance, 2017a).

3.4.2 Upstream Data Exchange

Taking the mobile device as the source of the data that should be communicated, upstream data exchange defines the capability to exchange data with remote services and systems in a structurally and semantically distinct way. Wireless transport technologies that use wide area networks enable the mobile device to communicate messages and/or clinical documents to the dedicated communication end-points. Since multiple different possibilities and technologies are available, interoperability of systems requires certain restrictions how, and what kind of data need to be transmitted. The IHE provides different integration profiles for solving this technical task to communicate data over institutional, organizational or - in general - system boundaries. The reason why different possible integration profiles exist, and not one single solution, is due to the different use cases and different technological boundary

conditions that exist. The PCHAlliance, specifying the complete chain how data can be exchanged from the very beginning (a PHD) to the final data sink (an electronic health record system), references to IHE integration profiles. Hence, from the mobile device (personal gateway device) to the electronic health record system, PCHAlliance uses IHE profiles.

The classic approach to communicate data over organization borders according to IHE is the implementation of either a *Cross-Enterprise Document Sharing* (XDS) infrastructure or the implementation of the *Cross-Enterprise Document Reliable Interchange* (XDR) profile. Both approaches are introduced in IHE's *IT-Infrastructure* Technical Framework Vol. 1 (IHE International Inc., 2018b). The first specifies an IT architecture where documents can be shared in a way that they are made retrievable for other entities within this XDS domain, i.e. documents are not sent from the sender to the receiver but stored in a repository where the documents can be loaded. In contrast to this approach, XDR deals with a direct communication between sender and receiver and the secured transmission of information (e.g. clinical reports).

Another approach to forward information is based on HL7's messaging standards. These standards are used by IHE's *Device Enterprise Communication* (DEC) integration profile which is specified in IHE's Technical Framework for *Patient Care Device* (PCD) (IHE International, 2015). The patient care device domain was formed in 2005 to enable the integration of medical devices into the professional health care domain. Hence, the DEC profile defines how HL7 messaging standards shall be implemented in order to transport data acquired on medical devices outside hospital boundaries to the treating health professionals. Apart from this approach, which does not demand too many requirements to IT-architecture, another, an even easier approach is introduced in the Volume 1 IT-Infrastructure Technical Framework. IT-architecture can be neglected (partially) completely when data is communicated following the specifications of IHE's *Cross-Enterprise Document Media Interchange* (XDM). This integration profile defines physical media like CDs or USB flash drives as carriers of information. By only defining the folder structure

and a set of required meta-files, this profile leaves the file format for the clinical document open to different implementations. Besides the use of physical media carriers, this profile also specifies the needed requirements when clinical documents are exchanged via email services.

3.4.3 Criteria Catalog

Based on the introduced technical guidelines, technical frameworks and available test tools, the following table summarizes the criteria that are stated for data exchange and semantic interoperability. Other criteria that are not connected to the exchange of data are not listed in the table below. If applicable, further restrictions introduced in this section before are applied for the use cases. This means, in cases when specific criteria are defined for certain device classes, those are considered for the devices as described in the use case descriptions. Another restriction concerning the available guidelines is that only requirements and criteria are listed that can be addressed by a mobile application running on a mobile device. Continua uses the term *client device* for this side of the communication, whereas the term *service device* is used for health or fitness devices.

Criteria and Requirements for data exchange with downstream devices can be found in Table 3.3. This table indicates that PCHAlliance with its guidelines for the PHD-IF has a more technical approach compared to criteria that are stated within the HL7 functional framework.

Table 3.3 – Criteria and Requirements for Downstream Data Exchange. The sources referenced in this table are Personal Connected Health Alliance (2016); Bluetooth SIG (2014); Health Level Seven International (2018)

Id	*Criteria / Requirements*	*Conformance Criteria*	*Source(s)*
DS_1	Pairing with service devices after service device discovery	SHALL	Continua PHD-IF
DS_2	Available documentation of the pairing procedure	SHALL	Continua PHD-IF
DS_3	Possibility to delete previous pairing	SHOULD	Continua PHD-IF, HL7 CMHAFF
DS_4	Possibility to store pairing information	SHOULD	Continua PHD-IF
DS_5	Indication of successful pairing	SHALL	Continua PHD-IF
DS_6	Filtering the list of discovered service devices	SHOULD	Continua PHD-IF
DS_7	Communicate failure during pairing procedure	SHALL	Continua PHD-IF
DS_8	Support *Just Works* or *Passkey Entry* for pairing	SHALL	Continua PHD-IF
DS_9	Data received from a service device shall be compliant to IEEE 11073 nomenclature if its get transcoded	SHALL	Continua PHD-IF
DS_10	Implementation of the collector role as defined by the Bluetooth profile for glucose meter	SHALL [IF Blood Glucose]	Continua PHD-IF, Bluetooth SIG
DS_11	Implementation of the collector role as defined by the Bluetooth profile for weight scale	SHALL [IF Weight Scale]	Continua PHD-IF, Bluetooth SIG

Table continues on next page

Id	*Criteria / Requirements*	*Conformance Criteria*	*Source(s)*
DS_12	User is authenticated to an application and has an active session before pairing with sensor devices	SHALL	HL7 CMHAFF
DS_13	User is informed about the collection of data by an external sensor device before this device is paired	SHALL	HL7 CMHAFF
DS_14	User is informed about the kind of data collected and the purpose of this collection before the pairing	SHALL	HL7 CMHAFF
DS_15	User can review the data that has been received from an external sensor device and can block the forwarding of the data	SHALL [IF Application acts as "pass through" device]	HL7 CMHAFF
DS_16	User can review and comment on the data that has been received from an external sensor device, but cannot delete the data	SHOULD [IF Application does not forward the data]	HL7 CMHAFF
DS_17	Use of standard formats for data communication	SHALL* SHOULD**	Continua PHD-IF*, HL7 CMHAFF**

Table 3.4 lists criteria and requirements for *Data at Rest*, i.e. the requirements for handling data once it has been received from a PHDs, but before it gets sent to a remote service. This criterion should also be considered for use cases where data is

gathered on the mobile device without any interfaces to the outside world.

Table 3.4 – Criteria and Requirements for Data at Rest. The sources referenced in this table are Health Level Seven International (2018)

Id	*Criteria / Requirements*	*Conformance Criteria*	*Source(s)*
AR_1	Storing of personal health information and personally identifiable information in an encrypted way	SHALL	HL7 CMHAFF
AR_2	User is able to delete collected information	SHALL	HL7 CMHAFF

Table 3.5 lists requirements and criteria for the forwarding of data to remote services. The HL7 functional framework promotes the use of standardized terminologies and transport formats but does not specify in detail what standard should be applied. Examples include LOINC, SNOMED CT, HL7 FHIR, HL7 CDA, and PDF. PCHAlliance defines more strictly what standards need to be implemented, but it does not consider the used IHE XDM profile as one of those standards. Hence, the implemented Android application uses a standardized format and way to communicate data (based on IHE) but does not follow the specified interfaces based on the Continua Design Guidelines. Therefore, these guidelines cannot be applied to identify criteria.

Table 3.5 – Criteria and Requirements for Upstream Data Exchange. The sources referenced in this table are Health Level Seven International (2018)

Id	*Criteria / Requirement*	*Conformance Criteria*	*Source(s)*
US_1	Use of standard terminologies	SHALL	HL7 CMHAFF
US_2	Use of standard formats	SHALL	HL7 CMHAFF

3.5 Prototype Implementations

Part of this work is to implement prototype mobile health applications to solve quality aspects of data interoperability based on the requirements and use cases that are introduced in Section 4.2. The goal is to implement these applications for Android. This decision is based on the circumstance that implementation of Android applications are a part of the curriculum of the study degree program *Biomedical Engineering Scencies* at the University of Applied Sciences Technikum Wien. Another reason for choosing Android is that ISO/IEEE 11073-20601 using the Bluetooth *Health Device Profile* (HDP), as requested by the Continua Health Alliance, is only available on Android systems: The Android Bluetooth stack has implemented the HDP starting with Android 4.0 (API level 14) (Android Developers, 2018b), whereas Apple's IOS never supported this profile. This circumstance has induced the implementation of Android applications in the past years, especially in the time when Bluetooth Low Energy was neither available nor recognized by the Continua Health Alliance. Since then, the curriculum and the author have focused on Android implementations resulting in the fact that Android and its Integrated Development Environment (IDE) *Android Studio* (Android Developers, 2018c) (in the most recent version) have been used for the prototype implementation of mobile health and fitness applications.

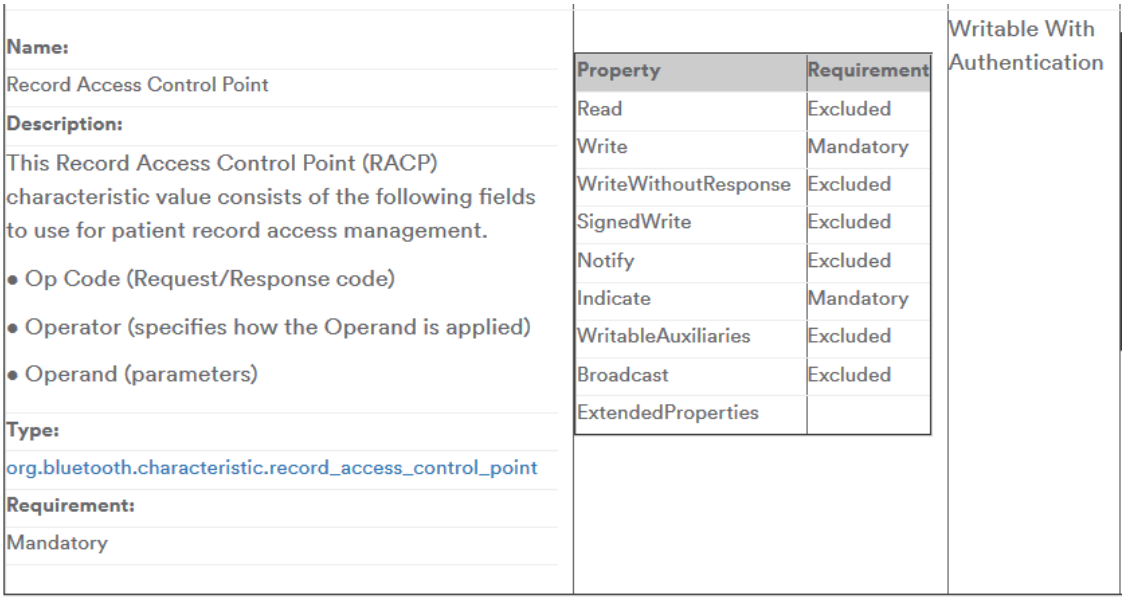
3.5.1 Interfacing a Personal Health Device

Based on the use case for reading blood glucose values from a blood glucose monitor device, an Android application is implemented. This application should be able to communicate via BLE with glucose meters that follow the profile definitions from the Bluetooth SIG in order to receive the most recent blood glucose reading, its timestamp, and the annotations of the measurement taken. These annotations provide the context of the measurement in terms of indicating if the measurement was taken, for example, before a meal or after a meal. The implementation of

the interface is based on specifications from Bluetooth SIG and the PCHAlliance. Bluetooth SIG Inc. (2018c) specifies the use of the *Record Access Control Point* (RACP) in order to receive stored blood glucose measurement data from the device. This form of data retrieval can only be achieved via a secure connection where the mobile device and the blood glucose meter needs to be paired and bounded in advance. Other services can be used without this security feature, enabling the user to receive general information about the device and retrieving only the latest blood glucose reading. Figure 3.2 shows the mandatory properties that need to be implemented for the communication of stored blood glucose readings. The control point demands the implementation of remote writing capabilities and indication. The first is used to enable management functionalities by the connected mobile device and the latter is used for reporting functionalities. The mobile application remotely writes the record access control point characteristic to trigger the sending of stored data. This is achieved by the application by sending the desired *Operation Code* and the *Operator* and a set of additional parameters based on the operator (e.g. when filtering for readings between a certain period of time, these parameters are the two points in time).

The values received at the mobile device are stored in Android's SQLite database. The demographic data of the patient, like his/her address or contact information, is stored in this database as well. This application is used in lectures to introduce the topic of interoperability and standardized interfaces. The possibility to adapt the demographic data is therefore only available directly from the code. The application, at the time being, does not provide a GUI enabling users of the application to change their demographic data. The demographic data is not necessary for exchanging information with the blood glucose meter, but might be used to further transfer data via messages (e.g. HL7 messages or HL7 FHIR) or reports (e.g. HL7 CDA documents) to health care providers.

Beside the implementation of the described use case for blood glucose measurement, the implemented Android application was adapted to interface body weight scales. This step was done on the one hand to validate the flexibility of the implemented



Name:
Record Access Control Point

Description:
This Record Access Control Point (RACP) characteristic value consists of the following fields to use for patient record access management.

- Op Code (Request/Response code)
- Operator (specifies how the Operand is applied)
- Operand (parameters)

Type:
org.bluetooth.characteristic.record_access_control_point

Requirement:
Mandatory

Property	Requirement
Read	Excluded
Write	Mandatory
WriteWithoutResponse	Excluded
SignedWrite	Excluded
Notify	Excluded
Indicate	Mandatory
WritableAuxiliaries	Excluded
Broadcast	Excluded
ExtendedProperties	

Writable With Authentication

Figure 3.2 – Specification of the Record Access Control Point services for blood glucose as defined by Bluetooth SIG Inc. (2018c).

code to enable students to take over the existing code and adapt the application for their own tasks within projects. On the other hand, this adaption was made for dissemination purposes, e.g. this application was used in presentations at the University of Applied Sciences Technikum Wien's Open Days or *die lange Nacht der Forschung*, an event promoting sciences and enabling the wider public to get in touch with different areas of research. Taking a weight reading instead of a blood glucose reading allows interested people to take their own reading more comfortably.

In contrast to the implementation of the record access control point characteristic that is specified for glucose meters, the weight service specification does not include this characteristic. The weight service only specifies the *Weight Scale Feature* and the *Weight Measurement* characteristics. The weight scale feature specifies in 32bits weight scale capabilities (see Table 3.6). Based on the information contained in the weight scale features, the weight measurement characteristic is composed and the receiver is enabled to decode the received bytes. The implemented application needs to read this set of features and alter the *descriptor* of the weight measurement characteristic in order to receive indications whenever the weight scale has conducted

a measurement. Compared to the RCAP used by the glucose meter, the application will get automatically the latest readings but is not able to manage the data on the weight scale, i.e. there is no possibility to query for stored readings or delete the stored values on the remote device.

Table 3.6 – Specification of the weight scale feature characteristic Bluetooth SIG Inc. (2018e)

Bit	*Size*	*Name*	*Definition*
0	1	Time Stamp Supported	0...False 1...True
1	1	Multiple Users Supported	0...False 1...True
2	1	BMI Supported	0...False 1...True
3	4	Weight Measurement Resolution	0...Not Specified 1...Resolution of 0.5 kg or 1 lb 2...Resolution of 0.2 kg or 0.5 lb 3...Resolution of 0.1 kg or 0.2 lb 4...Resolution of 0.05 kg or 0.1 lb 5...Resolution of 0.02 kg or 0.05 lb 6...Resolution of 0.01 kg or 0.02 lb 7...Resolution of 0.005 kg or 0.001 8-15...Reserved for future use
7	3	Height Measurement Resolution	0...Not Specified 1...Resolution of 0.01 meter or 1 inch 2...Resolution of 0.005 meter or 0.5 inch 3...Resolution of 0.001 meter or 0.1 inch 4-7...Reserved for future use
10	22	Reserved for future use	

3.5.2 Send Clinical Document to Health Care Provider

The second use case that is implemented as a prototype and is used for teaching purposes, is an Android application that takes blood glucose readings or vital

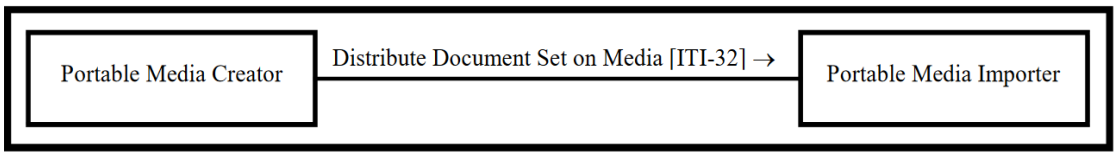


Figure 3.3 – The actor diagram from IHE's XDM profile, taken from IHE International Inc. (2018b)

parameters that are available on mobile devices and formats them to fit into an HL7 CDA document. This document is then sent via secure email to a recipient who could be a health professional. In order to address the issue of interoperability, profile definitions from IHE are used. The specifications to send clinical information via email are available in the *Cross-Enterprise Document Media Exchange* (XDM) profile that can be found in IHE's technical framework *IT Infrastructure* (IHE International Inc., 2018b). This profile specifies how clinical data (e.g. CDA documents) can be exchanged between stakeholders in cases where a sufficient IT infrastructure is missing. Therefore, other means of transport are defined, like USB flash drives, CDs, or using secure email services. IHE defines the actors *Portable Media Creator* and *Portable Media Importer* to be implemented in the XDM profile. Figure 3.3 shows the *Actors/Transaction Diagram* as stated in the *IT Infrastructure* Technical Framework Volume 1 (IHE International Inc., 2018b) where the two actors are defined and the transaction is specified. This transaction *ITI-32* is not bound to a specific electronic communication technique but specifies the requirements for communicating data using physical media or email. The Technical Volume 2b (IHE International Inc., 2014) introduces the *Portable Media Creator* as a software component with the task to assemble the media content to be stored or sent to the *Portable Media Importer*. This task includes the generation of meta-data in form of a *Document Submission Set* that describes the clinical document but it does not include the generation of the clinical document itself. This task is assigned to another actor, called *Content Creator*. The role of the media importer is to read the submission set and access import the clinical document that is described in the submission set.

Concerning security issues XDM specifies that media that is transported on a CD or USB memory drive shall not be encrypted. However, if the email option is implemented, the transaction shall be secured by S/MIME (Secure / Multipurpose Internet Mail Extensions), encrypting and signing the message. Since the default Android email client does not support S/MIME, *MailDroid* (Flipdog Solutions, 2018b) with its extension *Crypto Plugin* (Flipdog Solutions, 2018a) is used for sending an encrypted and signed email. For validation purposes, the author's digital certificate issued by the University of Applied Sciences Technikum Wien is used. The CDA document contained within the generated zip file generated by the mobile application is forwarded to MailDroid, using Android's interprocess call technology *Intents*. For the content of the clinical document, blood glucose readings are taken from a SQLite database containing previously taken and stored values or simulated values. The clinical document that is sent via email is an XML document following the specifications from HL7 CDA. The generated document uses CDA's features to transport the information in a human readable, as well as a machine readable format. Since CDA only defines the generic structure of the document in form of single XML building blocks, further restrictions for the content and the document structure are in place. Those restrictions are based on IHE's *Patient Care Coordination* (PCC) (IHE International Inc., 2016) and HL7's *Continuity of Care Documents* (CCD) (Health Level Seven International, 2007) as well as on the Austrian health record system ELGA's specification CDA documents in Austria (ELGA GmbH, 2017c). These documents specify which HL7 CDA classes shall be used, and which terminology and identification schemes shall be applied in order to communicate health information from a patient in a human and machine readable format. The designed CDA document structure that is used for the reporting of medical information, is discussed with the head of standardization of the Austrian electronic health record system (ELGA), since ELGA has the best overview of document standardization projects that might be of relevance for the document specified in the context of this thesis.

For machine readability of the transported information not only a highly structured document is needed but the content must also be coded using common terminologies.

For the coding of parameters a person acquires at home, LOINC (Regenstrief Institute, 2018) or ISO/IEEE 11073-10101 (IEEE Engineering in Medicine and Biology Society, 2002) vocabulary can be used. Besides the basic terminology standard ISO/IEEE 11073-10101, additional vocabulary is introduced in the device class specific IEEE 11073 sub-standards. For blood glucose readings the ISO/IEEE 11073 Part 10417 for glucose meters is relevant (IEEE Engineering in Medicine and Biology Society, 2015). Another well established and widely used terminology in health care is SNOMED CT (SNOMED International, 2018), but its use need a license which Austria does not have and therefore the use of SNOMED CT codes is limited. Exceptions can be made whenever an international CDA document specification demands the use of SNOMED CT codes for labeling sections of the document. Table 3.7 gives an overview of the concepts that are applicable for blood glucose readings.

3.6 Validation of Prototype Implementations

The validation of the implemented prototype mHealth applications for data transfer between a PHD and the mobile application, and the exchange of medical reports between a mobile application and a health care provider system is based on the criteria that are listed in Tables 3.3 to 3.5 in Section 3.3. Whereas the first prototype application, implementing a BLE interface and a local database, deals with the criteria for downstream data exchange and for data at rest, the second prototype implementation, implementing the CDA reporter and the IHE *Portable Media Creator* actor, will be validated using the criteria for data at rest and the criteria for upstream data exchange. The validation of each criterion can result in *pass*, *fail*, *not applicable*, and *partially passed*. The result *partially passed* is introduced to demonstrate that the intention of a criterion is met but maybe not based on the stated criterion description. *Pass* indicates that the criterion has been fulfilled completely, the other three possible validation results need to be accompanied by a remark giving more detail on the result.

Concepts Used for Blood Glucose		
BLE Measurement Context	*ISO/IEEE 11073-10417*	*LOINC*
[1] Preprandial (before meal)	[29260] MDC_CTXT_GLU_MEAL_PREPRANDIAL	[88365-2] Glucose [Mass/volume] in Blood –pre-meal
[2] Postprandial (after meal)	[29264] MDC_CTXT_GLU_MEAL_POSTPRANDIAL	[87422-2] Glucose [Mass/volume] in Blood –post meal
[3] Fasting	[29268] MDC_CTXT_GLU_MEAL_FASTING	[41604-0] Fasting glucose [Mass/volume] in Capillary blood by Glucometer
[4] Casual (snack, drinks, etc.)	[29272] MDC_CTXT_GLU_MEAL_CASUAL	[?]
[5] Bedtime	[29300] MDC_CTXT_GLU_MEAL_BEDTIME	[?]

Table 3.7 – Blood glucose measurement context. Mapping of coded information from codes used in Bluetooth Low Energy to codes that are available in ISO/IEEE 11073-10417 *Health Informatics - Personal health device communication Part 10417: Device specialization - Glucose meter* and LOINC. The numbers in squared brackets represent the code, whereas the text following the code represents the clear text representation of the code. For *casual* and *bedtime* no corresponding representations have been found in LOINC. Taken from (Frohner et al., 2018b).

3.7 Interoperability Testing of Mobile Applications

The implementation of interfaces, whether for mobile device platforms, computer or server systems, brings the challenge to provide a reliable counterpart for testing the implemented interface. When this counterpart for testing purposes is implemented by the same developer as the system under test (including the interface) fault masking can be expected to happen, since both communication sides might contain the same software bug. Due to a common mistake on both sides, the interface might appear to run perfectly fine since this bugs are masked. Therefore, other solutions for interface and interoperability testing are preferable. IHE and PCHAlliance provide the Continua Plugfest and the IHE Connectathon as a stage where different developers from different companies can test their software solutions against the others. At these test events information needs to be exchanged between the different systems under test according to the criteria and requirements that are stated in the Continua Design Guidelines and the IHE Technical Frameworks. Another possibility for testing the implemented interfaces is to use software systems or devices that already have demonstrated conformance to the specifications. This method is used within the Continua product certification. This certification demands to test the system/software under test against Continua certified products that are available on the market (Personal Connected Health Alliance, 2017b).

Considering now the implementation of mobile health applications with a personal health device interface, this would require the purchase of personal health care devices offering the interface technology that should be implemented within the mobile application. This PHDs can then be used for tests starting with early unit tests of the interface, integration tests, as well as system tests that are conducted for the mobile application or part of its implementation. Based on the multitude of different test cases that might get derived for the different development stages, it can be expected that the PHDs is used quite often during the test phases. This number of use will even increase, when more complex test cases are defined. Not

only a single transmission of a single vital sign reading will be tested but also the transmission of multiple readings that were buffered by the PHD (store and forward capabilities). In order to conduct the more complex test scenarios the test input conditions on the PHD need be set up. For the store and forward scenario this would mean that before the interface can be tested, multiple readings need to be available on the PHD. Testing this feature with a weighing scale is time consuming but for setting up the conditions on, for example, a blood pressure monitor, this is not only even more time demanding but - more importantly - unhealthy, since blood pressure shall not be measured multiple times in a row. Therefore, another possibility for testing the implemented interface is desirable, to decrease the needed time and to comply with medical guidance on how the PHDs should be used.

Besides these issues that addresses the implementers, another scenario where the above mentioned restrictions and challenges apply is the area of teaching. When multiple students are taught interface technologies and communication standards and are asked to implement eHealth or mHealth solutions in order to apply the gained knowledge, the use of real world PHDs has drawbacks as well. On the one hand, providing a whole classroom with PHDs is normally not within the budget, and on the other hand, the maintenance of the PHDs and the administrative effort to keep track which student has which device for what time period is quite high.

A solution that suits the implementers and the trainers/trainees demand would be the simulation of real world PHDs. Such a simulator can be implemented as a mobile application, can offer different PHDs to be simulated, and various different test cases that are executed faster and more comfortable than using read PHDs. Especially for teaching purposes or for testing of early prototypes this simulator will be highly welcome (see Figure 3.4).

In this simulator, the single test cases, including the test data, are defined in an XML on the mobile device, enabling the introduction of new test cases or the manipulation of existing test cases without the need to alter the source code of the simulator. The XML is read when the simulator is started. Based on the number of test cases and the meta-information that is available for a single test case the user interface then

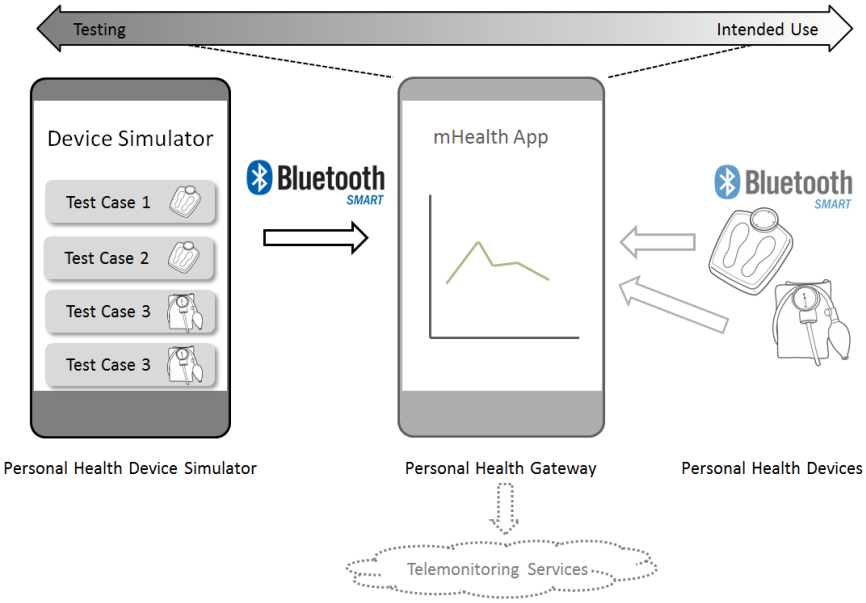


Figure 3.4 – Personal health device simulator enabling faster and more comfortable testing of BLE interfaces. Picture take from Frohner et al. (2017)

adapts. Since the simulator uses Bluetooth Low Energy as the transport channel and acts as the source of the data that should be exchanged, BLE's requirements for *Peripheral* devices need to be respected. This peripheral role, including the needed capabilities, were introduced in Androids version 5.0 (Android Developers, 2018a). Nevertheless, the feature of the peripheral role is not solely depending on the Android version but might be restricted by the devices underlying firmware. Additionally, this mode is not available on all devices running Android 5.0 or above. Using LLC U7's *BLE Peripheral Detection* mobile application (LLC U7) the following mobile phones were tested for the peripheral role support:

- HTC Google Nexus 9, 16 GB WiFi, Android 7.1.1 (Build-Number NMF26F)
- OnePlus 3, A3003, Android 7.0 (Build-Number ONEPLUS A3003_16_170114)
- Honor 8, FRD-L09, Android 6.0 (Build-Number FRD-L09C432B131)

From the tested devices, the HTC and the OnePlus model support the peripheral mode and can therefore be used as a platform where the PHD simulator is executed.

For the XML configuration containing the data for the test cases the common components which are used for BLE communication and are specified by the Bluetooth SIG in different profiles are considered. A first prototype implementation was implemented, capable to connect with other mHealth applications, simulating a weight scale and a blood pressure monitoring PHD.

3.8 Smart Grids - Transfer of Knowledge

The experience the author has gathered in the field of solving interoperability challenges in the field of eHealth and mHealth has been recognized by another project consortia that was working on a funded research project in the field of Smart Grids. The term *Smart Grids* describes an architecture of energy networks where single components are not only connected to the electrical power net, but also via a communication network. This enables to orchestrate different assets and software components that share information. Such networking devices and software solutions are of specific interest because the change towards an extensive use of renewable energy will bring a higher demand for communication. In scenarios where large bulk power plants based on fossil energy sources are regulated based on the demand and the capacity of the transmission net, less communication is needed when compared to a multitude of different assets in the field where each asset dependents on the availability of renewable energy sources like wind or sunshine. The complexity of the energy landscape in terms of its components and infrastructure might even increase with the introduction of eMobility. Electrical vehicles that are connected to the net will stress the electricity infrastructure with their high demand, but can also act as some form of energy reservoir. This would require a solid level of energy management, especially on and close to the single premises and the distribution networks. This will also affect the transmission network to a certain level, since large amounts of electrical energy might be transferred over wider areas. The typical example for this is Germany with many photo-voltaic farms in the southern regions (e.g. Bavaria), and larger on- and off-shore wind parks in the northern areas.

Comparable to the world of medical IT, standards exist and are used in the electric domain to share data between systems. However, on a second glance, organizations like IHE or PCHAlliance, which harmonize the use of standardized communication protocols and content formats in the medical IT, do not exist on an international scale in the energy sector. Smaller consortia can be found, like *VHPready* (VHPready Services GmbH, 2018) but their methodology used for harmonization does not cover the field from the very beginning when use cases are formulated to the end when software implementations and products are tested on their level of interoperability. At this point, the author joined the research project *IESAustria* (Smart Grid Austria, 2016), in order to investigate the applicability of the methodology used by IHE in the energy domain. Based on the IHE method, use cases were defined for the first domain *Virtual Power Plant* (VPP), dealing with the communication of data between *Virtual Power Plant Operators* (VPP OP), the *Distributed Energy Unit Controller Operator* (DEUC OP), and multiple *Distributed Energy Unit Controller* (DEUC). The use cases include the reading of current values, the remote setting of targeted values, and the communication of a schedule. The latter is used to command an asset in the field to deliver a certain amount of energy in a given timespan, i.e. a VPP OP or a DEUC OP communicate the expected amount of energy to a DEUC for the next day. Figure 3.5 depicts the defined actors in the context of sending a schedule within the entities of a virtual power plant.

Frohner et al. (2018a) describes the first interim results of applying the IHE methodology to the energy domain. Technical specifications, in form of Technical Frameworks, have been developed that define how the introduced actors shall communicate data (which data and how the data is formatted). Furthermore, the first experiences with the test tool Gazelle (IHE International Inc., 2018a) have already been gathered. Gazelle is a software test management platform used by IHE to run, on the one hand, conformance tests, and, on the other hand, interoperability tests. For the first, Gazelle is equipped with multiple validation tools that relate to single conformance criteria. For the latter, Gazelle enables the recording of messages that are exchanged between the different software systems that take part in a software test instance. This means that the messages are not directly sent

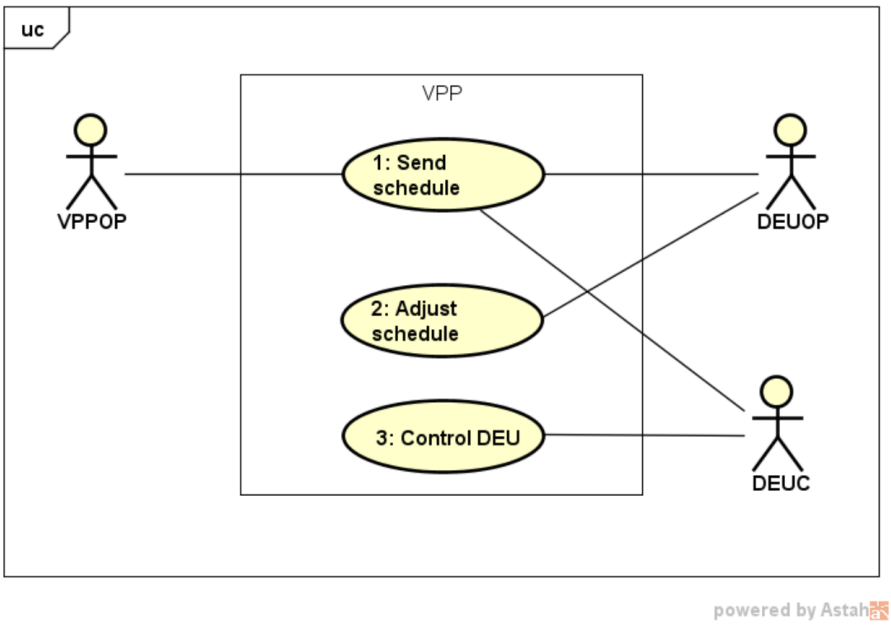


Figure 3.5 – Use case diagram *Send Planned Schedule* (SPS) as defined in Technical Framework *Virtual Power Plant* (IES Team, 2018)

from the sender to the receiver, but the receiver sends the message to Gazelle's *Proxy Server*, which then persists the message (including the meta information about the test case) and forwards the message to the dedicated receiver. Apart from the benefit that the test case documentation is made easier by this automatic recording, the stored messages on the proxy can be forwarded to different validation tools to check the conformance to the specifications stated in the single technical frameworks. For the project IES, an own Gazelle instance was installed at the University of Applied Sciences Technikum Wien in a cooperation and with support from IHE Services. Having a dedicated instance of the test tool enabled the project to adjust Gazelle to fit the needs of the project IES and the demands for the communication standards used in the energy domain better. One key aspect of this adjustment was that components in the energy domain use binary data formats and not XML based data formats at least for the use cases and profiles that have been defined by IES till today. The IEC standards 61850 used for data modeling and the message specification of the *Manufacturing Message Specification* (MMS) (IEC, 2004) used. for en- and decoding information into the transfer syntax, result

in messages that are binary coded based on *Basic Encoding Rules* (BER). Since Gazelle did not provide a validation service for binary message formats by default, another approach for message validation has been considered. This includes the transfer of the recorded binary data into an XML representation of this data using the *Data Format Description Language* (Open Grid Forum, 2014). Using this XML-schema-like syntax, a set of mapping rules to transform from binary data into XML representation is achieved. For this transformation a *Daffodil* engine (The Apache Software Foundation, 2018) was included in the Viennese Gazelle instance.

This also provides benefit for applications in health, since the new technologies that have been introduced in the Viennese Gazelle instance for validation purposes of binary coded energy messages, can be used for other binary coded message formats as well. In the field of mHealth the ISO/IEEE 11073-20601 standards use the *Medical Device Encoding Rules* (MDER) for coding data. Using the BER or the MDER does not make a difference, since the DFDL mapping rules need to be written specifically for the format and the message anyway.

4 Results

4.1 Results of the Expert Interviews

The survey was done, as planned, at the annual Austrian eHealth conference 2018. In total, seven interviews were conducted. Each interview took approximately ten minutes. Three research scientists, two software engineers, and two disease management program providers took part. The following sections provide condensed feedback on each of the five questions that are stated in the questionnaire (the questionnaire can be found in Appendix A.1).

4.1.1 Stakeholders

The first question targets to identify stakeholders that are relevant for mHealth scenarios and that are not listed in the definition section of the questionnaire (the stakeholder description can be found in Section 3.3. The question was: *Is the above stated definition complete, or are types of stakeholders for mHealth scenarios missing?*

The interviewees state that, in general, the three stated stakeholders (primary user,

secondary user, and indirect user), as taken and adapted from ISO/IEC 25010 (2011) were found to describe the stakeholders to a sufficient level. Additionally, two interviewees stated that, based on the rather short description of the single stakeholders, they would explicitly include *researcher* in the list of *indirect users* and one interviewee felt that people and organizations dealing with the *secondary use of data* seemed to be missing. Two interviewees added that *informal care* was not clearly perceptible from the three stakeholders groups and that they had difficulties to specify to which stakeholder group they could be accounted. Furthermore, two interviewees answered that for mHealth disease management programs, the financing partners (e.g. public health insurance companies) were not depicted in the list of stakeholders. One interviewee addressed that he could not clearly state to which group legal guardians belonged or if this would introduce a new stakeholder group. One of the interviewees emphasized that for the secondary user group, *support* should be included in the examples for the secondary users.

4.1.2 Quality in Use Model

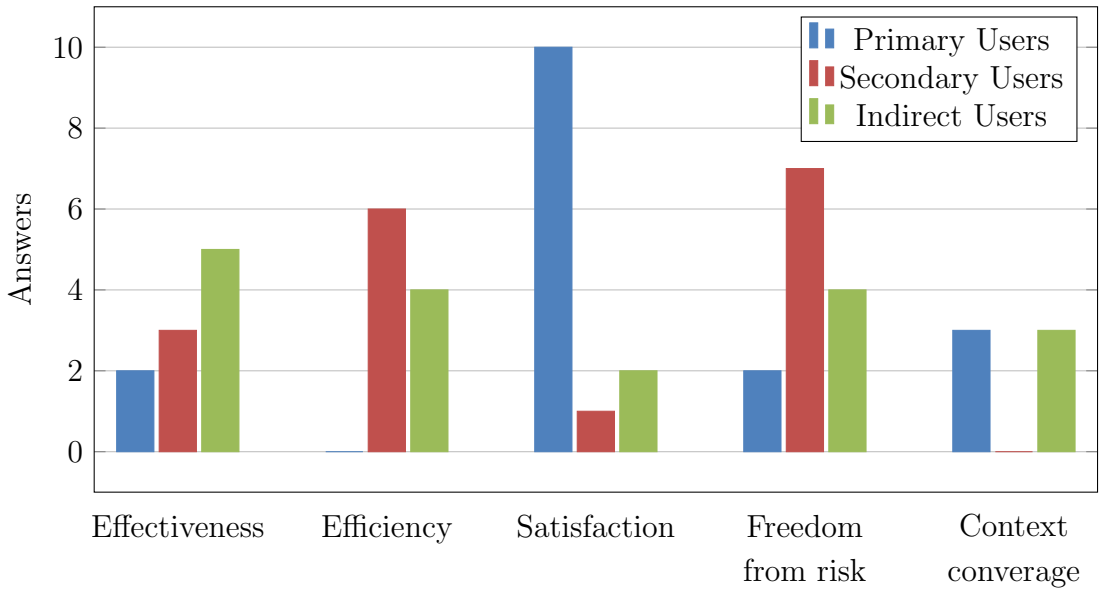
The second question of the survey addresses the connection between the stakeholder groups, as defined in the questionnaire's definition, and the quality in use characteristics, as specified in ISO/IEC 25010 (2011).

The questionnaire contains the model shown in Figure 2.2 and the question was: *What are, in your opinion, the three most important subcharacteristics for a) the primary user, b) the secondary user, and c) the indirect user in mHealth scenarios?*

In the interviews some interviewees faced difficulties when deciding for a subcharacteristic and therefore the interviewees were asked to at least decide on the characteristics level and not on the subcharacteristic level. This had the consequence that in the evaluation of the survey that values might have been counted twice for single subcharacteristics in the Figures 4.1.

For each of the selected characteristics and subcharacteristics, one point was assigned

Figure 4.1 – Number of answers to the question of quality in use characteristics for primary users, secondary users, and indirect users



for the final score, i.e. although the interviewees implicitly put up a ranking, this fact has been neglected for the analysis.

Figure 4.1 shows the scores of the question on subcharacteristics based on the quality in use model. The graph groups the subcharacteristics to the corresponding characteristics.

Whereas the characteristics *Effectiveness* and *Efficiency* do not specify any subcharacteristcs, the other three do. A closer look at the evaluation of the subcharateristics can be found in Figures 4.2 to 4.4. In some cases the interviewees were not able to decide which of the stated subcharacteristics is more important than another one, e.g. for the characteristic *Freedom from risk*, they did not want to decide which of the three subcharacteristics is most important but they stated that all of these have the same weight. In such cases the answer is distributed equally between the possibilities. Therefore this figures might include bars having a fraction of a whole number.

Figure 4.2 – Number of answers to the characteristic *Satisfaction*, itemized for the subcharacteristics and the different stakeholder groups

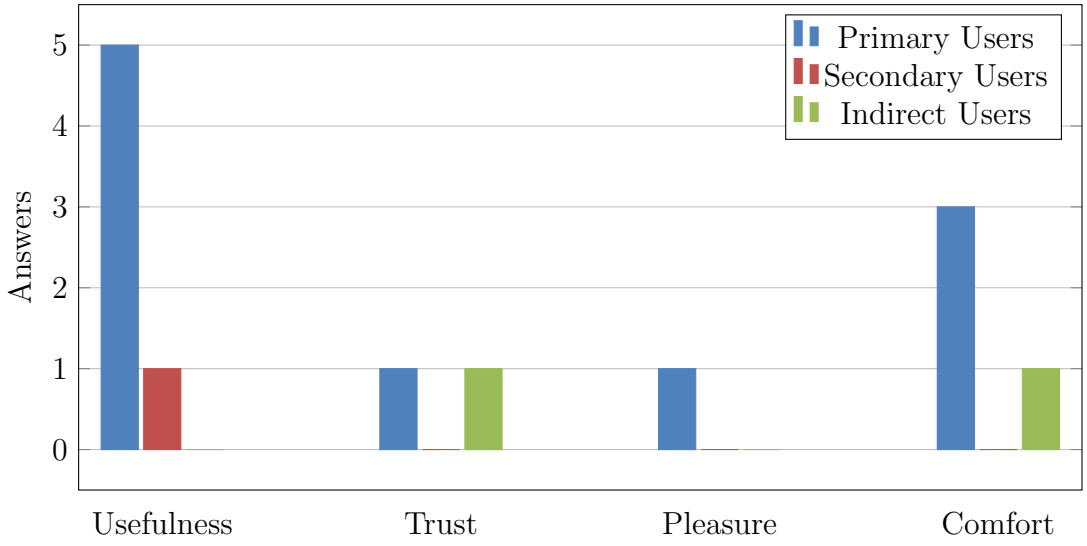


Figure 4.3 – Number of answers to the characteristic *Freedom of risk*, itemized for the subcharacteristics and the different stakeholder groups

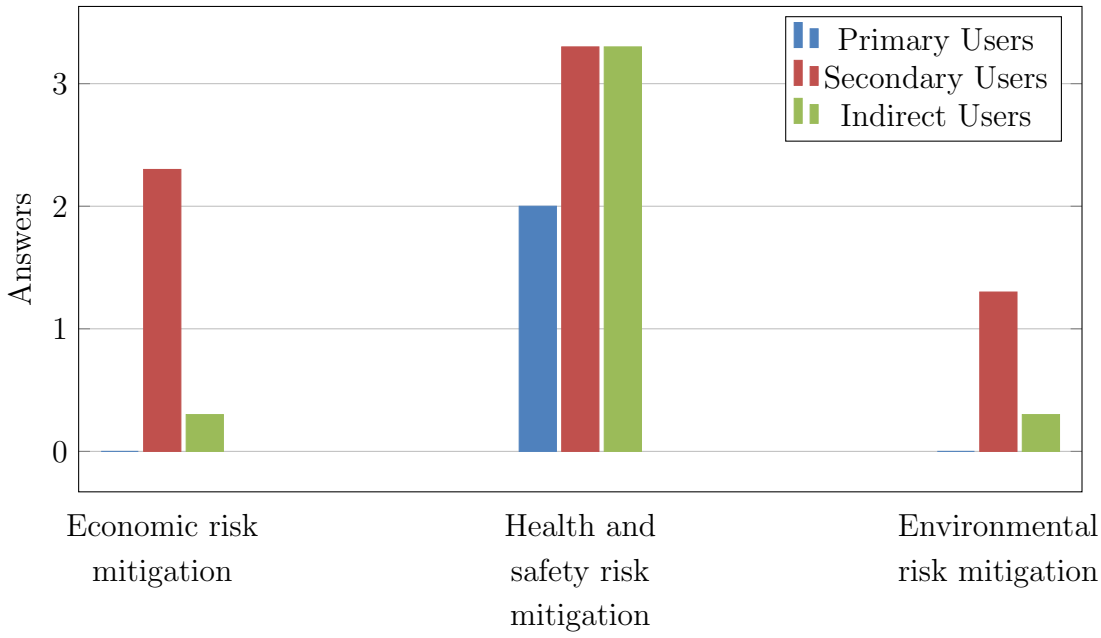
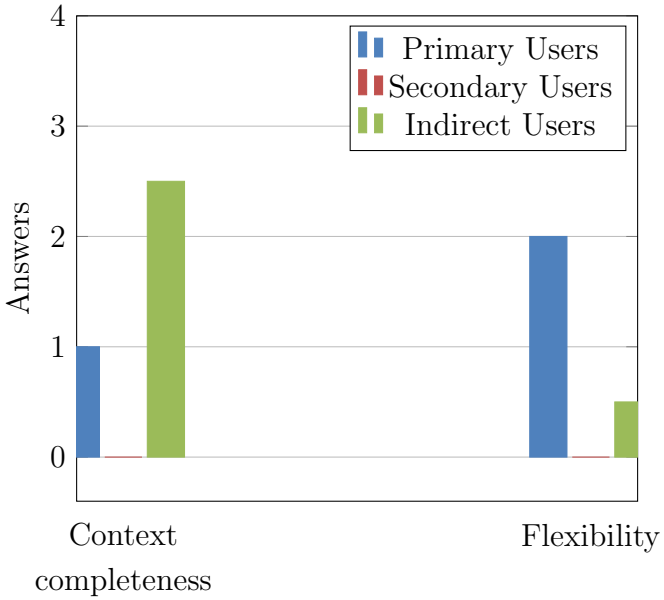


Figure 4.4 – Number of answers to the characteristic *Context coverage*, itemized for the subcharacteristics and the different stakeholder groups



4.1.3 System/Software Product Quality

The third question is to name the five most important (sub)characteristics form the system/software product quality model, as stated in ISO/IEC 25010 (2011) for mHealth scenarios.

The survey included the figure from the standards (see Figure 4.5) and the question was: *What are, in your opinion, the five most important subcharacteristics for mHealth applications in mHealth scenarios?*

The interviews showed that the interviewees started this task by identifying the most important characteristics since those summarized in more generalized and commonly used terms the single terms for the subcharacteristics. Identifying the three most important characteristics (were the subcharacteristics belong to) was rather easy, but deciding on characteristics ranked after the top five was rather difficult. Therefore, the interview ended in some cases after the interviewee had decided on the three most important characteristics.

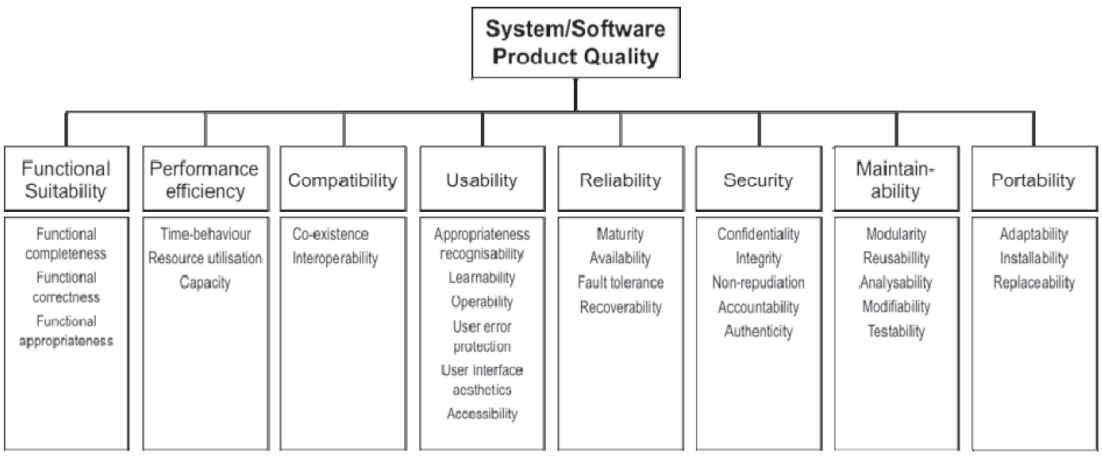


Figure 4.5 – ISO/IEC 25010 System/software product quality model. Taken from ISO/IEC 25010 (2011)

Figure 4.6 shows the scores for the characteristics as defined in the system/software product quality model from ISO/IEC 25010:2011 (ISO/IEC 25010, 2011).

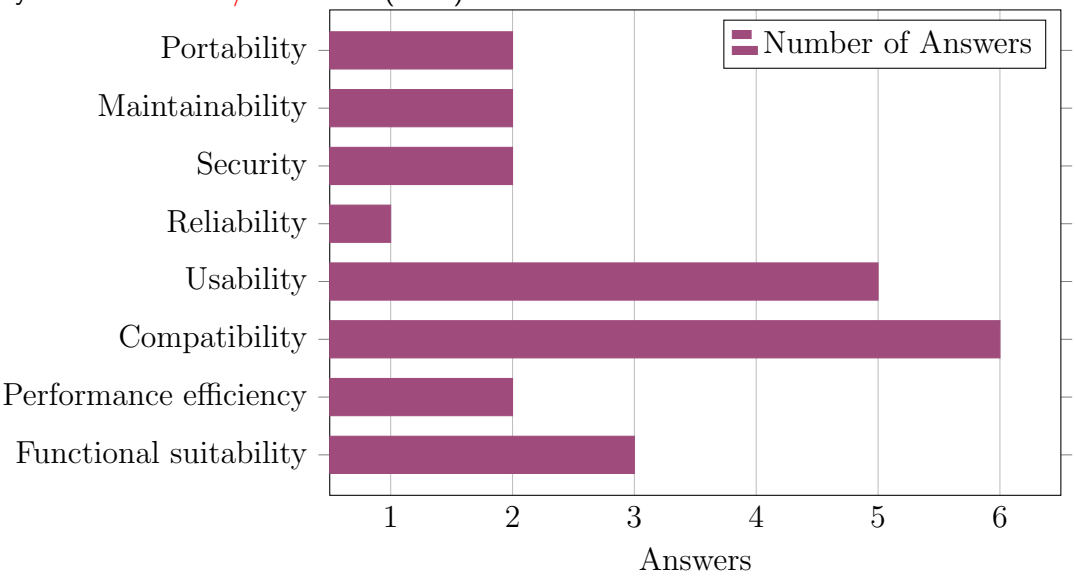
4.1.4 Need for Certification Programs

The fourth question of the questionnaire asks the interviewees about their opinion for the need of certification programs. The question was formulated as an open one and the interviewees were asked to state some key points.

The question was: *Which characteristics and subcharacteristics need a certification program in mHealth scenarios (incl. programs that are already in place)? What are the most important subcharacteristics?*

Four out of seven interviewees stated that a certification was needed for testing and verifying interoperability of the systems involved. Five answered that security certification programs needed to be considered. One interviewee answered that accessibility is a subcharateristic where certification should be considered. One interviewee stressed that for mHealth applications that are considered as medical products, a) functional, b) performance, c) usability, and d) reliability certification were expedient, and continued that security among the others was one of the most

Figure 4.6 – Number of answers for the characteristics based on the system/software product quality model from ISO/IEC 25010 (2011).



important factors.

4.1.5 User/Mobile-Application Engagement Model

The fifth and last question that the questionnaire contains is about the interviewees' opinion on the user/mobile-application engagement model (see Figure 3.1). The interviewees decide if this model reflected the single stated phases, user types and characteristic points in time correctly.

The question was: *Do you think that these phases represent the user's experience sufficiently? Is a phase missing? Are the derived user types comprehensible and legitimate?*

In general, the model was found very suitable for describing the basic phases and the different user types in a comprehensible and understanding way. One interviewee pointed out that especially the duration of the *demand* phase was highly dependable on whether the user's demand was intrinsic and rising over time, or if the user took part in a program where the decision to solve a demand by an application was not

based on the user's free will, but by a third party. This differentiation was not directly observable in the model. A similar issue was addressed by the feedback of another interviewee by stating that applications might have been suggested to be used by a third party, which decreased the estimated time span of the *demand* phase drastically as well. Another feedback was that user engagement in the *usage* phase could be more complex than the three suggested engagement levels in the model suggested. The engagement level could be constant over a certain period of time, but then decreased or increased drastically due to an updated version of the applications used (e.g. new features became available or things that had been possible before were not any longer working after the update). It could also be considered that the engagement level with a *trial* or *free to use* version is rather low, but when the user purchased the *pro-version*, unlocking new features, the engagement level could increase afterwards. This interviewee also described user behaviors where multiple applications for solving a common demand were used in parallel for evaluation purposes. The model where the engagement level of the user with a single application is described, can result in a rather indeterministic engagement of the user, where he/she might try the different applications to investigate which one serves best. Another interviewee suggested mapping this model against existing marketing models for *customer journeys*.

4.2 Use Case Definition

The following section specifies the two use cases that were implemented. The use case description uses the use case template that is defined in section 3.2. The first use case deals with the transfer of blood glucose readings from a glucose meter to a mobile application. The second use case specifies the generation of a clinical document and the transfer of this document to a health professional using secure email services.

4.2.1 Use Case I: Interfacing a Personal Health Device

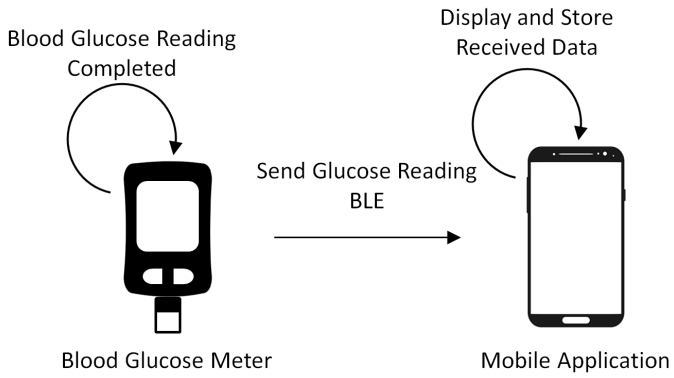
The first use case that is described following the use case template structure deals with the interface between a PHD and a mobile phone.

Table 4.1 – Use Case I: PHD-IF

Name of the Use Case	Data exchange between a blood glucose meter and a mobile device for teaching purposes	*Identifier*	PHD_IF_BG_1
Version	*Author: Matthias Frohner* *Status: V0.2 Draft* *Last Modified: 09.12.2018*		
Nomenclature			
BLE –Bluetooth Low Energy **PCHAlliance** –Personal Connected Health Alliance **Bluetooth SIG** –Bluetooth Special Interest Group **GUI** –Graphical User Interface **BLE indication** –Feature from BLE, enabling remote devices to subscribe to a specific data point.			
Narrative of the Use Case			
For teaching BLE interfaces at the University of Applied Sciences Technikum Wien, a mobile application is developed to provide the basic structure and functionality of the needed BLE interfaces. Students should be enabled to start working on the interface challenges and should not consider development work that is not related to the core BLE part too much. The mobile application shall interface with blood glucose meter, found on the consumer market, and the blood glucose level shall be transferred automatically after the measurement is completed. The interface shall be implemented according to specifications from PCHAlliance and Bluetooth SIG. A simple user interface shall display the received blood glucose data. The received values shall be stored in a database implemented on the mobile device.			

Table 4.2 – Use Case I: Architecture of the Systems and Transactions

Architecture



Systems

Blood Glucose Meter –Blood glucose meter supporting a BLE interface according to Bluetooth SIG.

Mobile Application –Application for mobile devices implementing the BLE interface for blood glucose meter, a database, and a GUI.

Actions

Blood Glucose Reading Completed –The blood glucose meter indicates that the blood glucose level reading is completed.

Display and Store Received Data –The received blood glucose reading including the measurement unit and the time stamp is displayed on the GUI. The received data is stored in the mobile application's database.

Transactions

Send Glucose Reading –After the *Blood Glucose Reading Completed* action, the glucose meter will use BLE indication feature to provide the measured values for transfer. Together with the glucose level, the time stamp of the measurement and the physical unit of the measurand gets transferred. When the mobile applications has received the readings from the glucose meter, it shall trigger the action *Display and Store Received Data*.

4.2.2 Use Case II: Send Clinical Document to Health Care Provider

The second use case describes the sending of a clinical document from a patient's mobile device to the health care provider. This use case consists of the generation of CDA document holding vital parameters, or blood glucose readings from a patient and the forwarding of this document via email to the health care provider. This procedure is based on IHE's XDM profile that specifies how clinical information can be exchanged between entities in case no required health IT infrastructure is available. This profile includes specifications how information can be transported using portable media gadgets, like USB flash drives or CDs. Furthermore, the communication over secured email is described.

Table 4.3 – Use Case II: CDA generation and XDM email

Name of the Use Case	Forwarding of clinical documents via email for teaching purposes	*Identifier*	CDA_XDM_1
Version	*Author: Matthias Frohner* *Status: V0.2 Draft* *Last Modified: 09.12.2018*		

Nomenclature

CDA –Clinical Document Architecture, a standard defining clinical XML documents specified by HL7

HL7 –Health Level 7, a standard developing organization

XDM –Cross-Enterprise Document Media Exchange, a integration profile defined by IHE

IHE –Integrating the Healthcare Enterprise, an initiative promoting standardization and interoperability in the field of eHealth.

XDM Portable Media Creator –A software module (IHE actor) that is capable of rehashing a document for exchange.

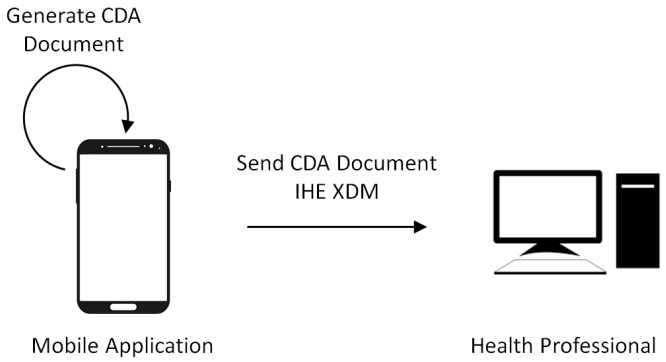
GUI –Graphical User Interface

Narrative of the Use Case

CDA documents are a common way to transport medical information between stakeholders. Hence, this document shall be used to communicate health information that a patient has gathered at home to a health care provider. Vital parameters that could be received via digital interfaces from PHDs or data that the patient enters via the GUI shall be formatted according to CDA specification. This specification includes that the gained data is included in a human readable and a machine readable way. The latter demands the use of standardized terminology. After the document is generated on the mobile device, it shall be sent in compliance to IHE's XDM profile via email. For the purpose of teaching the prototype implementation should use health information that has been received from PHDs beforehand.

Table 4.4 – Use Case II: Architecture of the Systems and Transactions

Architecture



Systems

Mobile Application –Application for mobile devices implementing the CDA generator and XDM's portable media creator.

Health Professional –IT system of health care provider, e.g. the email client

Actions

Generate CDA Document –The CDA document is generated by the mobile application. All required vital data has been entered manually, has been received from PHDs, or has been fetched from the mobile phone's database. The CDA document should follow the requirements stated by ELGA. The health information shall be presented in a tabular form and shall be included in a machine readable way using standard terminology for semantic interoperability. Demographic data describing and identifying the person that has conducted the measurement can be hardcoded.

Transactions

Send CDA Document –After the action *Generate CDA Document* is completed, a file structure as specified by IHE XDM shall be generated on the mobile device. The needed files containing meta data shall be filled accordingly. The generated file structure, containing the CDA and the meta data shall be zipped by the application. This zip file shall be forwarded to the mobile phone's email client application using Android intents. The email shall be encrypted and signed, using digital certificates before it is sent. For teaching purposes, the students should use their digital certificates provided by the University of Applied Sciences Technikum Wien.

4.3 Implemented Prototypes

The following section presents the results of the implemented prototypes based on the two use cases described in Section 4.2. The implementation focused on the interoperability challenges of the described use cases and on the use for teaching purposes at the University of Applied Sciences Technikum Wien. Over time, the two single implementations of the use cases have been combined in one application in order to fulfill a larger business use case. In the end, the application received measurement values from blood glucose meters or weight scales, generated a CDA document, and forwarded this document via email. Nevertheless, the use cases were introduced separately, since both solved a certain interoperability issue. Data gained from a PHD and sent to a mobile application might be used only locally on the device and data that is available on a phone might be communicated to another party. Those use cases can also be applied to other business cases. Data might be communication using the PHD interface, but once the data is on the mobile device, another technology might be used to forward data. This can be the case whenever the forwarding of readings is facilitated using HL7's messaging standard or HL7's FHIR specification.

4.3.1 Interfacing a Personal Health Device

The Android implementation was tested with Roche's Accu-Chek® for the transmission of the most recent blood glucose reading. This transmission included the meta-information concerning the context when the measurement was taken. The received data was stored on the device's SQLite database. The blood glucose meter needed to be paired before the transfer of data using Android's Bluetooth setting. The application was adapted to connect with weight scales, in order to extend the application's functionality with non-invasive measurement devices. This enabled, on the one hand, an easier gathering of measurements for testing purposes and, on the other hand, improved the use of the prototype application for demonstration

and dissemination purposes. Since Bluetooth pairing is not required for getting data from a weight scale, the mobile application was to only communicate with a single weight scale at a time, coding the Bluetooth MAC address of the desired weight scale in the application's code. This had the advantage that during lectures, when multiple devices were used simultaneously, the single connections would not interfere. The adapted application was tested with four different weight scales from different vendors. The communication between the mobile phone and the weight scale worked right away with two weight scales. One weight scale delivered data but lacked a stable connection and the communication with the fourth weight scale did not work at all.

4.3.2 Send Clinical Document to Health Care Provider

The implemented Android application enables users to trigger the generation of the CDA document. Before the user can trigger this procedure, measurement data needs to be available. For this purpose, the application includes the PHD interface as implemented for the first use case. The received values are displayed on the GUI, enabling the user to check the proper transfer of the data.

The CDA document is designed following guidelines from HL7, IHE, and ELGA in order to achieve interoperability with available specifications. The header of the CDA document contains the demographic data of the user that is pre-configured in the application. The single glucose or weight readings are visualized in a table. This visualization is achieved by using an XML stylesheet to transform the content of the XML into an HTML representation. This transformation step has the advantage that the CDA document can be visualized by any web browser and, by exchanging the stylesheet, the representation can be changed. Figure 4.7 shows the rendered blood glucose readings that are contained within the generated CDA document.

Since the information should be transported in a machine readable way, CDA *observations* have been implemented on CDA's entry level. A single observation represents details of the information that is visualized to the user in one table

Vital Signs

Blood Glucose

Value	Meal	Unit	Timestamp
120	postprandial	mg/dL	20.02.2018 14:39
123	postprandial	mg/dL	20.02.2018 18:17
115	postprandial	mg/dL	21.02.2018 07:12

Figure 4.7 – Visual representation of the blood glucose reading using the ELGA reference stylesheet taken from the ELGA webpage (ELGA GmbH, 2017a)

line (see Figure 4.7). Listing 4.1 illustrates the XML code that is generated on the mobile device. Inside the *observation* element, the three *templateId* elements identify the origin of the specifications that are used to form and fill this entry. In this example, three references to templates defined by IHE and HL7 are present. TemplateIds are also used for validation purposes, since a Schematron validator is aware of the context and is able to check if the requirements for this observation are met by the implementation of the whole observation object. The templates are followed by an *id* element, stating a unique identifier for this observation. Its *root* attribute defines the realm, using an *Object Identifier* (OID), whereas the *extention* element defines the unique entity. After the id, the *code* element provides machine readable information about the mean of the observation. In this example, the *code* attribute of the code element holds the LOINC code for a glucose measurement that has been taken before a meal. Beside the code attribute, the *codeSystem* attribute is required in order to identify the code system that is defining the used code. For this purpose an OID is used as well. Those two attributes would be sufficient for machine readability, but can be accompanied by additional attributes like *displayName* and/or *codeSystemName* providing human readable information on the code and the used code system, respectively. The next element, the *text* element, is a place where textual information can be placed within the machine readable observation element. Best practice is to refer to the human readable information (outside of the observation element), in order to enable computer based receiving systems to include the ”narrative” information by dereferencing of the reference. The *statusCode* provides information on the current status of the observation at

the time of the document generation, whereas the *effectiveTime* element holds the timestamp when the observation was made. Finally, the last element in this given example, is the *value* element. This element codes the manifestation of the concept (as coded in the code element). The data type used for this value element is from the type *ANY*, which needs to be addressed especially. Normally - and for the other elements used in this example - an element is based on a restricted type, e.g. the *code* element is based on the *coded entity* datatype, demanding an implementation of a code element to have at least a code and a codeSystem attribute. Another example would be *effectiveTime* based on the datatype *timestamp* (TS) demanding the use of a value attribute. Since the datatype of the *value* element is *ANY*, the datatype is not restricted to a certain type. This is a necessity since the manifestation of an observation is also not restricted to a specific datatype. An observation for coding a found illness might use a datatype capable of coding the illness based on a standard vocabulary like ICD-10 in form of a code. Another observation might indicate if a specific pathogen has been found, using a boolean datatype for coding the observation. In the example that can be found in Listing 4.1, a specific blood glucose level should be coded. Therefore, the datatype *physical quantity* (PQ) can be found. Based on the data type that is defined using the *type* attribute (coming from another namespace), other attributes must be available. For the physical quantity, the quantity of the reading must be available (*value* attribute) as well as the coding of the physical unit (*unit* attribute). The physical unit is coded following the specification of *The Unified Code for Units of Measure* (UCUM) (Schadow and McDonald, 2017).

Listing 4.1: CDA observation coding a single blood glucose reading

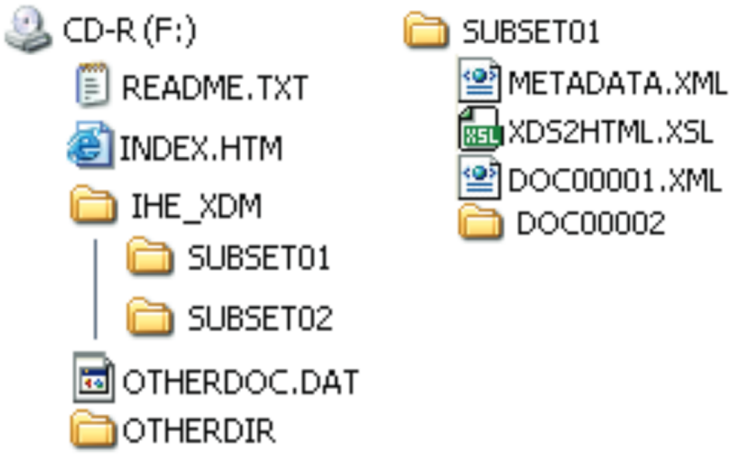
```
<observation classCode="OBS" moodCode="EVN">
   <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"
      assigningAuthorityName="IHE PCC"/>
   <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.2"
      assigningAuthorityName="IHE PCC"/>
   <templateId root="2.16.840.1.113883.10.20.1.31"
      assigningAuthorityName="HL7 CCD"/>
   <id extension="1" root="1.2.40.0.29.99.0.1"/>
   <code code="88365-2"
```

```
      displayName="Glucose [Mass/volume] in Blood --pre-meal"
      codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC">
   </code>
   <text>
      <reference value="#vitsig1"/>
   </text>
   <statusCode code="completed"/>
   <effectiveTime value="20171220125408+0100"/>
   <value xsi:type="PQ" value="125" unit="mg/dL"/>
</observation>
```

The Listing 4.1 codes only the information from a single observation. In order to have multiple observations within one part of the document, the CDA *organizer* element is used to group multiple blood glucose reading together. In order to enable the generation of a valid CDA document with a generic number of single observations, XML CDA templates structures were defined. These templates are loaded by the application and included multiple times within the CDA document, based on the number of single values that should be transported.

Following the specification from IHE's XDM profile, the transaction *Distribute Document Set on Media* [ITI-32] needs to be implemented. The Android application becomes the *Portable Media Creator*, the actor that is in charge of preparing the document for transfer to the *Portable Media Importer*, an actor played by the email client of the health care provider. This preparation includes the generation of a defined folder structure, containing the generated CDA document, the desired stylesheet for the representation of the CDA document, meta-information documents, and a *readme* file (see Figure 4.8).

These documents and the folder structure are generated on the mobile phone's internal storage and afterwards zipped into a single file. The zip file is handed over to the email application MailDroid, using an Android intent. The intent triggers the opening of a new email, where the recipient is already entered (based on hardcoded information), the subject of the email is filled in and a default email



(a) (b)

Figure 4.8 – Folder structure within the ZIP file (based on IHE International Inc. (2014)). (a) General structure of media that shall be transmitted. (b) Structure of the submission set directory, including the CDA document, needed metadata, and the stylesheet to visualize the CDA. Taken from Frohner et al. (2018b)

Figure 4.9 – Snapshot of the incoming email containing the XDM zip file and the information that this email has been signed and encrypted

text is available. The zip file is attached automatically and the user can send the email. Since MailDroids Crypto plugin is installed on the device, the email, including the attachment, is going to be encrypted and signed using the pre-installed digital certificate. On the receiving side, the email client (Thunderbird) flags the incoming mail with icons informing that the email has been signed and encrypted (see Figure 4.9).

4.4 Validation of the Implementation Against Criteria Catalog

Based on the defined criteria and requirements from Section 3.4.3 the implemented Android prototype implementation with the feature of receiving data from PHDs (blood glucose meter and weight scale) and the capability to create a CDA document and forward this document via secured mail to a health professional is validated. The validation result is depicted in single tables, where the first column references to the unique id of the criteria that are introduced in Tables 3.3 to 3.5. The second column is a short description of the criteria, where the narrative is based on the criteria tables but might be shortened to a certain extent. The third column reflects the conformance level of the criteria. The next four columns are used to code the validation result with one of the four characteristics: passed, failed, partially, or NA, where NA stands for *Not Applicable*. The last column is dedicated to a validation step remark that is required for the validation results *failed*, *partially*, and *NA*. For *passed* validation tests, providing a remark is optional.

Concerning the criteria for *Downstream Exchange of Data* Table 4.5 shows the results of the tested prototype application interfacing a blood glucose meter and a body weight PHD. In general, the validation is based on the standalone prototype application as implemented based on the use case stated in Section 4.2.1. Validation steps that are testing the communication with the weighting scale are based on a final prototype, where the single applications implemented for use case I and use case II were included in a single mobile application and the feature to support weighing scales was implemented.

Table 4.5 – Validation of the prototype application capable of communicating with blood glucose meter and body weight scales using Bluetooth Low Energy profiles. The validation follows the criteria for *Downstream Data Exchange* that can be found in Table 3.3

Id	*Criteria*	*Conf.*	*Results*				*Remark*
			Passed	Failed	Partially	NA	
DS_1	Pairing with service device	SHALL			X		Pairing proceeded is done on the OS level and not by the single application
DS_2	Documentation of pairing procedure	SHALL		X			Documentation for the prototype implementation is not available
DS_3	Delete previous pairing	SHOULD			X		Paired devices can be managed and deleted using the OS mechanism
DS_4	Storing pairing information	SHOULD			X		Information about paired devices is stored by the OS
DS_5	Indication of successful pairing	SHALL			X		Indication is available on the OS level
DS_6	Filtering list of discovered service devices	SHOULD		X			This feature is not available using the OS Bluetooth manager

Table continues on next page

Id	*Criteria*	*Conf.*	*Results*				*Remark*
			Passed	Failed	Partially	NA	
DS_7	Communication of failure during pairing	SHALL			X		Indication for failed pairing is available on the OS level
DS_8	Support of *Just Works* or *Passkey Entry* for pairing	SHALL			X		The demanded pairing possibilities are supported by the OS
DS_9	Data shall be compliant to IEEE 11073 nomenclature when it gets transcoded	SHALL	X				The concepts used by BLE communications can be mapped to concepts available within the IEEE 11073 family of standards
DS_10	Implementation of the glucose meter profile	SHALL [IF Blood Glucose]	X				The implemented prototype application follows the specifications for a blood glucose collector
DS_11	Implementation of the weight scale profile	SHALL [IF Weight Scale]	X				The implemented prototype application follows the specification for a weight scale collector

Table continues on next page

Id	*Criteria*	*Conf.*	*Results*				*Remark*
			Passed	Failed	Partially	NA	
DS_12	User is authenticated and has an active session before pairing	SHALL			X		Authentication is achieved partially by the OS itself (PIN, pattern, finger print) enabling the user to enter the OS Bluetooth manager. The prototype application does not ask the user to confirm identity and/or authenticity
DS_13	User is informed about the collected data before pairing procedure	SHALL		X			The pairing procedure is not implemented in the application itself but the pairing is done using the OS pairing mechanism. No information will be presented to the user addressing the data that will be collected.

Table continues on next page

Id	*Criteria*	*Conf.*	*Results*				*Remark*
			Passed	Failed	Partially	NA	
DS_14	User is informed about the kind of data collected and the purpose	SHALL		X			The prototype application does not inform the user about the kind of data that is going to be received/collected nor for what purpose the data is collected
DS_15	User can review the data and can block forwarding	SHALL [IF *pass through application*]	X				Considering the application integrating both use cases, the user sees the received value (from the PHD) and can then decide whether to forward the information or not
DS_16	User can review and comment on received data but is not entitles to delete the data	SHOULD [IF application does not forward the data]			X		The user sees the data but is not able to comment the data that is stored in the device's database. The user is not enabled to delete received data.

Table continues on next page

Id	*Criteria*	*Conf.*	*Results*				*Remark*
			Passed	Failed	Partially	NA	
DS_17	Use of standard formats for data communication	SHALL	X				Data is communicated between the PHD and the prototype application using Bluetooth Low Energy based on the profiles defined by Bluetooth SIG

Table 4.6 shows the validation results for *Data at Rest* criteria defined in Table 3.4. For this validation, the final prototype application has been used implementing the features that were previously in separate mobile applications; an application interfacing PHDs and another application for CDA generation and transfer of the generated CDA. This means that the validation table shows the result of a single mobile application that implements requirements derived from use case I (see Section 4.2.1) and use case II (see Section 4.2.2).

Table 4.6 – Validation of final prototype application capable of communicating with blood glucose meter and body weight scales using Bluetooth Low Energy profiles and the generation of a clincial document and the forwarding of this document to a health care provider. The validation follows the criteria for *Data at Rest* that can be found in Table 3.4.

Id	*Criteria*	*Conf.*	*Results*				*Remark*
			Passed	Failed	Partially	NA	
AR_1	Storage of data in an encrypted way	SHALL		X			Data is stored using Androids default SQLite database, and the provided Android feature to read and write data. This solution does not provide means for data encryption innately

Table continues on next page

Id	*Criteria*	*Conf.*	*Results*				*Remark*
			Passed	Failed	Partially	NA	
AR_2	User is able to delete collected information	SHALL			X		The application does not provide a way for deleting the user data, but the data will be deleted whenever the user decides to un-install the application. Anyhow, deleting the data locally on the device does not affect the data that has been sent via email to a health care professional in any way.

Table 4.7 contains the results for the single validation steps based on Table 3.5 listing the criteria for *Upstream Exchange of Data*. The prototype application implementing the requirements stated in use case II (see Section 4.2.2) is tested on the criteria and the results are shown in the table.

Table 4.7 – Validation of the prototype application capable of generating a CDA document and the transfer of this document to a health care provider via email. The application is implemented based on use case II (see Section 4.2.1) and for validation purposes the criteria are used that can be found in Table 3.5.

Id	*Criteria*	*Conf.*	*Results*				*Remark*
			Passed	Failed	Partially	NA	
US_1	Use of standard terminologies	SHALL	X				The generated CDA document uses LOINC terminology to code single sections within the CDA document as well as for coding the observations for machine readability. In addition the physical units are coded using UCUM (Schadow and McDonald, 2017)
US_2	Use of standard formats	SHALL	X				Use of HL7 CDA as format for the medical report

4.5 Mobile Health Applications Tested

The prototype implementation following use case I, as described in Section 4.3.1, was tested with different PHDs that were available, and accessible. Beside

the result of the criteria validation (as described in Section 4.4), showing the compliance or non-compliance to guidelines, tests with real world devices proof the interoperability features of the developed software application. The first prototype was able to communicate with blood glucose meters over BLE and has been tested successfully with Roche's Acco-Chek®. Further improvements of this prototype extend its capabilities to communicate with body weight scales. The reason for this software adaptation was to ease showcases due to the noninvasive measurement of a person's body weight. The adapted prototype application was tested with devices manufactured by *A&D medical*, *Medisana*, *smartLab*, and *Xiaomi*.

The prototype implementation of use case II (refer to Section 4.3.2) is able to generate a CDA document. The generated documents were validated using the official CDA schema file that is available on the ELGA web page (ELGA GmbH, 2017a). The document was zipped with the IHE XDM meta-files and send encrypted and signed via email. For dissemination purposes, when this application was used for example at the University of Applied Sciences Technikum Wien's open days, the encryption feature was disabled, in order to send the generated CDA document to the visitor's email account. This deactivation of the encryption enabled sending an email without installing the visitor's digital certificate (containing his/her public key) beforehand.

4.5.1 Personal Health Device Simulator for Bluetooth Low Energy Testing and Education

Based on the Bluetooth *Generic Attribute Profiles* (GATT) that need to be implemented in different PHDs supporting a BLE interface a common XML structure was defined. These GATT services include:

- Device Information,
- Battery Service,
- Weigth Scale,

- Blood Pressure, and
- Glucse

Where the device information service and the battery service, including the attributes defined within these services, are used by different PHD classes the latter are the specific services that are considered for this first prototype implementation. Listing 4.2 shows the basic structure of the XML document containing the single test cases specifications (in terms of test input variables).

Listing 4.2: Structure of the test case XML as suggested in Frohner et al. (2017)

```
<TestCases>
  <TestCase tId="1" profile="WS">
    <DeviceInformation
       manufacturerString="ManufacturerXY"
       modelNumberString="ModelAB"
       serialNumberString="123456789"
       hardwareRevisionString="asdf"
       softwareRevisionString="12.34"
       systemId="dev123"
       regulatoryCertificationData="65551"/>
     <Measurements>
       <Measurement mId="1">
         <flag type="timeStamp" value="20160115121500"/>
         <flag type="userId" value="1"/>
         <flag type="BMI" value="24.1" unit="1"/>
         <flag type="mass" value="83.4" unit="kg"/>
         <flag type="height" value="1.86" unit="m"/>
       </Measurement>
    </Measurements>
  </TestCase>

  <TestCase>
      <!-- .... next test case definitions ... -->
  </TestCase>
</TestCases>
```

The XML structure defines *TestCases* as the XML root element holding a unrestricted number of single *TestCase* instances as child elements. Each TestCase element contains a unique test case identifier using the *tId* attribute and a rough device type identifier using the attribute *profile*. On the next level, the *DeviceInformation* contains a set of attributes describing the device that will be simulated, in more details. Beside attributes of the manufacturer, the device's serial number, or its system identifier, the *regulatoryCertificationData* elements contains a reference to the IEEE device class. The DeviceInformation element is followed by the *Measurements* element, which acts as a grouping mechanism for one or more single *Measurement* elements. Each Measurement element contains the data for a single observation, i.e. the simulated values that are normally generated whenever a patient/persons uses the PHD. The contained child-element do not show a distinct manifestation, but are defined generically in a *key-value*-like format, i.e. each *flag* elements has one *type* attribute defining *what* is going to be communicated and the *value* attribute codes the value.

4.6 IES Interoperability Test Using Gazelle

The first set of conformance and interoperability tests of energy components and energy systems were conducted at the European IHE Connectathon 2018 in Den Haag. Although IHE provided a Gazelle instance on site for medical IT tests, the IES test team and test partners connected via a *Virtual Private Network* (VPN) with the Gazelle instance that is installed on the premises of the University of Applied Sciences Technikum Wien. For interoperability software test cases and the documentation of these test cases, the test parties were asked to exchange messages using Gazelle's proxy server. The recorded messages were derived from 12 test case instances and four software products from different vendors. For automated conformance tests, the binary exchanged and recorded messages had to be transferred in XML-like representations using a *Daffodile* transformation engine. The needed transformation rules could be found in an XML file formatted

in compliance with the *Data Format Definition Language*. These rules thoroughly describe in an XML-schema-like way, how the binary data shall be interpreted.

Listing 4.3: *Data Format Definition Language* example for the *InvokeId* element

```
<xs:complexType name="InvokeId">
  <xs:sequence>
    <xs:element name="type" type="xs:byte" dfdl:alignment="
       implicit" dfdl:hUnits="bytes"/>
    <xs:element name="length" type="xs:unsignedByte" dfdl:
       alignment="implicit" dfdl:hUnits="bytes"/>
    <xs:element name="value" type="xs:byte" dfdl:lengthKind="
       explicit" dfdl:alignment="implicit"
       dfdl:length="{(xs:unsignedInt(../length))}" />
  </xs:sequence>
</xs:complexType>
```

Listing 4.3 shows the mapping rules for the *invokeId*. The invokeId is a unique identifier of a request message in form of integer values. The receiver of the invokeId will use this number again for the receiver's response to enable the sender to link the response to the correct request. Using the BER to encode this invokeId will result in at least three bytes. An example for the invokeId in binary format can be found in Listing 4.4.

Listing 4.4: Example of the binary representation of the invokeId using three bytes

```
0x02, 0x01, 0x3C
```

The mapping rules specify that the invokeId shall be represented as a complex XML element, containing first the *type*, followed by the *length* and the *value*. This information is depicted in the example in Listing 4.3, using the single *element* specifications and the attributes *name* and *type*. Moreover, the remaining attributes from the *dfdl* namespace provide additional information concerning the length and the interpretation. Especially the *length* attribute of the *value* element specification is of interest, since a reference to the *length* element is used to define how many bytes shall be read by the transformation processor. Applying the transformation rules from Listing 4.3 to the invokeId example found in Listing 4.4 will result in an

XML representation that can be found in Listing 4.5.

Listing 4.5: Example of an invokeId after the transformation to XML

```
<invokeID>
  <type>2</type>
  <length>1</length>
  <value>60</value>
</invokeID>
```

Once an XML representation of the transferred content is available within Gazelle, the already existing XML-validation routines (check for well-formed XML, XML schema validation, and Schematron validation), can be applied. Based on the gained knowledge about the potential of transformation, further future possibilities for validation purposes of medical communication standards can be considered. Especially, conformance tests of binary coded ISO/IEEE 11073-20601 messages that are exchanged between a PHD and a personal health gateway, seems feasible. The binary data (transfer syntax) could be generated by one of the devices and then handed over to Gazelle for validation of the correct syntax and the correct semantics. These X73 tests are constrained to conformance test for the most cases. Gazelle is capable of observing TCP/IP based traffic and is not able to observe traffic that is communicated using other communication protocols, like USB or Bluetooth.

5 Discussion

The acquisition of vital data in the context of telemonitoring programs using PHDs, requires a common digital interface with harmonized and standardized communication protocols. Using these PHD interfaces, the users are more flexible in orchestrating the different PHDs that are necessary to document the health status. This feature enables interoperability of all the systems involved and is depicted in different quality models for software and system development.

Quality Characteristics and the User/Mobile-Application Engagement Model

The expert survey conducted at the biggest Austrian eHealth conference, the *eHealth2018* (it will be renamed to *dHealth* with the upcoming conference in spring 2019), clarified if such quality models for software development can be applied for mHealth application in the same manner. The interviewed experts working in the field of system design, standardization, and telehealth programs stated that compatibility is an essential requirement in order to maintain device interfaces and enroll and manage telecare programs. Based on the viewpoint of different users and user groups that are defined in ISO/IEC 25010:2011, the standard for *System and*

software engineering - Systems and Software Quality Requirements and Evaluation (SQuaRE) - System and software quality models, different quality characteristics are more important than others. Concerning the *quality in use* model, *Satisfaction* is most important for primary users. *Efficiency* and *Freedom from risk* is rated as most important for secondary users, whereas *Effectiveness* extends the quality characteristics for indirect users. Since these mentioned quality characteristics rate the system's/software's quality during the usage of the product, more concrete and tangible characteristics, like functional and non-functional characteristics, play an important role in how the system is perceived. Whereas for one user cohort a responsive and smooth user experience might be most important, for others the seamless integration of various devices might be a key aspect. Especially for mHealth applications, where non-professionals and laypeople are intended to play an important role in the acquisition and communication of the needed health data, the capabilities and expectations of this user group need to be considered. Other health software systems are operated by health professionals with a common understanding of the information that is handled by the applications. They can be trained easier than the participants of telemonitoring programs showing a more heterogeneous picture. Today, the main focus group of the people attending telemonitoring programs can be considered to be digital immigrants, not used to handle a smartphone or tablet in such a natural way as the younger population does. This additional entry barrier needs to be addressed in terms of usability aspects of the applications and the phones or tablets, in terms of maintenance and support, and in terms of provided training. "Simple" issues, like the unintended disabling of the wireless network that will result in the failure of communicating data, can be considered as a not-easy-to-solve-problem for the inexperienced user.

In general, problems due to missing usability or a delta between the user expectations and the features an application provides can cause a user to reject using the application. This circumstance is depicted in the user/mobile-application engagement model presented in this work. From a developer's or distributor's perspective, the goal is to keep users interested in using an application or to draw attention to a specific application to be installed in the first place. Multiple, very

similar applications can be found on the application markets that target to solve common tasks. Users might search for ratings from third parties, might inspect the available screenshots, might consider the requested permissions, or might follow recommendations from friends and relatives whether to install an application or not. The single time phases, from *demand*, *pre-install*, *post-install*, and *usage*, all bear the potential that a user will neglect the installation or the further use of this application. The interviewed experts concluded that this model depicts the different possible pathways of how a user interacts with a specific application in an appropriate way. During all those phases, users might drop out of the potential pool of active users when the expectations deviate from the perceptions, or the usage behaviors changes over time. On the one hand, time spent with the application might decrease since the usage of the application is not required on a daily basis, or, on the other hand, the amount of time might increase when, for example, more features become available after upgrading to a pro-version.

Use Cases for a Common Understanding

In order to address the users needs, either for custom development or for development of a standard software product, a clear picture needs to be presented of what the customer/user desires. The definition of use cases allows the harmonization of the intended software product between all stakeholders. Use cases describe the setup where the software is intended to be run, the parties that are involved, the features and requirements, and they can be used to derive test cases based on the use cases. Such use cases can be defined on a more abstract basis where relevant information might be provided from a market perspective, or on a more detailed level defining functional and non-functional requirements.

Methodologies for writing use cases exist, for example, based on IEC 62559 where part 2 of this standard defines templates to be used. Experience using this template structure was gathered in the funded research project *Integrating the Energy Systems* (IES) (Smart Grid Austria, 2016) where use cases were collected and defined for the operation of a *Virtual Power Plant*. Although having extensive and highly

structured templates, it can be considered as beneficial when complex use cases need to be defined. The effort needed to fill those structures, to maintain and to read the content is not negligible. These structured templates turned out to be too extensive for the use cases that are stated in this work and a reduced use case template was introduced, only focusing on the most relevant information that is needed to communicate the intended goals. This proposed use case template was used to define two use cases in the field of data acquisition at the patient's place and the standardized communication of clinical documents. The first describes the communication of data between a PHD and a mobile device using Bluetooth Low Energy as the transmission channel and the Bluetooth Low Energy profiles to ensure syntactical and semantical interoperability. PHDs that are registered as *Bluetooth Smart* devices require the implementation of the above mentioned profiles that are specified by the Bluetooth SIG for various device classes. Besides the use of Bluetooth Low Energy, classic Bluetooth profiles can be considered to be used in such cases as well (if specified by the use case). In this case, a closer look into the *Design Guidelines* from the *Personal Connected Health Alliance* show in which way classic Bluetooth profiles should be implemented and what the stated requirements for the application layer are. The interested reader will identify that PCHAlliance describes the use of Bluetooth's *Health Device Profile* (HDP) together with ISO/IEEE 11073-20601 optimized exchange protocol. For the last 10 years, the author of this work observed the availability of PHDs supporting HDP and the mentioned ISO/IEEE standard on the consumer market. Based on this observation the author found that such devices were never available in a broader number, but in the last years, the number of Bluetooth Smart PHDs has risen significantly. Weighting scales, blood pressure meters, blood glucose meters, and multiple different sport and fitness devices have become available. Nonetheless, when the author tries to purchase additional devices to be used during lectures teaching interfaces of PHDs, detailed information about the interfaces are not really visible or promoted. In the best cases, the product shows the Bluetooth Smart logo, but in many cases, the devices' description only states that Bluetooth is available and at a closer look, someone might find that an application is available at the different markets for mobile device

platforms running a certain version of the OS. Knowing the different features that became available with a certain API level, someone can deduct, whether it is a Bluetooth Smart or classic Bluetooth interface.

The implementation of the first use case described was first tested with a blood glucose meter from the company Roche, where blood glucose data and meta data describing the values in more detail were gathered using Bluetooth's *Record Access Control Block* services implementing a *pull* mechanism, i.e. the Android application accessed the stored data available on the blood glucose meter actively. This approach was chosen, on the one hand, to fit the data acquisition to the defined workflow for caregivers (triggering the transfer of data), and, on the other hand, to have access to more than only the last measurement. This approach was then adapted to a *push* mechanism for teaching reasons since this method is supported by a wider range of device classes. These devices enable the mobile application to register for *indications* and will be automatically provided with new measurements. The application has been further adapted to read values from weighing scales where data can be gathered painlessly (at least without physically induced pain). Integration tests with four different weight scales manufactured by A&D medical, smartLab, Medisana, and Xiaomi and acquired via Amazon, were conducted. From these four devices, the tests were successful with two of them. With one weight scale the connection was unstable, i.e. some of the weight readings taken were sent to the mobile application whereas sometimes the values were not communicated. For the fourth weight scale, the Bluetooth connection could not be established at all. Besides the test with the mobile applications introduced in this work, the suggested applications from the vendors of the devices were installed. To the disappointment of the author, every single application required to set up a user account before the application could be used. Although being aware that by the use of an account, weight reading could be shared between different devices assigned to the user, the demand to sign up and share all kinds of data for dubious reasons disqualified the device and the application from further use by the author.

The second application that was developed includes the generation of a CDA

document based on criteria that are formulated by HL7, IHE and ELGA, and the forwarding of this document following IHE's XDM profile. The XDM profile is of special interest when data should be communicated between different stakeholders engaged in the health management of a person and a complex IT infrastructure (e.g. XDS, XDR) is not available. It describes, among other things, how data can be transmitted using classic mail services. This method was implemented to forward a clinical document in form of a CDA document to a healthcare provider. The generation on the CDA document is triggered by the user and not done automatically whenever a new measurement was available. For the latter, other, more suited transfer methods are applicable. In such cases, the implementation of IHE's *Device Enterprise Communication* profile from the *Patient Care Coordination* Technical Framework (IHE International, 2015) can be applied, where an HL7 message is generated when new data becomes available. This message is then forwarded over TCP/IP services to the healthcare provider. A more recent adaption of this profile enables the exchange of HL7 FHIR bundles as well. In contrast to this message-like representation with the characteristics of messages in terms of completeness, context or stewardship, HL7 CDA satisfies all the requirements that are needed for clinical documents. With the possibility of transferring information that targets human readability and machine readability within one single document, data can be further processed by computer based systems. The use of standardized vocabulary is a core requirement and the search for fitting code lists and concepts is a task that is not always easy. For the document that is presented in this work, discussions with the head of the standardization office of the Austrian electronic health record system were very valuable. Especially the way how meta-information for a blood glucose reading is represented best was very interesting. Different possibilities have been suggested by the author, and in the end, the simplest was chosen, i.e. the information that a blood glucose reading has been taken before the meal (preprandial) is directly coded in the CDA's *observation/code* element by using the LOINC code 88365-2 (standing for *Glucose [Mass/Volume] in Blood - pre-meal*). Another method which has been favored by the author before the discussion with ELGA was the use of a *qualifier* element as a child element of the *observation/code* element. This *qualifier*

element can be used to provide additional information for the concept represented in the code element. This method, called post-coordination, is more difficult to process and therefore the decision was made to *just* describe the concept on a detailed level using solely the code element. Another used feature of CDA is the capability to list a device as the author. For such cases, like the application that is introduced in this work, CDA's *AuthoringDevice* class can be used to state that the content that can be found in the CDA's body has been stated by a device and not by a human.

Criteria Catalog for Validation of the Implemented Prototypes

Concerning the validation of the prototypes implemented, based on the criteria that are defined in Section 3.6, all of these were fulfilled which deal with interoperability of data exchange. Criteria that deal with the Bluetooth pairing procedure are fulfilled only partially since this procedure is not implemented within the application itself but uses the operating system functionalities and user interfaces. The reason for this is that the main concern was to include the applications in the lectures at the University of Applied Sciences Technikum Wien. The lectures include *Mobile Computing in Medical Imaging and Data Engineering*, where students implement applications that can consume or create CDA documents. Other lectures in the master study program *Biomedical Engineering Sciences* are *Medical Information Systems* and *Advanced Programming in Medicine*, where the communication of medical information according to the PCHAlliance is taught in theory and practice. Students are entitled to use parts of the prototypes to gain knowledge on how data can be received and managed for their own projects. The requirements that deal with the documentation on how to connect PHDs via Bluetooth is not available due to the fact that the pairing procedure is not part of the implemented prototype, but is achieved using Android's Bluetooth settings. This also results in only partially passed tests for other Bluetooth management tasks. Concerning the criteria for *Data at Rest*, the results were gathered in the final combination of the two separate prototypes. The main issue that needs to be addressed is that the data that is gathered by the connected PHDs is not stored in an encrypted database. For further

implementations, this point needs to be considered. Solutions would include using a different database framework than the default SQLite solutions. An example would be the use of *Realm* (Realm, 2018), where data will be stored being encrypted by default. Beside this storage issue, the possibility for the user to delete previously recorded values needs to be reworked. At the time being, the user is able to inspect the received values from the PHDs and can then decide whether to forward this information or not. However, storing the data in the database is currently not affected by the actions the user takes. The best results were achieved for the criteria that concern the *Upstream Data Exchange*. The identified guidelines and standards state that the data format and the data itself shall be based on standardized and harmonized technologies and terminologies. The use of CDA (as the format) and the chosen terminologies for coding information in a machine readable way (LOINC) are well established and recognized within the health IT community. The implemented prototype applications, based on the identified criteria and the intended use for teaching purposes demonstrates how data can be exchanged between the used PHDs and how this data can be communicated to an health care provider. Where these prototypes focus on the exchange of information, in terms of the Bluetooth Low Energy services and the generation and use of CDA documents, and therefore did not comply with all stated requirements, applications that are intended to be published and used in telemonitoring settings shall implement all criteria. For teaching the focus on the communication standards and protocols is reasonable, since these come with a high level of complexity and the students are encouraged to gain the knowledge how to read and implement communication standards in the addressed courses.

In order to achieve interoperability for CDA levels, further restrictions on the single elements defined by HL7 CDA must be in place, otherwise two different instances of, for example, laboratory reports will not only look differently, but also the computer based processing of the document must be done differently. Therefore, specifications in form of implementation guidelines need to be established and harmonized to be used in a certain realm. In the last years, the author's contribution with such harmonization and specification processes for the Austrian electronic health

record system ELGA provided a deep insight into the tools that have been used in the past and that are slowly superseded by other tools. In the first years, these implementation guidelines were developed as plain documents (word or pdf), example documents were defined in parallel (XML reports), and assertions for CDA validation were formulated by a third party. This three-folded effort to establish and maintain the artifacts often resulted in discrepancies. In recent years, this method was replaced by, *ART-DECOR*® (ART-DECOR Open Tools, 2018), a web-based software solution. This software solution provides the means to specify CDA documents on a template basis, handles the required terminology, and assists in the generation of Schematron rules for validation purposes. Beside the possibility to specify the requirements for a clinical document class, ART-DECOR®comes with a framework to collect *datasets* that should be included in a document. The concept of these datasets is to harmonize the data and information that a report should contain without the need to settle for a certain implementation strategy, i.e. with medical experts, the acquisition of data and data formats can be conducted which is then the basis for the definition of CDA structural elements.

Addressing the interoperability and integration tests with PHDs the developed device simulator application, introduced in Section 4.5.1, can be used as a test driver. Following device classes are supported by the developed Android application: (1) blood pressure monitoring devices, (2) weight scale device, and (3) blood glucose meter. The introduced XML structure for test case configuration has been used to send of a set of measurements, including the systolic, the diastolic, and the mean blood pressure, as well as the pulse. Simulating a weighing scale, the configuration holds a test case for sending three different body weights taken at three different points in time, and the blood glucose meter configuration simulates a bulk message forwarding five blood glucose measurements. These are examples of how the configuration file can be used to define single test cases. Whenever this configuration file gets adapted and updated, the user interface that is displayed after the start of the application will change, i.e. for each defined test case in the XML configuration file, a separate button will be rendered enabling a user to execute the specified test case. The application can be used during the first conformance tests

but is not intended to replace other certification schemes that might be available. For example, when a Continua Certification is desired for an application that can communicate with PHDs according to the PCHAlliance specifications, the use of the *Profile Tuning Suite/Bluetooth Developer Studio Radio Module* (BluetoothStore, 2017) should be considered (AT4 wireless S.A.U. and Personal Connected Health Alliance, 2016). The simulator application enables users to define new test cases based on specific needs. Some restrictions are in place, since a set of *flag* elements, with their *key/value* approach, is used to provide the test input data. This generic way of providing the data asks of the user to have an understanding of the possible data that can be coded in the flag-elements. Another approach would be to provide pre-defined structural XML-elements that can be used for building test cases. This would ease the conceptualization of test cases and would require to adapt the application code to fit the new structures. The efforts made for the implementation of this simulator application were continued in two Bachelor theses with partners from research facilities others than the University of Applied Sciences Technikum Wien.

Transfer of Knowledge with other Domains

Interoperability of systems is not only a crucial topic in the field of health IT. The author is currently involved in a funded research project targeting interoperability in the energy domain. Based on the experiences from IHE and the methodology that is defined by this organization, the applicability of specifying implementation profiles based on use cases and using the test framework Gazelle from IHE for energy systems(-of-systems) is investigated. The used communication standards to communicate data between assets that are intended to generate, store, or consume energy and a SCADA unit are based on binary coded data. In order to use Gazelle and the available validation services for testing the exchanged information, mapping rules need to be defined enabling the transformation from binary format to XML syntax. These rules are formulated using the *Data Format Definition Language* (DFDL) in an XML-schema-like set of definition. This transformation step was

included in Gazelle and successfully tested at the European IHE Connectathon in The Hague, in spring 2018. Following the IHE test procedure, the data exchanged between sender and receiver was captured on a proxy server implemented between sender and receiver. In total 12 test instances were started, testing the communication of data between software applications from four different companies. Once the message is recorded it will get transformed and subsequently validated. This validation is based on XML-schema and XML-Schematron mechanisms. The test cases so far deal with the automatic validation of messages coded based on IEC 61850 (IEC, 2004) and are currently extended to validate messages sent following IEC 60870-5-104 (International Electrotechnical Commision, 2006) (IEC 104). This additional effort is based on the fact that during the specification of the implementation profiles, the decision was made to use IEC 61850, since it is the more modern approach to communicate data than IEC 104. Retrospectively, this decision did not really got a broader attention on the market, due to the fact that many companies in German, Austrian, and Swiss regions do not implement this standard, due to its complexity. They tend to stick with the easier to implement IEC 104. The lesson learned was that during the earlier design and implementation phases of the implementation profiles, the market situation was not clear enough, i.e. the customer requirements were not clear. Nevertheless, the experiences that were acquired during the testing of binary coded information using Gazelle, can be used for the validation of ISO/IEEE 11073-20601 coded information. In order to enhance Gazelle's validation tools for this task, DFDL specifications need to be developed. In addition, and based on the DFDL specification, XML-schema files and XML-Schematron files can be defined. When these steps are completed, an interested user can fork the binary coded transfer syntax to an "offline" validation service of Gazelle and check whether the binary data stream is encoded correctly.

Start with the User, End with the User

Keeping in mind that the first step towards interoperability and, more generally speaking, to high quality software or systems, the user's needs and expectations

must be considered. Based on these requirements, further characteristics of a system to be developed can be stated, and the implemented system can be tested against these. For custom software, direct feedback on whether the needs were addressed appropriately or not can be considered. For standard software that is published on one of the mobile markets, this kind of feedback is harder - or even impossible - to achieve. The implementer of the application can react to comments that are provided by users, but other potential users might find these (negative) remarks as well and might consider not using this application. Therefore, the need to clearly communicate the features, capabilities, and characteristics of an application is of the utmost importance. Since this information might end up to be very extensive, a potential user might not be willing to read everything in detail. Nevertheless, the communication of the most important characteristics is of interest in order to avoid the disappointment and frustration of the users, because if those users decide to comment, it might not be positive for the promotion of the application. In the end, maybe a harmonized visual representation of the main characteristics will be feasible to define. A suggested graphical representation, showing the most interesting characteristics might is depicted in Figure 5.1.

If such a visual representation is available on the market, users might find it easier to investigate the pros and cons of an application. Such a representation is considered to be responsive in terms that a user being able to get further details by selecting one of the petals. In the end, users might face the challenge of having to choose one out of multiple applications that are available in order to satisfy their very own needs.

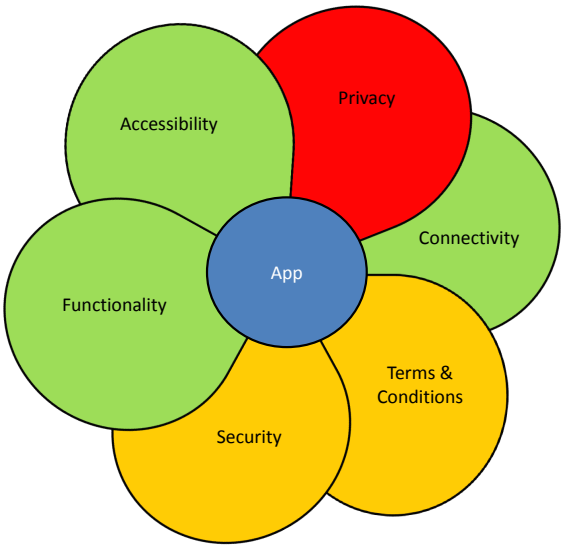


Figure 5.1 – Suggested graphical representation of the most important application characteristics from a user's perspective. The color of the single petals represent the rating of the stated characteristic on a three leveled scale. Green stands for a good rating and red for a poor rating.

6 Conclusion and Future Work

Data is a key enabler for modern-day health care. Data can be generated when a patient is examined by a doctor or other health professional but data can also be generated without this classic patient/doctor contact. Today, technology enables us to generate data that is valuable for clinical processes by using a multitude of different devices that can be used by the patients themselves. Those devices are designed to be operated by laypeople enabling them to monitor their health status and be an active part during the treatment or prevention of an illness. This monitoring can be conducted in a pen-paper principle, where the patient manually copies the readings provided by the health device into a diary. Another and more convenient and safer approach is to communicate the device readings automatically from the health device to another computer based system. For this cases, the mobile phone of the patient is considered. Since the mobile device manufacturer and the manufacturer of the health device are not the same entity, they need to use a common understanding which transport technology is used and which communication protocol is implemented. Different standards and frameworks are available but additional information is required to specify *how* these should be implemented. Based on a common use case definition and the derived criteria an application can be implemented and validated. The criteria catalog

introduced in this work is a valuable mean to do this. This catalog condenses the available information on how standardization between a personal health device and a mobile application should be implemented and how data can be communicated from a mobile application to health professionals. This feature of interoperable data communication is depicted in system/software quality characteristics. Beside these system quality characteristics, quality characteristics during the use of the application - *quality in use* - need to be considered during the implementation and the launch, since those characteristics are evaluated by the user. The introduced *user/mobile-application engagement model* considers this fact by demonstrating that (potential) users might assign the application with a poor quality when the application does not fulfill their very own needs during usage in their very own contexts.

The standardization and harmonization of quality criteria require a lot of resources. In the best cases, this efforts are visible for, and accepted by a large group of users. These user groups include developers of software systems who are implementing the specified requirements, it includes end users who are work with software systems and might observe the manifestations of standardization work, and it can also address user groups that can continue specification work based on previously defined standards. Especially in the area of interoperability, where for example, clinical document structures are specified for a targeted domain, artifacts can be reused by standardization efforts from other domains. Examples hereto include results from the Austrian electronic health record system that is based on specifications of IHE and uses document elements defined by IHE or other HL7 affiliate members. Likewise, efforts by ELGA in Austria and HL7 Austria are acknowledged and partially used for German CDA implementations. These circumstances bring the community closer together and improve harmonization between different realms. On a broader basis, the author can report benefits that can be achieved when existing knowledge is transferred between different domains. The project IES applies the methodologies and tools that have their origins in the medical IT domain to the energy domain where similar issues concerning interoperability of systems can be found. Plenty of different communication standards are available

and data to be exchanged can be considered as sensitive information, similar to medical setups. Therefore, well established processes and frameworks of test software might be applied in fields where such structured and holistic approaches are not available. Besides, common specifications can be transferred between domains. Using IHE's *Audit Trail and Node Authentication* profile, which is specified for the communication of medical data can also be used in energy domains, since the content of the transferred data is not specified, but the security requirements are addressed. This profile demands the mutual authentication of the communication systems involved, the collection of audit messages, and a communication using secure transport channels. With European efforts to bring different fields of applications together and define a common set of requirements for various aspects, this might even be emphasized. The same can be applied in mobile environments, since those mobile platforms interact in many cases with back-end systems to support larger use cases. Such system-of-systems rely on the functioning of all the participating entities, and the mobile platforms, with their strong personal relationships, will be a very prominent part of it.

The needs concerning quality criteria and concepts that we address for mobile applications today are foreseen to influence decisions that might be taken in the future. Especially, for telemonitoring purposes and telehealth scenarios, where data is gathered at the patient's place, this data can and maybe should be used for analyses that are to come. If we do not solve today how data should be transmitted in a semantically proper way, this information will be lost for future analyses. When the context of a single measurement is not clear and the characteristic was not described in detail, further and future processing of high quality is not possible. Such scenarios not only include the secondary use of data, but also the addressed purpose of telemonitoring, which is to provide a more gapless and unbroken acquisition of patient data, in order to provide faster feedback and a fast adjustment of the therapy. Interfaces between the involved and used systems must be harmonized. A certain brand loyalty can end up in a vendor lock-in, where a service provider or the patient/user is not any longer free to choose the set of used hard- and software. In order to overcome such situations, clear requirements on the systems

and their interfaces need to be in place, enabling system developers and hardware manufacturer to provide systems that comply with these criteria. To forward the information about the features and the relevance of mobile applications used in eHealth efforts have been made towards certification schemes. Unfortunately, these gratifying attempts show that these issues are not easy to solve. In the US, Happtique, an application store promoting mobile health applications that were tested and certified by Happtique, suspended their certification program when security flaws in previously certified applications were found by third parties. A similar case can be found in UK's NHS, which provided a list of NHS approved mHealth applications to be used by UK citizens. This list included multiple application where personal information was sent over the Internet in an unencrypted way. Such cases demonstrate that certification schemes and test routines need to be implemented in a way that users can rely on the suggested applications.

Security and privacy aspects are important aspects a user considers, apart from other quality aspects. Quality can be a measure of how well or poor an application reflects the requirements stated by the user or users. Paraphrasing the quote which can be found at the beginning of this work, taken from the *Hitchhiker's Guide to the Galaxy*, by Douglas Adams, a mobile application might turn out to "be almost, but not quite, entirely unlike" the application the user was searching for.

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Appendix

A.1 Survey

The Figure A.1 and A.2 show the two pages long survey used for expert interviews.

Figure A.1 – Page 1 of the Survey

Survey concerning **Quality criteria** and concepts for **mHealth** Applications

This survey targets to identify if the Quality Models defined in ISO/IEC 25010 are applicable to mHealth applications or if additional considerations are needed. Another aspect of this survey deals with the user engagement with mobile applications and this survey states an adapted application lifecycle from an end-user's perspective.

Definitions:

Stakeholder definitions according to ISO/IEC 25010:2011 adapted for mHealth scenarios are:

- **Primary user**: a person who installs an application from the app-market and uses the application voluntarily, or who has been instructed by a third party to use a certain application.
- **Secondary user**: a person who provides support (e.g. by providing content) or maintains and manages the use of a mobile application.
- **Indirect user**: a person who receives output from the application (e.g. health professionals for tele-health).

Question 1

Is the above stated definition complete, or are types of stakeholders for mHealth scenarios missing?

Question 2

The image below shows the *Quality in Use* model taken from ISO/IEC 25010:2011.

What are, in your opinion, the three most important subcharacteristics, for a) the primary user, b) the secondary user, and c) the indirect user in mHealth scenarios?

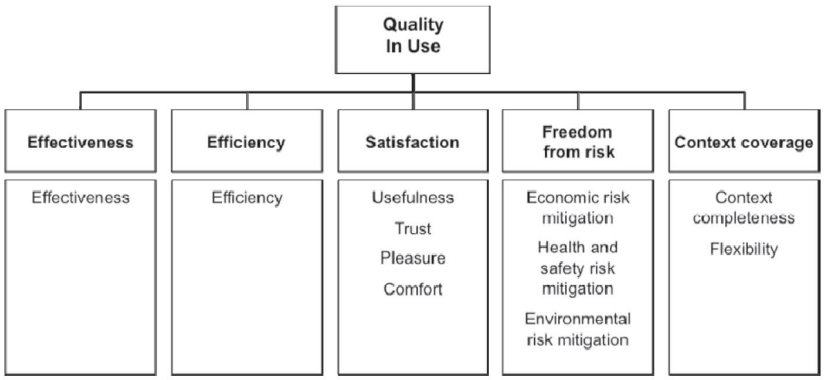
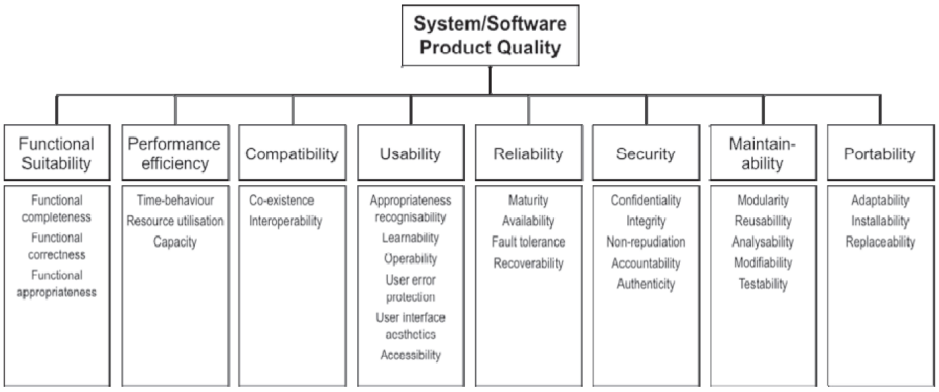


Figure A.2 – Page 2 of the Survey

Question 3

The image below shows the *Product Quality* model for System and Software taken from ISO/IEC 25010:2011.

What are, in your opinion, the five most important subcharacteristics for mHealth applications in mHealth scenarios?

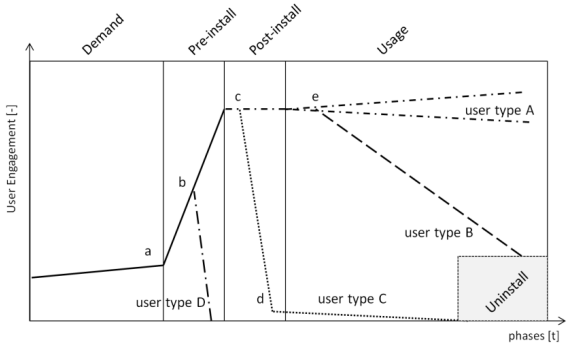


Question 4

Based on the *Product Quality* model as shown in the image above: Which characteristics and subcharacteristics need a certification program in mHealth scenarios (incl. programs that are already in place)? What are the most important subcharacteristics?

Question 5

The image below represents the “user-engagement-level” (primary user) with a mobile application over time. Do you think that these phases represent the user experience sufficiently? Is a phase missing? Are the derived user types comprehensible and legitimate?



A.2 Use Case PHD-IF based on IEC 62559

1. Description of the Use Case

Patients are encouraged to measure health related parameters on a regular basis at home. The measurement will be conducted by the patients themselves or with the assistance of a home care professional or a relative. The data generated by the measurement device should be transmitted electronically to the patients' smartphones.

This use case is a pre-conditions for other potential use cases, since the first step in handling vital parameters includes the transfer of those from the measurement device (PHD) to a computer based system where further processing or transmission can be done.

1.1. Name of Use Case

Table A.1 specifies the name of the use case described and provide an unique identifier for the use case to be referenced and used. Furthermore, this table contains information about the effected domain(s) in which the use case is situated.

Table A.1 – Use Case Identification - Acquiring Data from a PHD

Use case identification		
ID	*Area domain(s)/Zone(s)*	*Name of use case*
Telemon-001	Telemonitoring/Device	Acquiring data from a PHD

1.2. Version Management

Table A.2 introduces the version management of the use case. Since a use case definition might get adapted and changed over time, it is necessary to follow these changes and reflect use case derived artifacts from a certain version.

Table A.2 – Use Case Version Management for Use Case Telemon-001

Version Management				
Version no.	*Date*	*Name of author(s)*	*Changes*	*Approval status*
0.01	11.10.2017	M. Frohner	Initial creation	Draft

1.3. Scope and Objective of Use Case

Based on the scope of a use case, single objectives are formulated, stating the desired outcomes. The scope restricts the boundaries of the use case. However, related other use cases or dependencies to other use cases are listed as well (Table A.3).

Table A.3 – Scope and Objectives of Use Case Telemon-001

Scope and objectives of use case	
Scope	Patients are asked to measure their vital parameters on a regular basis using one or more PHDs, depending on the indication. The PHDs offer a Bluetooth interface enabling the communication with the patients' smartphones or tablet. These measurements are supposed to be done by the patients themselves, but are not limited to that. The recorded parameters on the smartphone or tablet can be further used to be visualized on the device itself, or can be forwarded to people involved in the healthcare process.
Objective(s)	• automatic transmission of vital parameters from the PHD to the smartphone / tablet • decreasing the potential error when the communication chain is broken, i.e. handwritten notes
Related business case(s)	• telemonitoring • telehealhcare • improving the patients' engagement with their illness

1.4. Narrative of Use Case

Table A.4 describes the use case in a shortened and in a complete fashion. The actors (human as well as hardware/software) and their roles within the use case are described narratively.

Table A.4 – Narrative of Use Case - Telemon-001

Narrative of use case
Short description
PHDs are provided to the patients in order to enable them to monitor their vital information. The used PHDs shall communicate over digital interfaces (USB, Bluetooth, Bluetooth Low Energy) in order to forward the gained data to smartphones or tablets operated by the patients. When new data is available on the smartphones or tablets, further processing of it is possible as well as the transmission of it over wide area interfaces. Hence, data can be shared with health professionals and related people.
Complete description
Patients are known to have a certain disease or health status that should be monitored. The patients get equipped with one or a set of medical devices - PHDs - enabling the acquisition of vital parameters of interest at home. The classic pen-paper-based notebook approach lacks usability and poses a certain safety risk since errors can easily occur when the measured value is read from the device and copied into a notebook manually. Since modern PHDs communicate the measured information to a remote device (most probably a smartphone or a tablet that patients own) over interfaces, a digital and automatic transfer of the measured parameters is preferable. After the initial setup of the system (e.g. Bluetooth pairing), the data is send automatically or triggered by the user to the phone or tablet when a new measurement has been taken. If the phone or tablet is not available during the measurement, the PHD stores the values, and sends them when a connection is available (e.g. during the next measurement). On the smartphone or the tablet, the received values can be displayed, post-processed, persisted, or forwarded using wide area interfaces.

1.5. Key Performance Indicators (KPI)

Table A.5 lists the indicators that are derived from the use case description and those indicators can be used as a metric showing if the desired features, based on the use cases, have been achieved. Usually, those indicators are based on the objectives defined in Table A.3.

Table A.5 – Key Performance Indicators (KPI) - Telemon-001

Key performance indicators			
ID	*Name*	*Description*	*Reference to mentioned use case objectives*
kpi_01	automatic transmission of vital parameters	After the initial setup of the systems, acquired vital parameters are automatically sent from the PHD to the patients' smartphones or tablets. This increases the usability of the measurement routine.	automatic transmission of vital parameters from the PHD to the smartphone / tablet
kpi_02	digital transmission of vital parameters	The automatic transmission of vital parameters decreases the potential for failures during the manual transcription of the measured value to the notebook	decreasing the number of potential errors when the communication chain is broken

1.6. Use Case Conditions

Table A.6 states the assumptions that have been drawn based on the use case and reflects the needed prerequisites that need to be in place. This table will also be used to state conditions where the assumptions are not aligned with the stated use case, or "reverse-engineer" conditions where the prerequisites cannot be met due to boundary conditions. For the use case *Telemon-001* one possible scenario, where the prerequisites are not met is that the patient does not own smartphone or tablet.

Another scenario would include that the patients do not live on their own where they have a dedicated, person-bound PHD, but share it with other people living in the same household. Since the PHDs do not offer a profound mean of identification (and authentication) the PHDs measurement cannot be automatically assigned to the correct person of the household. A similar issue arises when the smartphone/tablet is shared between the residents. Depending on theses situations, it might be hard, to

either pair multiple devices the same time, or to identify and ensure the authenticity of the people sharing one device, i.e. assigning the transferred vital parameters to the correct user.

Table A.6 – Use Case Conditions - Telemon-001

Use case conditions
Assumptions
Patients need to have PHDs that are on the one hand suited for their medical indications and the PHDs must follow regulatory requirements and need to have implement a digital interface. Moreover, the patients need to have a smartphone or a tablet.
Prerequisites
Health services should be installed that provide the fitting hardware and maintain this hardware if the patients are not able to this by themselves.
Use case conditions
Assumptions
Patients should be able to operate the smartphone or tablet in order to get the data transferred automatically. The patients should be able to solve easy tasks with their devices e.g. enabling Bluetooth once it has be disabled (by accident).
Prerequisites
The patients need to be trained how to operate the smartphone or tablet based on the requirements for automatic measurement transmission. A first level support might be installed where the patient can address issues and malfunctions of the system.

1.7. Further Information to the Use Case for Classification/Mapping

Table A.7 provides additional information about the setup of the described use case. Among other information this table depicts dependencies between different use cases, the level of detail, and whether the use case are technically or business use cases.

Table A.7 – Use Case Classification - Telemon-001

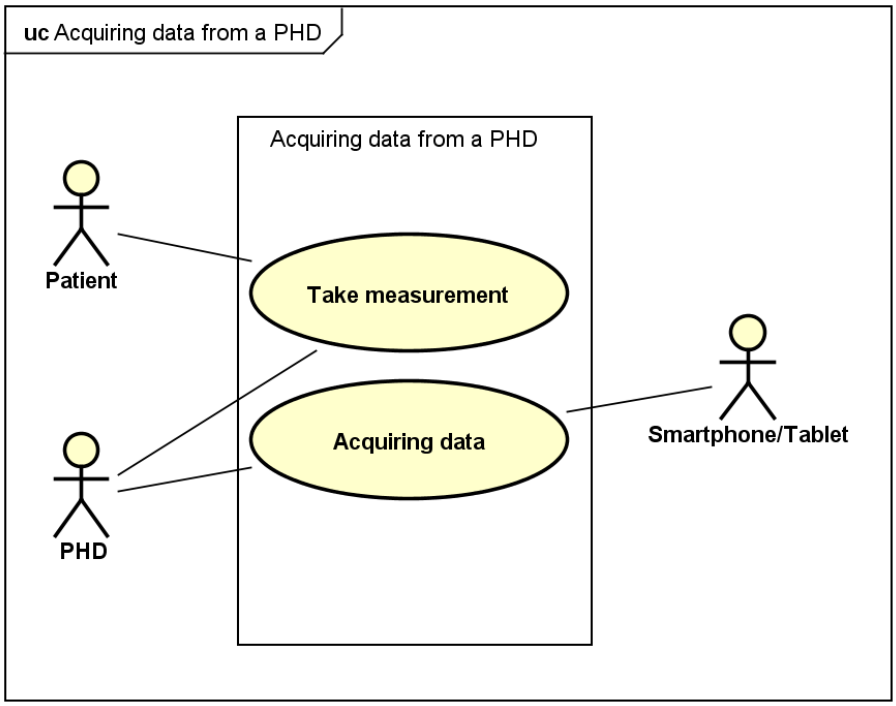
Classification information
Relation to other use cases
e.g. Send Health Information to Health Care Provider via eMail (Telemon-002)
Level of depth
Detailed use case
Prioritisation
Mandatory
Generic, regional or national relation
Generic
Nature of the use case
Technical
Further keywords for classification
Improve the patients' self management

2. Diagrams of Use Case

In Table A.8 the use case diagram is depicted.

Table A.8 – Use case diagram - Telemon-001

Diagram(s) of use case



3. Technical Details

This section deals with technical details based on the use case descriptions and the diagram introduced in this appendix. Based on the actors defined in the UML diagram, they are formally specified in this and the following chapters. References to artifacts outside of this use case description are stated as well.

3.1. Actors

Since this chapter specifies the technical details, the term *actor* as it is used in UML notation is now restricted to hardware and software entities It does not describe the more generalized concept of a participant within a use case. If the number of actors exceeds a certain number, it is recommended to group actors based on

their capabilities (e.g. sensors, actuators, etc.) For this use case, a grouping is not necessary since the amount of actors involved is small.

Table A.9 – Actors - Telemon-001

Actors			
Actor name	*Actor type*	*Actor definition*	*Further information specific to this use case*
PHD	Device	A medical device that is operated by the patients at home.	Typically, this device is a regulated medical device and needs to implement a specific interface for communication.
Smartphone / Tablet	Software module	A device that is characterized by running a specific application or an application implementing the needed features for communicating with external PHDs.	Actors, according to IHE specifications, describe a software module with a set of specified communication features.

3.2. References

The Table A.10 shows the references to external standards, specifications, and recommendations that are used or that are required for the implementation of the use case described.

Table A.10 – References to Standards, Specifications and Recommendations - Telemon-001

References						
No.	*Reference type*	*Reference*	*Status*	*Impact on use case*	*Originator/ organisation*	*Link*
BT	Standard	Bluetooth Core Specification v5.0	final	high	Bluetooth SIG	www.bluetooth.com/
BT LE	Specification	Bluetooth LE GATT Services	final	high	Bluetooth SIG	www.bluetooth.com/

4. Step by Step Analysis of the Use Case

This section contains a detailed look on the scenarios that are part of the described use case. Failure scenarios can be formulated as well and alternatives can be included in order to describe circumstances where assumed use case conditions are not in place and therefore would influence the scenarios described so far.

4.1. Overview of the Scenarios

Based on the use case diagram depicted in Table A.11, the two scenarios *Take measurement* and *Acquiring data* are described.

Table A.11 – Overview of Scenarios - Telemon-001

Scenario conditions						
No.	*Scenario name*	*Scenario description*	*Primary actor*	*Triggering event*	*Pre-condition*	*Post-condition*
01	Take measurement	The patient uses the PHD according to its purpose in order to measure a certain vital parameter. This might include adjusting the cuff for a blood pressure monitoring device, or to take a blood sample for a blood glucose measurement. Apart from the measurement, the patient might provide meta-information.	PHD, Patient	Patient decides to take measurement.	PHD is fully functional and ready to be used by the patient	The PHD visualizes the measured parameter on the device screen and - if applicable - relevant meta-data is entered by the patient
02	Acquiring data	The patient has conducted the measurement (incl. filling in of meta-data) and the measurement has been displayed on the device. The PHD will send the measured data (incl. meta-data) to the patient's smartphone or tablet.	PHD, Smartphone/ Tablet	The measurement is completed.	The measurement is completed, the PHD has been paired with the patient's smartphone or tablet, or the PHD is wired (connected)	The smartphone or tablet app confirms the received values sent from the PHD.

4.2. Steps - Scenarios

Table A.12 – Scenario steps

Scenario			
Scenario name:		Take measurement	
No.	*Event*	*Name of process/ activity*	*Description of process/activity*
01	The patient prepares himself / herself for the measurement.	PHD is turned on.	PHD is turned on and might check for a connection to a smartphone or tablet. Measurements that are not sent yet, can get transmitted now. If the connection is already available before the measurement, the PHD might synchronize its internal clock with the time and date available on the smartphone or tablet.
02	Patient takes measurements.	Take measurements.	The PHD reads/calculates the patient's vital parameter using its sensors.
03	Measurement finished.	Taking the measurement is finished.	The PHD has acquired the vital parameter(s) and visualizes them. Depending on the device, the patient might enter additional information related to the measured parameter (e.g. post-pradial for blood glucose measurement)

5. Information Exchanged

Table A.13 – Information exchanged

Information exchanged			
Inf. ID	*Name of information exchanged*	*Description of information exchanged*	*Req.ID*
I-01	Vital parameters are transmitted from the PHD to the smartphone / tablet.	The vital parameters are sent from the PHD to the smartphone / tablet of the patient. For Bluetooth communication, it is assumed that the device pairing has been done beforehand. For Bluetooth Low Energy communication, the specified GATT services defined by Bluetooth SIG need to be implemented. Further requirements are stated by the Personal Connected Health Alliance.	Co-Is-01

6. Requirements (option)

This section can be used to state further requirements of the use case. Such requirements can address configuration issues, data privacy, and/or security issues.

7. Common Terms and Definitions

This sections contains the explanation of terms and definitions introduced and used in this use case specification.

8. Custom Information (optional)

Additionally, use case related informational concepts can be stated in a key-value-pair representation.

About the Author

Matthias Frohner, MSc, is researcher and lecturer at the University of Applied Sciences Technikum Wien. His main area of research lies in the field of standardized communication of medical device data and he is part of the core team of the research focus *Secure Services, eHealth & Mobility*.

In 2008 he started his work in the field of Personal Health Devices Communication by implementing standardized interfaces in order to seamlessly integrate those devices (e.g. blood pressure monitor, personal weight scales) into patient centric integrated care paths. Mr. Frohner contributes to different funded research projects, develops (mobile) software applications, is part of standardization efforts on a national and international scale, and forwards gained knowledge in lectures for students and industry. He is a certified software tester and took part on interoperability test events hosted by IHE and Continua.

He is actively involved in the development of CDA Implementation Guidelines for the Austrian electronic health record system ELGA and for the Austrian Ministry of Health and Women