HOLISTIC SYSTEM DESIGN FOR DISTRIBUTED NATIONAL eHEALTH SERVICES

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UiA University of Agder

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for Distributed National eHealth Services

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Für Tatjana und meine Eltern Sigrid und Wulf

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Martin W. Gerdes
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Abstract

The dynamic development of Information and Communication Technologies (ICT), Human-Computer-Interaction (HCI), Internet of Things (IoT) and Artificial Intelligence (AI), drive the ongoing *Digital Revolution*, that creates the ground for an *Information Society*. The *Digital Age* or *Information Age* affects all aspects of social organization, including particularly the health sector.

eHealth systems and services utilizing information and communication technologies (ICT) have the potential to increase the efficiency of professional and informal caretakers when monitoring the healthcare status and assistance needs of patients and their relatives. Patients with chronic diseases and age related medical conditions receive support through technologies that allow them to live independently and securely with a high quality of life (QoL). Independent from the public health systems, further services and applications are emerging to promote individual fitness and wellness goals to maintain a healthy life style.

This study covers the design, development and evaluation of a reference solution for integrated eHealth services and applications targeting remote monitoring and decision support in telehealth and telecare.

The design of the proposed system is based on a holistic view, providing for the definition of *Reference Requirements*. Furthermore, the *Reference Design* as well as the development of a proof-of-concept trial system have followed a User Centered Design (UCD) process, involving all user groups in the trial system's design and testing.

The proposed solution seeks for the empowerment of citizens to carry out monitoring and self-assessment of their health and well-being over longer periods of time, and by that to contribute to their independence and self-management of health

and wellness at their point-of-care. It includes an end-to-end eHealth system architecture, and outlines a solution to connect citizens' point-of-care with formal and informal caregivers through a common, secure and reliable health information services infrastructure. The underlying reference requirements include functional, operational and socio-economic requirements, legal, ethical and regulatory policies, relevant emerging technologies, and interdependencies between the different requirement domains for its development and verification. The required logical functionalities, protocols for information exchange and graphical interfaces for user interaction have been implemented in a trial system, covering applications and services for monitored citizens, healthcare professionals, and for the health information service infrastructure. The components have been tested first in an academic test environment as part of the UCD process. Results have led to a successful deployment and integration of the system in the Norwegian Health Network for a 2-year-field trial, including more than 100 patients with Chronic Obstructive Pulmonary Disease (COPD), a municipality-operated telehealth service and medical specialists in a hospital.

The validation of the proposed reference design considers aspects of the design methodology, the reference requirements and their elicitation methodology, the acceptance of the proposed solution by the different user groups, and the quality of the support provided to the healthcare professionals. The UCD process has implicitly been validated, as it was utilized in the system development from the initial design to the routine operation of the trial system. The evaluation of some important performance indicators (interoperability, cooperation aspects and applicability of standards for the information exchange through communication protocols between the different system domains; security and access control technologies; the accuracy of the automatic healthcare status assessment; potential advantages and efficiency gains achievable through the evaluation of continuous remote monitoring data; usability and user acceptance) in the clinical trial have revealed advantages and limitations of the proposed solution, and has led to the identification of improvement potential. This has resulted in a conceptualization of a system for personalized health and wellness promotion, utilizing AI and IoT technologies. This conceptualization bears numerous new interdisciplinary research questions and forms part of the research agenda of the author.

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Abbreviations

A list of the used abbreviations:

3G	3rd Generation Mobile Network
AI	Artificial Intelligence
b2b	business-to-business communication
BAN	Body Area Network
BLE	Bluetooth Low Energy
BT	BlueTooth (short-range communication standard)
CA	Certification Authority
CDSS	Clinical Decision Support System
CEH	Center for eHealth (at the University of Agder, Grimstad/Norway)
COPD	Chronic Obstructive Pulmonary Disease
Core-EHR	Core-Electronic Health Record
CPOE	Computerized Physician Order Entry
DDSS	Distributed Decision Support System
DS	Design Science
DSRM	Design Science Research Methodology
DSS	Decision Support System
ECG	ElectroCardioGram
EHR	Electronic Health Record

EMR	Electronic Medical Record
FHIR	Fast Healthcare Interoperability Resources (by HL7)
GPS	Global Positioning System
GP	General Practitioner
HCI	Human-Computer-Interaction
HIE	Health Information Exchange
HIS	Health Information Service
HIT	Health Information Technology
HL7	Health Level Seven
HMI	Human-Machine-Interface
HW	Hardware
ICT	Information and Communication Technology
IHH	In-Home Healthcare
IIB	Information Integration Bus (IBM product)
IIP	Information Integration Platform
IoT	Internet of Things
LTE	Long Term Evolution
m2h	machine-to-human communication
m2m	machine-to-machine communication
NHN	National Health Network
O&M	Operation and Maintenance
P-EHR	Personal Electronic Health Record
PCHA	Personal Connected Health Alliance (Continua Alliance)
PCIS	Patient Care Information System
PHD	Personal Health Device
PHR	Personal Health Record
PIR	Pyroelectric (”Passive”) InfraRed motion sensor
PKI	Public Key Infrastructure
PLMN	Public Land Mobile Network

PMD	Personal Medical Device
PoC	Point-of-Care
QoL	Quality of Life
RFID	Radio Frequency IDentification / Identification Device
RPM	Remote Patient Monitoring
SpO_2	Transdermal, peripheral capillary oxygen saturation of the blood
SBRE	Scenario-Based Requirements Elicitation
SW	Software
TMon	Tele-Monitoring programme
U4H	United4Health - UNIversal solutions in TElemedicine Deployment for European HEALTH care (EU FP7 project)
UCD	User-Centered Design
UI	User Interface
UiA	University of Agder
VPN	Virtual Private Network
WHO	World Health Organization
WiFi	Wireless Fidelity (synonym for WLAN)
WLAN	Wireless Local Area Network
WSN	Wireless Sensor Network

Nomenclature

The following definitions have been used for this thesis:

eHealth	Electronic Health; E-Health; ”eHealth is the use of information and communication technologies (ICT) for health. Examples include treating patients, conducting research, educating the health workforce, tracking diseases and monitoring public health.” (WHO, 2016) [7] ”eHealth is an emerging field of medical informatics, referring to the organization and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology.” (Oh et al., 2005; Boogerd et al., 2015) [8, 9]
EHR	Electronic Health Record; ”Health records are longitudinal records of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports.” (Munoz et al., 2011; HIMSS definition) [10, 11] ”Repository of patient data in digital form, stored and exchanged securely, and accessible by multiple authorized users. It contains retrospective, concurrent, and prospective information and its primary purpose is to support continuing, efficient and quality integrated health care.” (ISO/DTR, 2004) [12]

EMR	Electronic Medical Record; a type of EHR; ”Generally focused on medical care; Contains all or most of patient’s clinical information from one particular or from multiple hospitals.” (Munoz et al., 2011) [10]
Health	traditionally focused on the individual in relation to illness status; ”Health is the physical, mental and social well-being. Individual’s health perception is assessed by questionnaires, and its functional and bodily reserves is measured by physical means.” (WHO, 1972) [13]
mHealth	Mobile Health; M-Health; ”Healthcare facilitated by the convergence of mobile and desktop healthcare information systems, wireless technology and other networks such as Bluetooth and cellular network.” (Yu et. al. 2006) [14] ”Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices.” (WHO 2011) [15] ”Healthcare using mobile wireless technologies.” (Ciarini et. al. 2013) [16] ”The practice of eHealth assisted by smartphones, which are used to capture, analyze, process, and transmitt health-based information from sensors and other biomedical systems.” (Adibi et. al. 2015) [17]
Patients vs. Citizens	Patients - People using healthcare services for health problems or conditions. Citizens - The general public not immediately using healthcare services, but (potentially) using wellness management services for promoting health and an active lifestyle.
PHR	Personal Health Record; a type of EHR; ”Controlled by the patient and contains information at least partly entered by the patient.” (Munoz et al., 2011) [10]
Quality-of-Life (QoL)	”Individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (Power, Kuyken, and WHOQOL Group, 1998) [18]

Remote Patient Monitoring	RPM; Remote patient monitoring is an eHealth service, which is used to collect and transfer biosignal data from the patients to the eHealth service provider (e.g., healthcare center).
Telehealth	”Telehealth equipment is used as a tool in the management of long-term conditions in the community to pro-actively monitor patients and respond promptly to indicators of acute exacerbations. ’Vital signs’ monitoring is believed to reduce hospital admissions and uses equipment in patients’ homes to identify trends and alert when preset parameters are breached.” (Stowe et al., 2010) [19]
Telecare	”Telecare is the use of communications technology to provide health and social care directly to the user (patient). This excludes the exchange of information solely between professionals, generally for diagnosis or referral.” (Stowe et al., 2010) [19]
Telemedicine	”The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.” (used interchangeably with *Telehealth*) [WHO2010]
Wellness	often considered the endpoint of physical, mental or social interventions; ”a dynamic process maximizing an individual’s potential” (Dunn, 1959) [20] ”a way of life orientated toward optimal health and wellbeing in which body, mind, and spirit are integrated by an individual to live more fully within the human and natural community” (Myers, Witmer, & Sweeney, 2000) [21] ”a construct reflecting the process of enhancing life quality by integrating and balancing one’s physical, mental, and spiritual wellbeing” (Harari, Waehler, & Rogers, 2005) [22] ”the optimal state of health of individuals and groups. There are two focal concerns: the realization of the fullest potential of an individual physically, psychologically, socially, spiritually and economically, and the fulfilment of one’s role expectations in the family, community, place of worship, workplace and other settings.” (WHO; Smith, Tang, & Nutbeam, 2006) [23]

Wellbeing ”Wellbeing is the balance point between an individual’s resource pool and the challenges faced. Stable wellbeing is when individuals have the psychological, social and physical resources they need to meet a particular psychological, social and/or physical challenge.” (Dodge et al., 2012) [24]

Part I

Chapter 1

Introduction

Many patients with physical or mental disabilities, reduced mobility or increased need for support still wish for an independent lifestyle, without frequent visits to their doctors or a hospital.

Provisioning of high-quality public healthcare services for all of us is getting more and more challenging, as demographics of the world's population are shifting towards elderly people with higher and higher life expectancy.

Public healthcare strategies must identify new solutions that enable more and more patients a high quality-of-life while resources and personnel are unlikely to increase.

Artificial Intelligence (AI), cloud computing, Internet-of-Things (IoT), service oriented architecture (SOA), smart sensors and actuators, high-speed mobile communications, and affordable portable devices and "wearables" are examples of technologies that have matured in recent years and are now widely used for distributed applications.

These technologies are key enablers for more efficient and effective healthcare services. Used in a right and respectful way, they can offer opportunities to prevent life-threatening situations while collecting valuable real-time information for following up. Applications can coach patients who want to pursue a healthy life style.

Integrating new solutions into existing national and regional healthcare systems is challenging. New solutions require to collect, communicate, evaluate and provide big amounts of health-related data across business, organizational, administrative, technical and legal boundaries. There is a need for an overall reference

solution as a starting point for migrating today's systems into a more flexible and reliable future infrastructure.

The design of such a reference solution requires a close multi-disciplinary cooperation involving computer science experts, medical and healthcare professionals, representatives from public healthcare service providers, and finally representatives of the different user groups of such solutions.

1.1 Background and Motivation

The *Health System* considered in this project involves different end-user groups with heterogeneous objectives and needs. Each *Citizen* is both a user of *Services & Applications*, as well as a receiver of physical and digital services to support their individual health and well-being at any *Point-of-Care*; *Healthcare Providers* provide physical support at a citizen's point-of-care, or remotely via digital support services; *System Operators & Administrators* operate and maintain the health information services infrastructure. A *Health Information Services Infrastructure* utilizes *Technologies* to provide *Services & Applications* to all end-user groups. This system is embedded in a *Socio-economic, Political and Legal Framework*, and is affected by a continuous development and integration of new *Technologies*.

The corresponding *Health System Reference Model* as considered within this thesis is illustrated in Figure 1.1.

1.1.1 Socio-Economic, Political and Legal Challenges

More than 20% of the global population will be aged 60 or above in 35 years. While in 2013, 841 million people (12% of 7.2 billion world population) were 60 years old or more, the United Nations expect a rapid growth of that population group to about 2 billion (of a world population of 9.6 billion) in 2050 [25]. Ageing comes along with a longer active life, but also with an increase of functional limitations, disabilities, and with an increased demand for long-term care for chronic diseases in hospitals, residential care homes for the elderly and private homes, challenging current health and care systems [26]. The higher demands for long-term care and the general economic pressure to control healthcare expenditures and to limit the cost increase means a growing requirement for efficient utilization of

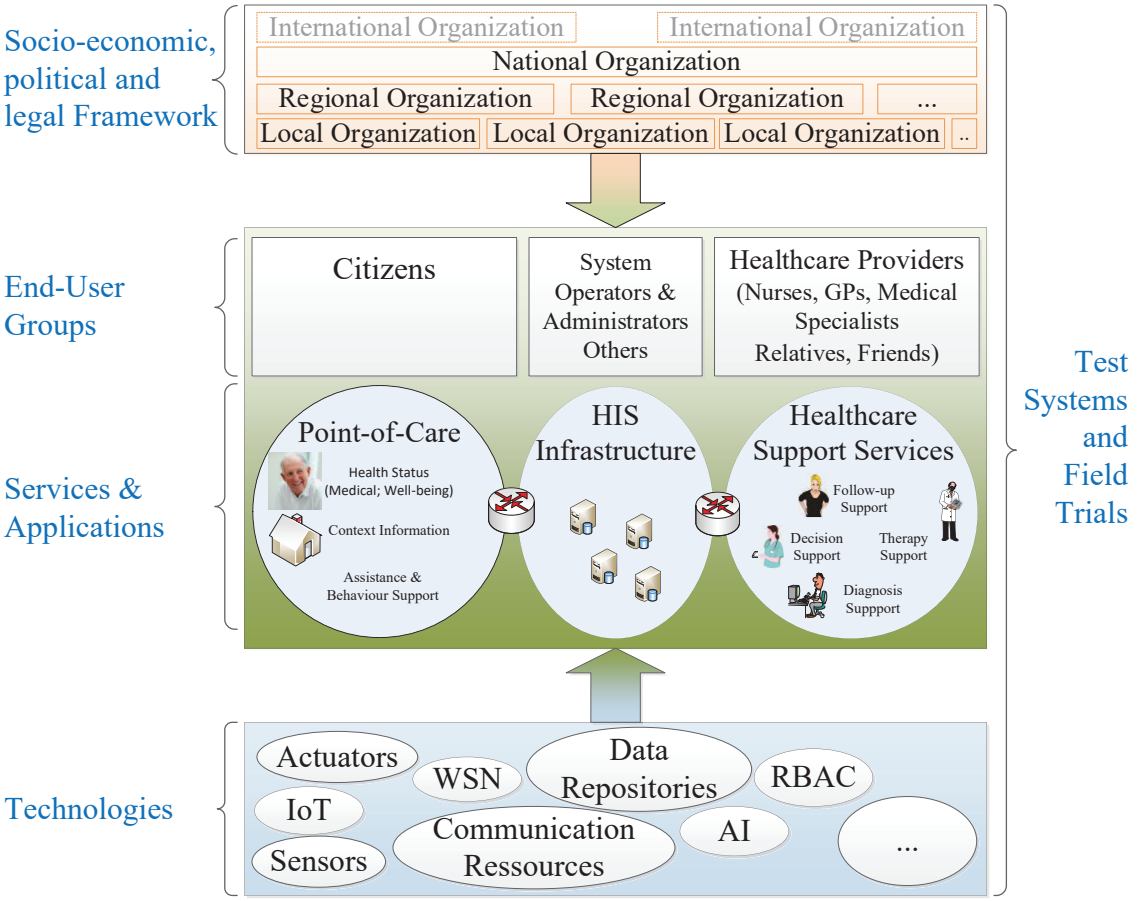

Figure 1.1: Health System Reference Model

health information technologies for a more collaborative diagnosis, treatment and care support in the professional healthcare sector.

This requirement is accompanied with the geographical and organizational fragmentation of the national health sector (see Figure 1.1). On the one side, there are the *healthcare providers*: general practitioners (GPs), independent medical specialists, smaller hospitals, nursing services and care homes for the elderly, etc., provide local services for example at municipality level. Bigger hospitals with various medical specialists, alarm and emergency support centres typically have responsibilities with a regional scope. On the other side, there are *political and administrative institutions* that are responsible for legal and economic policies of the health system on regional, national and international level. In the centre of the system are the *citizens*, with their individual goals for wellness, health and quality-of-life, and the desire for optimal support to achieve and manage those goals.

1.1.2 Challenges for Services and Applications

A heterogeneous health information services infrastructure of various distributed health information systems has been established, analogously to the geographical and organizational fragmentation of healthcare service providers and their superior policy-making and administrative institutions.

Many of those systems are - for economic and historic reasons - tailor-made for the specific needs of local institutions or regional organizations. Typically, they have not been designed for the exchange of any data and information with other local, regional, national or international systems.

Services that are essential for the national health system operate on national level, as information services for the management of basic patient data, insurance information, services to provide statistic information for policy making, but also dedicated services to exchange certain information between different stakeholders of the health system. To support the location-independence and mobility of citizens, the provision with medical support and healthcare services is maintained also across national borders by dedicated international services that facilitate the exchange of required personal data. Those services are typically provided by systems that allow the exchange of specific data or information with specific peer systems, restricted to proprietary data formats and communication protocols.

The introduction of new services and solutions to support an extended collaboration within the professional healthcare sector, as well as the inclusion of informal care providers is hindered by the heterogeneity of the health sector. Fragmentation between the healthcare services provided by the different stakeholders in the public healthcare system (municipality nurses / primary care; general practitioners (GPs) and hospital specialists / secondary care) leads to *cooperation barriers* that limit the efficient provision of telehealth services [27]. These barriers can be of legal nature, cross-sector policy conflicts, lack of organizational integration of care and treatment processes in the daily routines, and the absence of technical interoperability between the support systems commonly used by different stakeholders.

1.1.3 Technological Challenges and Opportunities

The continuous development of Information and Communication Technologies (ICT) has led to an ongoing transformation of the health sector. A key element is

the digitalization of personal and medical patient data in Electronic Health Record (EHR), Electronic Medical Record (EMR) and Personal Health Record (PHR) systems (as defined in Nomenclature, p.xxi ff). Such systems have been widely introduced in office-based physician practices and in clinical environments, aiming for improved patient safety (through reduced medication and other medical errors etc.), improved quality and efficiency of patient care, and reduced healthcare delivery costs. Key functionalities of EHR systems are the health information exchange (HIE) and storage within the health information services (HIS) infrastructure, clinical decision support (CDS) systems, computerized physician order entry (CPOE) systems, and the exchange of health information in telehealth and telecare systems for remote patient monitoring (RPM).

Independent from developments in the professional health sector, there are trends towards more self-monitoring and self-management of fitness and wellness in the private sector. A variety of sensor-equipped personal wearable devices (short *wearables*) as smartwatches, sensor wrist bands, interactive breast belts, ECG headsets, insulin pump patches, and more (Figure 1.2, [28]) measure vital signs data, utilize Internet of Things (IoT) technologies to upload the data to cloud services (typically making use of smartphones for connectivity), and provide support for a healthier life-style by motivating for physical activities, a better nutrition, etc.

The IoT is a technology domain emerging in many industries [29]. It is commonly defined as ”a dynamic global network infrastructure with self-configuring capabilities based on standard and interoperable communication protocols where physical and virtual *Things* have identities, physical attributes, and virtual personalities and use intelligent interfaces, and are seamlessly integrated into the information network”, and utilizes key technologies as the Services Oriented Architecture (SOA), RFID, ad-hoc networking, cloud computing, and many more.

Although telehealth and -care systems for remote monitoring and healthcare support in the public healthcare sector on the one hand, and commercial applications and services for the personal fitness and wellness tracking on the other hand are not integrated or cooperating today, they have several fundamental characteristics and requirements in common. Data from vital signs or other health-status indicators are collected by medical-certified sensor devices or wearables, and are transmitted into either EHR systems in the public health information infrastructure or cloud-based fitness-related information and recommendation services. Such

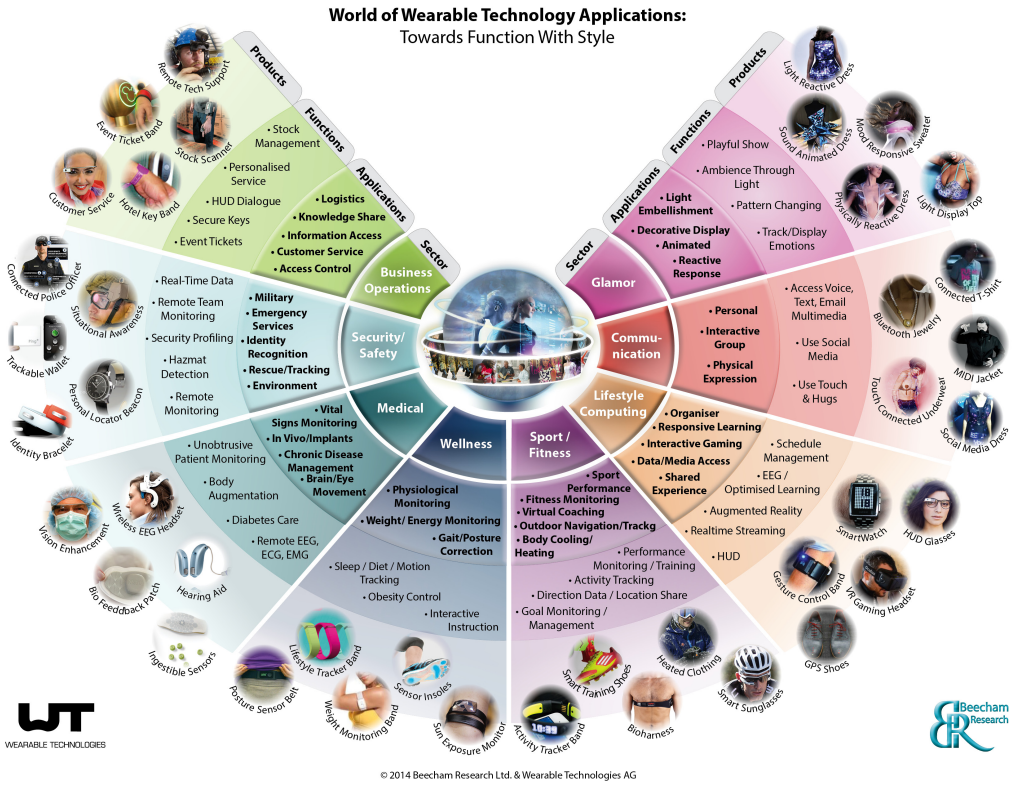

Figure 1.2: The Wearable Market (Photo courtesy of J. Mischke, WearableTechnologies AG.)

data has to be analysed for the determination of value-added information.

Providers of telehealth and -care services need support to assess the status of monitored patients, to be alerted of critical conditions, to prioritize follow-up interventions, and to decide about needed support and treatments. Fitness and wellness support applications and services should determine individual and health-promoting suggestions for optimal activities, nutrition, etc. A major drawback is that today they generally have no access to well-founded medical knowledge for that.

Artificial Intelligence (AI) and machine learning have an increasing relevance in the health sector. In medical, clinical and pharmaceutical research, the analysis of epidemiological studies serves as input for the development of clinical guidelines for treatments, interventions and medication, and contributes to the development of new drugs. Machine learning systems as IBM's *Watson* supercomputer support this "Big Data" approach by creating the basis for statistical reasoning in

medicine [30].

Enormous potential is seen in the real-time assessment of patient data and the determination of suggestions by decision support systems (DSS) to guide clinical decisions and to support the long-term monitoring and identification of risks and trends [31] in telehealth systems.

1.1.4 Test Systems and Field Trials

The development of test and pilot systems and the execution of field trials is essential to verify and promote new technologies and innovative solutions for telehealth and wellness management, to proof the commercial viability, and to study their social and clinical effectiveness. By applying a *Quadruple Helix Model* [5] involving academic research and education, public healthcare service providers, commercial and industrial technology and solution vendors, and representatives of the target end-user groups, sustainable solutions and services can be tested, improved and introduced in the national health information system for broad usage (refer also to section 2.2).

To increase the sustainability and chance for later broad-scale success of new technologies and innovative pilot systems, they have to follow international ICT standards and interoperability guidelines for health information systems. A multitude of projects in the past years have developed and tested specific services and solutions in field trials following the specific local requirements of the involved project partners. That has contributed to a further fragmentation of the health information services infrastructure.

1.2 Management of Health and Wellness in the Future

Healthy citizens want to keep and increase their fitness and quality of life; citizens belonging to certain health risk groups require monitoring and preventive care due to their general health condition; ageing citizens require long-term monitoring and ad-hoc support due to age-related risks and limitations; patients with chronic diseases require regular monitoring and treatment; and a growing number of citizens will prefer continuous monitoring and on-demand support in case of emergency situations as traffic accidents, disasters, or other incidents impacting their physical

integrity.

It will not be possible to fully satisfy the resulting efforts with today's operations, processes and solutions. Instead, driven by increasing economic pressure and the capabilities of emerging technologies there is a growing potential for the development of more personalized, more integrated, more intelligent, more efficient, citizen-centred eHealth solutions.

More personalization will allow providing the citizens with the optimal information and support they need, considering their individual health condition, the context they are in, and the type of support they want and need. Also, the user interfaces of applications and services for the support of remote monitoring and information provisioning will be adapted to the preferences and needs of the citizen. Better integration of the point-of-care (PoC) infrastructure of the citizen with devices and applications for wellness tracking and remote monitoring on the one side, and of the eHealth systems of the involved professional and informal healthcare providers on the other side in one common health information service infrastructure will provide for a closer cooperation between the caregivers. This will include a more efficient exchange of all available health and wellness related data and information from the citizen and a better coordination of the support and follow-up processes.

Furthermore, the citizens will be more closely involved in the provisioning of decision support information, and in the planning, coordination and execution of treatments and interventions. This will give them more control and self-management of their wellness and quality-of-life. The utilization of smarter recommendation and decision support technologies will enable the determination of the wellness status, health trends and medical risks of the individual citizen. As a result, individual suggestions for optimal activities and interventions can be provided to support the citizens in their wellness self-management, and decision support information and recommendations can be provided to professional and informal healthcare providers for the follow-up and treatment of their patients. Overall, an increased efficiency of the wellness management and healthcare support processes can be expected.

A *Prognosis* of future eHealth services and their characteristics for wellness management and healthcare support is described below. Rather than a concrete point in time, a gradual enhancement of today's telehealth and wellness tracking

services and a transition to services and applications based on new technologies is expected. Services with the described characteristics are likely to be technically ready for deployment by 2025, while a number of organizational, judicial and social barriers will have to be removed before the services will have become daily routine of citizens and in the healthcare services sector. Some trends may be predicted:

Wellness Status Assessment

- Citizens have the choice to adopt and use measurement devices as wearable or implanted sensors that seamlessly measure and quantify wellness parameters: physiological and functional well-being, social well-being, mental and cognitive well-being, and spiritual well-being.
- Subjective parameters corresponding to the individual perception of various wellness aspects are gathered by e.g., remote queries or online face-to-face follow-ups.

Context Assessment

- Various sensors, either wearable or in the environment surrounding the citizen, seamlessly measure and quantify context parameters providing additional information related to the wellness status of the citizen. Examples are the location, temperature, air quality, etc.

Data Communication and Information Distribution

- Citizens and healthcare providers are not limited to specific vendors , but can select according to individual preferences and healthcare requirements from a range of certified products.
- Data collected from citizens (e.g., measured wellness parameters, questionnaire responses, context data) are pre-processed, and in (near) real-time transmitted to the health information services (HIS) infrastructure, independent from the location of the citizen.
- The appliances at the citizens' point-of-care (PoC), e.g. communication-enabled sensor devices, smartphones, tablet PC devices, etc., work across

a range of communication channels, thus increasing availability and robustness.

Smart Decision Support

- Measured and quantified wellness data is aggregated in the HIS infrastructure, forming a holistic representation of all citizens' wellness.
- With the help of artificial intelligence (AI) technologies, this "Big Data" is evaluated and analysed. This unfolds knowledge about the individual citizens' wellness, drawn from parameters of all other citizens of a comparable reference group. That knowledge allows predicting trends of the citizen's individual wellness status and potential risk or emergency conditions.
- The impact of various behavioural actions and other possible interventions, including medication, nutrition and the change of context and environmental influences on the wellness development can be better forecasted under consideration of statistical knowledge from the "Big Data" from all citizens, and the observed specific reactions of previous actions and interventions on that individual citizen.

Personalization of Support for Self-Management & Living of Wellness & Diseases

- Suggestions to manage their wellness are personalized according to the individual preferences and needs of each citizen.
- The personalization of the personal application device platform comprises the adaptation of interfaces and interaction design to the needs and preferences of the citizen. Suggestions target for example training and fitness optimization, preventive activities and behaviour, acute and emergency interventions, and rehabilitation treatment.
- The personalization of the PoC environment of the citizen includes a selection of actuators. Actuators can be wearable, attached to, implanted into or surrounding the body of the citizen. They may be remotely controllable by medical or healthcare professionals, or may operate with a configurable level of autonomy by utilizing artificial intelligence (AI). They can positively influence the citizens' medical condition (e.g., configurable cardiac pacemaker,

insulin dispenser, breathing control and support, etc.) or can provide other types of on-site support (e.g., medicine dispenser, care-support robot, etc.).

- Applications on the personalized device platform(s) and other appliances in the point-of-care (PoC) may utilize personalized knowledge for automatic and autonomous reasoning.

Cooperation and Efficiency

- A close cooperation between institutional and informal healthcare providers and the involvement of citizens will lead to increased efficiency of the operations and processes for the understanding, management and living of health & disease in all phases of the citizens' life.

- All institutional healthcare providers across different health system sectors (including GPs, medical specialists at hospitals, municipality nursing services, regional telehealth, telecare and emergency services) and informal providers of health and care support (as relatives, friends, and other voluntary careproviders) have controlled and privacy-protected access to relevant data at the health information systems.

Security

- Citizens own their data. They control who should get access to which data and for which purpose, and follow who accessed their data, when, and for which purpose.

- Citizens do not actively have to identify and authenticate themselves with user names, passwords, PINs, etc. Instead, seamless identification and authentication technologies are in place in order to provide optimal usability to access all applications and services.

Reliability and Robustness of Support Infrastructure

- The hardware (HW) and software (SW) components for the monitoring and provisioning of healthcare are designed, developed and operated to guarantee highest possible availability. This will ensure that in failure situations (as e.g. outage of the electricity grid, interruption of any part of the communication infrastructure, malfunction of any application device, sensor appliance

or service platform, failure of any user application or infrastructure service) the operation of potentially vital healthcare services can be continued or re-established with shortest possible interruptions.

1.3 Project Goals

Today's telehealth and telecare solutions as well as applications and services for wellness tracking and fitness optimization have various limitations and obstacles.

The overall goal of this PhD project is to analyse the manifold requirements for an eHealth system that provides smart and collaborative services for efficient wellness management, and to describe a reference design. The proposed solution shall provide support for the different user groups of the system, and realize service characteristics as described in the prognosis (section 1.2 above). A holistic view on the end-to-end architecture and the components of the reference design has been taken to satisfy the demands of the different user groups, which relate to different service characteristics and corresponding technical requirements, that cannot be provided isolated from each other by the system. Specific attention has been paid to the provision of individual suggestions and decision support for citizens and collaborating healthcare providers.

1.3.1 Guiding Use Case Scenario

This PhD project incorporates findings from the design and deployment of telehealth and telecare systems documented in the literature (refer to chapter 3). In due consideration of the methodologies and methods explained in chapter 2, the research work aims at a corresponding *guiding use case scenario*. This includes the monitoring of the health and context status of citizens at their point-of-care (PoC), and the provision of recommendations and decision support information for activities and interventions by remote support services in the Health Information Services (HIS) infrastructure to the monitored citizen and to formal and informal healthcare providers. Data about the wellness of the citizen and the context at the PoC are continuously and seamlessly measured or actively reported by the citizen, and securely transmitted to data collection, storage and provisioning entities in the HIS infrastructure. Telehealth, telecare and other support services make the

data available to the health and care sources that are responsible for the monitoring and support of the citizen. Dedicated evaluation services detect emergency conditions, and determine recommendations and decision support information to provide for efficient follow-up actions and interventions. Citizens are kept informed about their condition, and are provided with diagnosis information and recommendations for activities and interventions.

The reference architecture for a system providing the described use case scenario is illustrated in Figure 1.3.

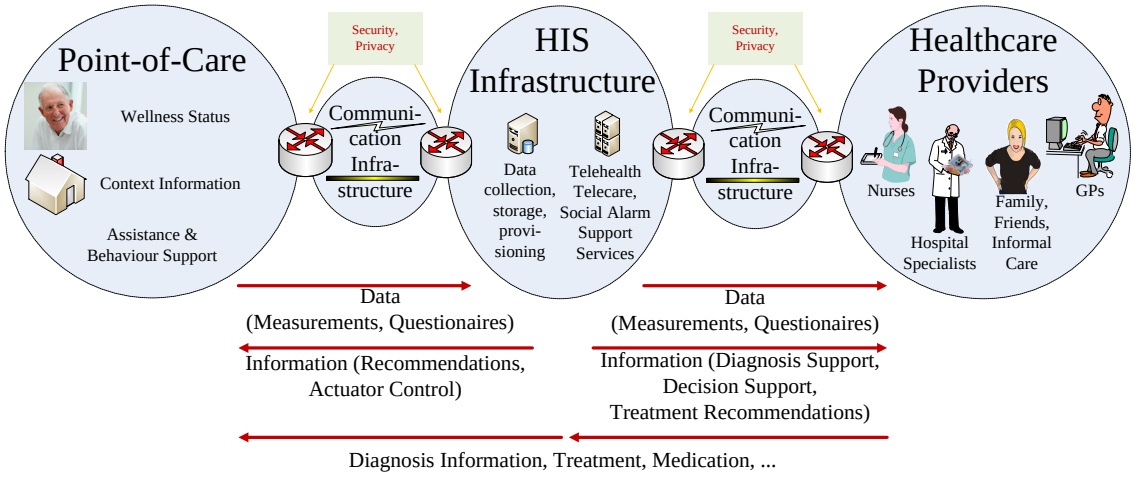

Figure 1.3: Reference System Overview

1.3.2 Requirement Domains

A complex distributed system for remote health monitoring and wellness management should support the requirements of different user groups, while complying with legal and regulatory policies, and being economically viable.

Considering the identified problems and limitations of existing systems (following in the *State-of-the-Art* chapter 3), the general expectation on *Management of Health and Wellness in the Future* (section 1.2), and the specific objectives of the guiding use case scenario, this thesis addresses the requirement domains outlined in Table 1.1.

The result of the systematic requirements elicitation under consideration of selected formal methods (refer to chapter 2 on *Research Discipline, Methodologies*

Table 1.1: Overview of Requirement-Domains

Functional, Operational and Economic Requirements:
Smart Assistance for efficient Decision Support Flexibility, Adaptability, Expandability, Scalability Usability & Accessibility
Legal and Regulatory Policies:
Security & Privacy Reliability, Robustness, Availability Interoperability & Interworking

and Methods) is described as part of the *Design and Development* (chapter 4, section 4.1).

1.4 Scope and Research Questions

This study portrays a holistic perspective on telehealth and telecare services and applications, for remote monitoring and decision support, as well as for the empowerment of citizens to manage their own health and wellness at any point-of-care.

The focus is put on the design, development and evaluation of a reference design for the end-to-end solution providing the desired services and applications. This includes in particular the selection and verification of an applicable requirement elicitation methodology, under specific consideration of the diversity of involved stakeholders, their cooperation needs, corresponding interoperability needs of solution components, and the diversity of the requirement domains and the corresponding needs for interdisciplinary cooperation in the whole design, development and evaluation process.

The *evaluation of the trial system*, that has been implemented as proof-of-concept for the validation of the reference design, addresses in particular the following aspects:

- Interoperability needs and applicable communication protocol standards for the information exchange between the different system domains within the national health information infrastructure

- Security aspects as privacy protection and access control technologies
- User acceptance of the patient support application
- Reliability of the evaluation algorithms for the monitoring data and the resulting decision support information provided by the system to the tele-nurses

The main limitations of this thesis consist of the not conducted evaluation of the following aspects, which were explicitly *out of the scope* (but have partly been subject to other studies utilizing the trial system developed as part of this project):

- Usability evaluation (including the selection of appropriate methods) of the support applications and services for the involved stakeholders, during the system development and trial operation
- Integration of the proposed solutions implemented in the trial system with the installed base of public health information systems or services and applications for healthcare professionals
- Sensor technologies, medical compliance of sensors, wireless sensor networks
- Organizational aspects and evaluation of potential efficiency gains within the healthcare sector achievable with the proposed solutions
- Verification and evaluation of the medical efficiency and improvements of the health and wellness of the monitored patients

In order to guide the research work within this project and to contribute to achieving the overall goals, the following research questions have been formulated:

RQ-1: *What is an appropriate* ***Methodology to identify the Reference Requirements*** *for an ICT system that shall realize the guiding use case scenario described above?*
What are the identified ***Reference Requirements****?*

RQ-2: *What is an appropriate* ***Methodology for the Design and Development*** *of an end-to-end solution, fulfilling the multi-disciplinary requirements of multiple different stakeholder groups?*
How does an applicable ***Reference Design*** *look like?*

RQ-3: *How can the* ***Acceptance of the proposed Solution Design by the Patients*** *be evaluated?*
How well is the proposed Solution Design accepted by the Patients, and how could that be improved?

RQ-4: *Can* ***Healthcare Professionals be effectively and efficiently supported*** *by the proposed Solution Design?*
How can the proposed Solution Design be improved based on identified real-world issues and limitations learned from a proof-of-concept implementation and field trial evaluation?

1.5 Structure of this Dissertation

The basic form of this dissertation is a collection of scientific papers. It is structured in two parts: the first part provides an overview of the topic space, the methodology and the research work, and an overall discussion of results and conclusions; the second part contains the scientific papers that address specific aspects of the project.

Part I

Part I provides the overall background, motivation, state-of-the-art and methodological introduction for the project. This serves as common input for the research work, that addresses solution proposals for the different requirement domains. It follows with a coherent discussion of the results, conclusions and the contributions.

Chapter I (this introduction) informs about trends in the society, their impact on existing and coming challenges for healthcare and wellness management, and technological trends that motivate the research approach to meet those challenges. A basic use case for telehealth services and the corresponding requirement domains are described as underlying objective of this project, guiding the research work. The chapter concludes with the scope and focus of this dissertation, including the research questions addressing a reference design realizing the guiding use case scenario.

Chapter II informs about the methodological framework for this project. This includes the identification of the research discipline, the selection of an applica-

ble methodology, and the explanation of the tools and methods selected for the execution of this research project.

Chapter III gives an overview of the state-of-the-art of the field along selected scientific articles, aiming at the identification of limitations of existing systems and service, and of corresponding challenges and requirements for new solutions.

Chapter IV addresses the design and development process of the reference design and the field trial system, covering also the requirement elicitation along the identified requirement domains, and links the results from the corresponding publications.

Chapter V discusses the results of the proposed and tested solutions in terms of their advantages, but also their disadvantages and identified limitations, which have led to the proposal of a new conceptualization for personalized wellness management (paper X, Appendix K). It identifies several potential sociological implications caused by the tested solutions, which have to be expected and addressed when approaching the solutions for general deployment in the public health systems.

Chapter VI summarizes the main contributions and specific findings from the work in this project and its relevance for the field of health informatics and wellness management in the future. It concludes with an overview of identified open questions in related research fields, and of ongoing and planned follow-up research.

Part II

Part II contains nine peer-reviewed scientific articles - six articles in conference proceedings, one book chapter, and two journal articles - that have been published during the course of the PhD project. Additionally, a project report is included. The author of this dissertation is the first author of all these publications.

Paper I addresses the interoperability and interworking requirements of point-of-care (PoC) appliances and electronic health record (EHR) systems in the health information services (HIS) infrastructure, in order to allow the information exchange for telehealth and remote monitoring services. An overview of relevant standardization bodies will is given, and of their scope and guidelines, in order to achieve interoperability on ICT level.

Paper II looks at the usability of eHealth applications and services and the needs of the different involved user groups. It focusses on an end-to-end infrastructure for

the collaborative usability evaluation of such applications, considering in particular the implications of the collaboration of different user groups as part of the tested service scenarios.

Paper III studies security aspects, reliability precautions in the context of patient safety, and usability aspects of mHealth environments. Requirements are analysed for the solution design and realization of actual use-case scenarios where future mobile technologies can enable and support health and care services to elderly people and patients.

Paper IV introduces the target services, the technical requirements and the software architecture overview of the field trial system for remote monitoring and care support of patients with Chronic Obstructive Pulmonary Disease (COPD). It outlines how the needs of all involved user groups could be addressed by following a User-Centred Design and Privacy by Design approach, while fulfilling national requirements with emphasis in security and privacy protection.

Paper V analyses in more detail the different requirements on security and privacy protection of health and care data in cooperative telehealth systems, and explains solution proposals for the trial system for remote supervision of home-living patients with COPD.

Paper VI presents a future telehealth and telecare reference design. A secured health cloud infrastructure for commercial well-being, health and care services complements the national health network (NHN) infrastructure, and provides the basis for secure collaboration between commercial, professional and informal health and care providers, aiming for personalized, smarter, and more efficient health and care services.

Paper VII analyses selected emerging technologies as the Internet of Things (IoT), Semantic Sensor Networks (SSN), Artificial Intelligence (AI) and Decision Support Systems (DSS) concerning their potential to make eHealth systems smarter, more collaborative and more efficient. Aiming to overcome selected limitations of the trial system for remote monitoring of COPD patients (see also papers VIII and IX) a future end-to-end system architecture is described with specific focus on the personalization of point-of-care devices.

Paper VIII presents results and experiences from a trial for remote monitoring of COPD patients by telehealth service providers. It contains a quantitative analysis of 4970 datasets from 94 patients, and discusses advantages of the solution as well

as disadvantages and limitations.

A detailed description of the developed and implemented trial system for remote monitoring of COPD patients is included in paper IX, which focuses on the verification and evaluation of the proposed solution aspects along the identified requirement domains. The document contains also the results and experiences from the clinical trial involving 94 patients, which have been published in paper VIII.

Paper X introduces a new concept of a personalized health and wellness coach system, namely *eCoach*. Utilizing machine learning techniques and knowledge from continuous observations of multiple citizens, the conceptualized system combines specialized medical evidence available from randomized control trials, with holistic individual and reference knowledge to create and reinforce recommendations, which had optimal health and wellness outcomes in the past.

Chapter 2

Research Discipline, Methodologies and Methods

This chapter identifies the appropriate research discipline for this project, and explains the selection of a research methodology to address the objectives. Furthermore, methods and tools particularly for the identification and analysis of requirements, and for the evaluation of the proposed solutions are described, looking at alternatives described in the literature, and explaining how selected methods and techniques are used in the research work.

2.1 Research Discipline

The research objective of this project is the design, development and evaluation of an Information System providing eHealth services to patients, healthcare practitioners, relatives, and other stakeholders. This type of research has to address multi-disciplinary aspects, and the needs and interactions of different groups of people. It involves social, behavioural, and human-phenomenological aspects, and the study of practical and organizational impacts of a technical solution (*artefact*) on citizens, practitioners, and on organizations.

The problem space and the requirements for the target eHealth services should be well understood, a technical solution (*artefact*) should be developed, applied, tested, and it should be evaluated to which degree the technical solution fulfils the requirements to support the involved individual people, to solve the identi-

fied organizational problems, and to be compliant with socio-economic and legal guidelines.

These objectives fall into the ***Information Systems (IS) Research*** discipline. According to Hevner et al., *Information Systems Research* is characterised by two foundational and complementary research paradigms - *behavioural-science* and *design-science* [1]. *Behavioural-science research* develops and verifies theories explaining or predicting human behaviour. *Design-science research* creates and applies new innovative artefacts, which are used to achieve knowledge and understanding of the corresponding problem domain, and with that to extend the boundaries of human and organizational capabilities.

Figure 2.1 presents the conceptual framework for IS Research by Hevner et al., built around two complementary research phases. In the *Develop/Build* phase, theories are developed by behavioural-science research, and artefacts are built by design-science research. In the *Justify/Evaluate* phase, the theories are justified, and the artefacts are evaluated. Developed theories and built artefacts are assessed by justification and evaluation activities, leading to refinement of theories and artefacts.

Another well-established and applicable research paradigm is *Action Research (AR)*. As summarized by Cole et al. [32], the basic goal of AR is the resolution of practical problems and simultaneously contributing to scientific theory. The goal(s) of the researcher aiming at theoretical knowledge, and the practical goal(s) of the research sponsor must be balanced. The ideal domain for AR contains a social setting where the researcher is actively involved, where the knowledge obtained can be immediately applied, and where the research is a process linking theory and practice.

Cole et al. identify similarities of Action Research with Design-Science Research, and propose ways to facilitate cross-fertilization between both approaches. Also Järvinen ([33]) identifies the concordance of Action Research and Design-Science Research, following the comparison of the aspects concrete study results, the knowledge produced, activities, the intent and the nature of a study, the division of labour in a study, and the generation, use and test of knowledge. He concludes that action research and design-science research should be considered as similar research approaches.

In order to address the design and development of an artefact within this re-

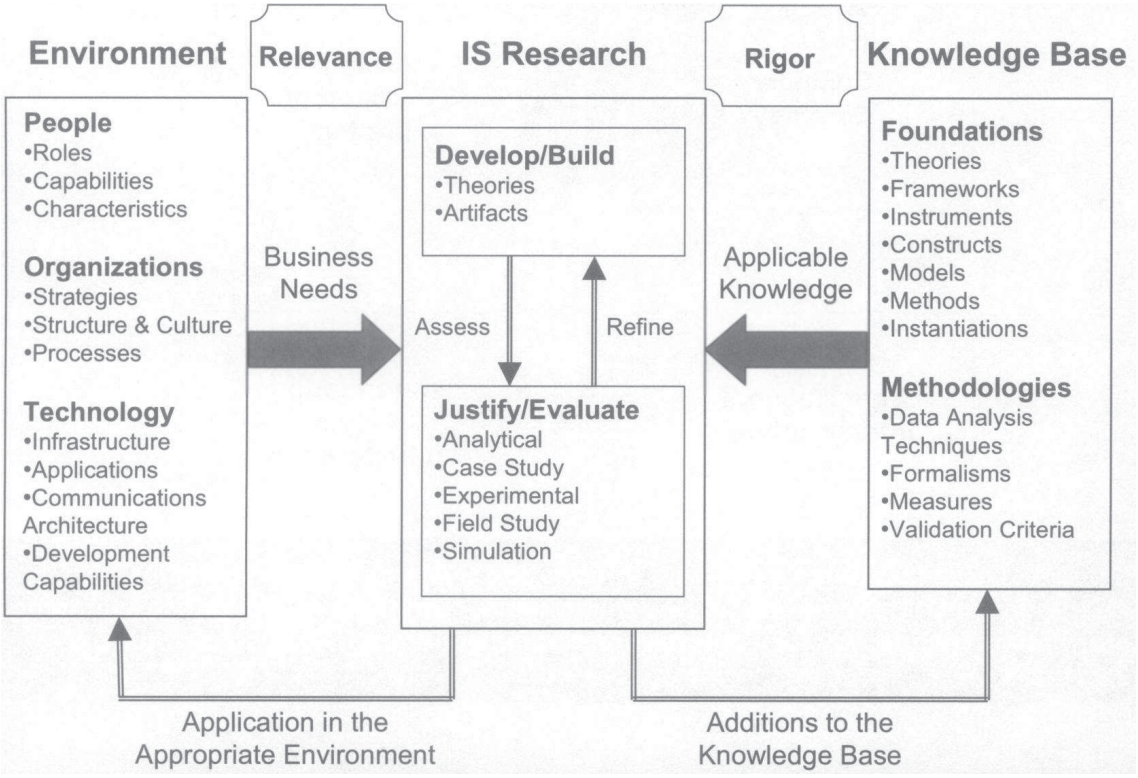

Figure 2.1: Information Systems Research Framework (Hevner et al. [1])

search project, including the multi-disciplinary scientific elicitation of holistic requirements of the target services, the implementation and the evaluation of the proposed solution design by deploying and testing the artefact as a trial system within the real target environments of the different interacting user groups, the design-science research paradigm has been selected.

2.2 Research Methodologies and Processes

Peffers et al. have proposed a methodology for conducting design science (DS) research in information systems (IS). Their Design Science Research Methodology (DSRM) [2] satisfies three objectives: to be consistent with prior literature, to provide a nominal model for doing DS research, and to provide a mental model for evaluating and presenting DS research in IS. Furthermore, the DSRM complies to the practice rules for conducting DS research in the IS discipline, formulated as seven DS research guidelines by Hevner et al [1].

The process follows six steps (Figure 2.2): (1) problem identification and mo-

tivation, (2) definition of the objectives for a solution, (3) design and development, (4) demonstration, (5) evaluation, and (6) communication.

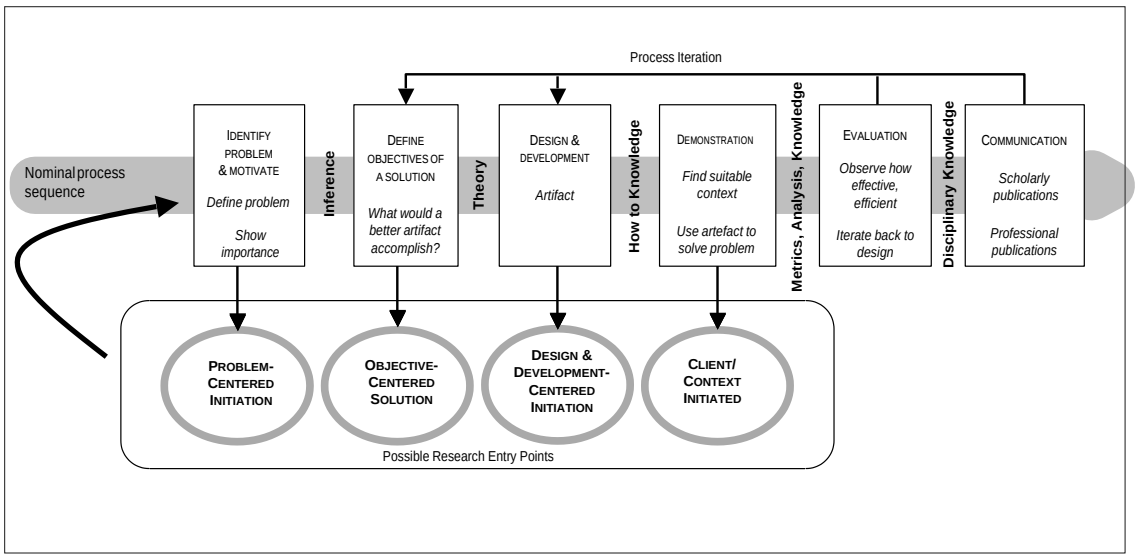

Figure 2.2: Design Science Research Methodology (DSRM) Process Model, Peffers et al. [2]

In reality, the research process may actually start at almost any step of the process, reflected by different possible research entry points in Figure 2.2. The nominal sequence starts with activity one in case of a problem-centered approach, for example when a specific observed problem has led to the idea for the research.
Hevner has described Design Science Research as an embodiment of three closely related cycles of iterative activities (Figure 2.3, [3]), related to his Information Systems Research Framework (Figure 2.1).

The *Relevance Cycle* initiates DS research with an application context that provides the requirements for the research and also evaluation criteria, defining acceptable research results. The research output, e.g. the artefact, is returned into the environment for study and evaluation in the specific application context.

The *Rigor Cycle* ensures innovation by the consideration of established scientific theories and methods together with domain experience and expertise in the setup and execution of the project. The research results (i.e. new knowledge) is added to the growing knowledge base (KB).

The central *Design Cycle* is the heart of any DS research project, where a rapid process of research activities iterates between artefact construction, evaluation, feedback and refinement of the design.

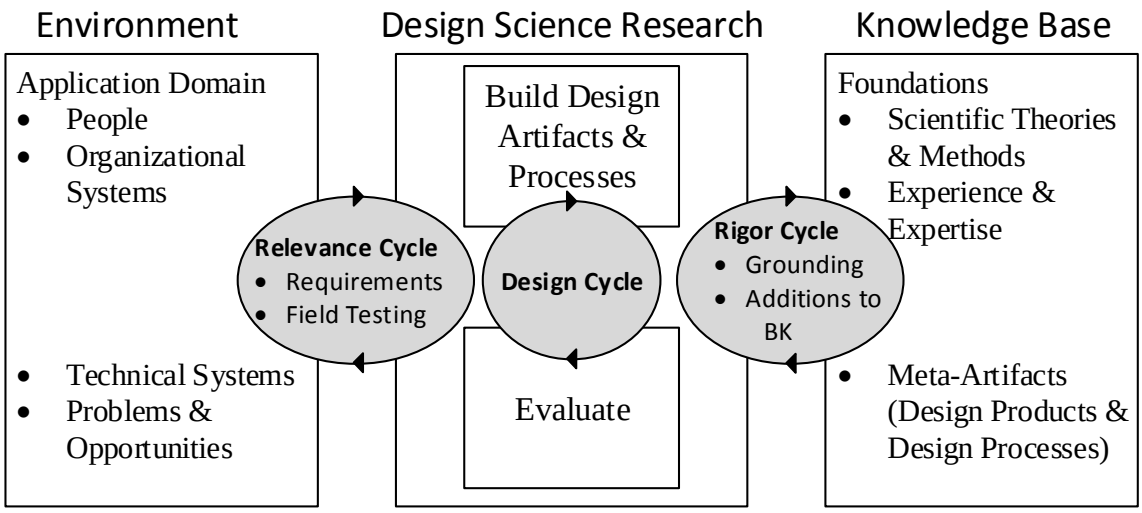

Figure 2.3: Design Science Research Cycles, Hevner [3]

As basis to study the roles and relations of the main institutional stakeholders of research and innovation in knowledge-based societies, the *Triple-Helix-Model* (Figure 2.4) of university - industry - government[1] interactions has been well established (e.g. [34, 4, 35]).

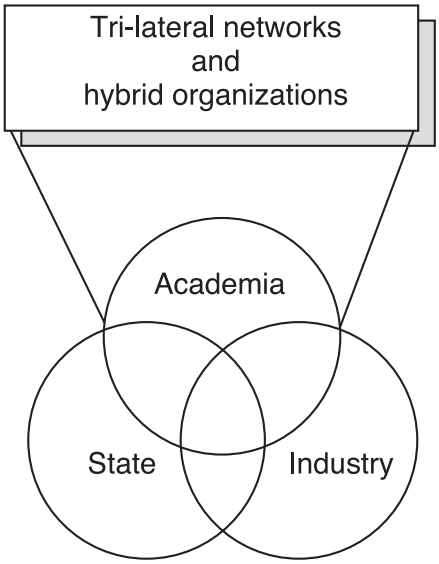

Figure 2.4: Triple Helix Model, Etzkowitz and Leydesdorff [4]

The model has been used to study for example the increased importance of

[1]In Figure 2.4 the term ”State” is used as synonym for ”Government”. In this thesis, the term ”Public Sector” is used instead, to indicate the involvement of public stakeholders on any organizational level (national, regional, local).

universities in the incubation of technology-based industries, or the role of governments in the development of research, innovation and economy on regional and national level.

The target system of this study has to consider the objectives of different institutional stakeholders, but explicitly also the needs of different end-user groups. Correspondingly, this research project has to involve university researchers, healthcare industry partners, and public healthcare service providers, in line with the Triple-Helix-Model, and additionally representatives from the target user groups.

Arnkil et al. explored and further defined a Quadruple Helix (QH) concept with emphasis on broad cooperation, representing a shift towards more user-oriented innovation policies [5]. By applying their *Citizen-centered Quadruple Helix Model* (Figure 2.5) in this research project, the joint development and evaluation of innovative and sustainable services is facilitated, involving academic research and education, public healthcare service providers, private healthcare and wellness technology industry partners, and citizens (i.e. healthcare service providers and end-users) in innovation teams.

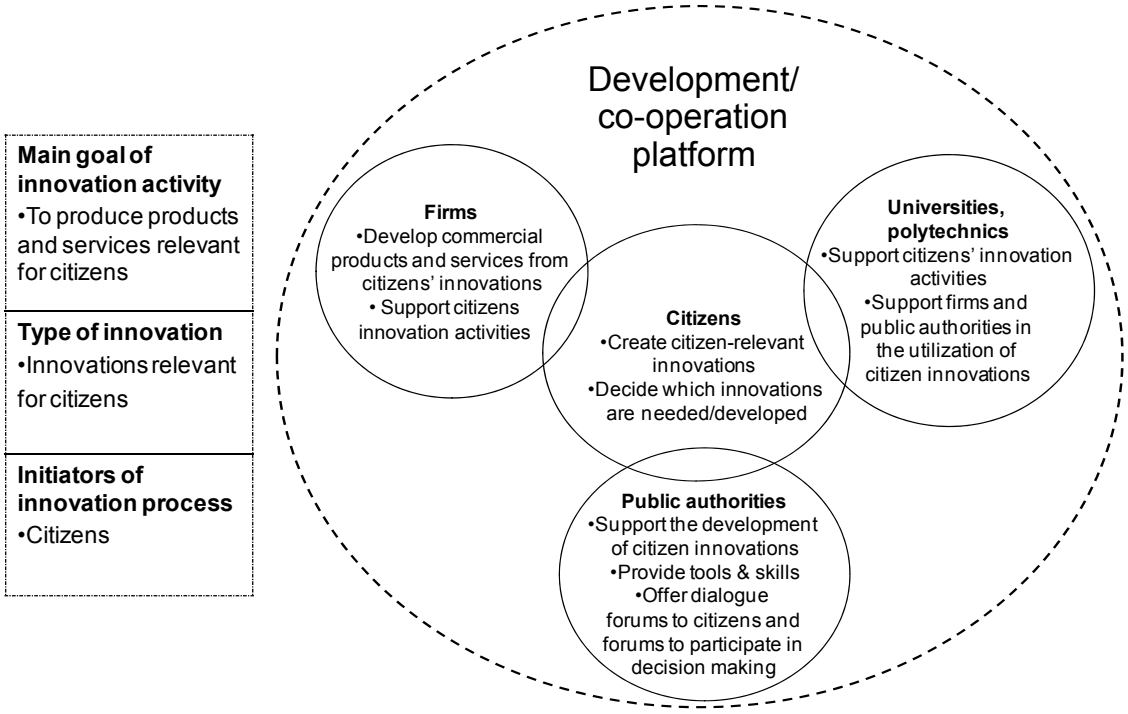

Figure 2.5: Citizen-centred Quadruple Helix Model (Arnakil et al. [5])

2.3 Selected Research Methods and their Application

Due to the applicability for the objectives and the environment of this project, the Design Science Research Methodology (DSRM) [2] has been selected, with a problem-centered initiation of the research process sequence. Based on results and experiences achieved during the execution of the project, a refinement of the DSRM process is proposed (section 5.1.1, Figure 5.3).

The methods applied for this project are explained in the following along the DSRM process steps.

2.3.1 Problem Identification and Motivation

Secondary research, in particular the analysis of research papers, has revealed open challenges in health information systems, and limitations of state-of-the-art eHealth solutions with regards to the target use case scenario. Those are documented in the *State-of-the-Art* (chapter 3).

The general background and underlying motivation for the research in this project is described in the Background and Motivation section of the Introduction (chapter 1, section 1.1).

2.3.2 Objectives of the Solution

The overall objective of the project is a generic reference design for an eHealth system supporting individual and organizational needs of different end-user groups as described in the *guiding use case scenario* (chapter 1, section 1.3.1).

The main challenges of the project are:

- multiple stakeholders, representing different user groups with heterogeneous requirements on the eHealth system
- multi-disciplinary research, addressing people, technology, and organizations, and requiring inter-disciplinary cooperation

2.3.3 Design and Development

The design and development of an artefact realizing the guiding use case scenario requires a broad holistic ***Requirement Elicitation*** to fully understand the needs of

all involved user groups, the socio-economic, political and legal requirements, and to transform them into technical requirements for the solution design and development.

2.3.3.1 Overview of Established Methods and Techniques

Requirement analysis is the process of identifying a user's needs and determining what to build in a system [36]. According to Holbrook, in *requirement elicitation* tacit information about what to build is obtained from the user(s) and their environment. He describes the method of *Scenario-Based Requirements Elicitation (SBRE)*, which develops a set of initial requirements by a structured interaction between users and designers.

With the focus on hospital information systems, Staccini et al. explain that the elicitation of requirements has to meet users' needs in relation to both the quality (efficacy, safety) and the monitoring of all health care activities (traceability) [37]. Their proposed methodology to elicit and structure users' requirements use a process-oriented analysis.

Hickey and Davis present a *unified model for requirements elicitation* within software development [38].

Zowghi and Coulin describe requirements elicitation as the process of seeking, uncovering, acquiring, and elaborating requirements for computer based systems [39], and present a comprehensive survey of techniques, approaches and tools to perform the activities needed for the complex elicitation process.

2.3.3.2 Application of Selected Methods and Techniques

The design and development of the proof-of-concept system as artefact for this research project has followed a ***User Centered Design (UCD)*** process, which also extends to the *demonstration* and *evaluation* steps of the DSRM process.

The UCD process is illustrated in Figure 2.6 and has been described and evaluated in separate publications [6, 40], with specific focus on usability aspects.

It is based on well-established methods and techniques, selected from the literature above (section 2.3.3.1). Their application within this project is explained in the following:

(a) Requirements Workshops

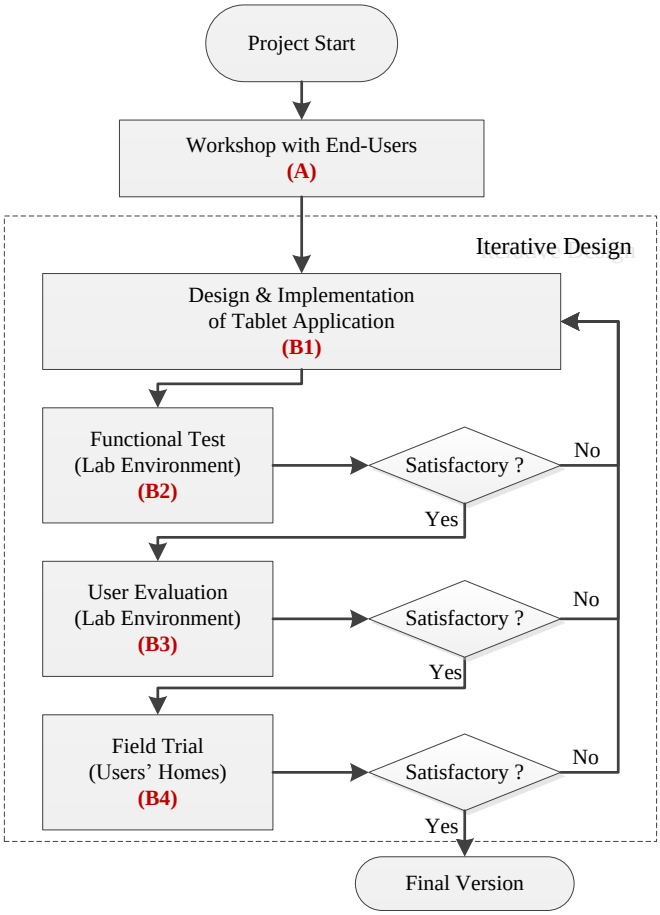

Figure 2.6: User Centered Design (UCD) Process [6]

An initial *cross-functional requirements workshop* has been held, involving representatives from all stakeholders. The participants included 2 patients, 4 nurses from a municipality healthcare service, 1 hospital doctor, 2 IT-specialists from the hospital (being responsible for the operation and maintenance of the trial system in the trial phase), 2 representatives from a software development and consultancy company for healthcare solutions, and 4 academic researchers. The cross-functional workshop facilitated the initial collection of the requirements from the different end-user groups, and the discussion and clarification with the designers and developers. This helped to minimize common and almost inevitable conflicts between stakeholders and their requirements [39], or just misunderstandings of requirements.

Further workshops involving different groups of stakeholders have been arranged to further clarify and specify different requirement aspects.

(b) Group Work

Within the cross-functional requirements workshop and subsequent collaborative meetings, different requirement aspects were discussed in dedicated Group Work sessions. A key aspect of the group work sessions has been to make the patients - as the primary end-user group - comfortable and confident in speaking openly and honestly about their needs and requirements for the support application for health-status monitoring. This was achieved by dedicated group sessions of patients with the nurses, who are their well-known point of contact. Further group works were organized for the specification and clarification of technical requirements for the design and development of the end-to-end service infrastructure, involving software developers, IT specialists, and academic researchers, including the author of this thesis, acting as the overall solution architect for the target system.

(c) Prototyping

As a result of the wishes and requirements collected at the initial requirements workshop, simplified prototypes of the graphical user interfaces (GUI) of the applications and services for the end-user groups patients and tele-nurses, respectively, were created and presented to the corresponding representatives. Those prototypes came without functionality, but allowed an active involvement of the target users and an early testing of the interaction design and usability. Integrated in the iterative UCD process, the test results were used as input for the further refinement of interaction design and the graphical UI aspects, and for the specification of the requirements on the logic support functionality for patients and healthcare professionals.

(d) Interviews

The method of stakeholder interviews has been used a lot to gather initial wishes and requirements from all stakeholder groups. During the requirements workshop and cooperative meetings mainly unstructured (i.e. no predetermined set of questions) and semi-structured (partly predetermined questions) interviews [39] were carried out. The interviews provided in the first place insights into functional and user interaction requirements to the support applications, which were documented and communicated to gain common un-

derstanding and agreement.

(e) Domain Analysis

Besides wishes and requirements from end-users of the target system, also non-functional guidelines regarding the design of the end-to-end ICT system have to be considered. Such are in particular security and privacy regulations for eHealth systems. As part of the literature analysis for this project, special attention has been put on national laws and guidelines concerning health information systems, and on the identification of reusable corresponding concepts and solutions from existing trial systems and research studies.

(f) Task Analysis

A detailed task analysis has been performed, in order to decompose the high-level user wishes and functional requirements into subtasks and detailed sequences describing the interactions of the different user groups with the system. These were used to determine the knowledge needed by the users or the system to carry out certain tasks, to determine the information flows through the system, and to determine the required system functionalities on detailed technical level corresponding to the system tasks.

(g) Communication and Understanding

The process of objective and subjective health status monitoring and reporting by the patients and the provision of follow-up support by the tele-nurses represented the main requirement for the decision support algorithms to be provided by the target system. The initial process was gathered from the nurses, quality-approved by the hospital doctor, and iteratively refined and communicated with the other stakeholders to gain common understanding and clarity.

(h) Introspection

The author's experience in solution design of ICT systems has contributed to the initial outline of requirements to the end-to-end system design, which were the further refined with the support of prior knowledge from the domain analysis and with contributions from domain experts. Furthermore, the author contributed to the design and development of early prototypes for the determination of detailed end-user requirements.

2.3.3.3 Design and Implementation

Based on the identified requirements, conceptual solutions were proposed along the different requirement domains, aiming to overcome the limitations of existing systems. The solution proposals have been incorporated in the reference design for the target end-to-end telehealth system. Following the UCD process (see Figure 2.6), the functionality has been implemented in the proof-of-concept system, and iteratively refined and tested.

Different system components as the patient tablet-PC solution and the infrastructure service for healthcare professionals have been implemented in parallel by different stakeholders, and have been integrated and tested in dedicated workshops.

2.3.4 Demonstration

The research work on this PhD project has been carried out at the Centre for eHealth (CEH) at the University of Agder in Grimstad, Norway. The CEH hosts extensive laboratory facilities, including a SmartHouse, a hospital ward, and a usability laboratory, jointly used for education, training and research purposes.

To support the study and evaluation of the proposed eHealth service and the included solution components and aspects addressing the different requirements, a corresponding artefact had been implemented within the CEH. This prototype system was used for functional tests and early user evaluation within the lab environment at the CEH (steps B1, B2 and B3 of the UCD process, Figure 2.6).

Subsequently, the artefact had been deployed as a trial system within the Norwegian Health Network, and was tested in the real-life setting with the following user groups (step B4 in Figure 2.6):

- Patients: 99 home-living COPD patients, who were selected by medical professionals from the involved hospital, used the system for about 4 weeks (each) during 2014 and 2016
- Healthcare Professionals: a *Telemedicine Centre* had been established by the municipality of Kristiansand/Norway to host 4 trained telehealth nurses who tested the decision support service component for the remote monitoring and follow-up support of the patients

- System Operators: IT specialists at hospital tested the operation and maintenance (O&M) of the system - in particular of the patient device, which had to re-initialized for each patient during the trial execution

2.3.5 Evaluation

The objective of the *evaluation* activity of the DSRM process is to observe and measure how well the artefact represents a solution to the problem [2].

2.3.5.1 Overview of Established Methods and Techniques

Stoop et al. suggested to address six *domains* for the evaluation of Patient Care Information Systems (PCIS), referring to different viewpoints of the evaluation [41]: *technical, professional, organizational, economic, ethical, and legal*. For each domain they formulated different *evaluation questions*, that should be addressed during the three phases *pre-implementation, during implementation, and post-implementation*. They recommend qualitative research methods as interviews, observations and document analysis to ”understand a phenomenon from the points of view of the participants and in its particular social and institutional context.” According to them, ”quantitative research methods are most suitable for establishing the size, extent or duration of certain phenomena (*how much*), or to establish *that* a specific cause or intervention results in a predefined effect.” Examples for quantitative research methods are questionnaires, time studies, and tracking of clinical outcomes.

Similarly, Ammenwerth et al. point out that

> ”Evaluation is the act of measuring or exploring properties of a health information system (in *planning, development, implementation, or operation*), the result of which informs a decision to be made concerning that system in a specific context.” [42]

They suggest that the evaluation typically uses quantitative and qualitative methods to address the following questions:

1. Is the technology usable in the intended environment and for the intended user group and task?

Do the different user groups (e.g. physicians, nurses, and administrative staff) accept the ICT and use it as intended?
What are the patterns in the users' attitude towards the (future) system, and their pattern of behaviour?
Have the users had sufficient training and guidance to be able to use the technology appropriately?

2. How does the technology affect structural or process quality (e.g. time saving, data quality, clinical workflow)?
   What are the effects of an information system on the quality of patient care (outcome quality)?
   To what extent does the information system meet not only the requirements but also the objectives?
   What are the reasons for the observed effects?

3. What are the investment and operational costs of ICT-based solutions?
   Are they cost-effective?
   What is their return on investment?

4. What are the problem areas of an information system in daily operation?
   What are current pitfalls with it, and how can it be improved?

5. What are the organizational and social consequences of introducing ICT into health care environments and how can we include these aspects into design, development and installation to achieve the planned changes in the working structures, work content and work environments?

Hevner et al. emphasise that

> "the utility, quality, and efficacy of a designed artefact must be rigorously demonstrated via well-executed evaluation methods", and that "IT artefacts can be evaluated in terms of functionality, completeness, consistency, accuracy, performance, reliability, usability, fit with the organization, and other relevant attributes." [1]

They provide a summary of methods from the knowledge base that are typically used for the evaluation of designed artefacts (Table 2.1).

Table 2.1: Design Evaluation Methods [1]

1. Observational	Case Study: Study artefact in depth in business environment
	Field Study: Monitor use of artefact in multiple projects
2. Analytical	Static Analysis: Examine structure of artefact for static qualities (e.g., complexity)
	Architecture Analysis: Study fit of artefact into technical IS architecture
	Optimization: Demonstrate inherent optimal properties of artefact or provide optimality bounds on artefact behaviour
	Dynamic Analysis: Study artefact in use for dynamic qualities (e.g., performance)
3. Experimental	Controlled Experiment: Study artefact in controlled environment for qualities (e.g., usability)
	Simulation - Execute artefact with artificial data
4. Testing	Functional (Black Box) Testing: Execute artefact interfaces to discover failures and identify defects
	Structural (White Box) Testing: Perform coverage testing of some metric (e.g., execution paths) in the artefact implementation
5. Descriptive	Informed Argument: Use information from the knowledge base (e.g., relevant research) to build a convincing argument for the artefact's utility
	Scenarios: Construct detailed scenarios around the artefact to demonstrate its utility

Chiasson et al. suggest to use qualitative methods in medical informatics research for five main reasons [43]:

1. Understanding how a system's users perceive and evaluate that system and what meanings the system has for them;

2. Understanding the influence of social and organizational context on systems use;

3. Investigating causal processes;

4. Providing formative evaluation — evaluation aimed at improving a program under development, rather than assessing an existing one;

5. Increasing the utilization of evaluation results.

The "Guideline for good evaluation practice in health informatics (GEP-HI)" from Nykänen et al. [44] identifies 60 issues, that are of potential relevance for evaluation studies in health informatics, and cover the six phases *preliminary outline, study design, operationalization of methods, project planning, execution and completion* of evaluation studies.

2.3.5.2 Application of Selected Methods and Techniques

The following questions and aspects are within the scope of this project (refer also to section 1.4), and have been evaluated.

Usability and user acceptance: The evaluation of usability, user perception and user acceptance of the artefact follows question 1 of Ammenwerth et al. [42] and reason 1 of Chiasson et al. [43].

As part of the User Centered Design (UCD) process (see also section 2.3.3.2 and Figure 2.6 above), the different components and services of the artefact were iteratively tested with representatives from the different involved user groups and refined. For interactive usability testing in a controlled lab setting, a dedicated end-to-end lab infrastructure for usability evaluation has been established (refer to Paper II, Appendix C).

The evaluation made use of observational as well as experimental methods following Hevner et al. [1] (Table 2.1).

- **Experimental**
  - *Controlled experiment*: patients testing early prototype of patient support application in controlled lab environment, followed by an *interview* for qualitative analysis of limitations and problems
  - *Controlled experiment*: healthcare professionals (tele-nurses) testing early prototype of remote monitoring service in controlled lab environment, followed by a *questionnaire* for qualitative identification of problems and requirements for improvement
- **Observational**
  - *Field study*: monitoring patients in their home environment, using the artefact (prototype of patient support application during development),

followed by a *questionnaire* for qualitative identification of problems and requirements for improvements

- *Field study*: monitoring healthcare professionals (tele-nurses) in their target business environment (i.e. telemedicine center), monitoring their use of the artefact (prototype of remote monitoring and decision support service), followed by a *questionnaire* for qualitative identification of issues and requirements for improvements
- *Case study*: studying system usage during trial operation (post-implementation), for evaluation of patients' acceptance of the artefact based on *quantitative analysis of collected usage data* of patient support application in their every-day life in home environment (usage patterns as duration and usage frequency/intensity)

The usability evaluation of the artefact during the implementation phase and in the trial operation phase (post-implementation) was subject to another dedicated study. The specific usability evaluation methods have been published by Smaradottir, Gerdes et al. [40, 6]

Smart decision support algorithms: The evaluation of performance, acceptance and efficiency of the implemented decision support algorithms follows question 2 of Ammenwerth et al. [42], aiming for improving the artefact during development (reason 4 of Chiasson et al. [43]) and for evaluation of the implemented algorithm.

The evaluation made use of testing, experimental and observational methods following Hevner et al. [1] (Table 2.1).

- **Testing**
  - *Functional Testing*: testing the correct functionality of the decision support algorithms with defined input data and comparison of the output value against the expected result
- **Experimental**
  - *Controlled Experiment*: testing the artefact in controlled lab environment for correct decision support functionality, including measurement

with sensor device, transmission to patient support application, transmission to health information infrastructure, decision support information calculation, and presentation by healthcare support service

- **Observational**
  - *Field Study*: monitoring the use of the artefact by the tele-nurses during the trial operation (post-implementation) in the business environment (telemedicine center), and quantitative analysis of accuracy of generated decision support information

Efficiency and efficacy evaluation: The quality of the artefact in terms of impacts on the process quality (e.g. improvements to the healthcare workflow) and on the quality of patient care (outcome quality) following question 2 of Ammenwerth et al. [42] has been evaluated by other related PhD projects, and are not covered in this thesis. Those studies used the trial system developed as part of this project and **observational** methods (Table 2.1 [1]) during and after the field trial operation.

- *Field Study*: qualitative and quantitative evaluation of the medical efficacy of the support provided to patients by the system
- *Field Study*: qualitative and quantitative evaluation of the impact of the system on the operational efficacy of the healthcare service provider

2.3.6 Communication

The purpose of the *communication* activity of the DSRM process is to communicate the problem and its importance, the artefact and the rigor of its design, its utility and novelty, and its effectiveness to researchers and other relevant audiences in the general public [2]. As part of this PhD project, different objectives and requirement domains of personalized eHealth services have been addressed in separate publications, including the evaluation of the reference design with focus on those requirement domains. Based on the evaluation of the trial system, a proposal for the concept of a refined reference solution has been published. Refer to Part II, Appendix A, for detailed information.

Chapter 3

State-of-the-Art

3.1 Services, Applications and Infrastructure

Telehealth applications can offer significant socio-economic benefit, to patients and families, healthcare providers and the healthcare system. The *main benefits* identified in systematic reviews were increased access to health services, cost-effectiveness, enhanced educational opportunities, improved health outcomes, better quality of care, better quality of life and enhanced social support [45, 46, 47].

A systematic literature review of home telehealth (home telemonitoring and telephone support) for patients with chronic obstructive pulmonary disease (COPD) revealed that home telehealth can reduce rates of hospitalization and emergency department visits, while the mortality rate can be greater with telephone-support compared with usual care [48]. The perceived quality of life and patient satisfaction outcomes from home telehealth interventions were similar or better than for usual care. Challenges and need for further studies of telemedicine have been identified in the areas of patients' perspectives, economic impacts, complexity of processes and collaboration [49].

Telehealth solutions for remote patient monitoring often do not incorporate the specific care support needs according to the individual health condition to a sufficient extent. Furthermore, most applications cannot provide for the specific usability, accessibility or illiteracy-support needs and preferences of each individual user. But as there is no "one-size-fits-all" approach [27], the development of health care solutions without adequate personalization following a user-centered design pro-

cess can lead to low usability and slow adoption of e.g. mobile health (mHealth) technologies for elderlies [16].

A *major barrier* for the introduction of telehealth technologies is the fragmentation between hospitals and municipally-based health care services as for instance identified in the United States and the European Union [27]. Telehealth technologies can cause jurisdictional and policy conflicts in fragmented healthcare systems, which limits the integration of innovative telehealth solutions and pilot systems into the health care infrastructure and care practices, and minimizes the collaborative care among health care professionals across sectors.

There are various reasons for the high fragmentation of ICT infrastructures for health- and wellness-data. Telehealth services in the public healthcare system are specialised and effective in their clinical speciality or organizational context, and collected patient data is processed in disparate data repositories and departmental systems, following different information models, syntaxes, semantics, or formats [50, 51]. Physiological and activity data from personal wellness tracking and fitness optimization applications are typically stored and processed in service-specific cloud infrastructures, in proprietary information models and formats. These *data and information silos* result in challenges to transpose data between different healthcare settings, for example to reuse data from personal fitness tracking applications in the context of telehealth and remote patient monitoring (RPM) carried out within the public primary care.

Besides the heterogeneity of health data from different applications and services in terms of syntaxes, semantics and formats (see above), there are further shortcomings concerning completeness and correctness. Physiological and activity data measured by the citizen with remote monitoring devices or wellness and fitness trackers can be defective due to wrong operation or technical issues (as e.g. insufficient battery power etc.) of the measurement devices. Questionnaires or assessment tools for the self-reporting of wellness symptoms are subject to misunderstandings of questions or possible answers. The resulting *insufficiencies of the data quality* cause challenges for the integration and automatic processing of the data [52].

Significant improvement potential is seen in the incorporation of informal care provided at the patient's home by family members, friends and voluntary organizations [53]. Supported by the exchange of alerts and further information through

information and communication technologies, a better coordination of healthcare interventions can be achieved. The involvement of informal caregivers in the collection, assessment and exchange of information about older adults' health status and needs can support timely interventions that may reduce adverse health events [54]. This potential should be utilized more in upcoming health information systems.

Deployment Options

The point-of-care applications for user interaction with the citizen, sensor device integration and assistance for measuring and assessment of monitoring data, and for the decision support logic for data analysis, detection of alert conditions and the generation of recommendations for activities and interventions can be deployed following different approaches. Typical stand-alone *apps* contain all functional entities within the implementation on the user device, while communication with the health information services infrastructure only serves the purpose of exchange of data and information. The main limitations of that approach are the restriction to the implemented use case, the lack of adaptability to the users' needs and the specific point-of-care environment (sensors, actuators), a static UI and interaction design, and the fixed evaluation and user support logic. Flexibility and adaptability of the user application on the point-of-care device platform can be achieved with a modular software architecture [55], which can be remotely managed and adapted from a cloud-based management services as needed. One well-established set of specifications for modular assembly of software is OSGi [56, 57].

Another approach to achieve high flexibility and adaptability of the service provisioning to the user at the point-of-care across multiple user device platforms is the implementation of *thin clients* following a Web Approach [58] utilizing latest cloud technologies. In this approach all service logic, interaction and user interface (UI) generation is implemented as cloud service, while on the client platform only the UI is rendered in a Web browser. The main disadvantage of this approach for health monitoring applications is the difficulty or even impossibility to access hardware devices connected to the point-of-care platform, as in particular sensors. Furthermore, Web applications are dependent on stable and high-performance connectivity. Interruptions of that can lead to precarious situations, if for example critical health conditions cannot be detected and required support cannot be provided

to a remotely monitored patient.

To make potentially mission-critical data evaluation, reasoning and decision support logic adaptable to the specific point-of-care environment on the one side, while on the other side independent from high-performance connectivity, solutions for Distributed Decision Support Systems (DDSS) have been proposed. Data evaluation and reasoning logic is updated and distributed for execution in the point-of-care environment. Combined with IoT technologies, also the machine learning logic for classification of sensor data can be distributed.

Andreasik et al. have proposed a distributed decision support system based on Semantic Web technologies for the analysis of the medical procedures [59].

Other proposed systems utilize *software agent* technologies (also *mobile agents*, or *multi-agent systems*) for the management of distributed healthcare systems [60, 61, 62, 63, 64].

3.2 Health Information Technology

3.2.1 Health Status Measurement & Assessment

The Wearable Sensors Market

According to market studies, the global wearable technology market is expected to grow significantly: Transparency Market Research predicts US$5.8 billion in 2018 from US$700 million in 2012 [65], Juniper Research expects revenues from smart wearables hardware of US$53 billion by 2019 compared to US$4.5 billion in 2014 [66]). The forecasts diverge widely in terms of concrete market volume figures due to the relatively immature industry. The sectors of healthcare and medical together with sport/fitness and wellness have been dominating the global wearable technology market in 2015/2016, and are expected to do so by 2018. Strong growth is expected in the services market around connected healthcare and fitness devices. Juniper predicts that ”people will track their fitness and health data for free, but they will pay for apps and services that interpret and analyse that data and make it meaningful” [67], and expects a market of US$ 1.8 billion from smart wireless healthcare and fitness device services by 2019.

Semantic Structuring and Interoperability of Sensor Data; Ontologies
In order to enable interoperability for sensors and sensing systems, semantic technologies have been proposed that can assist in managing, querying, and combining sensors and observation data. The Semantic Sensor Network Incubator group (the SSN-XG) of the world wide web consortium (W3C) has produced the Semantic Sensor Network (SSN) ontology [68] to describe sensors and observations. Utilizing these machine-interpretable semantics, autonomous or semi-autonomous agents can collect, process, reason about, and act on sensors and their observations. A well-established ontology for medical data and information is the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT). Julina et al. have proposed to use Electronic Medical Records (EMR, alike Electronic Health Records, EHR) based on the SNOMED CT ontology for decision making [69].

3.2.2 Remote Monitoring, Data Collection and Transmission

Wireless Sensor Networks
Wireless sensor network (WSN) technologies are crucial for the utilization of sensor-devices as wearables in pervasive healthcare monitoring applications. Results from pilot systems and solutions [70] indicate the strong potential of wireless sensor networks for ad-hoc deployment of multi-modal sensors for an improved quality of medical care, and also challenges related to sensor sensitivity and reliability, interoperability, security, user-friendliness, and among others also the organization of the data to allow an efficient analysis and evaluation to produce meaningful information. A number of those requirements are addressed by the Continua Alliance [71, 72], an industry consortium establishing an ecosystem of connected personal health and fitness products and services.

Internet-of-Things Technologies
The application of Internet-of-Things (IoT) [73] technologies in the health information systems domain can help to overcome a number of identified limitations. Potential for IoT applications is identified for example in patient monitoring, personnel monitoring, and the assistance of practitioners in the field with real-time health status and predictive information. Central for the IoT framework is the cloud computing infrastructure, which integrates storage, computation and visual-

ization paradigms. Based on the architectural reference model for the IoT defined by the IoT-A project consortium [74], Distefano et al. have proposed a top-down utility paradigm for the implementation of a *Sensing Cloud* to provide Sensing and Actuation as a Service (SAaaS) [75]. A key point of the SAaaS is the abstraction and virtualization of the underlying physical (sensing and actuating) resources to provide a uniform way to access them. Paschou et al. have worked on metrics and methods for efficient data transfer in a Health-IoT [76]. Niewolny looks from an industry perspective at the role of IoT in healthcare delivery, and provides examples of standards-based end-to-end processing and connectivity solutions for IoT-driven healthcare systems which are revolutionizing healthcare [77].

Furthermore, IoT provides promising opportunities particularly in the healthcare service industry, as for in-home healthcare (IHH) services [78] and improved healthcare for people with disabilities [79]. IoT's ubiquitous service characteristics like identification, sensing, and versatile communication capacities allow to constantly track and monitor all objects in healthcare systems - people, equipment, medicine, etc. [70]. The collected healthcare-related data and information (monitoring data about activities and health status, location of patients and care providers, information about diagnosis, therapy, interventions, and medication, management and finance) can be managed and shared efficiently by IoT's global connectivity. Mobility and personalization are further crucial characteristics of IoT-based healthcare services, that are enabled by using wearables, personal computing devices (laptop, mobile phone, tablet, etc.) and mobile Internet access (WiFi, 3G, LTE, etc.) [80]. Security and privacy concerns are two major challenges. Despite technological advances coming with IoT, there is no clear picture of the human, socio, economic, and political impacts and changes it will bring [81].

3.2.3 Evaluation of "Big Data", Inference and Reasoning

"Big Data"

The increasing deployment of IoT-systems for the collection and transmission of healthcare-related data in Electronic Health Record (EHR) systems leads to a vast and rapidly expanding amount of data. Extracting information and knowledge from this "Big Data" has huge potential to improve the quality and efficiency of healthcare delivery [31]. "Big Data" may expand the capacity to generate new know-

ledge for the healthcare sector, it can help with the dissemination and utilization of the knowledge in the field by physicians (in particular the intuitive approach of diagnostic reasoning [82]), it may help to translate personalized medicine initiatives into clinical practice, and it may allow for a transformation of health care by delivering information directly to patients (and citizens in general), empowering them to play a more active role. Key for dealing with the large information sets and hence for the realization of the potential of the ”Big Data” are advances in analytic techniques in the computer sciences, especially in machine learning.

The analysis of the ”Big Data” includes information and knowledge about the context of the citizen, and allows to provide context-aware healthcare services [83]. Different context reasoning techniques are available to provide diagnosis support for medical professionals, to adapt healthcare workflows dynamically to the condition of patients, and to provide recommendations and decision support information for interventions and behavioural aspects.

Machine Learning; Probabilistic Modelling for Reasoning

For the handling of uncertainty involved in determining the probability for dangerous health conditions, for establishing diagnoses of disease, in predicting the success potential of different treatment options, and by that in selecting optimal treatment alternatives, Bayesian networks and other probabilistic graphical models and their associated methods have emerged in biomedicine and health-care since some decades [84, 85]. Techniques from machine learning are being used at the same time to discover patterns in biomedical ”Big Data”, and to derive statistical relations as basis for the representation of the uncertainties in the models. Xiujuan et al. have proposed Bayesian networks for the analysis of monitoring data from heart disease patients [86], and a method that can improve the accuracy of the modeling and shorten the modeling time to some extent. Pavlin et al. show that Bayesian networks (BNs) are suitable for the development of robust and efficient distributed fusion systems for information obtained from sensors and humans [87].

3.3 Test Systems and Field Trials

As pointed out in section 2.3, *demonstration* and *evaluation* are two major elements of design science research methodology in information systems [2]. Evaluation

refers to the ”observation of effectiveness and efficiency”. Evaluation of health information systems is the ”act of measuring or exploring properties of a health information system in planning, development, implementation, or operation” [42].

In order to achieve the anticipated evaluation and demonstration, telehealth test systems have to be designed, implemented, tested, and then operated and demonstrated in field trials. Critical performance indicators have to be measured and evaluated iteratively through all development phases.

In the past years, a multitude of corresponding telehealth and telecare test systems have been developed and operated (or are still in operation) in field trials. The main design limitations as well as results and findings are subject for the solution proposed in this study (as far as possible within the set scope).

Andriopoulou et al. have proposed a Next Generation Service Delivery Platform (NG-SDP) for the eHealth domain [88], with the focus on estimation of the patients' current health condition based on real-time acquired contextual data and bio signals, and on the selection and deployment of healthcare services for the required service provision. The work did not address the decision support for actions and interventions as such.

For the AMICA project [89] a pilot system was developed for the telemonitoring and self-management support of COPD patients. This aimed at new means for quality health care management improving the patients' quality of life. Though the system development tried to follow a market-oriented approach by integrating sustainable business models for products and services based on existing healthcare market structures and regulations, the pilot system did not show any standard compliance for the integration with existing EHR or other healthcare systems.

Also the randomised controlled trial of the EDGE platform [90], a telehealth platform to support self-management for people with COPD, assessed the extend of quality of life improvement. The system does not solve yet the consistent experience with existing commercial telehealth systems that the high rates of false-positive alerts have been unacceptable to clinicians and patients.

The EU FP7 project ”universAAL - UNIVERsal open platform and reference Specification for Ambient Assisted Living” [91] has aimed to produce an open platform that provides a standardized approach making it technically feasible and economically viable to develop Ambient Assisted Living (AAL) solutions. As pointed out by Hanke et al. [92], a lot of work had been done in the field of

AAL, but most of the project outcomes were proprietary and thus impossible to be combined. Accordingly, universAAL was aiming for an universally applicable platform. The *universAAL Reference Architecture* is documented in deliverable D1.3 [93].

The EU ICT-PSP project ReAAL [94] investigated the assumptions that open platforms are the enabler for a gradual system evolution and support products and services to become more affordable, future-proof, adaptable, and accessible. Based on the universAAL platform a number of pilots were carried out, each with a different focus.

The EU FP7 project "ALFRED – Personal Interactive Assistant for Independent Living and Active Ageing" [95] aimed at overcoming the increasing social isolation of older people because of missing social interactions or age-related physical or cognitive impairments. The main goal was to allow older people to live longer at their own homes with the possibility to act independently and to actively participate in society by providing the technological foundation. To achieve that, the virtual butler ALFRED was developed, that was entirely voice-controlled. One of the objectives was to improve the care process through direct access to vital signs for carers and other medical staff as well as alerting in case of emergencies. Data was collected by unobtrusive wearable sensors monitoring vital signs.

"ACTIVAGE - Environments for ageing well" [96] is an EU HORIZON2020 project on Smart Living Environments, which will build an European Internet-of-Things (IoT) ecosystem, using open and proprietary IoT platforms, technologies and standards, and integrating new interfaces needed to provide interoperability. It works on a set of techniques, tools and methodologies for interoperability at different layers between heterogeneous existing IoT Platforms and an Open Framework for providing Semantic Interoperability of IoT Platforms for Active & Healthy Ageing (AHA), addressing trustworthiness, privacy, data protection and security.

The Centre for eHealth and Health Care Technology (CEH) at the University of Agder (UiA) hosting this PhD project is a user-centred multi-disciplinary research and education institution in the health sector. It has experience with the execution of project following a quadruple-helix-model: end-users / citizens, representatives from the health care sector, business partners and academic researchers cooperate in research and innovation. It hosts a *Living Lab* environment, including facilities for realistic tests with end-users and healthcare professionals, and a secured health

network infrastructure connected to the Norwegian National Health Network. The CEH is partner in several EU-projects, and is representing the south-Norwegian counties Aust-Agder and Vest-Agder as a 3-star reference site in the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA).

Chapter 4

Design and Development

This chapter addresses the ”Design and Development” step in the Design Science Research Methodology (DSRM) process model (section 2.2, Figure 2.2).

Section 4.1 covers the *Requirement Elicitation*, with a more detailed analysis of the requirements of the target services and applications. It utilized the methods and tools described in section 2.3.3.2, and serves as basis for the proposed *Reference Solution Design* in section 4.2, that realizes the guiding use case scenario *monitoring and decision support for activities and interventions* as outlined in section 1.3.1.

The requirement domains (as introduced in Table 1.1 in section 1.3.2) include the functional, operational and economic requirements of the different involved end-user groups, considering in particular the needed functionalities and the desired sustainability and efficiency gains in development and operation of the solutions. They include furthermore the legal and regulatory policies and guidelines that are induced by the socio-economic, political and legal framework of the health system (see Figure 1.1).

(a) Functional, Operational and Economic Requirements

Smart Assistance for Efficient Decision Support

The healthcare solution must automatically determine information and behavioural suggestions to empower the citizens in their understanding, management and living of health and disease. Formal and informal healthcare providers must be provided with decision support information allowing them to efficiently decide about the follow-up action and intervention for the citizen.

Flexibility, Adaptability, Expandability, Scalability
The health care solution must be scalable to handle growth in user number, services and devices. It must be adaptable in terms of the citizens' support needs for wellness management, as well as in terms of the healthcare providers' decision support needs. The solution must be efficient and flexible in terms of the integration of different types of wearable sensors, health monitoring devices and medical actuators.

Usability & Accessibility
The personalization of the interaction design of the solution according to the preferences, needs and limitations of citizens, healthcare professionals, and informal care-providers will allow an efficient operation of the solution for different user groups. End-user relevance and intuitive handling will increase user acceptance and error free handling.

(b) Legal and Regulatory Policies

Security & Privacy
The solution must be trustworthy and allow for implementing complex, distributed security policies and rules.

Reliability, Robustness, Availability
People's lives and health require a solution with high dependability and low risk of failure.

Interoperability & Interworking
The solution must enable interactions with regional, national and international service domains, and shall support efficient collaboration and cooperation between them.

The solution approach presented subsequently has the goal to achieve a "holistic solution" based on existing technologies that overcomes the isolation of specific requirements and corresponding "silo solutions". Instead, all requirement domains should be addressed together and under consideration of potential impacts resulting from dependencies between the requirement domains.

4.1 Requirement Elicitation

4.1.1 Functional, Operational and Economic Requirements

Smart Assistance for efficient Decision Support.
In order to realize the envisioned future wellness management as described in section 1.2, the services within the national health information service infrastructure (HIS, illustrated in Figure 1.3) and the end-user applications shall support the different user groups - *citizens*, *healthcare professionals*, as well as the *social environment* - with efficient and secure access to monitoring data and additional information for assistance and decision support.

The additional information shall follow an individual health status assessment based on the collected monitoring data under utilization of clinical guidelines and latest knowledge from clinical studies and medical praxis. The ***citizens*** shall be provided with **information and advice to understand and manage their life with the highest possible quality**, depending on their health status and according to their own goals and preferences. For the determination of relevant information and advice, the general health status of the citizen has to be taken into account (i.e. whether the citizen is generally healthy, whether she/he belongs to a certain patient group with a temporary or chronicle disease and is under treatment or rehabilitation, whether she/he belongs to a certain health risk group, etc.), the specific, momentary health status, as well as the change and trend of the health status in terms of exacerbation and a prediction of certain health risks, or convalescence.

The ***social environment*** of the monitored citizen (as relatives, friends, and also voluntary healthcare providers) shall be provided with **information about the health status and well-being of the citizen, and with recommendations for needed care support**.

The ***healthcare professionals*** (as the nurses, general practitioners and medical specialists, telehealth and telemedicine service providers, emergency service providers and others that are responsible for the remote monitoring and professional healthcare of the citizen) shall be provided with **relevant information about the health status of all monitored citizens** to efficiently support the prioritization, planning and provision of the required healthcare interventions.

Flexibility, Adaptability, Expandability, Scalability.
Different end user groups of the support applications and services, including different groups of patients, different types of professional healthcare providers, different informal supporters, etc., have their specific and individual support needs and preferences regarding the provided support. An efficient deployment and operation of those support applications and services consequently requires a high flexibility and adaptability in the design of their hardware and software environments to the different requirements of the different user groups.

The applications and services to support the ***citizens*** shall be independent from specific operation systems and hardware platforms, and allow to be installed and used on a variety of devices (as stationary PCs in the home, or portable devices as tablet PCs or smartphones). It shall be possible to use wearables and other sensor devices as needed for the individual health status and context monitoring. The user interaction flows, dialogues for individual assessment tools as questionnaires, the user interfaces and the support logic shall be easily adaptable. The adaptation shall consider the general health condition of the citizen, to which patient groups she/he belongs, and which preferences for monitoring and support she/he has.

The support services for ***healthcare professionals*** shall be on the one hand adaptable to the information and support requirements of the healthcare professional group (nurse, general practitioner, medical specialist, etc.), and on the other hand to the monitored and supported citizen group and the corresponding support needs.

The support information shall be provided independently from the location of the receivers, to any devices or systems they use, and in near-real-time. The professional providers of primary and secondary healthcare are geographically and organizationally distributed, with local, regional and national responsibilities, and links to international health information services (Figure 1.1). Therefore the technical design and realization of the national health infrastructure and in particular of the smart assistance services has to provide the collection, aggregation and storage of monitoring data from a multitude of distributed monitoring sensors and devices, and it must support the distribution and accessibility of the decision support information independent of the location of the receivers, and across organizational boundaries.

The services for data collection, storage and provisioning must be flexible in

order to support the different information models, syntaxes, semantics, and data formats used by sensors, applications and IoT-services for the monitoring of health, wellness and context-related data. Furthermore, the ICT services for data evaluation and generation of decision support information must be adaptable to utilize the data from the storage and provision services, and to provide the information for assistance and decision support according to the needs of the different healthcare service providers, and through protocols and formats as required by the applications and information systems used by the healthcare professionals.

All ICT components in the national health information services infrastructure must be scalable to meet the capacity needed for the amount of monitoring data transmitted into and processed in the systems. The data storage systems must be expandable to cope with the increasing number of monitored and assisted citizens, monitoring devices and supervision data. The processing power of the support services shall be scalable as needed for the evaluation of the monitoring data and the generation of alerts, health status information and other decision support assistance needed by all supported citizens and healthcare service providers.

For the ***administrators*** of the HIS systems and of the monitoring devices and applications, the management of additional monitored citizens in the HIS systems as well as the administration and adaptation of devices and applications according to the needs and preferences of the monitored citizens shall be efficient.

Usability & Accessibility.

Usability reflects the effectiveness, efficiency and satisfaction a user experiences when using an application, a service, a device, etc. [97, 98] The capabilities and functionalities of a system for remote monitoring, recommendation and decision support as illustrated in Figure 1.3 can only be fully utilized if all applications and services provide a high level of usability and accessibility for each involved user group. The means to utilize certain functionalities of a system differ depending on the target users, the purpose of the applications and services, and the specific usability and accessibility features of the user devices that are involved. Usability aspects to be taken into account for the design of the Human-Computer-Interaction (HCI) are the design of the user interface (UI, also called Human-Machine-Interface HMI), and the interaction design of support processes for the measurement of health data, of questionnaires, the presentation of infor-

mation about the health condition and corresponding advices, etc. Accessibility aspects are for example sight difficulties or blindness, difficulties to hear or deafness, loss of tactile sense, being illiterate, etc.

For each of those aspects multiple factors have to be considered, such as the needs, capabilities and limitations of the different user groups and individual users: for example, a *doctor* might have different UI requirements than a *nurse*, a *blind citizen* has obvious sensory limitations and a *dementia patient* cognitive impairments. The adaptation of HMIs and UIs has to be realized either in adaptable, configurable applications, or by the dynamically generated UIs of services in the HIS infrastructure, based on configured user preferences and needs.

In order to make monitoring data available to the different end-user groups, and also to different local, regional, national or international support services according to the different support and assistance requirements, the applications and services for the measurement and assessment of monitoring data and the transmission into the health infrastructure must be decoupled from the applications and services that provide monitoring data, assistance and decision support information to the different end-user groups through dedicated, adapted UIs. The portable personal user devices of the citizens have to be able to carry out certain local data evaluation logic based on data gathered from connected sensors and Personal Medical Devices (PMDs), in order to be usable for offline emergency detection and basic care support features.

The importance of usability & accessibility for all involved user groups and the complexity of usability-related requirements stress the need that representatives of all user groups are involved from the beginning of the development process. Also the applications and services have to be tested for the achievement of the usability-related requirements and iteratively refined as needed.

4.1.2 Legal and Regulatory Policies

Security & Privacy.
The fundamental objectives of the security of automated information systems in general and eHealth systems in particular are the preserving of the integrity, availability and confidentiality of information system resources. Such systems have to comply with a number of ethical and legal regulations and laws. In Norway for ex-

ample, the ”Code of conduct for information security in the healthcare and services sector” [99] is based on ”EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data”, and has been incorporated in Norwegian legislation.

In paper V the ”End-to-end Security and Privacy Protection for Co-operative Access to Health and Care Data in a Telehealth Trial System for Remote Supervision of COPD-Patients” has been studied [Appendix F; pp. 203-223]. As part of that, potential threats and corresponding requirements have been analysed for the end-users in the Point-of-Care (i.e. for the *citizens*) and for the Health & Care Sources (i.e. for *healthcare professionals*).

The corresponding security laws, regulations and guidelines have to be implemented and enforced in all service components within the HIS, and also in all end-user devices, services and applications for the *citizens*, *healthcare professionals* and for the *social environment*. Local, regional and national differences of the legal and regulatory policies have to be followed.

Reliability, Robustness, Availability.
The availability of hardware (end-user application devices, wearables, sensors, PMDs) and of software (end-user applications and services) for the support of *citizens* and *healthcare providers* can be of vital importance, in particular for the fast detection of potentially life threatening health conditions of monitored citizens and patients, and the immediate provision of appropriate support and interventions. The transmission of vital signs from citizens and patients to the HIS infrastructure needs to be ensured, together with additional context information, such as the person’s location, as well as the availability of that data for evaluation and decision support services and for healthcare professionals in critical situations.

Robustness is required to protect all involved HW and SW against the following failure scenarios:

- HW failure (malfunction of any service component in the HIS infrastructure, or any device in the point-of-care environment or the healthcare providers environment)
- SW failure (failure of any firmware, OS, application, or service)
- Power failure (loss of electricity supply from public grid or battery)

- Connectivity failure (loss of wired or wireless connectivity provided by a third party communication infrastructure and service provider)
- System overload (failure or delay of transmission, storage or processing of monitoring data, alerts and support information due to capacity limitations in the HIS infrastructure)
- False data (faulty monitoring data due to wrong use or measurement device errors)

The design guidelines for typical consumer ICT equipment do not include high availability requirements. Hence, the reliability of end-user support solutions for health & wellness monitoring and support depends on the one side on the availability of the involved equipment, and on the other side on solutions for a centralized or de-centralized monitoring of all involved HW and SW components. It requires effective measures to react on detected malfunctions in order to restore the functionality.

Interoperability & Interworking.
The end-user support applications for *citizens* and *patients* shall be interoperable with any sensor devices - wearables, PMDs, context sensors - in the point-of-care environment. That puts requirements on the supported communication protocols for the data exchange between the end-user application device (for example a tablet PC device) and the sensor devices, in particular regarding the automatic identification of the available sensor devices to be used, and the semantic and syntactic data formats. Data that have been measured once shall be provisioned to all required health status assessment and follow-up recommendation applications, and to all involved healthcare professionals and informal healthcare providers.

The support applications and services for the *healthcare professionals* shall on the one side be accessible on any applicable device within the healthcare provider environment, and shall support the efficient exchange of data and information with other healthcare professionals to enable collaboration across different organizations on local, regional, national and international level. On the other side they shall enable the exchange of wellness status information and recommendations with any point-of-care device of citizens and patients, and of involved informal care providers as relatives and friends. In order to provide for interoperability of

the central support services for storage and exchange of monitoring data and decision support information in the HIS infrastructure with the dedicated, specialized applications and systems of the different healthcare service providers, common data formats and ICT protocols have to be supported.

4.1.3 Test Systems and Field Trials

The general purpose of test systems is the validation of the system design and implementation against the defined requirements not only under laboratory conditions, but also under real operation conditions, involving all target user groups in time-limited field trials. Limitations and errors shall be found, corrections and improvements shall be implemented and tested, and the systems shall be prepared for deployment in their target setting and for full operation.

Following the ”Demonstration” step of the DSRM process model, a prototype implementation of the proposed solution should be demonstrated in a suitable context. In line with this purpose, the prototype system developed within this project should be designed to allow the deployment as trial system for the EU project United4Health (U4H) [100, 101] (refer to section 2.3.6). The U4H field trial had the aim to demonstrate and verify the following outcomes:

1. **Clinical outcomes**
   The introduction of a short-term intensive TeleMonitoring programme (TMon) followed by a less intensive ”step down” TMon for COPD patients discharged from the hospital after an exacerbation, reduces hospital re-admissions from COPD exacerbations over the following year.

2. **Organisational outcomes**
   The required organisational changes can be implemented at scale in a timely way. The TMon will result in an acceptable work load for the staff.
   The required organisational changes and new ways of working are agreed and approved by the appropriate management structures within the relevant local agencies involved in the delivery.
   The intervention models can be successfully transferred to other regions and mainstreamed as part of usual care.

3. **Economic outcomes**
   The TMon for COPD care pathway is more cost-effective compared to usual care.

4. **Other outcomes**
   The new service is acceptable to all stakeholders including patients and health professionals.

In paper IX "Telemedicine Trial System for Personalized Follow-up Support of Patients with Chronic Obstructive Pulmonary Disease (COPD) - Results and Experiences from Health Status Assessment and Risk Estimation Algorithms" [Appendix J; pp. 263-302] the technical requirements of the trial system are described, based on the clinical trial protocol. The focus of the trial system functionality is on the health status assessment of remotely monitored patients, and on the generation of colour-coded health status levels and alerts to support the decisions of the responsible health professionals in the prioritization and planning of follow-up interventions.

Besides the "smart assistance for efficient decision support", also the other functional, operational and economic requirements as well as the legal and regulatory policies explained above have been considered in the design and development of the prototype. The aspects "flexibility, adaptability, expandability, scalability" and "reliability, robustness, availability" had only limited priority for the trial system development.

While the assessment and evaluation of the clinical, organizational, and economic outcomes has not been within the scope of this thesis (refer also to section 1.4), the "other outcomes" (i.e., the acceptance of the demonstrated applications and services by all stakeholders) have been evaluated and are presented in the *Results and Discussion* chapter (refer to section 5.1).

4.2 Reference Solution Design

4.2.1 Reference Architecture

In line with the considered view of the health system as illustrated in Figure 1.1 and the reference system overview in Figure 1.3, the solution proposed in this study

follows the reference architecture in Figure 4.1.

Point-of-Care (PoC)

At the Point-of-Care (PoC), which can be any location of the citizens as for example their home or somewhere on the move, the health and wellness status of the citizens as well as their corresponding context is determined.

Objective physiologic life signs (as for example the blood pressure, temperature, pulse rate, blood oxygen level, blood sugar level, etc.) are measured with a variety of *Medical Sensor* devices. This group of devices includes weight scales, thermometers, pulse-oximetry devices, spirometers, and also ”wearables” fitness trackers as pulse belts, wrist bands, and sensors embedded into SmartWatches. *Social Alarm* indicators are devices the citizens carry with them, and which send an alarm signal in case the citizens press a button, or the device automatically detects a fall or another critical condition.

Subjective health and wellness symptoms are reported by the citizens via surveys as questionnaires and assessment tools. Such surveys and assessment tools are provided electronically to the citizens on their personal communication device, which can be a tablet PC device, a SmartPhone, but also another application platform with a connected monitor or TV.

Context information (including for example the citizen’s location, the local temperature, air humidity and quality) are measured by corresponding *Context Sensors*. Examples for context sensors are room thermometers, smoke detectors, Pyroelectric (”Passive”) InfraRed (PIR) motion sensors, and Global Positioning System (GPS) location devices.

The data from personal sensor devices is typically transmitted using a near-field communication technology as Bluetooth (BT) to the citizens’ communication devices (as their tablet PC or SmartPhone). Some sensor devices may be connected with a cable. The personal communication device acts as a PoC-gateway and forwards the collected monitoring data from sensors and surveys to the Health Information Services (HIS) Infrastructure, utilizing inbuilt cellular broadband communication technologies (3G/4G). Through the Public Land Mobile Network (PLMN), a Virtual Private Network (VPN) tunnel is established to provide for encrypted data transmission.

Alternatively the measurement data from sensors and survey data from the cit-

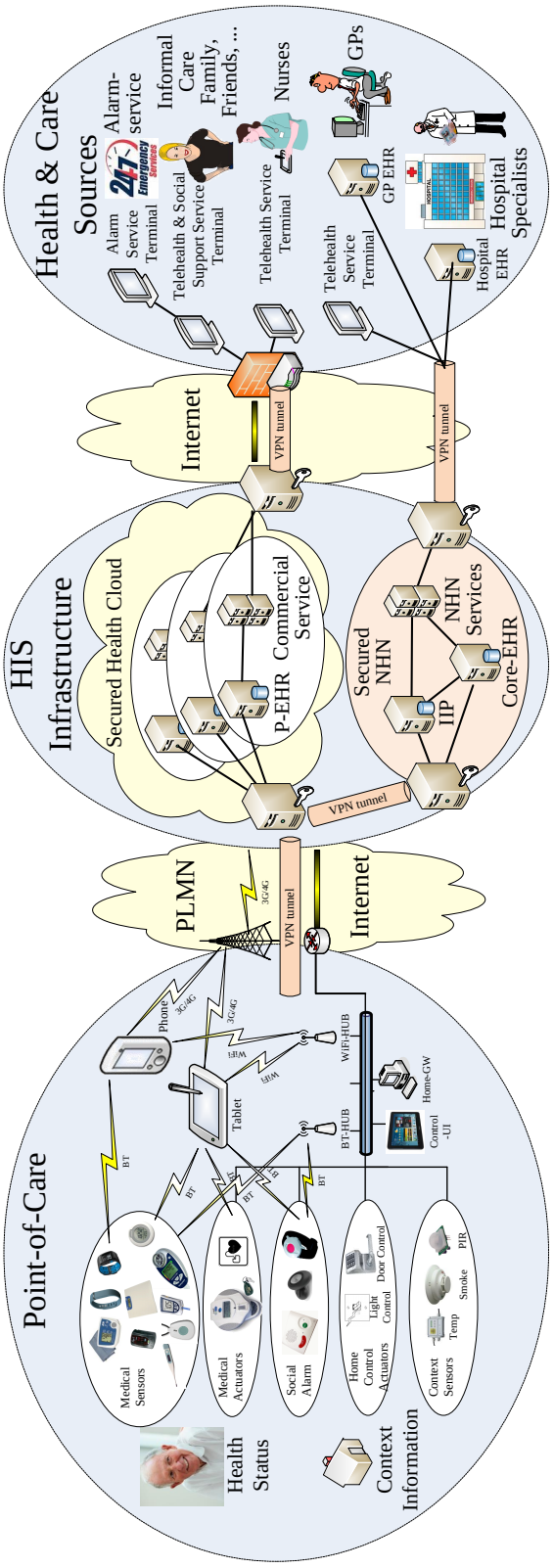

Figure 4.1: Reference Architecture [paper VII, Appendix H]

izens' personal communication devices is transmitted to a home-gateway via a headless BT-hub or a WiFi access point respectively. The home-gateway facilitates the transmission to the HIS Infrastructure through the Internet via a VPN tunnel.

The monitored citizens receive support in form of information, recommendations, or voice and video consultations also via their personal communication device.

Health Information Services (HIS) Infrastructure

The proposed HIS Infrastructure consists of two domains - a *Secured Health Cloud*, and the *Secured National Health Network (NHN)* (Figure 4.1).

The *Secured Health Cloud* provides a secured service hosting infrastructure for *Commercial eHealth Services* based on cloud technologies. Service-specific monitoring data from the citizens' PoC is managed by corresponding *Personal Electronic Health Record (P-EHR)* systems, and utilized by the specific service offered to either the citizens directly, or to support any health & care service provider.

The *Secured NHN* provides the secured national infrastructure for the electronic exchange, storing, and processing of health data within the national health system. For the purpose of telehealth, telecare and remote patient monitoring considered within this study, monitoring data from the PoC of monitored citizens is aggregated and transformed (as required) in an *Information Integration Platform (IIP)*. The IIP makes the data available to various *National Health Network (NHN) Services*. Basic personal and health data from all patients are stored in a *Core Electronic Health Record (Core-EHR)* system, which is utilized by all NHN services. NHN services for telehealth, telecare and remote patient monitoring provide data evaluation and reasoning for decision support according to the specific needs of the different health & care service providers.

Both domains are accessed through a common, managed access control infrastructure based on well established and trusted digital personal identifiers. This avoids that the citizens and the health & care providers have to maintain various identities and access control credentials.

Another important aspect of this proposed architecture is the interoperability between the two domains. Through secured VPN connections between the two domains (see Figure 4.1), monitoring data from commercial monitoring services

can be made available to NHN services and vice versa, based on the trusted identification and access control mechanisms.

Within the *HIS Infrastructure*, i.e., within the *Secured NHN* and each *Secured Health Cloud*, the data transmission is encrypted based on agreed public key infrastructures (PKI).

Health & Care Sources
A variety of different providers of health & care services utilize the electronic support services in the HIS infrastructure. This includes alarm and emergency support providers, informal and voluntary helpers, family members and friends, nurses from telehealth & telecare service providers, general practitioners (GPs), and medical specialists.

The monitoring data, and also the additional information for decision support and recommendations for follow-up support is accessed via Telehealth Service Terminals based on Web-technologies, or via dedicated EHR systems and applications for GPs and hospitals. The data communication of the services in the secured health cloud and in the secured NHN with the service terminals and EHR systems at the health & care service providers is secured with a common trusted VPN infrastructure.

In paper VII the proposed ”Reference Design for Smart Collaborative Telehealth and Telecare Services Based on IoT Technologies” has been published [Appendix H; pp. 233-242].

4.2.2 Information Architecture

In Figure 4.2 a closer look is taken at the main components of the proposed solution and the information flow between them.

Medical and context sensors and social alarm devices transmit their data over a machine-to-machine (m2m) interface to the citizen’s PoC gateway and application platform device. The main functionalities of this device, which can be a personal tablet PC or SmartPhone of the citizen, are the data collection and local storage, the data evaluation and reasoning according to specific algorithms and knowledge, and the provision of support information and recommendations to the citizen. The

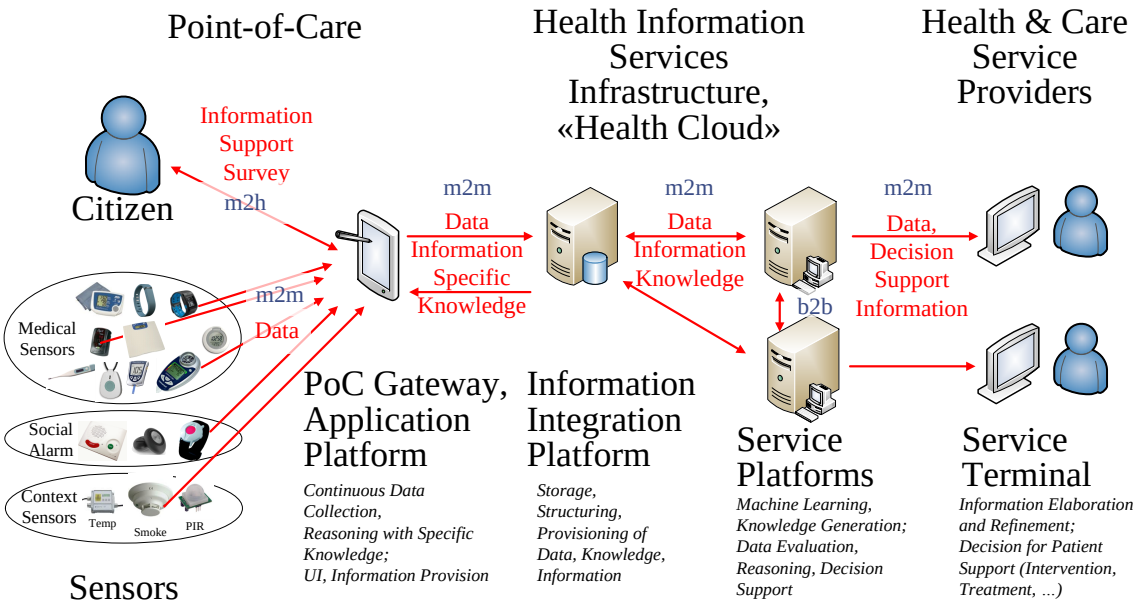

Figure 4.2: Information Architecture

user interfaces (UI) of the applications also include surveys to gather subjective health symptoms from the citizen.

The PoC gateway component forwards the monitoring data and information via an m2m interface to the IIP. There the data is (re-)structured, stored, and provided to the service platforms for health information services. Different services provide evaluation and assessment of data for the determination of decision support information for the citizens and health & care service providers, machine learning for classification of collected and aggregated ”Big Data” and generation of knowledge, and reasoning of monitoring data based on algorithms and statistical knowledge. Interoperability and exchange of data, information and knowledge between different service platforms is enabled through business-to-business (b2b) interfaces.

Telehealth & telecare support services provide monitoring data and decision support information according to the needs of the corresponding health & care service providers via m2m interfaces to service terminals that create the user interfaces for the service providers.

Specific knowledge for personalized reasoning is also made available from the corresponding health information services to individual citizen devices.

4.2.3 Solution Details

The following requirement domains have been addressed in dedicated publications:

4.2.3.1 Functional, Operational and Economic Requirements

Usability & Accessibility.
In paper II an ”End-to-End Infrastructure for Usability Evaluation of eHealth Applications and Services” has been described that was set up and used to support the User Centered Design (UCD) approach for the design, development and test of the field trial system [Appendix C; pp. 147-161]. A central requirement for that infrastructure was the possibility to simulate both the Point-of-Care and the Health and Care Service Provider environment, and to study usability aspects of different, co-operating user groups in interactive test scenarios. The infrastructure has been utilized for the usability evaluation during the design and development of the proof-of-concept solution, and for the testing of the user interface components of the trial system. This allowed to verify on the one hand the proposed and established infrastructure for usability evaluation of interactive use case scenarios with different user groups. On the other hand it supported the validation of the user centered (UCD) design approach.

4.2.3.2 Legal and Regulatory Policies

Security & Privacy.
Paper III studies aspects of ”Security, Reliability and Usability of mHealth Environments”, and describes solutions for specific mHealth use case scenarios [Appendix D; pp. 165-192]. The prototyping and verification of the solutions for three different use case scenarios has led to the recommendation to use a general open, standards-based infrastructure for the development of new mHealth solutions and services, and to follow the approach proposed also for the reference design in this thesis. One main finding has been the trade-off between security and usability: increased security (as e.g., more complex passwords for user authentication) can lead to reduced usability; high usability on the other side must not lead to compromises of security and privacy protection.

In paper V requirements and solution approaches for ”End-to-end Security and Privacy Protection for Co-operative Access to Health and Care Data in a Telehealth

Trial System for Remote Supervision of COPD-Patients" have been proposed [Appendix F; pp. 203-223]. Identified design limitations of the security concept and initial results from the trial system operation (developed as part of this project) are discussed. In particular the foreseen utilization of personal application devices (as smartphones and tablet-PCs) for downloadable healthcare applications will put high security requirements on the HIS infrastructure, to protect against potential vulnerabilities or attacks from patient devices.

Reliability, Robustness, Availability.
Paper III ("Security, Reliability and Usability of mHealth Environments") explains solution approaches to increase the reliability of mHealth infrastructure components, in order to safeguard the operation of (potentially) vital monitoring devices and alarm services in the situation of outages of electrical power, loss of connectivity to communication networks or their complete failure, or malfunction of certain mHealth devices. The proposed approaches include *Self-Monitoring*, *HW Redundancy*, *Power Fallback*, *Connectivity Fallback*, and *Capacity Adaptation* [Appendix D; pp. 165-192].

Interoperability and Interworking.
Paper I has discussed "Aspects of Standardisation for Point-of-Care Solutions and Remote Home Monitoring Services" [Appendix B; pp. 131-144], which are essential to provide for interoperability and interworking in the health sector.

4.2.4 Test System and Field Trial

The EU-project United4Health [100, 101] (2013-2015) was initiated with the aim of large scale deployment of telemedicine services for patients with chronic conditions as Chronic Obstructive Pulmonary Disease (COPD), heart failure and diabetics, and a trial system was implemented to study those services at scale and their adoption in routine care. The development of this system has followed to a large extend the proposed solution approach described above. Hence, the evaluation of the trial system also covers the validation of the solutions for those requirement domains realized in the trial system.

According to the regulations in Norway, patients discharged from acute hospital treatments are transferred to the municipality health and social care services. A new telehealth solution was developed according to the need for collaborative care across organizational borders, and according to the Norwegian health data security regulations. An overview of the solution architecture is illustrated in Figure 4.3.

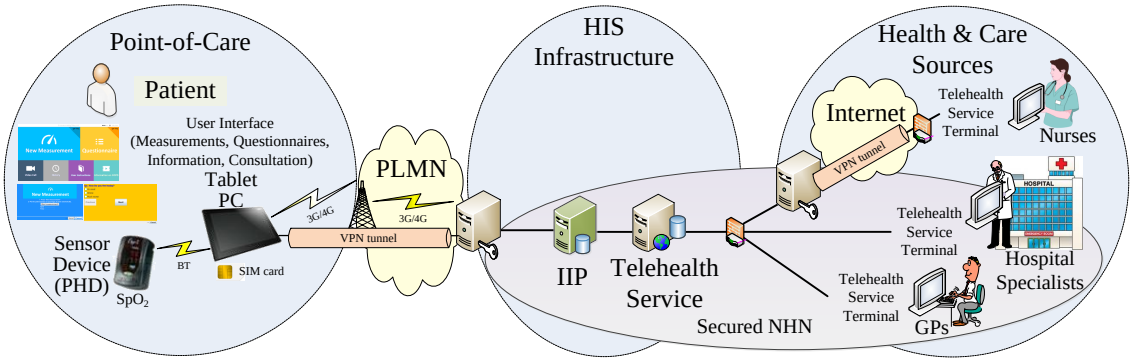

Figure 4.3: United4Health Trial System: Solution Architecture [paper IX, Appendix J]

In the following the use case scenario and requirements for the remote monitoring and follow-up support of home-based COPD patients as realized for the field trial are briefly explained. Furthermore, the main components along the major domains of the system are described, which are required to assess, transmit, evaluate and provide information from the Point-of-Care (typically the patient's home), via the Health Information Service (HIS) Infrastructure, to the Health & Care Sources environment, where the information is utilized by trained nurses, GPs and medical specialists.

The clinical protocol for the trial system is explained in paper IX [Appendix J; pp. 263-302; section 2.1].

An overview of the trial system services is shown in Figure 4.4.

The main purpose of the trial system was to support the primary care of home-living COPD patients by telehealth nurses. The support allowed to remotely and continuously monitor the health status of the patient, and to provide decision support information for the follow-up treatment. Furthermore, the system facilitated the inter-organizational cooperation of the telehealth nurses with GPs and medical specialists in hospitals, by making the patient's monitoring data available for further diagnosis support and treatment recommendations.

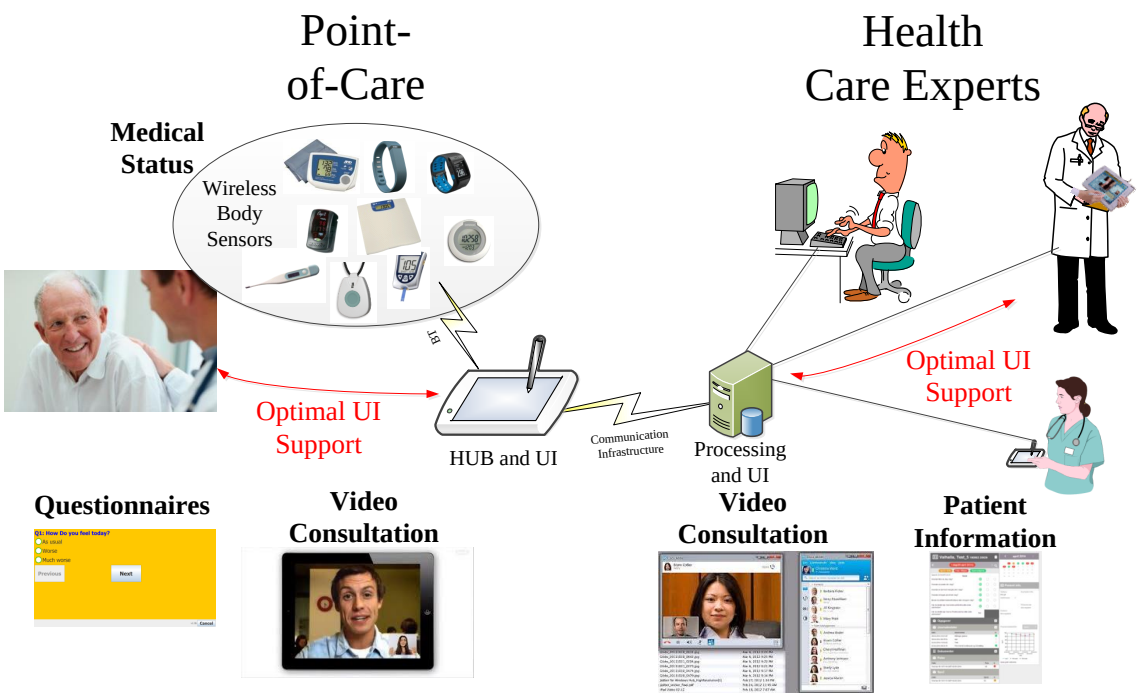

Figure 4.4: United4Health Trial System: Service Overview

The patients were instructed to perform a daily measurement of pulse and SpO_2, and in addition to fill in a daily questionnaire, where the patients had to answer seven pre-selected questions on symptoms focusing on general well-being, breath, sputum, sputum colour and use of extra reliever medication/nebulizers, extra oxygen, antibiotics or steroids. According to the general U4H protocol, the recorded data were assessed with algorithms to calculate the health status level based on defined cut-off values. An ”alert” was notified to the telehealth nurses if the recorded pulse rate or the oxygen saturation was above or below notable or critical thresholds. The telehealth nurses could contact the patients through an integrated video consultation service, on a regular basis at defined timeslots, or if required for example to clarify the status and to give immediate adequate support.

In order to make the self-measurement and –reporting process easy and user-friendly, the development of the tablet PC application, in particular of the interaction flow and the user interface (UI) design, had followed a User-Centred Design (UCD) approach [6]. For the usability evaluation a dedicated usability evaluation infrastructure for eHealth applications and services [paper II, Appendix C; pp. 147-161] had been established.

4.2.4.1 Ascertainment of Health Status

For the measurement of pulse and blood oxygen saturation (SpO_2), a fingertip pulse oximeter was utilized as Personal Health Device (PHD). Bluetooth communication technology was used for the transmission of the measured data from the PHD to the patient application on the tablet PC (see also Figure 4.3). By selecting "New Measurement" from the main screen of the tablet PC application (Figure 4.5), the patient was guided stepwise through the measurement process (Figure 4.6).

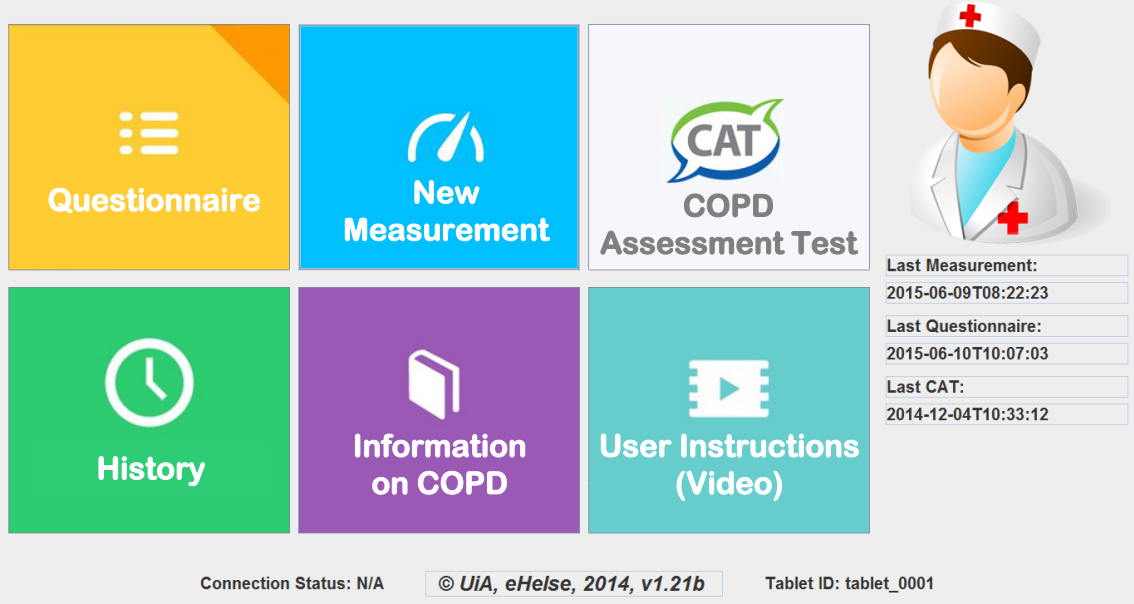

Figure 4.5: Main Screen of the tablet PC application

Pressing "Start measurement!" (screenshot 1 in Figure 4.6) activated the Bluetooth communication with the sensor device, which had to be configured as part of a one-time configuration phase, and which was initialized at start-up of the tablet PC. When the patient had put the sensor device on his finger (screenshot 2 in Figure 4.6), the measurement started and the data consisting of a pair of pulse and SpO_2 values were transmitted to the tablet PC application. The measured data were then shown in the application UI (screenshot 3), and the patient could actively initiate the data transmission to the Health Information Services (HIS) infrastructure by pressing "Send". For later evaluation and presentation purposes, each value pair was complemented with the exact date and time as well as with an identifier. At the same time the data was also stored in the application's database, from where the patient could retrieve it at any later time with the "History" function from the

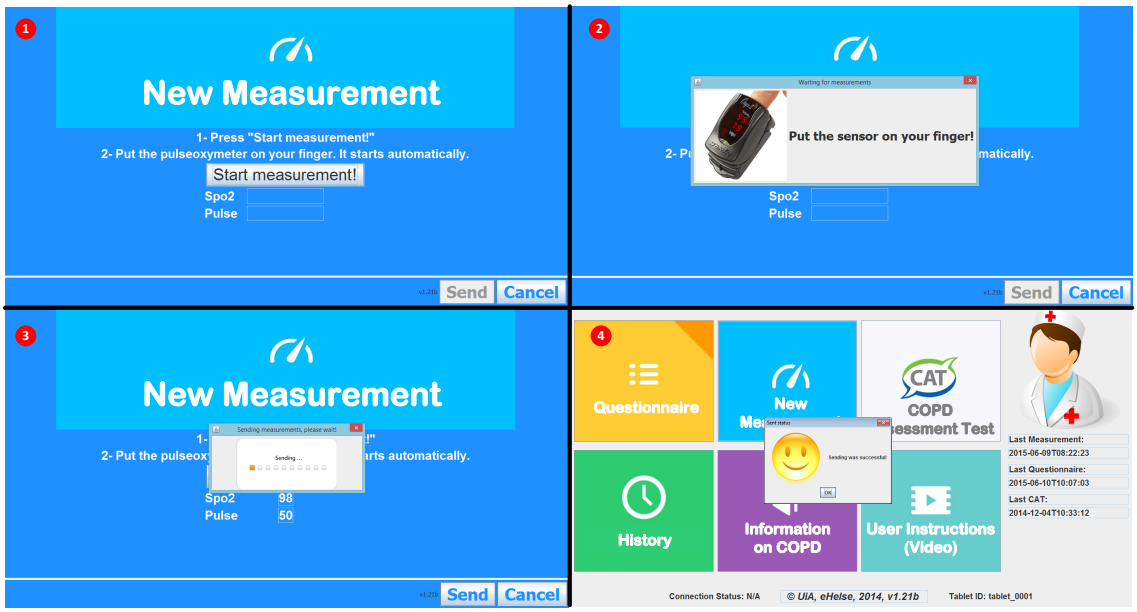

Figure 4.6: Measurement User Interface of the tablet PC application

main screen (Figure 4.5). Upon successful transmission, the ”New Measurement” UI was closed, and the patient was informed accordingly on the main page (screenshot 4 in Figure 4.6).

A questionnaire for the self-reporting of COPD-related health symptoms was implemented for the trial system, with seven questions, that should be answered by the patient on a daily basis.

Pressing ”Questionnaire” on the main screen of the tablet PC application (Figure 4.5) started a dialogue along the seven questions of the ”daily questionnaire”. There was a separate screen for each question (screenshot 1 in Figure 4.7 shows for example the screen for the first question), and at the end of the dialogue the patient could review all answers (screenshot 2 in Figure 4.7). Pressing ”Send” initiated the local storing of the questionnaire answer values - complemented also by the exact date and time and an identifier in the tablet PC application, and the transmission to the HIS infrastructure, which concluded again with a corresponding status information for the patient (as in screenshot 4 in Figure 4.6).

4.2.4.2 Transmission of Monitoring Data

A key requirement for the development of the remote monitoring system was the secure, reliable and fast transmission of monitoring data from the patients’ tablet

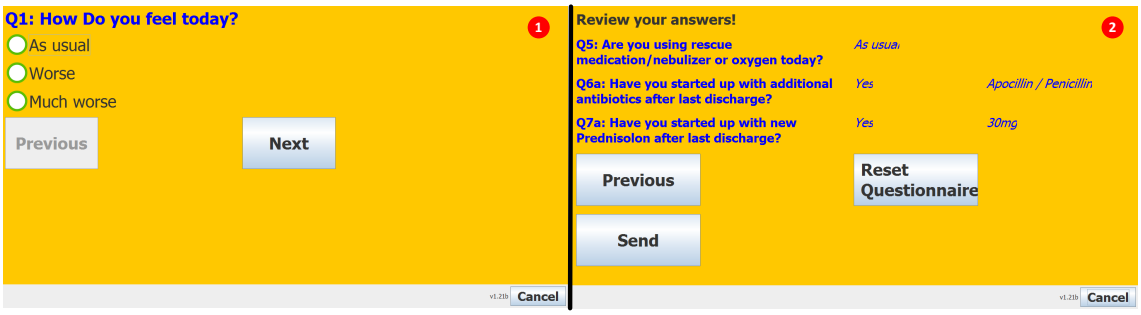

Figure 4.7: Daily Questionnaire User Interface of the tablet PC application

PC devices in their Point-of-Care to a Telehealth Service in the HIS Infrastructure (Figure 4.3). The Information Integration Platform (IIP) [102] received the monitoring data from all patient tablet PC devices, and forwarded it to the Telehealth Service. The Telehealth Service evaluated the Monitoring Data (refer to section 4.2.4.3 below) and provided it with additional decision support information to the health & care professionals (telehealth nurses, GPs, and specialists at a hospital) through a Web-based interface to their Telehealth Service Terminals.

For the deployment and operation of services within the secured Norwegian National Health Network (NHN), a ”Code of Conduct for information security in the healthcare and care services sector” [103, 104] had to be followed. In line with that, a Virtual Private Network (VPN) tunnel was established between each patient tablet PC device and a VPN gateway node at the NHN through the Public Land Mobile Network (PLMN). This provided for an encrypted data communication through a public wireless broadband network of 3rd or 4th generation (i.e. UMTS / 3G or LTE / 4G). On top of that, Transport Layer Security (TLS) was utilized between the patient application on the tablet PC and the IIP in the HIS infrastructure by using the HTTPS protocol [105] for the data transmission.

The Telehealth Service Terminals used the HTTPS protocol for the secure communication with the Web-based interface of the Telehealth Service in the HIS infrastructure. At login to the service portal, the health and care personnel had to authenticate themselves as basis for the Role Based Access Control (RBAC) [106, 107] carried out by the Telehealth Service. While the IT infrastructure of hospitals was operated directly as part of the NHN, the telemedical centre and the GPs were operated by the local municipalities. Due to corresponding IT security guidelines, the Telehealth Service Terminal(s) of the telemedical centre and the

GPs had to establish a VPN tunnel connection through the public Internet to the NHN. Figure 4.8 (created by *Sykehuspartner*, the IT operator of the NHN infrastructure) illustrates the deployment of the U4H trial system components and the link to the NHN. (Translation of names: *Pasient* = patient; *Sykepleier* = telehealth nurses at telemedical centre; *Fastlege* = GP; *Specialist SSHF* = specialist at the Sørlands Hospital; *Felles Nasjonal* = NHN backend infrastructure; *Forløpsjournal* = Telehealth Service).

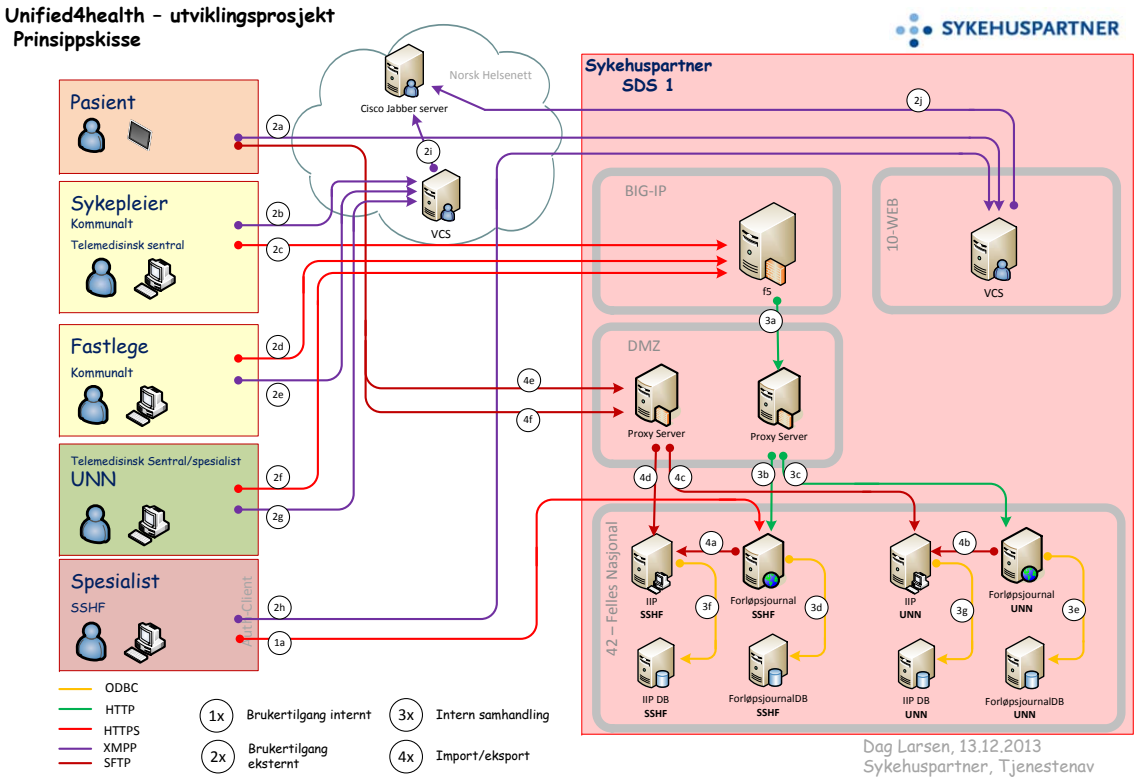

Figure 4.8: Deployment Diagram of U4H Trial System in Norwegian National Health Network (*by Sykehusparner, 2013*)

A dedicated study of "End-to-end Security and Privacy Protection for Co-operative Access to Health and Care Data" had been carried out accompanying the development of the U4H telehealth trial system [paper V, Appendix F; pp. 203-223].

4.2.4.3 Evaluation of Data and Provision of Decision Support Information

The Telehealth Service received, aggregated and evaluated all monitoring data reported by each patient, in order to provide immediate status information as basis

for the individual follow-up and treatment by the telehealth nurses and other involved health and care professionals as the patients' General Practitioners (GPs) and COPD specialists at the hospital. The personalized assessment of the health status of the patient is explained in detail in paper IX [Appendix J; pp. 263-302; section 2.2.3].

All monitoring data from each patient was provided to the telehealth nurses and other involved healthcare professionals through a user interface of the Telehealth Service. A few combined screenshots of that service UI are shown in Figure 4.9.

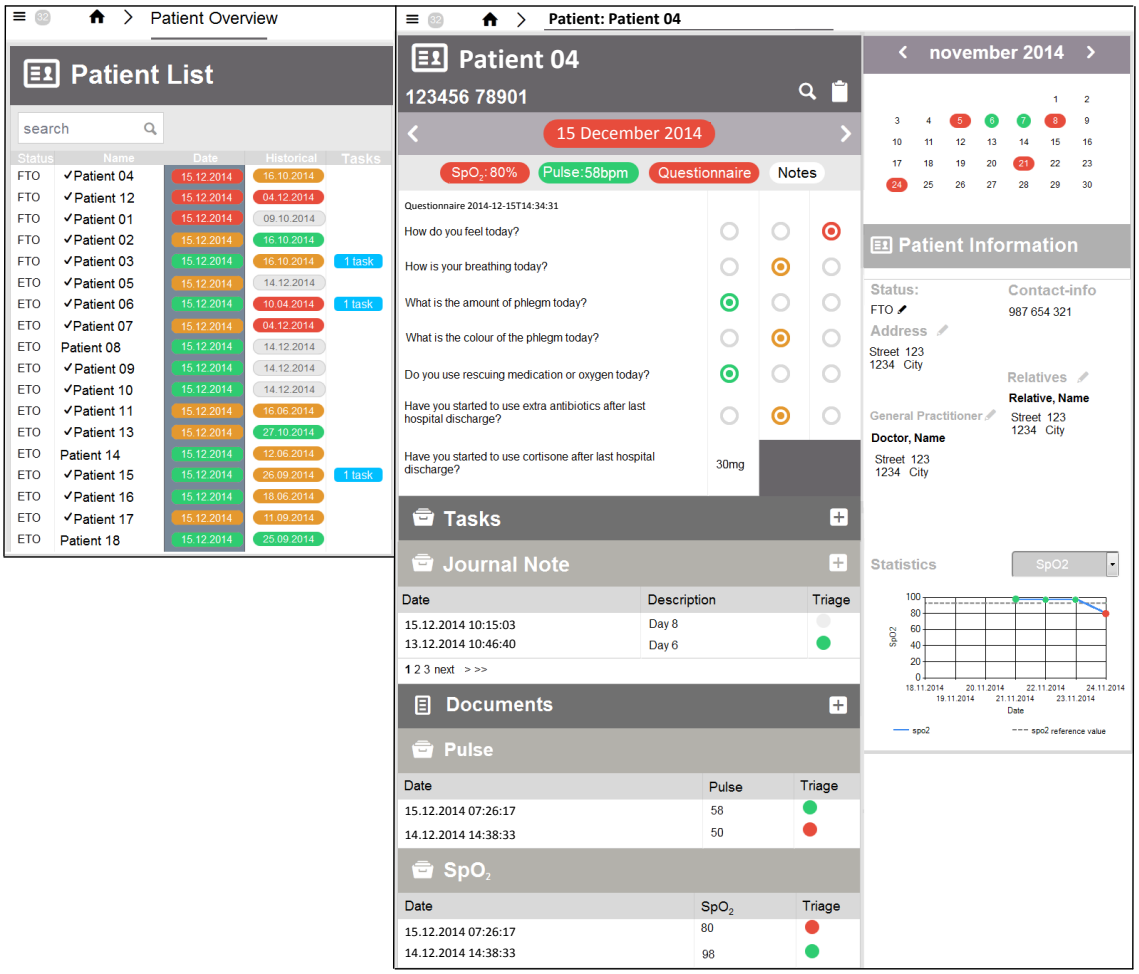

Figure 4.9: Screens for Monitoring Data and Decision Support Information

The outcome of the health status assessment was utilized to support the nurses in the prioritization of the patient follow-up, i.e. the decision about most urgent actions, including the initiation of immediate phone or video calls with patients to check their individual condition and needs, and the involvement of GPs or even

emergency support. For that, the ”Date” field in the ”Patient List” overview (area ”1” on the left side of the UI screenshot in Figure 4.9) was highlighted with the colour code representing the overall health status assessment level of all monitored patients, utilizing the latest received data of the ongoing day. The colour code highlighting the ”Historical” field represented the overall health status assessment level of the latest previous monitoring data received in the past. Area ”2” in the UI screenshot showed an individual patient's overview, in this case of ”Patient 04” for 15th December 2014. Again, the date is highlighted with the colour code corresponding to the overall health status assessment level, which is ”red” = critical in this case. Furthermore, the latest pulse-oximetry measurements, ”SpO_2: 80%” and ”Pulse: 58bpm” were shown, highlighted with SpO_2 assessment level ”red” and pulse assessment level ”green”, respectively. The field ”Questionnaire” was highlighted with the colour ”red” corresponding to the daily questionnaire assessment level, followed by the questions and the colour code for each answer value.

4.2.4.4 Trial Operation

An important aspect of the execution of a field trial is the operation of the trial system and its components during the trial. The IT department of the *Sørlandet sykehuset* (southern-Norwegian hospital) in Kristiansand had the responsibility for the equipment and technical support during the trial. The involved IT administration personnel was part of the trial system development team, and during the trial execution there was a close contact between the trial system operators and the scientific team, that was in charge of the system development and realization.

The equipment set for the home monitoring was used by each patient participating in the trial for typically one month. After that period the equipment had to be prepared for the next trial participant, as there was not one equipment set for each patient. For the personalization of the monitoring equipment set, a user account had to be created on the patient tablet PC, corresponding to a patient account in the telehealth system for the analysis and provision of health status and decision support information for the telehealth professionals. An anonymized identifier was transmitted from the patient tablet PC application together with the monitoring data to the IIP and further to the telehealth service. Only there the data could be linked to the corresponding patient, in order to provide for privacy protection of the data

during the transmission through the system.

The pulseoximetry sensor was connected to one specific tablet PC device, which had to be done only once, independent from the particular patient using that tablet PC. Also the configuration of security credentials in the tablet PC device and the VPN server in the HIS was done on equipment level, and did not have to be changed when the tablet PC was configured for another patient. When the participation phase of a patient in the trial ended, the complete user account with all locally stored monitoring data was deleted.

Chapter 5

Results and Discussion

The goal of this project was a reference design for the end-to-end ICT solution architecture of an eHealth system under consideration of functional, operational and socio-economic requirements as well as legal and regulatory policies. The system is intended to support remote monitoring of health and wellness symptoms and the automatic provision of decision support information for the management of health and disease.

5.1 Overview and Discussion of Results

5.1.1 Functional, Operational and Economic Requirements

Smart Assistance for efficient Decision Support.
The aim of the sought telehealth system for patient monitoring is to offload nurses from routine monitoring of patient status through automatic data assessment and pre-computing of information about patients' health status level. This should provide healthcare professionals with decision support information for patient recommendations and for the prioritization and planning of follow-up interventions. A key evaluation question is then whether the proposed solution effectively offloaded the telehealth nurses without compromising or reducing patients' safety.

The effectiveness of the decision support has been assessed in a field trial for the remote monitoring of Chronic Obstructive Pulmonary Disease (COPD) patients. Between 2014 and 2016, 94 patients have used the proof-of-concept system that had been implemented based on the solution proposals of this study (refer to

section 4.2.4). The main results have been published in paper VIII [Appendix I], covering participation duration of the patients in the study, their reporting rate and completeness, the development of the determined health status levels during the trial participation, and the accuracy of the health status level assessment. Further results and conclusions from the field trial are documented in paper IX [Appendix J].

The decision support functionality in the trial system is based on the automatic evaluation of the collected monitoring data, and the determination of a colour-coded health status level. The telehealth nurses get an up-to-date overview on their telehealth terminal of the latest health status of all their patients. They could manually overwrite the automatically calculated health assessment levels, based on their experience with the health condition of each individual patient, or after a phone or video consultation. In total, approx. 10% of the assessments were modified (i.e. 101 of the total of 990 "patient-monitoring-days"), 9% were impossible to assess due to lack of reported data, and about 81% were unchanged.

The support for the nurses in their monitoring work can best be demonstrated by the number of patients that were automatically assessed as "green", meaning a stable condition. From 33 patients monitored continuously for 30 days, 46% were automatically assessed as "green", 28% as "yellow" (= notable), and 19% as "red" (= critical condition) (Figure 5.1).

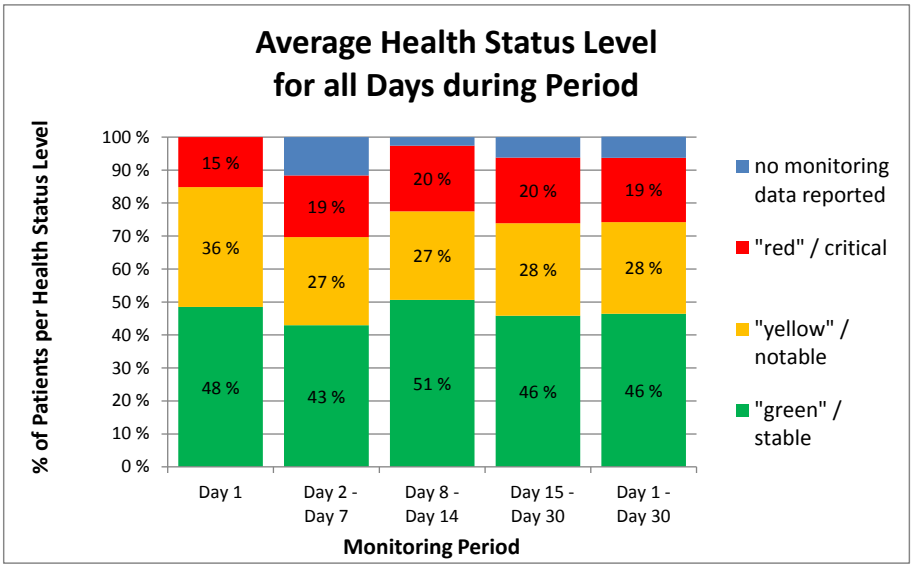

Figure 5.1: Unadjusted Average Health Status Level during selected Monitoring Periods

After manual adjustments of the patients' health status assessment by the telehealth nurses, even 53% of the health status levels were "green" (Figure 5.2). That means that more than half of all assessments were "green" (= stable) and also reliable. Correspondingly the nurses did not have to check actively the status of half of their patients, which was indicated as "stable" on the telehealth service terminal following the patients' reporting.

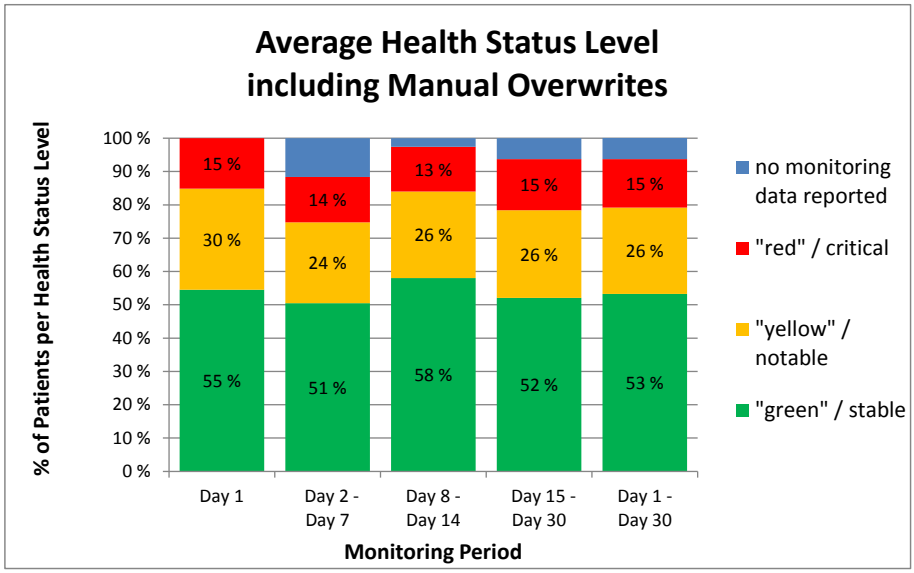

Figure 5.2: Adjusted Average Health Status Level including Manual Overwrites by Telehealth Nurses

The patients could self-report measurements and symptoms at any time of the day, also repeatedly. The nurses always got the latest health status assessments from the system, based on the latest reporting. This also led to an increase of patient safety due to a lower risk that nurses missed a worsening or critical health status, which could otherwise have appeared after a single daily manual health status check.

The main efficiency gain is that nurses only have to check and follow-up on the "yellow" and "red" status patients, giving them more time to take care for those patients who need most support. From the perspective of economic efficiency (the evaluation has been out of scope of this thesis), each nurse might, on average, be able to monitor a higher number of patients, as "green" status patients don't need a time-intensive personal follow-up.

Some optimization potential of the health status assessment can be seen in the

assessment accuracy, specifically in the reduction of *false-high* alerts. The quantitative analysis of the modifications had shown, that about 10% of the assessment levels were set lower by the nurses, mainly from ”yellow” to ”green” (refer to Table 3 in paper VIII, page 256). In relation to the modified assessment of the health status by the nurses, the automatic assessment by the telehealth service had been too sensitive, causing several unnecessary warnings or alerts. One critical reason for this undesired deficiency of accuracy of the health status assessments is the way cut-off values are determined. Cut-off values define certain health status levels, and are thus crucial for the rule-based assessment. Static, generic cut-off values, as used for example also for emergency medicine triage, are sufficient to trigger emergency alerts. They do not though support more detailed decisions about interventions and treatments to be made by telehealth nurses (or by GPs and medical specialists) with high accuracy and reliability. Instead, cut-off values should be personalized according to the individual health condition and normal (typical) levels of health parameters. Even cut-off values that were predetermined and personally adapted at the beginning of a telehealth monitoring period for an individual patient, did not adapt sufficiently with the dynamic general health conditions of the patients.

In order to keep the patients' security high, a complete elimination of *false-high* assessments interpreted as ”errors” can neither be seen as possible nor as necessary. A proportionately small number of ”yellow” or ”red” alerts that have to be checked by nurses although their status is OK will be admissible.

Flexibility, Adaptability, Expandability, Scalability.
The solution needs to show that it can address the monitoring needs of different groups of patients and their healthcare service providers, that it can be evolved with new services, that it can support different monitoring and application devices, that it can utilize different communication channels and that it can handle future growth.

The focus of the trial system for the remote monitoring field trial of COPD-patients (see section 4.2.4 and paper IX [Appendix J]) was on the demonstration and validation of concrete aspects of the implemented patient application and decision support service which are specific for this patient group and their healthcare providers. However, future patient support applications and decision support

services should provide the *Flexibility* and *Adaptability* to address also the data collection and analysis needs for other patient groups. The *Flexibility* and *Adaptability* of the solution also for other patients group was not validated as part of the field trial, and it is analysed and discussed theoretically here.

The sensor integration and the patient support logic and interaction flow implemented in the patient monitoring application for the COPD-patients include only the specific data measurements and questionnaires required for the health status assessment of these patients. Correspondingly, the *Flexibility* for an adaptation or configuration to the monitoring and support needs of other patient groups is low. In other words, the tablet PC application is not portable for other patient groups, because it would require major re-design work.

To avoid the development of tailor-made monitoring and support applications for each target user group (i.e. for any citizens in their specific desire to manage health and disease), a more flexible and adaptable application platform would be desirable.

The solution and deployment architecture for the end-to-end data transmission through the communication infrastructure into the HIS environment is transparent to the transmitted data, and can hence be adapted to other types of monitoring and support data. The health status assessment algorithms implemented in the telehealth service can be enhanced and adapted to the data analysis and decision support needs also for other patient groups. The healthcare service providers can access the monitoring data and decision support information via telehealth terminals from any healthcare environment. This solution is independent from any specific target patient group or from the devices and applications used in the point-of-care environment. That means, that the proposed HIS infrastructure can be flexibly enhanced to support other patient groups, as well as to fulfil the future support needs of other healthcare service providers.

Looking at the *Expandability and Scalability* of the proposed solution design, the services deployed in the HIS infrastructure can be scaled up as needed according to the number of patient monitoring devices and the amount of monitoring data transmitted. Additionally, the capacity of the telehealth services in the HIS infrastructure can be expanded according to the number of telehealth professionals using the telehealth service via distributed telehealth terminals in the healthcare service providers environments.

Usability & Accessibility.
All applications and services of the proposed system for remote monitoring, recommendation and decision support shall provide a high level of usability and accessibility for each involved user group, so that its capabilities and functionalities can be fully utilized.

To achieve high usability of the telehealth trial system as a whole, the iterative design, development and testing of the COPD remote monitoring application and of the telehealth service had followed a User Centered Design (UCD) approach. The UCD is illustrated in Figure 2.6 and has been described and evaluated in separate publications [6, 40].

For the usability assessment of the patient application and telehealth service realized in the trial system, a dedicated end-to-end infrastructure for usability evaluation of eHealth applications and services in a laboratory environment had been established and published in paper II [Appendix C]. The UCD led to iterative refinements of the user interfaces, and final usability evaluations showed positive results on the ease of use and user satisfaction regarding the interaction with the application and the service.

As an enhancement of the state-of-the-art, the ”Design & Development” step of the general Design Science Research Methodology (DSRM) process model ([2], section 2.3) should be enhanced by the User Centered Design (UCD) process as illustrated in Figure 5.3, to ensure a high level of usefulness, usability and user acceptance.

5.1.2 Legal and Regulatory Policies

Security & Privacy.
The protection of security and privacy is a fundamental objective particularly of telehealth systems for remote patient monitoring. The transmission, storing, processing and provisioning of personal medical data puts high demands on the integrity, availability and confidentiality of all information system resources. The security and privacy solution implemented in the trial system was in line with the Norwegian ”Code of conduct for information security in the healthcare and ser-

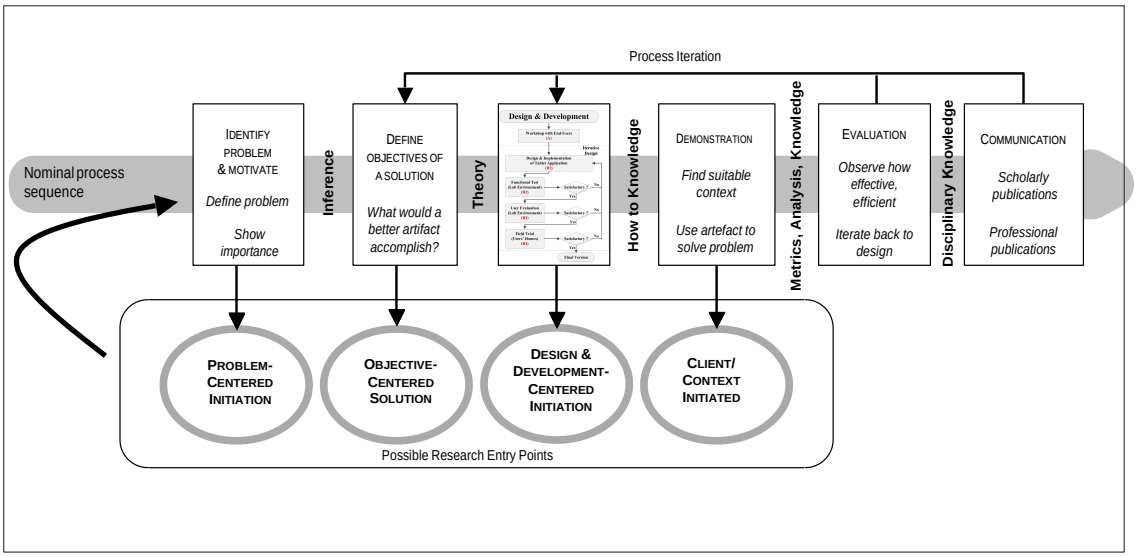

Figure 5.3: Design Science Research Methodology (DSRM) process model [2] with User Centered Design (UCD)

vices sector" [99], which was the requirement to get the approval for the deployment of the system within the Norwegian National Health Network.

A study of "End-to-end Security and Privacy Protection for Co-operative Access to Health and Care Data in a Telehealth Trial System for Remote Supervision of COPD-Patients" has been published in paper V [Appendix F]. The solution is based on state-of-the-art authentication and authorization mechanisms. All users - patients and healthcare professionals - must authenticate themselves with individual username/password pairs. A patient is authorized by the tablet PC monitoring application by Discretionary Access Control (DAC; possible types of access to applications and data on the device are granted discretely for each registered and authenticated user), while the authorization of the healthcare professionals by the telehealth service is based on Role-Based Access Control (RBAC; possible types of access as read, write or delete access to resources of the telehealth service are regulated based on common "roles" of individual or groups of users).

Although the user authentication by username/password pairs is acceptable as basis for access control mechanisms, it has practical limitations and risks:

- For elderly patients with health-related limitations (as e.g. dementia) it is practically difficult to remember their credentials (i.e. a username, and a password or identification number). Thus, security credentials often have to

be shared with their professional (formal) healthcare providers, or with informal caretakers (as family members). This significantly reduces the privacy protection.

- Under certain conditions patients will not be able to authenticate themselves by typing a username/password credential pair into a device, but will require assistance or even emergency help. For instance, patients with reduced sensory or motoric abilities can have problems to type their credentials into the application device (e.g. a tablet PC). Patients lying on the floor after a fall, or being suddenly physically immobile for other reasons, cannot even reach the support device, though they can still shout for help.

- The day-to-day operation in professional healthcare environments (as a telehealth service center, a hospital, etc.) has practical limitations for the authentication of each individual healthcare professional. Telehealth service terminals are often shared by many people. To avoid time-costly authentication operations between changing terminal-users, authentication credentials are shared by a group of staff, compromising individual authentication and access control.

In addition, the technically secure and generally used access control mechanisms for security and privacy protection have limitations:

- Only the owner of the username/password credential pair belonging to a patient's user profile of the application device can get access to the monitoring application, not e.g. a relative or a voluntary healthcare provider.

- Only the healthcare service providers registered in the telehealth system as responsible for the healthcare of a specific patient can get access to the monitoring data and health status information of that patient, i.e. those people that have the "role" to monitor that patient. Even in the situation of a critical health condition of that patient, other healthcare providers could not get access to alerts and patient monitoring data, although the "normal" authorized healthcare providers of that patient are not available or able to help their patient.

Generally, authentication and access control mechanisms should be smarter, meaning based on or adapted to the context and condition. A proposal to improve

the practical authentication limitations of username/password pairs, is to provide the monitored citizens and all medical and healthcare professionals with personal digital certificates, and that the HIS infrastructure carries out mutual authentication based on Personal Key Infrastructure (PKI) technology. Digital certificates for citizens can be stored for example in personal wearable smartcards, that can be read with a smartcard reader from any application device. Certificates for the healthcare professionals can typically be stored in individual employee key cards (which are also a form of smartcards). The utilization of PKI technology for authentication requires a common trust entity. This can be a Certification Authority (CA), as offered publicly on international level, or it can be established on organizational level, as for example just for services within a national health network.

Another proposal for (possibly condition-based) authentication would be to combine biometric identification with corresponding individual certificates. If the citizen had physical access to the device, the identification could take place with an optical or touch-based fingerprint sensor, or the device-camera could be used for face recognition. In case the citizen cannot reach the support device, the microphone could be utilized for voice recognition (potentially combined with certain keywords as *"Help!"* or the name of a caretaker). In all cases the recognized identity would be mapped to a corresponding digital certificate on the device, which would be used for the authentication of the citizen and to get access to a specific user profile of the monitoring application. Furthermore, it is proposed to adapt the access control mechanisms to the severity of a situation or the condition of a patient. In case of an emergency, the provision of fast support to keep the safety of a patient should have higher priority than the privacy protection of the patient's data. The access control requirements for the healthcare providers should be lowered under this condition. Also such "emergency healthcare providers" should get access to a patient's data that do not belong to the common authorized caretakers for that individual patient, and hence are not supposed to be granted access by the role-based access control mechanism.

Still, fundamental ethical guidelines for privacy protection must be kept. Only such information and data required to provide necessary help and support should be shared with others than the authorized healthcare providers, and strict transparency has to be enforced to comprehend who got access to which data and information, when, why, due to which condition, and for what type of access.

As a general conclusion, future authentication, access control and accounting (AAA) systems to provide secure and privacy-protecting access to personal data and medical and healthcare resources should utilize a combination of individual biometric features and digital certificates.

Reliability, Robustness, Availability.
Remote monitoring and support solutions (for example for home-living patients with chronic diseases) must operate at high reliability and availability, so that potentially life-threatening situations and support-needs can be detected continuously at any time of the day. The system shall be able to transmit corresponding alerts to the monitoring staff and healthcare professionals, and give applicable immediate recommendations to the patient.

General aspects and recommendations regarding reliability have been discussed in paper III (”Security, Reliability and Usability of mHealth Environments”, Appendix D). A detailed and systematic test and verification of reliability, robustness and availability solutions was not within the scope of this project. The execution of the field trial for remote monitoring of COPD-patients has not revealed any fundamental reliability or availability risks in the system design. Still, the following two potential causes for service failure have been identified:

- Hardware failure of patient monitoring equipment in the PoC (lack of electrical power due to empty batteries in sensor device)
- Failure of monitoring data transmission (lack of connectivity of patients’ application device due to lack of cellular radio coverage at PoC = patients’ home)

A simple and effective improvement proposal to avoid the ”empty-battery-problem” is to measure and send the battery power level together with the patients’ monitoring data to the monitoring staff, as an early indication that batteries have to be replaced.

To avoid the ”loss-of-connectivity-failure”, the patient support application should be designed in a way to identify and utilize alternative communication services. If Internet connectivity is available via fixed or wireless local access network (LAN or WLAN), a secured and encrypted end-to-end communication should be established with the health information service (HIS) infrastructure through that

link instead through the default cellular link. The connectivity status may be monitored for example by a *heartbeat* or *keep alive* service, that sends regular test messages from the telehealth centre to the patients' devices in their PoC environments, that have to be confirmed by a defined response message.

Generally, the failure of HW, SW, or communication infrastructure components is a major threat to patient security. Therefore, a future system must include condition monitoring and failure handling as central components. A telehealth centre should be automatically notified about any equipment or connectivity issues.

Interoperability & Interworking.
One main reason for inefficiencies in the healthcare system and for the slow introduction of telehealth technologies is the organizational fragmentation of primary and secondary healthcare service providers, and the administrative and operational separation of their ICT applications, services and the underlying communication infrastructure [27]. The development of ICT solutions without common agreements leads to different information models, syntaxes, semantics, and formats [50, 51].

Standards and guidelines can help to provide for better interoperability & interworking of eHealth applications and services and to overcome the fragmentation of systems and solutions for the different stakeholders of the international and national health systems. A variety of standardization organizations work towards agreements on common data formats, interfaces of communication components and communication protocols for the storage, exchange and processing of health and medical information.

As part of this study, an analysis and discussion of applicable standards has been published in paper I ("Aspects of Standardisation for Point-of-Care Solutions and Remote Home Monitoring Services" [Appendix B]).

The specific interoperability and interworking goals of the realized trial system for remote monitoring and decision support are manifold:

- Off-the-shelf monitoring devices, i.e. pulseoximetry sensor devices from different vendors.

- Monitoring data and decision support information may need to be shared by authorized healthcare professionals, hence enabling the cross-organizational

interworking between the telehealth nurses, general practitioners, and COPD-specialists at hospitals that are responsible for the healthcare of the corresponding patients.

- Utilization of the system across borders between different administrative districts (as municipalities or counties).

The proposed solution for the information architecture (refer to section 4.2.2) follows the results of paper I [Appendix B].

The transmission of measurements from the sensor device to the patient application device was implemented in line with the standards published by the Personal Connected Health Alliance (PCHA) / Continua Health Alliance [71]. By that, sensor devices (as pulseoximetry sensors in the trial system) from different vendors can be used when they are certified according to the corresponding device profile.

The communication of the patients' application device in their point-of-care with the HIS infrastructure, and between the services within the HIS infrastructure follows the HL7 [108] standard for "Fast Healthcare Interoperability Resources" (FHIR) [109]. This provides for the interoperability of the collected monitoring data with other EHR systems in line with the ISO definition (ISO TC 215, ISO/TR 20514,2005) that EHR interoperability is "the ability of two or more applications to communicate in an effective manner without compromising the content of the transmitted EHR".

The trial system implementation of the HL7-FHIR communication has been tested and verified with publicly available FHIR reference services for testing. The integration and interworking with other public EHR systems in the Norwegian national health network (NHN) could not be verified as the planned deployment of HL7-FHIR compliant EHR services is ongoing.

Another limitation of the implemented and tested system is related to the authorization and access control approach. Inter-organizational interworking on national level requires a common security solution for authentication and access control (see also the paragraph on *"Security & Privacy"* above). In order to provide for mutual authentication of services and users to each other based on digital certificates, a common trust entity for eHealth services has to be established on national level, which can be provided by existing certification authority (CA) service providers.

5.1.3 Test Systems and Field Trials

Test systems and field trials for telehealth and wellness management shall verify new technological solutions, evaluate economic aspects, and study social and clinical effectiveness (see also section 3.3 in the state-of-the-art). The evaluation of health information systems shall go along with all phases of the planning, development, implementation, and operation [42].

The test system we built for the Norwegian field trial within the EU project United4Health [100, 101] had to validate and demonstrate specific clinical, organisational, economic, and other outcomes (see also section 4.1.3 on the test systems requirements for more details). Further completed or ongoing studies have utilised the trial system and addressed the non-technical objectives of the trial, which are out of the scope of this thesis.

The evaluation of proposed solutions for the *Functional, Operational and Economic Requirements* and the *Legal and Regulatory Policies* utilizing results from the test system has been described and discussed in the previous sections.

The trial provided insights into additional important aspects for realizing a telehealth solution:

- A close involvement of the providers and operators of the regional or national health network infrastructure is required. Otherwise the deployment of the trial system in the underlying network infrastructure and the integration with other services and applications of the target user groups (particularly the healthcare service providers involved in the trial) will not be possible.

- The experience of the trial system operators and administrators is an important evaluation aspect. The operational feasibility and efficiency of the overall solution depends significantly on the amount, efficiency and usability of operation and maintenance (O&M) tasks. O&M tasks include the configuration, initialization and operation of devices and service required for the trial system. Examples are the administration and preparation of the patient tablet PC devices for new patients, and the administration of new patients and patient devices within the telehealth service.

5.1.4 Further Learnings

Besides the validation of the technical solution, the field trial has revealed further general findings, results and challenges of remote monitoring and automatic provision of decision support information and recommendations.

Data Quality and Patients Behaviour.
The automatic generation of efficient and reliable decision support information requires a high ***Data Quality*** of the monitoring data and subjective symptoms reported by the patient. This particularly refers to the availability of complete and continuous data. In the field trial with COPD-patients, the "Rate of Complete Day-to-Day Reporting" and "Average Reporting Rate [% of Days reported]" (Figure 5.4 and Figure 5.5) indicate the deficiency of complete reporting (refer also to paper VIII [Appendix I]). For example, less than 5% of the patients had sent pulseoximetry measurements and questionnaire responses every day during the first 30 days of their participation in the trial. On average, patients reported monitoring data on 22.5 days (75%) during those 30 days.

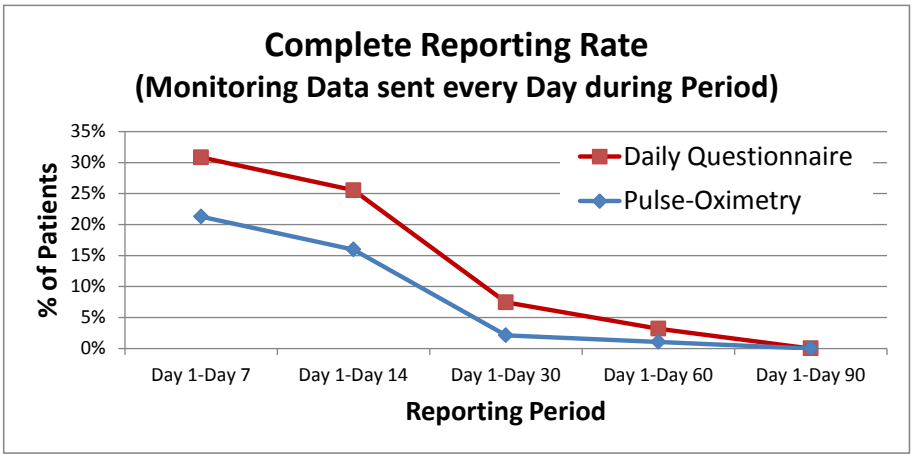

Figure 5.4: Rate of Complete Day-to-Day Reporting

The User Centered Design (UCD) approach achieves a high usability of the patient monitoring and support application. Usability difficulties as well as technical problems that still occur during the operation of a system after the field trial shall be collected and addressed in iterative improvements and updates of the system during its life-cycle.

The field trial has otherwise also revealed that some patients did not report

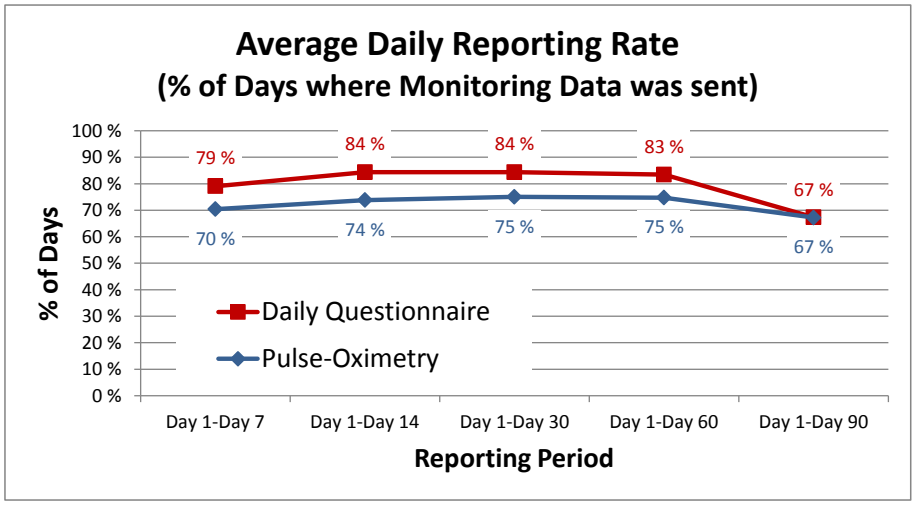

Figure 5.5: Average Reporting Rate [% of Days reported during Reporting Period]

monitoring data when they felt well and healthy, because they - subjectively - did not need any support from their healthcare providers. An improvement proposal would be that the system, via the patient support application, reminds the patient to report measurements and questionnaire answers. The reminders should be - in line with other patient support interactions - user friendly and adapted to individual accessibility needs and preferences.

To find solutions for increased completeness of monitoring data, the reasons for a lack of reporting continuity should be understood better, and are hence subject for further research. Also methods are required that allow a decision support system to interpret a lack of monitoring data appropriately: does it mean the patient feels ”too well” to see the need for reporting, or does it mean the patient is ”too bad” to be able to report?

Rule-based Data Analysis vs. Adaptive and Learning Algorithms.
Given that regular monitoring data is available, the field trial has shown that the implemented algorithms in the system are feasible to support the provision of personalized support by professional healthcare services in an efficient way. The results disclose on the other side also that the ***accuracy and reliability of the health status assessment*** and the determination of corresponding alerts are not reliable to the desired level.

A reason for that has been identified in the conceptual limitations of ***personalization*** of the rule-based evaluation and assessment approach of monitoring data.

The rules depend on thresholds and cut-off values, which are typically (as in emergency medicine) fixed and uniform. While such thresholds for certain measurable life sign parameters has been proven to be convenient and advantageous to detect critical conditions and to trigger alerts, they have disadvantages for the continuous long-term monitoring of citizens in their every-day-life, and to provide suggestions and recommendations for more fine-grained individual recommendations regarding medication and other interventions and activities.

Another uncertainty is the user behaviour. The daily questionnaire provides only limited information whether the users have understood the given recommendations, how they have acted and followed the advices given, and whether the interventions (e.g. changes of medication) gave the expected improvements to the patients' health status. This feedback would be important for the healthcare professionals and for automatic decision support systems.

An evolved system should be able to ***learn*** which thresholds of objectively measured and subjectively reported parameters reflect a *good* or a *bad* condition of the citizen. Furthermore, such a system should be able to ***adapt*** recommendations based on the experience from the impact of specific activities and interventions on the individual citizen in the past. The ***smartness*** of such a system would be embodied by the adaptation of the data assessment to the individual wellbeing condition, and the personalization of recommendations and decision support information according to individual needs, preferences, and known triggers for advances.

Besides the adaptation of the data evaluation and decision support algorithms to the individual citizen's condition, also the applications to support the measurement of life-sign values with sensor devices and the self-reporting of health symptoms (e.g. with surveys) should be efficiently adaptable to the monitoring and data collection needs of the individual citizen. Citizens belonging to different groups of chronic patients for example have different support needs, and their healthcare providers have corresponding monitoring needs. Specific applications and services targeting one specific patient group do not provide for the adaptation of HW and SW to the specific monitoring and support needs of other patients. A system that provides for the ***personalization and adaptation of HW and SW*** to the citizens' individual needs and preferences allows or more efficient development and operation of monitoring applications and services for all involved formal and informal healthcare providers.

A more detailed proposal for an evolved system approach utilizing machine learning and AI technologies is subject of the "*Conceptualization of a Personalized eCoach for Wellness Promotion*" (paper X, Appendix K).

Users and Technology Acceptance.
A fundamental need for the successful adoption and utilization of eHealth systems is the acceptance of the solution in the long-run by all involved users.

Neff wrote in her article "Why Big Data won't cure us (2013)": *"The biggest challenge for the use of "big data" in healthcare is social, not technical. Data-intensive approaches to medicine based on predictive modelling hold enormous potential for solving some of the biggest and most intractable problems of health care. The challenge now is figuring out how people, both patients and providers, will actually use data in practice."* [110]

The acceptance of technology by the users depends to a large degree on the human-machine interface for the interaction of the users with the technology behind that interface. Correspondingly, aspects that are important for the technology acceptance should be part of systematic usability and user friendliness studies, and the results have to be considered in the design of user interactions and interfaces.

One highly relevant aspect for the user acceptance is ***security*** and particularly the ***privacy protection*** of personal information. In this context, a relevant question was identified: *How does the **perceived security** relate to the **real, technical security** of an application or service?* Independent from the *"real"* implementation and verification of security and privacy protection mechanisms within an application and the ICT infrastructure, the user acceptance eventually depends on how secure the application or service appears to the users through the user interface presented to them. Hence, the development of a system does not only have to aim for the verification of *"real security and privacy protection"*, but it must also aim for *"user acceptance of the perceived security"*.

Another related aspect is that end-users may compromise on usability and security, if their need for the system affects their chances to survive. This would be a personal, well-informed decision, which has to be taken by each patient in advance of a potential emergency case, and based on the explanation of all involved risks.

Users and Trust.

An essential question regarding the successful adoption of eHealth systems for citizen support with automatic recommendations is whether patients (and citizens in general) will ***trust*** a *virtual* doctor, nurse or coach. How will citizens accept and follow recommendations from an application or services, compared to receiving those recommendations from a human healthcare provider? Technology (and artificial intelligence in particular) is a corner stone already in medical research, and also in clinical decision support systems (CDSS). Following the results of this thesis, technology can boost the personalization and adaptation of healthcare and individual wellness management.

In a first step, medical and healthcare professionals will get increased and improved decision support by technology solutions. In a second step, great efficiency gains can be expected by providing routine monitoring and support services to citizens directly through technology solutions, without direct involvement of professional healthcare providers. A ***lack of trust*** could be a potential show-stopper for the second step, or at least delay it significantly.

Hence, a high level of trust is needed for the required technology acceptance to successfully introduce automatic support and recommendation services in broad scale. As mentioned before, decision support systems as the one implemented for the trial system can free some time for routine monitoring that the nurses could use to interact more intensely with the patients whenever they needed more intention or healthcare support. Thus improving the patient relations, but also the trust in the healthcare support technologies for remote monitoring and video interaction.

Another important aspect to increase the trust (related also to privacy protection) is to ensure and enforce that citizens own their data, and perceive full control over it. How the citizens will perceive full ownership of their data, how that will be realized within the ICT solutions, and what other aspects influence the trust in eHealth solutions that should be considered in the design and development require further systematic research.

5.2 Revisiting Research Questions and Requirements

Research Question RQ-1

The development of an eHealth system must consider manifold requirements. While

many studies in the literature focus exclusively on one specific requirement domain (e.g. on the "*security of eHealth systems*" or "*usability of eHealth services*"), this study follows a holistic approach for the requirement analysis. In order to do so, all end-user groups had to be involved from the beginning of the design process, and experts from various disciplines had to be involved. The chosen and used methodology was a combination of the Design Science Research Methodology (DSRM) and a User Centered Design (UCD). The methodologies and the methods and tools used for the requirement elicitation / identification are described in sections 2.2 and 2.3. The reference requirements resulting from the corresponding holistic requirement analysis are documented in section 4.1. This addresses research question ***RQ-1***.

Besides giving a detailed overview over the broad spectrum of requirements, the chosen multidisciplinary approach has revealed interdependencies between different requirement domains. High security, if achieved with well-established authentication mechanisms based on usernames and long passwords, can create usability issues for the main user groups. Patients with cognitive or physiological limitations may have difficulties to remember long passwords or to enter them into their eHealth equipment. The daily routine operation of a telehealth centre might make it time consuming and impractical for the telehealth staff to authenticate themselves with individual user accounts and passwords at shared service terminals. Alternative approaches have been proposed and discussed.

Research Question RQ-2

Also the design and development of the reference solution within this project has followed the DSRM combined with the UCD (***RQ-2***). The central involvement of the different user groups in the iterative design, development, test and re-design of system and service components has been a key-aspect of the UCD.

The proposed reference design based on the holistic analysis of the requirements of future eHealth systems is described in chapter 4. Dedicated publications have addressed *Interoperability & Interworking* [paper I, Appendix B], *Security & Privacy* [paper III, Appendix D and paper V, Appendix F], and *Reliability, Robustness & Availability* [paper III, Appendix D]. Section 4.2 describes a holistic reference design for an end-to-end solution architecture based on the solution contributions for each identified requirement domain. This has been published in paper

VII [Appendix H], and answers research question ***RQ-2***.

A central component of the proposed end-to-end reference solution is the information integration component in the health information services infrastructure. It provides significant interoperability and interworking advantages compared to proprietary, closed end-to-end solutions, where monitoring devices for patients are directly connected to a single dedicated service component. The Information Integration Platform (IIP) utilized in the field trial system provides a secure way to distribute defined subsets of the monitoring data to different services providers according to their data requirements and access rights. Professional solutions as the Information Integration Bus (IIB) from IBM [111] support different communication standards, allowing to integrate telehealth devices, electronic health record (EHR) systems and other health information services supporting all different standards. As validated with the trial system, which has been deployed within the national Norwegian Health Network (NHN) infrastructure and operated in three different regions in Norway, the solution architecture allows for an increased cooperation of health information services across administrative borders.

Research Question RQ-3

The main prerequisites for a high and permanent acceptance of a new eHealth support solution by patients is a high usability, accessibility and also trust in the solution.

The different user groups of the target telehealth system for remote patient monitoring and decision support have different usability needs. In order to test the usability of interactive and cooperative service scenarios involving all user groups, a dedicated ”End-to-End Infrastructure for Usability Evaluation of eHealth Applications and Services” has been proposed and established, including dedicated test environments for each user group participating in a test. The end-to-end usability test infrastructure has been published in paper II [Appendix C]. The design and development of the telehealth trial system has followed the user-centred design (UCD) approach (as described above) in cooperation of all user groups from the early requirement elicitation phase, including researchers and students from the university, developers from a vendor of system components, healthcare staff and administrators of the monitoring and decision support service, and patients. Following the usability tests in the lab infrastructure during the early design and

development phase of the system, further tests and usability assessments have been carried out in the patients' homes, i.e. in the target environment for daily use of the telehealth equipment. The observations were considered in iterative refinements of the patient monitoring and support application. By iteratively testing, refining and validating usability aspects, the UCD process as such was studied and validated.

Research Question RQ-4

The proposed solutions have contributed to the implementation of a field trial system for a real-world study with chronically-ill patients. The execution of the field trial has led to a substantial data collection. The field trial system and the results from the data analysis have been extensively documented in paper IV [Appendix E], paper VIII [Appendix I], and paper IX [Appendix J].

The analysis of the data supported the validation of the proposed solution aspects. The decision support information provided to the tele-nurses had correctly indicated a "green" (= normal and stable) status of more than half of all daily patient assessments. Correspondingly, due to the support by the system, the nurses did not have to check actively the status of about half of the monitored and assessed patients, giving them more time to take care for those patients who needed more care and support.

Furthermore, the analysis revealed details about issues and limitations of the initial design that were used as input for the conceptualization of an improved design. This improved design has also the potential to complement existing solutions with a similar scope. The *Mining Minds* framework [112], for example, pursues to complement the role of specialists by intelligent monitoring and smart coaching mechanisms, while healthcare specialists handle the creation and management of health and wellness knowledge. The evaluation of recommendations provided by Mining Minds requires feedback from coached users. The proposed eCoach conceptualization (see also section 6.3 and paper X [Appendix K]) utilizes the concept of reinforcement learning. In contrast to the Mining Minds system, automatically derived knowledge about the impact of recommended activity and context changes on the wellness status of the user is utilized for the automatic determination of refined recommendations. *IBM Watson* [113, 114] is a cognitive computer system that originally utilizes AI for clinical research, i.e., for the generation of knowledge from analyzing structured and unstructured clinical data. The eCoach

conceptualization requires this type of reference knowledge, and complements the determination of recommendations for treatments and multimodal activities with personalized preferences and optimal impacts.

In addition, the close cooperation of stakeholders (academic researchers, business partners as technology developers and vendors, public healthcare service providers as system operators and users, and the citizens as end-users) in the development and operation of the field trial system has presented advantages for all partners. This *quadruple helix model* has revealed potential to overcome the fragmentation and lack of interoperability of eHealth systems in the healthcare sector.

Finally, the field trial execution allowed to collect continuous monitoring data reflecting the health status progress or exacerbation of the patients. This data contributes to further studies of the effectiveness of the tested telehealth service to support home living patients with chronic illness (such as COPD), and to support healthcare providers in their remote monitoring work. Similar baseline data supporting further comparative studies have (to the knowledge of the author) not been available before in Norway.

Chapter 6

Conclusions and Future Work

The objective of this thesis has been to investigate an eHealth reference solution design that utilizes information and communication technologies (ICT) to support the information exchange between home-living patients and healthcare professionals that are responsible for the monitoring and support of their remote patients.

Health information systems such as *telehealth*, *telecare*, or *remote monitoring* services involve multiple, heterogeneous stakeholder groups, with their specific needs, individual preferences, and different requirements. The design, development, test, deployment and operation of such systems needs interdisciplinary cooperation of all stakeholders.

Cooperation is required on different levels:

Methodology level *Interdisciplinary research* requires the cooperation of researchers with competencies in the very different domains, as e.g. usability and accessibility, eHealth technologies, health and medical care for patients with chronic diseases.

Design, Development and Operation level The solution design, development, test and operation requires cooperation of software designers, healthcare practitioners, IT specialists, data security and privacy experts, human-machine-interaction specialists and more.

The design, development, and evaluation of the specific eHealth trial system within this project has followed an interdisciplinary *User Centered Design (UCD)* process. This PhD project, which has followed all steps of the design science

research methodology, has confirmed the feasibility of the UCD process as a design methodology for this type of eHealth solutions.

The result of the multi-disciplinary requirements elicitation has been used for a reference design, which then has been validated and evaluated through the development, implementation, deployment and operation of a trial system in a life, operational business environment. Both the outcome of the multi-disciplinary requirement elicitation, i.e. the ”reference requirements”, as well as the outcome of the multi-disciplinary development cooperation, i.e. the ”reference design”, are applicable as ”blueprints” for the design of health information systems with similar service characteristics in similar settings.

The evaluation of results from the trial operation have proven that the system provides useful support to the different user groups, in particular to the patients and their professional healthcare providers. Furthermore it has revealed specific findings, potential for improvement, and input for future work.

6.1 Main Contributions

This project has resulted in the following five main contributions:

1. The *User Centered Design process* has been validated as a suitable methodology for the interdisciplinary design and development of eHealth systems (including requirement elicitation, development, iterative test and refinement, trial and evaluation) for multiple different cooperating or interconnected user groups, considering a holistic perspective on their heterogeneous needs.

2. The *Reference Requirements* for eHealth systems offering telehealth / telecare / remote monitoring services. These are holistic requirements from different user groups, including functional, operational and economic requirements with the objective to provide user-friendly support for patients' self-assessment and reporting of their health and well-being status, to provide reliable decision support information for healthcare professionals, and consider also legal and regulatory policies.

3. A *Reference Design* of an eHealth system solution with specific telehealth service characteristics.

4. A prototype system of that reference design, implemented, tested and verified as *trial system in a life business environment*, which can serve as blueprint for systems with similar objectives (while allowing for adaptations to specific requirements of other user groups or other business environments).

5. The *conceptualization of novel approach for personalized healthcare support and self-management of health and disease*, to improve the quality of life of patients, and assisting nurses in supporting patients efficiently.

6.2 Specific Findings

6.2.1 Reference Requirements

The proposed reference design for an eHealth system described in this thesis considers a holistic requirement analysis, which was part of the DSRM Design and Development step, and and was conducted with selected methods as described in chapter 2, section 2.3.5.2.

The reference requirements consist of *Functional, Operational and Economic Requirements*, covering the requirement domains *Smart Assistance for efficient Decision Import*, *Flexibility, Adaptability, Expandability and Scalability*, and *Usability and Accessibility*, and of *Legal and Regulatory Policies*, covering the requirement domains *Security and Privacy*, *Reliability, Robustness, and Availability*, and *Interoperability and Interworking*.

6.2.2 Trial System for Reference Design

A complete end-to-end system has been realized, consisting of end-user devices and infrastructure service components. The trial system focused on the validation of the proposed solutions for *Smart Assistance for efficient Decision Support*, *Usability & Accessibility*, *Security & Privacy*, and *Interoperability & Interworking*.

The system allowed the successful execution of a field trial for the monitoring of more than 120 patients[1] within the context of the European project United4Health.

[1]For the evaluation of the trial system in paper VIII and IX (Appendix I and J), intermediate data from 94 patients could be considered.

The tailor-made realization of the patient-support application addressing the self-monitoring and communication needs of one specific patient group, namely of patients diagnosed with Chronic Obstructive Pulmonary Disease (COPD), has proven the successful fulfilment of the patient-needs by the human-computer-interaction design and graphical user interfaces of the patient support application. This has validated both the feasibility of the User Centered Design process, as well as the Reference Design of the patient application. On the other side it revealed the limited flexibility and adaptability of that solution component to other patient groups and remote monitoring use cases, requiring different interaction of the application with the patients, or other communication flows with the health information services infrastructure.

Besides the validation of the technical solution implemented in the system, the trial system had also been utilized to study further non-technical objectives as the advantages enabled for the healthcare professionals, and organizational impacts related to the adoption of this telehealth service. These separate studies are out of the scope of this thesis.

6.2.3 Security & Privacy

An analysis of security and privacy requirements resulting from legal and regulatory policies has been carried out. The solution implemented in the trial system was based on state-of-the-art security mechanisms and technologies, and was approved for the deployment within the operational Norwegian national health network (NHN) infrastructure. The approval to deploy the trial system in the real-world business environment, following strict legal guidelines for security and privacy protection, confirmed the design of the security solution.

The field trial revealed usability and accessibility limitations related to the authentication mechanisms for patients and healthcare providers based on username-password credential pairs. Improvements for context- and condition-based authentication and access control mechanisms have been proposed, and will be evaluated as part of further work.

6.2.4 Usability & Accessibility

Given the high importance of user-friendliness and accessibility of applications and services for citizens with physical and mental health conditions, the realization of the trial system had followed a User Centered Design (UCD) approach. Representatives from all involved user groups - patients, healthcare professionals and system administrators - were involved from the early design to the iterative development and testing phases. The field trial confirmed the positive impact on usability and user satisfaction, and indicated efficiency gains of the remote supervision and the healthcare provision by the telehealth nurses.

In certain potential emergency situations, the authentication based on manual entry of username-password credentials as well as the access control rules for patients and healthcare staff can lead to reduced usability and accessibility, implying potential safety risks for the patient. Possible improvement proposals have been discussed, and will be tested and validated as part of further work.

6.2.5 Health-Data Evaluation & Decision Support

In line with the clinical protocol for the field trial, the implemented solution supported the continuous reporting of life-sign measurements and self-reported symptoms on (at least) daily basis by the patient. The results from the trial execution indicate the great value of time series of data from long-term continuous monitoring for the automatic assessment of individual patients' health status levels, and the identification of health trends and risks for worsening or potentially critical conditions.

Proposals to improve the reporting completeness by "triggering" the patients with user-friendly reminders to measure and report their monitoring data, or by providing for seamless automatic measurements and reporting without active patient involvement have to be validated through future work.

The evaluation of monitoring data and automatic determination of alerts and decision support information for nurses located in a public telemedicine center facilitated a number of benefits for the nurses. In the first place, routine assessment of the health status could be done remotely, avoiding that nurses had to regularly see the patients physically at their homes, and by that reducing potentially long distance drives and need of time. That allowed the nurses to focus on patients

who required more attention and specific follow-up support. The health status assessment based on generic ”rules” (with to some degree personalized cut-off values) has shown limitations regarding the personalization of the assessment to the individual patient's condition. For increased security, a rather conservative assessment approach was chosen, leading to *false-high* risk assessments (i.e. the health status of a number of patients was assessed as worse than it actually was). A more personalized approach has been proposed and is subject to ongoing research.

6.3 Future Work

6.3.1 User Aspects

To fulfil *Usability* and *Security* requirements at the same time without compromising one of them, more user-friendly authentication mechanisms based on the combination of biometric user identification and personal digital certificates should be implemented and evaluated. The impact of the European General Data Protection Regulation (GDPR) should be studied regarding the privacy protection of personal health-related data and the potential loss of usability or even availability of eHealth support services when strict user consent provision is required. Solutions for user-friendly consent provision and self-configuration should be studied.

The user support application shall be enhanced with user-friendly reminders to increase the reporting completeness by patients. The improved data quality is expected to contribute to accuracy enhancements of the health status evaluation. Also new and upcoming smart watches and other wearable devices should be utilized for a seamless recoding of health parameters, independent from time and location, and without the need of user interaction.

A high level of *user acceptance* is required for the successful launch of the proposed and trialled telehealth solution. The user acceptance depends on how much a user trusts the application or service. The perceived data security and the perceived health support reliability have been identified as important influences on the users' *trust* (p. 94). Hence, the influence of the human-machine-interface (HMI) on the perceived data security and perceived health security should be studied systematically - independently from the real data security.

The integration of *voice interaction* can potentially support both the usability

and availability of eHealth services. Voice-enabled smart homes, featuring products as Amazon's Alexa, Google Home, Apple Siri, Microsoft Cortana etc. could allow the patient to *talk* about his health status, and just ask verbally for help if needed.

6.3.2 Reliability of System Components

The failure of HW, SW, or communication infrastructure components of remote patient monitoring and support solutions is a major threat to patient security. Requirements and approaches for the reliability, robustness and availability of those components have been published in paper III and discussed in this thesis (p. 86). Solutions for condition monitoring and failure handling are planned to be implemented and validated in point-of-care components as well as in the health information services infrastructure.

6.3.3 Machine Learning and Artificial Intelligence

The rule-based algorithms with static (generic or individual) thresholds for data evaluation, health status assessment and the determination of decision support information for healthcare providers, that have been tested in the trial system, should be compared with personalized and adaptive algorithms (refer to the discussion of *Rule-based Data Analysis vs. Adaptive and Learning Algorithms*, p. 91). More accurate alerts and recommendations for follow-up interventions are expected with the support of artificial intelligence (AI) technologies for machine learning and reasoning, utilizing medical knowledge, evidence retrieved from Big Data, and continuous individual monitoring data.

In paper X [Appendix K] a corresponding *Conceptualization of a Personalized eCoach for Wellness Promotion* is described. The *eCoach*, a personal, electronic AI-based support and recommendation services, combines specialized medical evidence available from randomized control trials, with holistic individual and reference knowledge to create and reinforce recommendations, which had optimal health and wellness outcomes in the past. The eCoach adapts these recommendations in a continuous personalized coaching dialogue addressing the citizen's needs and preferences (Figure 6.1).

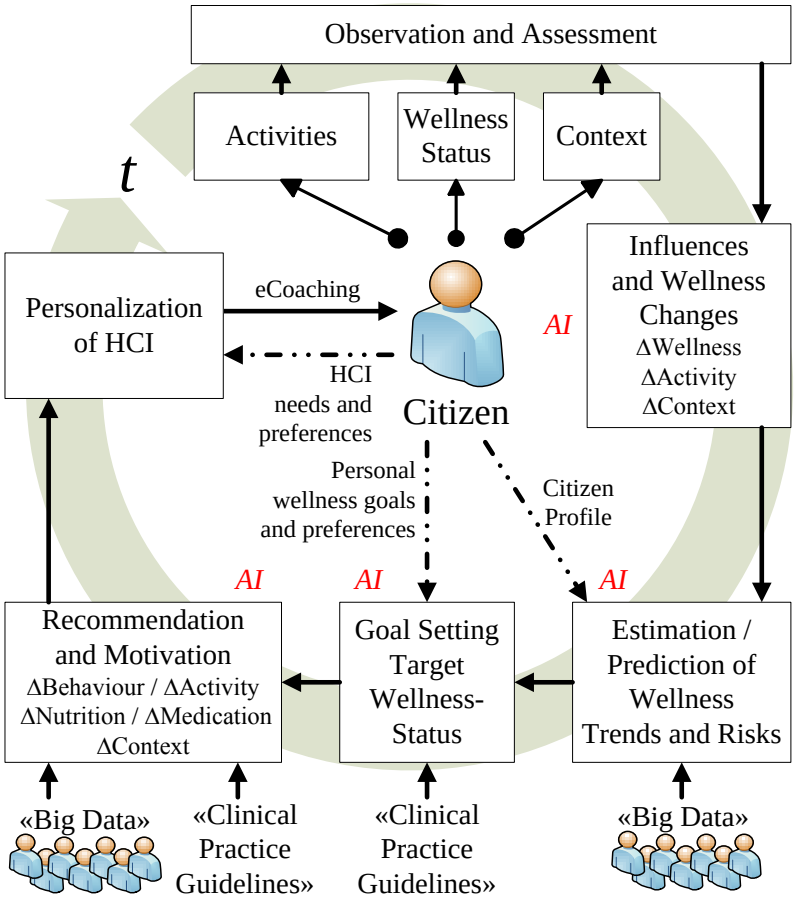

Figure 6.1: eCoach - Continuous Process of Wellness Management

Based on the expected continuing development of eHealth services as described in section 1.2, a further transformation of the healthcare system towards a citizen-centric wellness management system is envisioned. It puts emphasize on the central role of the citizens and their understanding, management and living of health and disease, on the consideration of a holistic understanding of wellness, and on the utilization of inclusively designed technologies to support the determination, distribution, evaluation, understanding and utilization of wellness-data and -information. The eCoach conceptualization can serve as basic element for this transformation, which involves the continuous development and adoption of technologies and innovations for continuous observation and data aggregation with health-Internet-of-Things (IoT) technologies. These technologies would include AI techniques for knowledge generation targeting evidence- and observation-based health and well-being support.

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Part II

Appendix A

List of Publications

The author of this dissertation has published nine peer-reviewed scientific articles as first author during the course of the PhD programme, and has contributed as secondary author to further articles. Additionally, one project report (not peer reviewed) is included.

These articles (*Paper I-X*) are included in the dissertation (*Appendix B-K*) to provide the reader with a reference and deeper insights of the author's work.

Scientific, peer-reviewed Articles

Paper I (Appendix B) M. Gerdes, Y. B. D. Trinugroho and R. Fensli, "Aspects of Standardisation for Point-of-Care Solutions and Remote Home Monitoring Services", *Proceedings of Scandinavian Conference on Health Informatics (SHI)*, Copenhagen, Denmark, 20 August 2013, pp. 19-24.

Paper II (Appendix C) M. Gerdes, B. Smaradottir and R. Fensli, "End-to-End Infrastructure for Usability Evaluation of eHealth Applications and Services", *Proceedings from Scandinavian Conference on Health Informatics (SHI)*, Grimstad, Norway, 21-22 August 2014, pp. 53-59.

Paper III (Appendix D) M. Gerdes, Y. B. D. Trinugroho, M. Næss and R. Fensli, "Security, Reliability and Usability of mHealth Environments", *"Mobile Health", Springer Series in Bio-/Neuroinformatics, Vol. 5, ch. 43*, Springer International Publishing, 2015, pp. 1043-1066.

Paper IV (Appendix E) M. Gerdes, B. Smaradottir, F. Reichert and R. Fensli, "Telemedicine and Cooperative Remote Healthcare Services: COPD Field Trial", *Studies in Health Technology and Informatics 2015, Volume 210*, IOS Press, ISBN 978-1-61499-511-1, pp. 455-457, https://doi.org/10.3233/978-1-61499-512-8-455.

Paper V (Appendix F) M. Gerdes and R. Fensli, "End-to-end Security and Privacy Protection for Co-operative Access to Health and Care Data in a Telehealth Trial System for Remote Supervision of COPD-Patients", *Proceedings of the 13th Scandinavian Conference on Health Informatics (SHI2015)*, Tromsø, Norway, 15-17 June 2015, pp. 25-32.

Paper VI (Appendix G) M. Gerdes, F. Reichert, J. P. Nytun and R. Fensli, "Future Telehealth and Telecare Reference Design based on IoT Technologies: From Remote Monitoring to Smart Collaborative Services with Decision Support", *"MedInfo2015: eHealth-enabled Health", Proceedings of the 15th World Congress on Health and Biomedical Informatics*, Sao Paulo, Brazil, 19-23 August, 2015, p. 891.

Paper VII (Appendix H) M. Gerdes, F. Reichert, J. P. Nytun and R. Fensli, "Reference Design for Smart Collaborative Telehealth and Telecare Services Based on IoT Technologies", *Proceedings of 2015 International Conference on Computational Science and Computational Intelligence (CSCI2015)*, Las Vegas, Nevada, USA, 7-9 December 2015, pp. 817-820.

Paper VIII (Appendix I) M. Gerdes, F. Gallefoss and R. Fensli, "The EU-project United4Health: Results and Experiences from Automatic Health Status Assessment in a Norwegian Telemedicine Trial System", *Journal of Telemedicine and Telecare, October 2017*, pp. 1-8, https://doi.org/10.1177/1357633X17735558.

Paper X (Appendix K) M. Gerdes, S. Martinez and D. Tjondronegoro, "Conceptualization of a Personalized eCoach for Wellness Promotion", *Proceedings of 11th EAI International Conference on Pervasive Computing Technologies for Healthcare (PervasiveHealth2017), Workshop 3 on "Health-i-Coach, Intelligent Technologies for Coaching in Health"*, Barcelona, Spain, 23-26 May 2017, https://doi.org/10.1145/3154862.3154930.

Not peer-reviewed Articles

Paper IX (Appendix J) M. Gerdes, F. Gallefoss and R. Fensli, ”Telemedicine Trial System for Personalized Follow-up Support of Patients with Chronic Obstructive Pulmonary Disease (COPD) - Results and Experiences from Health Status Assessment and Risk Estimation Algorithms”, *Internal report of the Center for eHealth and Healthcare Technologies at the University of Agder, Grimstad, Norway, August 2016*.

Appendix B

Aspects of Standardisation for Point-of-Care Solutions and Remote Home Monitoring Services

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Aspects of Standardisation for Point-of-Care Solutions and Remote Home Monitoring Services

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Abstract — **The health care services are focusing on seamless healthcare and defining typical patient flow conditions, where a close follow-up from the patient's home after hospital treatment can be important in order to avoid readmissions. In several international projects different technological solutions have been developed with the aim of obtaining an international standardized solution from end-to-end perspective in the information chain, where vital signs data are measured in the patient's home and transmitted to the hospital specialist. This is, however, a complex task without any clear recommendations, which leads to local variations in the implementations and to island solutions. The consequence will be no or limited interoperability of systems across organizations and local boundaries of services.**

In this paper we will highlight different levels of standards and give some recommendations for future research, based on a typical scenario for a remote home monitoring situation.

Keywords — **Remote home monitoring, Interoperability, Standardization, Data exchange, Mobile health, Seamless healthcare.**

Introduction

Remote home monitoring is a rapidly growing area, where the patient is supported to live in his own home and with daily use of necessary equipment for vital signs recording [1]. For the technical solutions to be used, this is a quite complex situation where a focus on standardization is needed in order to incorporate different medical recording devices from different vendors. This has been put into focus in several European projects with the aim of obtaining standardization both at the semantic level and at the technical levels [2].

In general, the existing solutions are mostly based on proprietary data formats and centralized servers with a typical "silo" setup for the technical solutions [9]. That means both the patient and the remote medical supervisor (e.g. at a hospital) will need to use the specific components from the same vendor. This limits the flexibility to incorporate new monitoring devices also from other vendors in cases where this can be a need based on the patient's condition.

In this paper, we will highlight the encountered problems by describing a typical user scenario. The particular challenge is that not only daily values of a single medical parameter are transmitted from the patient's home, but also Electro CardioGraphy (ECG) recordings should be transmitted on-line. In this focus, we will analyze applicable standards and explain the framework of standards for reference systems and solutions that allow realizing typical use case scenarios like the one described in this paper. As a result from that analysis we will give some recommendations for future research on deployments of point-of-care solutions and cloud-based system integration into electronic health records (EHR), .and on related standardization.

Materials and Methods

Description of a typical user scenario

In order to give recommendations for an end-to-end system design, we will focus on a typical home care scenario involving different use of vital signs monitoring solutions. As the first step, a patient suffering from cardiac heart failure (CHF) is recommended to perform a daily recording of the pulse and oxygen saturation in blood, using a standard pulse oximetry device. If the recorded pulse rate is above a defined threshold, the patient should put on electrodes connected to a device for performing an ECG recording. All data measured by the patient at home will be transmitted to a secured database containing a Personal Electronic Health Record (PEHR). From this database the doctor will have secured access to retrieve the

recorded information, in order to be displayed on his computer for diagnostic purposes. Such a system can be implemented according to the overview shown in Figure 1.

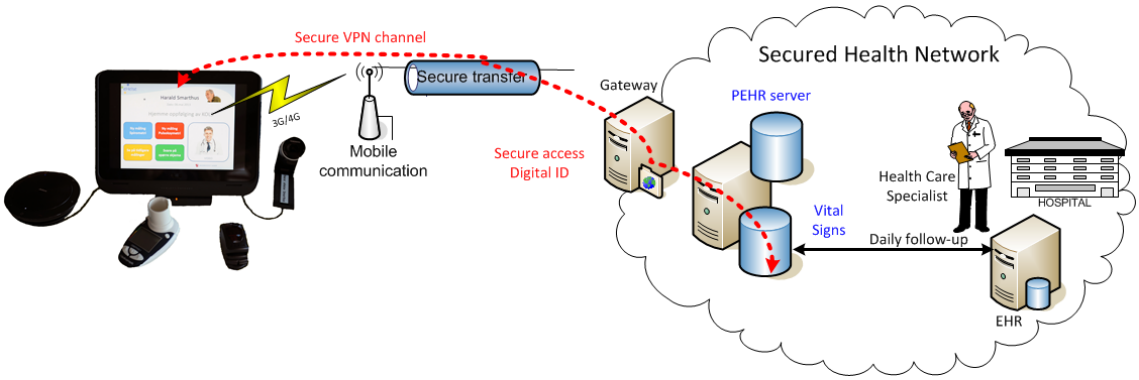

Figure 1- Overview of an end-to-end remote monitoring solution, where the monitoring devices are connected to a patient's tablet for secure upload into a PEHR from where the health care specialist can retrieve the actual data.

The tablet device carries out different essential functionalities which are required for the remote monitoring user scenario:

- Different types of medical devices (as the pulse oximetry device and the ECG device in the described scenario) are connected through a wireless near-field connection (as e.g. Bluetooth) with the tablet. The data carrying the information about the measured vital signs are transmitted through this link, and are stored in a local storage on the tablet devices.
- The tablet device establishes a communication link with the secured PEHR storage system, where the personal vital signs data is stored and made available to medical service providers. This can be e.g. general practitioners or specialized doctors at hospitals. The communication link can either utilize the inbuilt Wireless LAN capabilities, or cellular communication capabilities. The data transfer shall not be restricted to a single, proprietary PEHR system from a specific vendor. In order to protect the privacy concerns of the patient, the remote monitoring data shall be encrypted prior to transmission, and corresponding access control mechanisms shall allow only the intended doctor to get access to the data through his remote diagnosis appliances. This has to be implemented according to the legal constrains for access, storage and distribution of sensitive medical information, which might differ from country to country.

- A user interface (UI) is presented in order to support all required interactions of the system with the user during the measurement and monitoring session. Part of those interactions is the identification and secured authentication of the user, in order to confirm the relation of the measured data and the individual patient.

In a nutshell, the tablet device takes data from connected local devices and transmits those data together with the authenticated identity of the patient over an encrypted link to a remote storage system. As such it carries out the role of a personal communication gateway between the local devices and the remote PEHR storage system.

All these functionalities are realized as software running on the tablet device. From an interoperability perspective it shall be possible to run the software also on other tablet PCs or even desktop PC hardware without restriction to a single specific device model or vendor.

Interoperability and Standardization

In order to connect a plurality of medical devices from different vendors, there will be a need of standardization, both at the patient's side and at the doctor's side. At the same time, the transportation layer with necessary security precautions will have a need for standardization, and the stored measurements in a PEHR should be according to standardized formats.

Interoperability of complex systems requires standardization on different levels. Braa and Sundeep ([12], based on [13]) have described three levels of interoperability and standardization, spanning from an "organizational / political / pragmatic" perspective of interoperability via a "semantic level" down to a "syntactic / technical level". The EU-project HITCH [14] describes a similar four-level model of interoperability, covering:

- Organizational/political level, addressing the continuity and quality of the exchange of medical information,
- Application/software level, addressing the interoperability between patients and clinics/doctors with regards to software functionality and presentation of information,
- Logical level, addressing the semantic interoperability in terms of medical content and terminology,
- Technical level, looking at data formats and transmission protocols.

We do not address organizational and political aspects of interoperability in this paper.

Subsequently a selection of standards on the logical level is listed that are relevant for the discussed use case scenario. Then it will be explained how existing standards on technical level are utilized, and finally a number of interoperability challenges on application and software level will be discussed.

Pulse oximetry data formats

For a pulse oximetry recording scenario (Figure 1), the patient will put his recording device on to a finger, and automatically the device will start recording both the value of pulse rate, given as an ASCII value, and the measured level of oxygen concentration in blood given by another ASCII value. This device can be connected to an Android based tablet device by a Bluetooth connection, in order to wirelessly transfer the measured values to a typical portable device.

A dedicated application on the tablet device will receive the measured values together with a time stamp and an ID-code identifying the device. The international standard IEEE 11073-10404 is specifying the data exchange between the personal health device, i.e. the pulse oximetry device, and the hosting device, which is the actual tablet device enhanced with dedicated software.

ECG recordings and formats

From a wearable device ECG signals can be sampled for each of the leads used (normally 3-12 leads), and stored as a file containing a sequence of ECG data sampled for a certain duration of time. In order to later on interpret the actual recordings, the presentation software on the receiving device will need to know the parameters used by the recording device. This would be the sampling speed (normally 250 Hz or more), the signal resolution given by μV/bit, the number of leads used etc. Those parameters will normally be stored in the file, so that the viewer application can correctly read the file content and display the ECG data as waveform time series signal.

There are several international standards describing ECG formats [3]-[5], and also for remote home monitoring purposes. This can give challenges as there exist today only few solutions for converting ECG recordings between the different formats.

SCP-ECG is based on a European initiative from the Open ECG project[1], and is adopted by the international standard ISO/DIS 11073-91064:2009 which describes the interchange format and messaging procedures. This standard describes binary files for storing the actual samples, and in order to obtain a compact file structure, a data compression method based on Huffman encoding is

[1] http://www.openecg.net/

used. This requires some processing capacity of the mobile devices; however, this format is very suitable to be used for mobile solutions and remote monitoring purposes.

Medical Waveform Format (MFER) is accepted as an international standard, ISO/TS 11073-92001:2007 [6]. This standard is based on a Japanese initiative in the MFER committee, where the aim was to develop a universal standard description format for medical waveforms in general. This format is also using a binary file format, without any compression methods, but with a compact file header structure. Also this standard is suitable to be used for wireless solutions and remote monitoring purposes.

HL7 Annotated ECG (aECG) is an XML-based format for storing and retrieving of ECG recordings [7]. This format was developed based on the FDA´s digital initiative from 2001, and is published as ANSI/HL7 V3 ECG, R1-2004[2]. Based on the nature of XML-files, this ECG recording format is quite complex and contains huge amount of descriptive data compared to the amount of sampled ECG data. For wireless and mobile purposes, this format will hardly be used.

Digital Imaging and Communications in Medicine (DICOM) is a standard defined for storing, printing and transmission of information [8] related to medical imaging. Thus DICOM files can be exchanged between two entities and the supplement 30 was introduced to store medical waveforms together with images. DICOM was published in 1993, and accepted as a standard in 1995 (MEDICOM, ENV 12052)[3]. Because of the relationship to DICOM SOP-classes, the file structure is quite complex, and is difficult to use in a wireless mobile service. Thus it seems natural to store ECG recordings in the DICOM format only if the recordings are obtained in connections with medical images.

Information Integration Platform

To avoid “silo” integration and to promote reusability of information gathered/measured from medical devices by different applications/services, a broker between the two entities is needed. Publish/subscribe messaging pattern is suitable for such a broker which enables different applications/services to be notified of new information without having to repeatedly request updates from the information source.

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[2] http://www.hl7.org/documentcenter/public_temp_1179111A-1C23-BA17-0C3C1DA290147323/wg/rcrim/annecg/aECG%20Implementation%20Guide%202005-03-21%20final%203.pdf

[3] http://dicom.offis.de/dcmintro.php.en

The publish/subscribe messaging pattern was introduced more than a decade ago. It is still considered to be one of the most important communications mechanisms as it is well adapted for the loosely coupled nature of distributed interactions in large-scale applications. Subscribers have the ability to express their interest in an event or information update, and are subsequently notified of any event which is generated by a publisher and matches their registered interest [10]. This complies with an event-driven architecture where an event is asynchronously propagated to all subscribers. Different applications/services can make use of the information being sent from medical devices to the broker. This type of broker acts as an information integration platform [15]. Such platforms commonly use a store-and-forward approach underneath their publish/subscribe implementation, where the platform will also store information from medical devices and forwards them to subscribed applications/services. Figure 2 shows the general concept of an information integration platform.

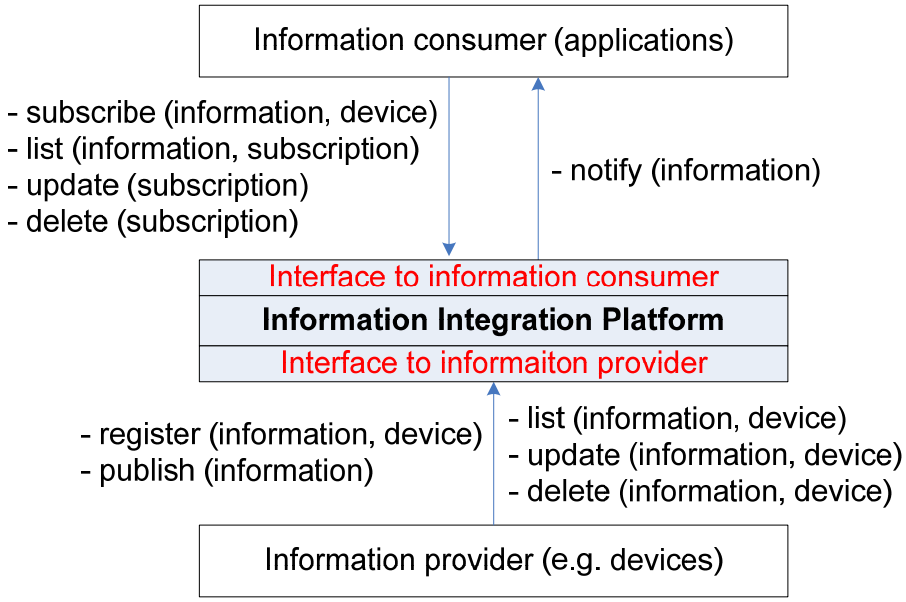

Figure 2- Information integration platform architecture

From standardization standpoint, at least two aspects should be considered related to the interfaces between the platform and information providers (e.g. devices), as well as between the platform and information consumers (e.g. applications/services).

Firstly, the communications protocol is very important as the platform is intended to become a "relay" between two communicating entities. Existing mature standards should be utilized as it will make the platform easier to be adopted by

different applications/services. One proposed application layer protocol for communication is HTTP/HTTPS, as it is widely used by a myriad of services on the Internet. Combined with REST architectural style [11], the HTTP/HTTPS protocol can become the prime choice for disseminating information in healthcare services.

Secondly, the format and content of the messages being exchanged should also follow well-known standards. Within the healthcare domain, HL7 v3 messaging has a strong position to be adopted as it is implemented by many healthcare providers, utilizing XML encoding. However, this standard is specifically designed for health-related information. Thus, if the platform is aimed to handle information beyond health, a separate HL7 adapter is a good option to be considered. This is of particular importance when novel services are about to be developed and integrated that require more information (e.g. ambient information) than the ones supported by HL7.

When focusing on publishing/subscribing of vital signs recordings, there are developed methods for using HL7 v3 exchange of messages (based on XML), where both the MFER [16] and SCP-ECG binary formats [17] can be used.

The IIP is a typical example for a cloud-based solution, with the information broker together with the EHR/PHR storage being deployed in the Internet service cloud. Commercial solutions as Telenor Shepherd [18], Microsoft HealthVault [19], and the Caradigm Intelligence Platform [20] (formerly Amalga) also follow the cloud-based solution approach,

Presentation of vital signs information

The remote diagnosis appliance at the doctor shall be able to present the measured vital signs data of the patient as illustrated in Figure 3.

In order to do so, the software must support the same protocols for authentication and encryption as the PEHR storage system. Further on it must support the same syntactic as the PEHR system for the data exchange, and the same semantics as the medical devices in order to be able to interpret and display the measured data correctly.

Similar to the display of the patient's pulse rate, the prototype of a Web based renderer of the remotely measured vital signs will also render ECG data.

End-to-end perspective

The transmission of arbitrary data containers through a communication infrastructure is covered by standardized protocols corresponding to the ISO/OSI model. This includes protocols for the secure authentication and for the encryption/ decryption of the data. The logical sequence of functionalities for a specific

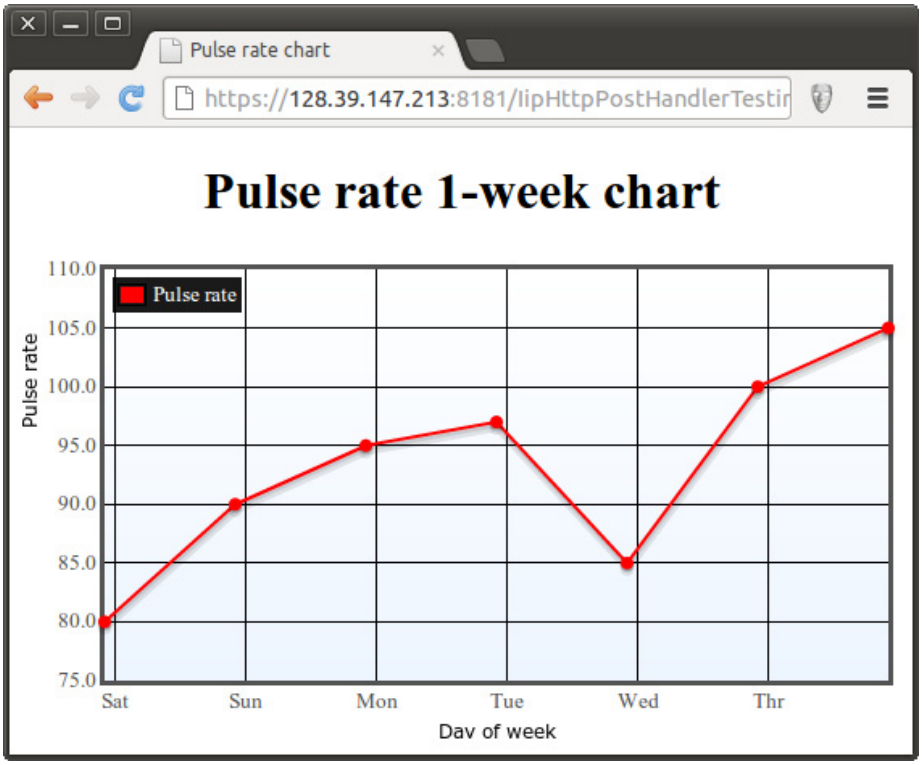

Figure 3- Pulse rate histogram (sample from prototype appliance)

use case scenario takes place on the *Application Layer*. A simplified view on the end-to-end protocol stack for the remote diagnosis scenario as described above is presented in Figure 4. Focus is put on the main devices and the main functionalities involved in the described scenario (i.e. SpO_2 and ECG devices, personal gateway, PEHR storage system, remote diagnosis appliance at doctor).

Integration into existing EHR systems

If the existing EHR system is a proprietary closed system, there's no straightforward possibility for the integration of the solution for the remote diagnosis scenario. If the existing EHR system otherwise provides an interface supporting any standard on semantic or syntactic level, the integration with the remote diagnosis system is possible by utilizing transformation of content and protocols between the different source and destination standards. This can be carried out by a broker as the IIP, as explained above.

Proof-of-Concept prototype

An end-to-end prototype system has been implemented covering the described use scenario and following the overview illustrated in Figure 1. It integrates off-

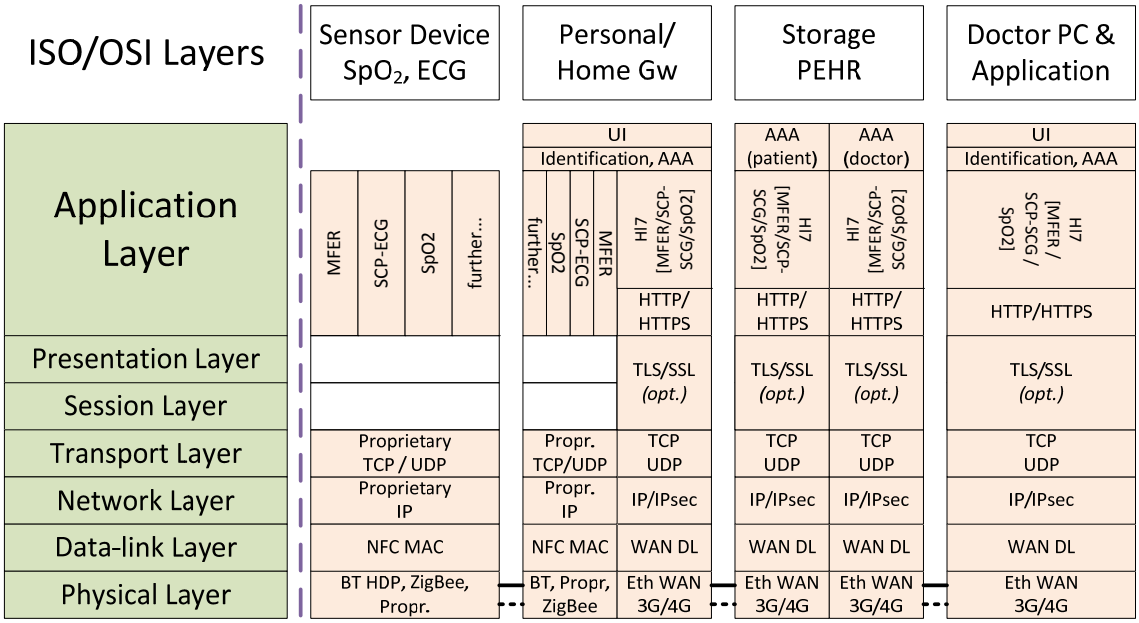

Figure 4- Overview of protocol stacks

the-shelf medical devices from different vendors, an Information Integration Platform (IIP) based on open standards (covering also the functionality of a PEHR system), and a Web based demonstration client for the access to and display of remote diagnostics data for e.g. a doctor. It proofs that a system with data access, transmission and storage based on open and flexible standards allows addressing the requirements of specific end-to-end use scenarios. Different interoperability requirements along corresponding interoperability levels can be addressed by flexible adaptation of data structures and interfaces, in particular looking at the semantics of the specific medical data, syntactic and data formats for the data exchange and storage, as well as protocols for the exchange of arbitrary data structures through a multitude of communication networks involved in the end-to-end scenario.

Results

Overview of eHealth related standards

Looking at the ISO/OSI model, the exchange of medical data utilizes known communication standards on layers 1-4 (see Figure 4), so no eHealth specific standardization is required for the transmission of medical data through an Internet-based network infrastructure. However, various standardization bodies specify different aspects of the communication of medical information, which all find their implementation in the *Application Layer* according to the ISO/OSI model.

Due to the tight relation between device hardware, medical content and communication technology, a few standardization bodies (as e.g. the Continua Alliance) specify Personal Medical Devices (PMD) or Personal Health Devices (PHD), covering aspects of the communication with the personal gateway on all ISO/OSI layers in a vertical manner.

A (non-complete) overview of eHealth related standards and standardization bodies is shown in Table 1.

Table 1- Overview of eHealth standards

Logical level Semantics, Terminology	ICD-10	Snomed CT (IHTSDO)	DICOM	LOINC
Technical level Messaging	HL7 v2.x IHE-XDS (Cross Document Sharing)	CEN EN 13606 (CEN TC251 Health informatics) IHE-RID (Retrieve Information for Display)	HL7 v3 /w CDA incl. MFER DICOM-SR (Structured Reporting)	OpenEHR Foundation OpenMRS Community
Protocols	ITU-T/SG 16 (Multimedia Systems)	ASTM F2761 –ICE (Integrating the Clinical Environment)	ISO/IEEE 11073 PHD / POC - SCP-ECG, SpO2 BT HD Profile USB PHD Class Serial, IrDA, LAN, PAN	Health Care and Life Sciences
Devices, Systems, Platforms	ISO TC215 (Health Informatics)	IEC/TC 62 (Medical Devices		IHE-PCD (Patient Care Device)

Evaluation of standards

Communication protocols will take care for the transport of arbitrary medical and health care related data by means of containers that are encapsulated in messages, which are carried then to the destination equipment. This includes specific protocols for encrypted transmission, as e.g. IPsec and TLS/SSL. Other security related issues like identification, authentication and access control are supported by corresponding application layer protocols (as e.g. HTTPS), and have not to be covered in eHealth standards (Table 1).

eHealth specific application layer standards will include the actual vital signs recordings. For wireless mobile recording purposes, there are two actual ECG formats defined as international standards that can be used; SCP-ECG and MFER.

In order to combine several recording devices as in this case both pulseoxymetry and ECG recordings, the MFER format can be used in both cases as this is a general encoding format for medical waveforms. In the header specifications, the actual recordings will be specified; thus by specifying a simple one-time measurement containing two parameters each with a single value will be possible. This opens for defining a common standard recommended for remote monitoring purposes. If future patient set-ups will require more devices for measurements of other vital signs parameters, this can be combined by a proper software application at the patient's personal tablet solution.

For the receiving partner, as in this case the doctor, such a set-up will only require that he has available suitable vital signs viewer solutions. Already there are free available open source viewers that can be used for both of the formats SCP-ECG[4] and MFER[5,6]. However, there exist today no free viewer that can be able to open and display both of the formats, and this will be a challenge for future development.

Future direction and recommendations

Most required standardization aspects for the described scenarios (remote diagnosis of SpO2 and ECG measurements) are addressed on different standardization levels by corresponding standardization bodies. They span from platform aspects of EHR systems and medical devices, via protocols and message contents and formats for the communication between the involved eHealth parties, up to the semantics of the medical and care related data to be communicated, stored and presented.

Also dedicated standards exist for various security aspects of the data communication in general, which are also applicable for the communication of eHealth data in particular, covering different technologies for encryption and access control.

What is missing are clear interoperability guidelines for the development and compliancy testing of complete end-to-end scenarios, in order to facilitate that medical devices from different vendors can work smoothly together with EHR storage systems from different vendors and also with devices and software solutions for the medical service providers as doctors and hospitals.

[4] https://play.google.com/store/apps/details?id=org.sribog.ecg

[5] http://ecg.heart.or.jp/En/DownLoad.htm

[6] http://cardiocurves.sourceforge.net/index.html

Standardization bodies to be addressed

About 10 years ago the entertainment industry has founded the Digital Living Network Alliance (DLNA), which standardizes guidelines focusing on the interoperability between networked entertainment and media devices that involve digital content in form of images, audio and video. Analog to that, clear interoperability guidelines should be developed and specified for the interoperability of networked eHealth devices, appliances, and software components. For that a standardization body or dedicated interoperability organization with a holistic view on end-to-end scenarios involving eHealth devices and appliances is required.

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[18]Shepherd Platform from Telenor Objects, http://telenorobjects.com/shepherd/

[19]Microsoft HealthVault, https://www.healthvault.com

[20]Caradigm Intelligence Platform, http://www.caradigm.com/en-us/products/caradigm-intelligence-platform/

Appendix C

End-to-End Infrastructure for Usability Evaluation of eHealth Applications and Services

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End-to-End Infrastructure for Usability Evaluation of eHealth Applications and Services

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***Abstract* — eHealth technologies are widely used in collaborative health care services involving multiple different user groups. A very important aspect of the design and development of such applications is the ease-of-use and user-friendliness of the user interface for the end-users. Usability testing is performed in a simulation or real environment to ensure that the system is adapted to the specific needs of the different end-users and to evaluate the interaction between users and system.**

The aim of this paper is to present an infrastructure for end-to-end usability testing of eHealth technologies in a con-trolled environment simulating both the Point-of-Care and the Health and Care Service Provider. The primary focus is on the requirements and technical aspects of the test infrastructure itself, but on top of that also a trial project is presented where the proposed usability testing infrastructure has been used and validated.

***Keywords* — eHealth, health informatics, usability evaluation, end-to-end test infrastructure, point-of-care, user centered design.**

Introduction

eHealth applications and services are designed for the exchange of information between different collaborating user groups of the same system, utilizing certain information and communication technologies (ICT) [1].

The reference system that sets the framework for the usability evaluation system discussed in this paper is illustrated in Figure 1. One of the major aspects is the collaboration between a patient in his point-of-care environment (e.g. his private home) and certain health and care service providers (as e.g. a specialized nurse in a telemedical central, a general practitioner, or a medical specialist in a hospital). Collaboration means in this context, that certain information about the medical and health status of the patient as well as about his current living context is made available to the health and care service providers via dedicated eHealth installations, applications and services. For that the information has to be transmitted through communication and health information system (HIS) infrastructures by means of information and communication technology (ICT). In turn this information shall enable the health and care service providers to provide optimal health and care support to the patient in an efficient and cost effective manner. For that the same eHealth infrastructure is utilized to get in contact with the patient, and to assist him with information, general support, and with dedicated treatment recommendations as e.g. medication changes.

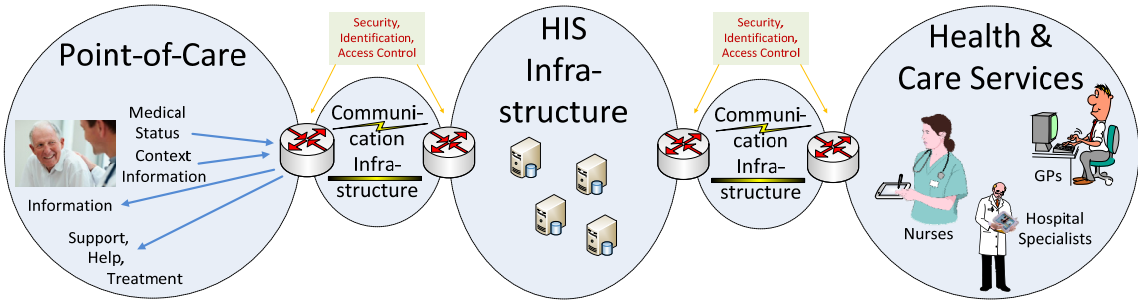

Figure 1: Reference System for Tele-Health and Tele-Care Services

The most important requirement on such a collaborative eHealth system should be the *usability* of the system for all involved user groups. In order to support the patient to derive the health and care related information required by the staff in the telemedical central, the design of all involved eHealth devices and user interfaces of applications have for example to consider physical and mental limitations of the patient. On the other side it has to be taken into account that health and care personnel have to take care for many individual patients. Consequently,

the design of the user interfaces of the eHealth services used by the health and care service providers have to consider for example an intuitive and optimal presentation of relevant and important information.

In this paper we present a usability test infrastructure addressing this utmost important requirement. It consists of an environment simulating both a point-of-care and a typical health and care service provider, and it allows performing end-to-end usability tests of applications and services for all involved user groups through a controlled health and care information system. The primary scope is on the technical aspects of the usability test infrastructure, from a health informatics and ICT perspective.

Following this introduction, a rough overview of the *state-of-the-art* of related usability testing infrastructures will be given. The section on *end-to-end infrastructure for usability evaluation* discusses first the identified requirements on the targeted usability testing infrastructure, and presents then the details of the different parts of the proposed infrastructure. Subsequently a trial system for the realization and verification of the proposed usability testing infrastructure is presented. That system was developed under the umbrella of the 3-year European funded project United4Health [2] for the usability evaluation of eHealth technologies.

State-of-the-art

eHealth applications and services have multiple user groups, and there is a need for systems supporting collaborative work across organizational borders of health care services. However, the development of such systems is a complex process.

The overall objective of usability evaluation is to improve both the interaction design between all involved users as well as the user interfaces of eHealth applications and services [3-5].

User-centered design methods, where real end-users are involved in all steps of the development of eHealth applications and services, are used to collect users' needs and to understand the context of use, in particular the clinical workflows and their impact of on the requirements on support applications and service. Applying user-centered design methods is the basis for the adaption of the eHealth applications and services to the users' needs [3, 6, 7].

The main benefits of systems with a high level of usability are increased productivity, reduced errors, less needs for user training and support, and an overall improved acceptance by the users [5].

With the focus on bringing a human-centered perspective to the formulation of system requirements and the configuration of effective user interfaces, Samaras presents a systems engineering method providing a framework for incorporating human factors (ergonomics) knowledge and integrating ergonomists in the interdisciplinary development of health information systems [8]. Validation and verification testing is an essential part of the presented iterative systems engineering lifecycle model.

User-based evaluation means that users participate in the evaluation. They are asked to do typical tasks or to explore a system, while being observed and recorded. The goal is to identify flaws that cause errors or difficulties in the use of the system. Measurements are performed on time for solving a task, on numbers of completed tasks, and on numbers and types of errors. The aim is to provide a better understanding of the interaction between the user groups and the graphical user interfaces provided by the collaborative eHealth services [3].

Usability evaluation can be performed in laboratory settings or natural environments such as the home of the patient or the work place of a health or care service provider. The strength of a laboratory setting is the controlled environment for the test, but it can also influence the behavior of the test participants. The unfamiliar environment and the knowledge of being observed and recorded can impact on the problem solving, which is also known as the Hawthorne Effect [7]. Natural settings are often easiest for test participants, but can be a challenge for the research team.

Usability evaluation can usually not be performed in real clinical environments because of the legal, ethical and privacy regulations to protect patients. Therefore simulation of the health care services environment is important to create a realistic test scenario for the user groups [9, 10].

In their paper on *Televaluation* Kushniruk et al [11] describe an integrated approach for distance evaluation for assessing Web-based clinical information systems. The development of methods for assessing the effectiveness and usability of such systems is identified as a critical issue.

Kaufman et al [12] present an approach to usability evaluation of computer-based health care systems designed for patients use in their homes. Their approach incorporates a cognitive walkthrough usability evaluation and methods for usability testing that can be conducted in the patient's homes. Based on the usability evaluation, they stress the importance of a multifaceted usability approach. However, an integrated usability testing framework is not presented.

The ALFA toolkit [13] offers support for the observation of computer mediated consultations of patients at a doctor. The Activity Log File Aggregation (ALFA)

serves as basis to provide an analysable overview of the Clinician-Computer-Patient interactions.

End-to-end usability evaluation infrastructure

In this section we describe an end-to-end infrastructure for the usability testing of tele-health and tele-care services corresponding to the reference system introduced above. In the following the underlying requirements towards the usability testing infrastructure are discussed.

Requirements on the usability testing infrastructure

The requirements on the infrastructure for the usability testing (including hardware components and software solutions) are determined by the main service scenarios that shall be tested.

Guiding service scenarios for usability tests

The usability test infrastructure shall support the evaluation of the following basic scenarios, which correspond to the reference architecture in Figure 1 for collaborative services.

1. Measurements of medical values

   Patients at the point-of-care shall measure certain data about their medical status, using corresponding measurement devices (as Personal Medical Devices, PMD). The measurement process shall be supported by dedicated patient services and applications that provide a user interface with information and instructions showing the progress of the measurement scenario. This shall for example include information regarding the transmission of the measured data to the health and care service providers via the Health Information Services (HIS) infrastructure, and shall provide instructions in certain possible error cases.

   The measurements shall in turn be made available to the health care professionals in their health and care services environment. Dedicated health care services and applications shall process and present the data in dedicated user interfaces that support an optimal and efficient support for the corresponding patient.

2. Questionnaires

   The patient shall provide subjective information about his health status by answering specific questionnaires, which shall be made available to the health care specialists. Corresponding user interfaces of the patient services and applications shall support the patient through the process of answering

the questions and with the delivery of the data through the HIS infrastructure to the health care professionals.

Dedicated computer services and applications for the health and care service providers shall then process the answers and present the (processed) questionnaire results to the health and care staff. The corresponding user interfaces shall support the utilization of the results for an optimal and most efficient patient support.

3. Video consultation

   The services and applications of both the patient and the health and care specialists shall include means to establish an audio-video communication session between each other. The user interface for the patient shall make it easy to establish an on-demand-video-call with their dedicated health and care service provider, and to accept an incoming audio-video-call. The user interface for the health and care service provider shall give optimal support to establish a video call with a selected patient (out of all patients the service provider has to take care for) following e.g. a timetable of appointments, or to initiate an immediate on-demand session as reaction on a critical situation determined by certain measurements or questionnaire outcomes.

Joint testing of collaborating user groups

One of the main requirements of the usability testing and evaluation of interactive and collaborative services is the study of interactions and dependencies between different user groups of the same system. For that it must be possible to monitor and study different user groups independently from each other, while they use interactive and collaborative applications and services (via certain equipment and user interfaces). The main aspect of interaction and collaboration is that each user group has to react on actions that the respectively other user group is carrying out.

User-group specific tasks for usability tests

The usability test infrastructure shall allow studying arbitrary test cases of each user group involved in a collaborative service. For that it is required that specific usability test tasks can be specified independently for each involved user group.

Full control over specific actions and events

The usability evaluation of certain specific test tasks for one individual user group might require full control of specific actions and reactions of the system they interact with. That means that the system should allow that the counter-part of the tested user group is either fully simulated (i.e. it carries out specific actions

and re-actions according to a defined test process), or that the actions and re-actions are carried out by the usability test staff according to a defined test plan.

Further general requirements

A few further aspects have to be considered regarding the usability test configuration and the infrastructure and technologies for the observation of the test persons.

- The users of all user groups (i.e. both "test-patients" and "test-health-service-providers") shall be able to focus on the user interfaces of the applications and service components they typically interact with in order to utilize a certain function or service of the tested system. Hence, the distraction by any test-specific device or functionality (e.g. for observation purposes) should be minimized.
- The interaction of the user with the tested applications and services should be recorded during the tests in terms of video and audio, covering as many aspects as required for future evaluation.

End-to-end usability test infrastructure

Considering the requirements presented above, an end-to-end infrastructure for usability tests is proposed as illustrated in Figure 2. The infrastructure is distributed over three interconnected rooms: a Point-of-Care Test Room, a Health- and Care Service Provider Test Room, and an Observation and Control Room.

Point-of-Care Test Room

The Point-of-Care Test Room contains all equipment needed to carry out the usability tests of the user group representing the "patient".

The patient test equipment should be similar or optimally the same equipment a patient would use in a real point-of-care to carry out the activities that are subject of the usability tests. That equipment runs the corresponding point-of-care services and applications, which are connected to the collaborative services in the Health Information Services (HIS) infrastructure, and provide the user interfaces to be tested. Besides the services and applications that are subject to the usability tests, the test equipment might also contain certain software to support the observation during a test session (refer to description of the Health- and Care Service Provider Test Room below).

For the observation of the test person during the test session a video camera with microphone is installed. Both the video and audio signals are digitized using an embedded capture device, and transmitted to the Observation- and Control Room via the LAN. The camera can be remotely controlled from the Observation- and

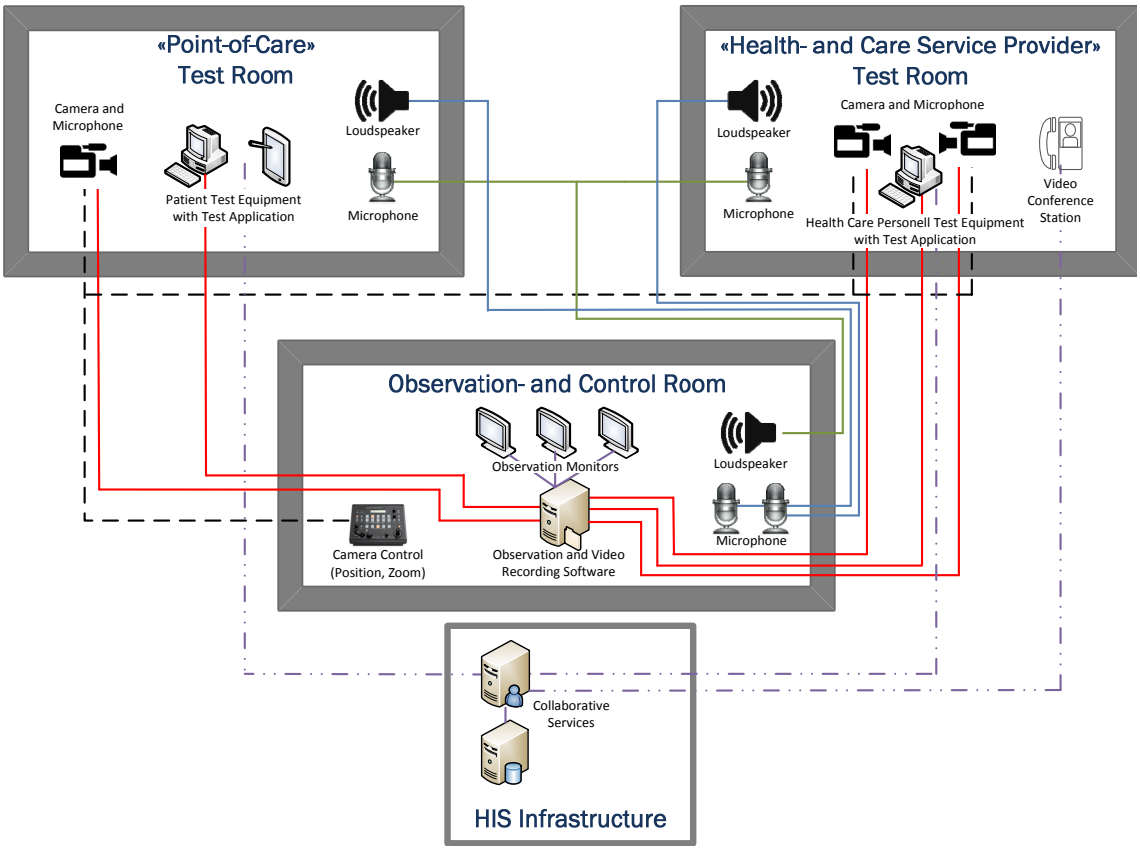

Figure 2: E2E Usability Test Infrastructure

Control Room in terms of observation direction and zoom.

Besides the test and observation equipment, there's also a simple microphoneand loudspeaker installed in the Point-of-Care Test Room. This allows communicating between the test persons and the test staff in the Observation- and Control Room independently from an ongoing observation and recording session.

An example Point-of-Care Test Room setup as deployed at the University of Agder is shown in Figure 3.

Health- and Care Service Provider Test Room

The Health and Care Service Provider Test Room is equipped for the usability tests with the user group representing the "health care specialists".

The health care personnel test equipment runs the test applications which are subject to the usability tests with health care professionals. The test applications communicate with the collaborative services in the HIS infrastructure via LAN, and provide the user interfaces that shall be assessed regarding usability. In order to support the observation and evaluation of the operation and usage of the test

Figure 3: Video Observation of Point-of-Care

application by the test persons, the user interfaces are captured and streamed to the Observation- and Control Room via LAN, using a screen capturing and streaming software.

Besides the test equipment, the Health- and Care Service Provider Test Room also contains a dedicated video conference station, which is also subject to the usability tests of collaborative services with the point-of-care user group.

Similar to the Point-of-Care Test Room setup, a set of video cameras with microphones allow observing the whole test session. The video cameras can also be remotely controlled, and their audio and video signals are digitized and streamed over the LAN to the Observation- and Control Room. Furthermore, a separate microphone and loudspeaker allow communication of the test persons with the test staff in the Control- and Observation Room independently from a test session.

In Figure 4 the Health- and Care Service Provider Test Room at the University of Agder can be seen as an example setup.

Observation and Control Room

The Observation- and Control Room contains the installations for the observation, control and recording of the usability test sessions.

Separate loudspeaker(s) and microphones allow communicating with the user groups in both the Point-of-Care Test Room and in the Health- and Care Service Provider Test Room. The devices are connected to embedded digitizing devices, which transmit and receive the digitized audio data over IP protocol. All data is sent through the common LAN infrastructure interconnecting all rooms of the test infrastructure.

Figure 4: Health- and Care Service Provider Test Setup

The central component of the Observation- and Control Room is a dedicated PC running the observation- and video recording software. The PC receives the IP data from all digitized audio-video sources in the two test rooms, i.e. from the video cameras with microphones, as well as from the streamed screen output from both the patient test equipment and the health care personnel test equipment. The observation and video recording software allows to observe selected sources (see left screen in Figure 5), and to record all sources simultaneously and synchronized in time on a data storage. Independently from that, selected (or even all) sources can be observed on separate screens. For that, embedded rendering devices, corresponding to the embedded digitizing devices in the test rooms, are connected to the screens, and are configured to receive a specific IP stream from the LAN.

During the whole usability test session, the video cameras in the test rooms can be remotely controlled by the test staff regarding camera direction and zoom. Also the control signals are transmitted from the control device to the cameras via the LAN infrastructure.

Figure 5: Observation and Control Setup

Realization of end-to-end test infrastructure

The end-to-end infrastructure as presented above has been realized in the usability test laboratory at the University of Agder, and has been used for user tests in the Norwegian part of the United4Health project [2].

The United4Health project

The European project United4Health involves more than 20 countries and includes 20.000 patients with chronic diseases. The idea of using eHealth technology in United4Health is to support the collaboration across organizational borders, and to support the management of the health care information related to home-monitoring.

The Norwegian project focusses on collaborative eHealth technologies to support COPD-patients after hospital discharge. In the South-Norwegian region of Agder 200 patients are planned to be involved in a field trial.

The University of Agder was responsible for the development of the eHealth technology for home-monitoring of the COPD-patients. The development included the design of a tablet application to be used by the patients for home measurements of blood oxygen saturation (SpO2), pulse and a questionnaire to be filled out daily. Already early in the design and development process, the user groups were invited to participate in workshops about the interface design and functionality.

The hospital partner is responsible for the selection of patients for the field trial, and introduces home-monitoring to the included COPD-patients. The municipality partner has established a pilot telemedical central run by specially trained nurses that use a dedicated health care information system for management of home measurements and daily follow-up of the COPD-patients. Video conversation with the patient is supported by a video conferencing system.

Usability evaluation in United4Health project

User-centered methods were applied in the development of the eHealth technology. The user groups participated in two usability evaluation sessions within two weeks. The tested eHealth applications were iteratively developed between the test sessions.

The infrastructure for the point-of-care and the health- and care service provider was used and tested in the usability evaluation. In the first test scenario, the health and care service provider test room represented the hospital, where the nurse and the COPD-patient prepared for home measurements (see Figure 6).

Figure 6: Introduction to eHealth technology

In the next test scenario, the point-of-care test room represented the home of a COPD-patient. The test participant took the role of a recently discharged patient (from hospital) and interacted with the eHealth tablet technology to make home measurements and fill in a questionnaire (see Figure 7).

Figure 7: eHealth Technology at the Point-of-Care

In the third test scenario, the nurse from the telemedical central interacted with the dedicated health information system to evaluate the home measurements and questionnaires from the COPD-patient (see Figure 8). A videoconference system was used for face-to-face communication between the COPD-patient in the point-of-care and the nurse in the health and care service provider test room.

Figure 8: Health- and Care Service Provider Test Setup

During the three presented scenarios, all sources of the test infrastructure were shown simultaneously on one master screen (see Figure 5) in the observation and control room. Each source could also be followed on a separate big screen.

In parallel the audio- and video sources were recorded for later evaluation of various usability aspects.

In this usability evaluation of eHealth technology, the end to end test infrastructure simulated a scenario which was difficult to test in a real health care environment, and the outcome was relevant feed-back on functionality and usability for further system refinements.

Discussion

In this paper we have presented an end-to-end test infrastructure to carry out usability evaluations of eHealth technology.

Collaborative eHealth services involving multiple user-groups have to be tested and validated before being released and taken into regular operation. Due to ethical reasons, usability testing can usually not be done in real clinical environments [9, 10]. Therefore a simulated test environment with an end-to-end infrastructure contributes to a realistic scenario for the test users.

In user-centered design projects, there is a need to perform usability evaluation iteratively in each step of the development process. The iterative evaluation is enabled by a controlled environment, where the test team has full control over all steps of the test scenario, including tasks and actions of the test participants.

The trial project for the verification of the test infrastructure has limitations such as a limited number of tests and user groups. However, the test scenarios and the end-to-end test infrastructure provided a highly realistic simulation of real point-of-care (i.e. patient at home and patient in hospital) and health and care service provider (i.e. nurses at telemedical central) environments.

Conclusion

eHealth technology is widely used by multiple user groups both at the point-of-care and at health and care service providers. Usability evaluation is essential in order to improve not only the interface design of the eHealth technology, but also the interactions between the devices and applications and the different user groups.

Our proposed end-to-end test infrastructure was validated through user tests within the trial project United4Health to carry out usability evaluations of collaborative eHealth technologies involving multiple user groups. We found that the end-to-end test infrastructure provided the flexibility to simulate highly realistic environments.

As further research of the utilization of the end-to-end test infrastructure we suggest usability evaluation of mHealth solutions, and of security management technologies in eHealth services and applications. In those areas, there's a particular need to balance technical design and functionality against the usability.

Acknowledgments

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Appendix D

Security, Reliability and Usability of mHealth Environments

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***Keywords* — privacy, identification, access control, relationship management, reliability, redundancy, self-monitoring, user interface, portable communication gateway, integration platform**

1 Introduction

Mobile technologies confer mobility and autonomy on patients with the advantage of access to home care and health care services on demand. However, these benefits impose challenges to the future health care services. For instance, computation capacity of a conventional smartphone provides applications and services with sufficient power of calculation and automation to assist in daily life activities and medical purposes. Combined with a user-friendly interface, mobile technologies can be an easy and efficient manner to help people who are in a condition of cognitive deterioration or have a chronic disease which demands a close connection to near family members and/or to health care services. These scenarios require a technical solution guaranteeing that the user will always be "on-line" and connected to the mobile telecommunication network. In addition, to be able to share personal information and specifically for sharing medical information with health care services, the current solutions have to take into consideration both security and reliability requirements. The security issues will be those of standard computer network security measures, because there will be a need for secured user authentication and data integrity. This means that the data must not be corrupted or modified during the transference from the user's mobile to the health care service. Finally, to comply with data protection regulations data will only be available to people who have been granted authorisation to access the relevant information in specific cases to provide necessary follow-up and support.

The need for system's reliability implies the use of technology proven against mobile network or computer failures. In addition, emergency alarms and their data must be ranked with the highest priority to ensure immediate transmission to rescuing personnel.

In this chapter, we will focus both on the security issues and reliability precautions, including the safety aspects and user-friendliness for the end-user. In addition, we highlight actual use-case scenarios where future mobile technology solutions can provide relevant health and care services to elderly people and patients. Based on these scenarios, we will discuss some important user requirements to be considered by the system designers and technical developers, and also by the support chain of services that has to be established by private health care and security companies, close relatives, and public health care services such as telecare and telehealth functions.

Examples of actual user scenarios as study cases

A) Elderly person at an early stage of dementia

A typical situation for an elderly person at an early stage of dementia can be that she/he is living alone at home. For the upcoming generations, most elderly people are born after World War II and an increasing number of them are used to modern ICT solutions at work. Thus, they are likely to be familiar to use smartphones and tablet PCs on a daily basis, in contrast with today's elderly generation. Even with gradual decline of cognitive abilities by aging, some smartphone functions can usefully be used for assisting elderly people in daily life activities, such as in situations where they experience difficulties and need remote assistance by their close relatives. This could lead to improvements in situations as:

- Elderly person does not remember appointments and intake of medication
  - Support from a memory planner and electronic pill dispenser
- Elderly person does not find her/his way back home
  - Support from a traveller guide with GPS positioning alarm
- Loneliness and lack of social contacts
  - Use of social media functions such as Skype and Facebook
- Need for permanent availability of electronic assistance
  - Hand-watch display for user-friendly solution
- Easy connection to family members
  - Smartphone with video and voice over IP system (e.g., "Face time") call-up functions

B) Mobile patient with chronic disease

In several European projects, there has been a focus on medical support for patients at home. When living with a chronic disease, it can be important to be able to make daily measurements of vital signs recordings. This could in particular be the case for patients with chronic diseases, such as diabetes, chronic heart failure (CHF) and chronic obstructive pulmonary disease (COPD). To date, experiences from the Renewing Health project[1] reveal that chronic disease patients need to go to hospital for treatment less frequently and they feel more secure being at home with remote home monitoring possibilities.

In general, current technology should allow recordings of the medical data at patient's home, and when traveling on vacation, etc., and to upload the data to a secure server storage. This storage should preferably be available within the

[1] http://www.renewinghealth.eu/en/

computer network of the health care services, from where the authorized medical personnel taking remotely care of the patient can access the recordings of specific patients. In principle, such a database for the patient's medical information will be a Personal Electronic Health Record (PEHR). The Markle Foundation (2003) has defined a PEHR as:

> *"An electronic application through which individuals can access, manage and share their health information, and that of others whom they are authorized, in a private, secure, and confidential environment."*

This leads to the requirements of authentication and authorization, i.e., based on the authenticated identity of the patient, they should be able to administer access authorization to this database and give privileges to the health care personnel for access to the actual information. This relates to the requirements of privacy protection, which can be defined as:

> *"The right of individuals to determine for themselves when, how and to what extent information about them is communicated to others"* (Agrawal et al., 2002).

Enabling patients to manage their own medical recordings taken from devices in their home can be achieved by a Patient administered Personal electronic Health Record (PaPeHR) as described by (Fensli et al., 2011).

There might also be situations where close relatives need access to the vital signs recorded. As an example, this can be the case when children carry out their regular measurements of blood glucose, and want to forward this information to their parents to get advice about the correct insulin dosage to be given (Gammon et al., 2005).

For patients at home a diary of their medical symptoms and feelings can be relevant for the correct treatment and corresponding follow-up. A Spanish multicenter study with COPD patients at home concluded that a report on symptoms in a diary carried out by the patients seems to be a valuable tool in primary care for at-home-treatment and rehabilitation (Llor et al., 2012).

In this scenario, several aspects need to be considered:

- Remote monitoring
  - Secure storage in PaPeHR solution
- Children with close supervision by parents
  - Secure transmission of medical data to close relatives
- Trend curves for medical measurements
  - Enable visual view of changes in medical conditions
- Daily writing on a medical diary
  - Electronic storage of the patient's day-by-day experienced medical situation
- Personal Health Record securely stored
  - Administered by the patient, with access for authorized personnel

C) Rehabilitation and physical training

Patient treatments at hospitals are highly time efficient. The average length of stay (ALoS) has, according to OECD indicators, fallen over the past decade in nearly all OECD countries (OECD, 2011). At the same time, the number of people receiving long-term-care is rising. OECD reasons for this trend the population's aging and the implementation of home-based-care.

In a review of wearable sensors and systems with application in rehabilitation, Patel et al. concluded that there was a focus towards health and wellness in the use of wearable sensors, and towards the area of remote rehabilitation (Patel et al., 2012). In a study of home-based versus in-hospital based cardiac rehabilitation after cardiac surgery, Scalvini et al. found that the tele-rehabilitation program was effective and comparable to in-hospital rehabilitation (Scalvini et al., 2013). However, it will be necessary to implement functional telemedicine services with rehabilitation equipment and training records deployed as a normal service from the physiotherapists. An interesting on-going project in North-Norway is using video support for at-home exercise where the patients have installed a treadmill and have to fill in a regular training report to the physiotherapist[2]. On the market for fitness products, numerous *apps* are available for recording of physical exercises together with pulse activity, step counters and GPS data in order to track the training route. In addition, game controllers, such as Wii and Xbox ones, create opportunities for home-based training guided by an avatar on the screen[3]. The Kinect 3D camera will track body movements and limb positions; those functions can be useful in systematic training of motoric functions, as can be the case for rehabilitation after cerebral stroke.

For the home-rehabilitation use-case, important aspects will be:

- Training activities
  - Step-counter, GPS tracking, etc.
- Personal training guide with reminders and stimuli
  - Patient identification
  - Training log and remote video follow-up by physiotherapist
- Avatar guidance
  - Training programs in game-controllers (e.g., Wii, Xbox)
- Integration of medical sensors
  - Pulse watch, respiration etc.

[2] http://telemed.no/chromed.5125023-247951.html

[3] http://www.youtube.com/watch?v=2v9ZtD6oVJY

2 Reference Architecture

mHealth environments are characterized by the mobility of patients, their health and care service providers and other supporters, such as relatives. On the one hand information about the medical status of patients and their context (e.g., the physical location) shall be gathered and made available as soon as possible when needed for health and care service providers. On the other hand, patients shall receive information and support as fast as possible from the remote service providers and relatives when needed, in particular in certain emergency situations.

The fundamental requirement of gathering medical and environmental information from mobile patients on the one side and making it available to doctors, nurses and other people involved in the health and care on the other shall be made independently from their physical location. This requirement determines the specification of devices, services, and the underlying information and communication technology (ICT) infrastructures. Fig. 1 illustrates the high-level reference architecture, comprising the main domains of a mHealth system, namely the *Point-of-Care environment*, the *Health & Care Services environment*, and the *Health Information Services (HIS) environment*. This reference architecture covers all user scenarios described above, and will support the studies and discussion of technical requirements and solutions needed to realize the use cases, with particular focus on security, reliability and usability aspects.

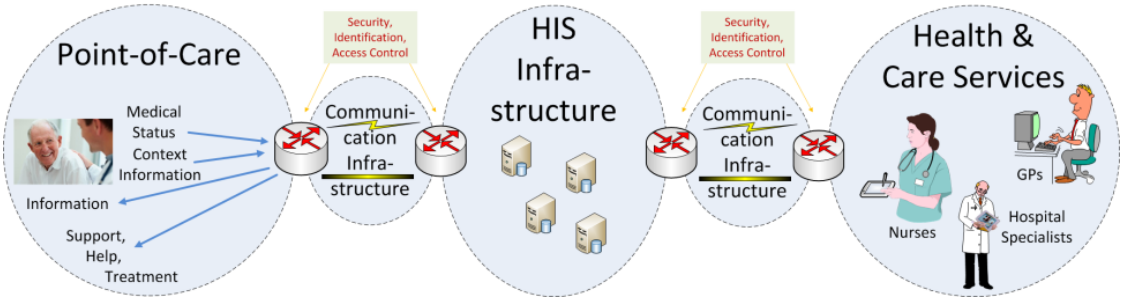

Fig. 1: High-level Reference Architecture

The main architecture domains comprising components and solutions from a variety of stakeholders are shortly described next.

***Point-of-Care*:**

The Point-of-Care (PoC) environment describes the immediate environment of the patient, see Fig. 2 for more details.

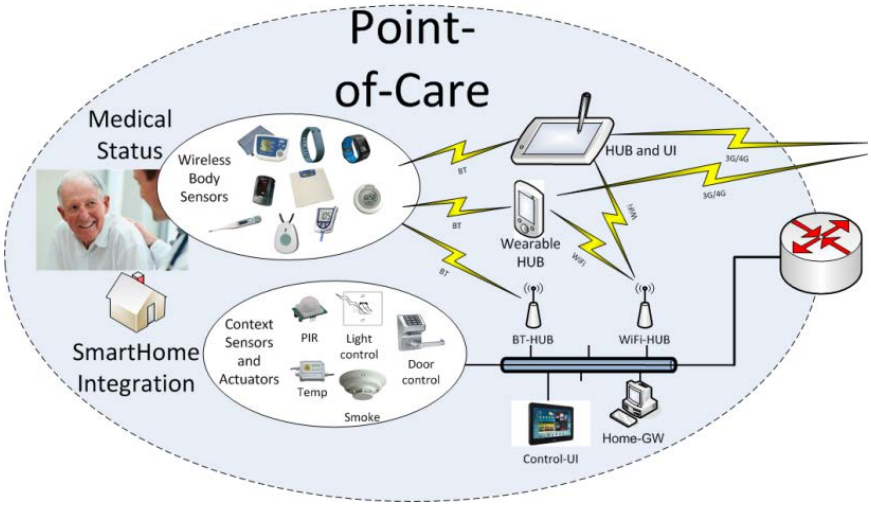

Fig. 2: Point-of-Care Environment.

It consists of a manifold mixture of wireless body sensors capturing medical, health and (potentially) other kinds of information from the patient's environment. Furthermore, multiple kinds of personal user devices (for example, smartphones and tablet PCs) carry out the support applications and services for the patient, while they may, at the same time, act as communication gateways between the Wireless Body Sensors and the HIS infrastructure. Besides that, the point-of-care environment also includes content sensors and actuators, communication as well as control application devices, all belonging to the facility infrastructure the patient gets connected to temporarily, e.g., his own SmartHome network, or a care home network.

***Health & Care Services*:**

The Health & Care Services environment (see Fig. 3) is an inhomogeneous world of various kinds of medical and care service providers and their systems, which are partly based on standards and partly are proprietary, including a significant base of legacy systems. A common demand of health care experts is to have access to latest patient data, either from the patient's devices in the point-of-care environment or from other health care expert, in order to carry out remote diagnoses, and to provide information and remote medical and care support to the patient. From a mHealth perspective, this demand applies in particular to nurses and doctors visiting the patient at home, or outside in case of emergency.

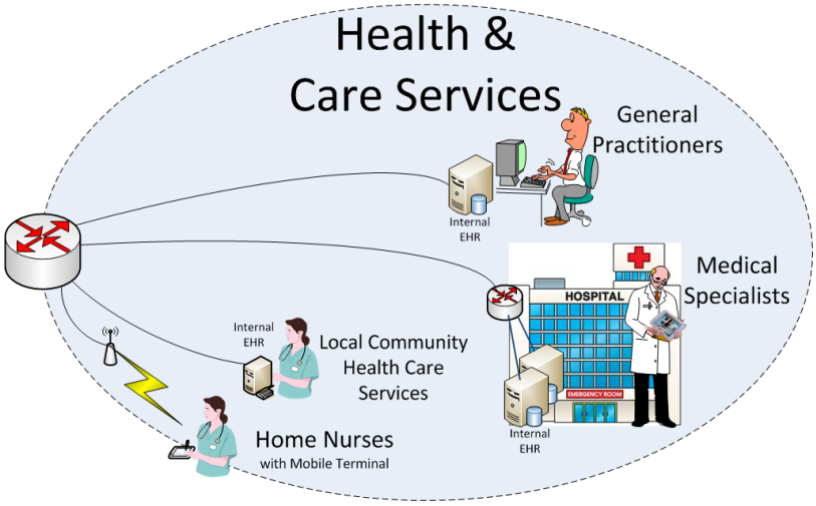

Fig. 3: Health & Care Services Environment.

***Health Information Services (HIS) Infrastructure*:**

Information from patients shall be available for medical and care specialists and vice versa. To achieve that, a heterogeneous Health Information Services (HIS) infrastructure (Fig. 4) is continuously being developed, which contains a multitude of Electronic and Personal Health Record (EHR, PHR, xHR) systems from commercial and public stakeholders, based on both closed, proprietary and on open standardized technologies. Through means of authentication, authorization and accounting (AAA), it interconnects private, commercial and open systems, including point-of-care infrastructures, with closed Health Information Infrastructures of national or international health systems.

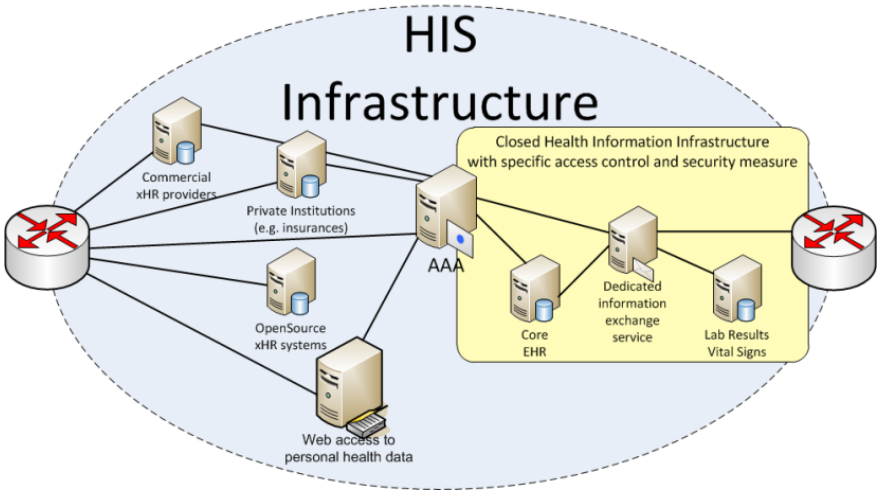

Fig. 4: Health Information Services (HIS) Infrastructure.

From a mHealth perspective, the main role of the HIS infrastructure is to enable information exchange between (potentially) mobile patients (=information sources) and (optionally) mobile health service specialists (=information receivers) in a secure, privacy protecting, and efficient manner, while allowing high flexibility with regards to the different types of information, devices and services.

3 Requirements

In order to realize the anticipated mHealth use cases, various ICT components within the different domains of the reference architecture have to fulfil certain requirements. Within this section the technical requirements are explained, which are based on an analysis of the user scenarios described in the introduction (section 1) above. Particular focus is put on those requirements that relate to the different security, reliability and usability aspects of devices, applications and services that have to be considered for the development of corresponding solutions.

Security

One of the major challenges of ICT systems are scenarios where different individuals use different connected devices to access different resources (= data and services) in a shared service and information infrastructure. This applies in particular to the user scenarios B) and C). Different people, identifiable by a certain individual identifier (e.g. a generic personID, a patientID, or a healthExpertID) can use certain devices (as personal smartphones, tablet PCs, etc.), which come with device-specific identifiers (deviceID), to get connectivity through certain communication gateway devices (as “Wearable HUB” or “HUB and UI” in Fig. 2), having certain gatewayIDs and network-specific addresses, and to access certain data and services. On top of that an infrastructure with multiple communication gateways has to be considered, together with multiple users (i.e., patients) per communication gateway, multiple personal medical devices (PMDs) per person, per gateway, and per application/service, multiple patient applications (in the point-of-care environment), and multiple health and care related services (in the health & care services environment).

The mapping of the different identifiers to each other requires a flexible and at the same time safe, reliable and trusted *relationship management*. Furthermore, smart and user friendly applications and services are needed for the configuration, provisioning and enforcement of such identity mappings.

Hence, *Security* in this context refers to the need for *access control* and *privacy protection*, based on unique *identification*, *authentication* and *authorization*.

These logical needs lead to the following functional requirements:

Table 1: Security Requirements.

Identification	Technical IDs for PMDs (sensorID, …), patient devices (deviceID, …), point-of-care applications (appID, ..), communication gateways (commGwID, …), patients, health & care experts (nurseID, doctorID, …), health & care experts services (serviceID, …), health & care experts devices (deviceID, …), HIS infrastructure services (xhrID)
Relationship Management	Mapping of PMDs, patient devices, point-of-care applications and communication gateways to a specific patient or point-of-care user (temporary, at the moment of use) Mapping of health & care experts devices and health & care experts services to a specific health & care expert (nurse, doctor, …)
Access Control	Authorize or deny access attempts from identified and authenticated users (point-of-care users, health and care experts) to any specific resource (data, service) in the mHealth infrastructures
Privacy Protection	Protection of access to transmitted and stored data and information about a specific patient, based on individual access grants specified by the patient, and corresponding access control

Reliability

The availability of mHealth services and components can be of vital importance, in particular when it comes to the fast detection of and appropriate reaction on potentially life threatening situations or medical conditions of the patient. This applies in particular to the user scenario A), and also to scenario B). The transmission of vital signs from the patient together with additional context information, such as the location while being outdoors, to the HIS infrastructure and the availability of that information to health and care experts in critical situations (e.g., critical vital signs recordings, or loss of orientation of a dementia patient) has to be ensured.

The design guidelines for typical consumer ICT equipment do not include high guaranteed availability requirements. Hence, the reliability of mHealth solutions corresponds on the one side to specific availability requirements for the involved equipment, but also to solutions for a centralized or de-centralized self-monitoring of all involved HW and SW components, and measures to react on detected malfunctions in order to restore the functionality.

The following technical requirements can be identified:

Table 2:.Reliability Requirements

Self-Monitoring	Monitoring of the operation status of HW and SW components (i.e., applications and services, in particular communication services)
HW redundancy	Provision of redundant HW (e.g., second communication gateway), that gets in operation triggered by Self-Monitoring component
Power fall-back	Switch to fall-back power (e.g., battery) in case of power breakdown, automatically or triggered by monitoring component
Connectivity fall-back	Switch to fall-back connectivity (e.g., fixed to cellular, cellular operator-1 to operator-2, cellular to WiFi, …) in case of connectivity loss, automatically or triggered by monitoring component
Capacity Adaptation	Automatic adaptation of processing and storage capacities of HIS Infrastructure services according to the load caused by growing number of active mHealth users (patients as well as health and care experts)

Usability

The capabilities and functionalities of a mHealth system as a whole can only be fully utilized, if its applications and services can be easily and efficiently accessed and used by the different users. The means to utilize certain functionalities of a system differ depending on the target users, the purpose of the applications and services, and the specific usability features of the user devices that are involved. A patient for example shall be able to use a tablet PC type of device, to check certain personal medical information at their current location, and to get in contact with a nurse or a doctor. Relatives or a nurse of the patient might utilize Web-technology based services on their smartphone or table PC device to access certain care and personal data via a dedicated portal service, independently from their own physical location. A doctor, visiting patients at their point-of-care, will use a laptop or tablet device with specific applications and services to access patients' medical and other data from the health information services infrastructure. Corresponding requirements apply to all three study cases from the Introduction section.

One requirement area concerning the usability of the applications and services comprises the various aspects of the user interface (UI, also called Human-Machine-Interface HMI), i.e., how the different user groups can be supported to optimally interact with the system. The UI design has to consider multiple factors, such as the needs, capabilities and limitations of different user groups and individual users: a doctor has UI requirements that may differ from a nurse's, a

blind patient has obvious sensory limitations and a dementia patient cognitive impairments.

Beside those requirements on the visual and interaction design, there are usability-related requirements on the underlying mHealth system infrastructure. The same medical, health and care and context data from a patient shall be, under protection of defined privacy rules, available for different user groups of the mHealth system and their specific applications and services. The vital signs recordings of the mobile COPD patient (user scenario B) shall be available for the patient for information, for the nurse for regular control, and for a doctor to support the diagnosis. Though using the same data, the user interfaces realized in the different applications and services have to be adapted according the specific needs of the users with regards to content, visual presentation, and used HW devices. The underlying requirement is a decoupling of the applications and services that gather patients' data and information, and transmit them into the HIS infrastructure, from the applications and services that present selected patients' data through dedicated UIs for doctors, nurses, and the patients.

Furthermore, the portable personal user device of the patient has to be able to carry out certain local logic based on data gathered from connected sensors and PMDs, in order to be usable for certain emergency detection and care support features of all described user scenarios.

This leads to the following overview of functional requirements related to usability:

Table 3: Usability Requirements.

Adaptive UI design	User interfaces (UIs) shall allow easy and user-friendly interaction with services and applications, while supporting personalization according to the patient's needs and preferences
Adaptation to PoC environment	User interfaces of point-of-care applications and services shall allow easy or automatic adaptation to the specific involved PMD(s) the user has to involve in an user scenario
Patient-friendly utilization of PoC data to support multiple support scenarios	Utilization of data gathered one time from PMDs in the point-of-care environment for different applications and services, locally in the PoC environment, and for health and care experts
Easy identification and relationship management	Identification of information (patientID, deviceIDs, …) shall be easily be configurable or seamlessly provisioned and propagated to support the relationship management (see Security requirements above)

4 Solutions

The solutions described in this section are those that address the three requirement areas: security, reliability and usability. Furthermore, it is explained how the solutions can be applied to realize the user scenarios from the Introduction section.

Security

Some of the main challenge areas of multi-sensor, multi-device, multi-patient, multi-gateway environments as described in the reference architecture are security management, access control and privacy protection.

User authentication is very important in healthcare information systems as it is the first step in the entire health information access process, and mHealth systems are not an exception. It is primarily used to assure that the user is indeed who they claim to be and, therefore, some mechanisms are needed to verify the user's identity. These mechanisms are commonly known as authentication factors. There are mainly three categories of authentication factors:

1. Something the user knows (e.g., password, pass phrase, PIN).
2. Something the user possesses (e.g., smart card, security token, cell phone).
3. Something the user is or does (e.g., fingerprint, retina pattern, signature, voice pattern).

There are previous works that focus on authentication of users for accessing healthcare information systems via mobile devices. Poon and Zhang (Poon et al., 2006) explored security mechanism of body area sensor network (BASN) by means of biometrics that uses intrinsic characteristics of the human body as the authentication identity. The system requires biometric sensors around the user's body for gathering the necessary human body characteristics, and thus, it is rather complex to be used in a multi-user environment. A wireless application protocol (WAP)-based telemedicine system was proposed and developed which utilizes WAP devices as mobile access terminals for general inquiry and patient monitoring services (Hung and Zhang, 2003). The users authenticate themselves by introducing username and password through a wireless markup language (WML) page loaded by the mobile devices. Marti et al. (Martí et al., 2004) presented security services required mobile eHealth applications with the MobiHealth project described as an example. The presented MobiHealth system makes use of mobile devices (e.g., smartphone) as gateways for body are network (BAN) sensors to communicate with back-end servers. However, multi-user environment where the sensors and mobile devices are used by more than one user was not described. A wearable mHealth system using a wearable wrist-worn platform called *Amulet* was proposed in (Sorber et al., 2012). The *Amulet* acts as a gateway between var-

ious sensors and the user's mobile device, which is connected to back-end servers in the cloud. The *Amulet* also acts as the user's identity proxy, so that the sensors can be used by other users, and different mobile devices can also be used as its gateway. The main issue of this approach is that every user should have his/her own *Amulet* which cannot be exchanged with other users.

To build up the authentication level, multi-factor authentication scheme is normally used by combining different authentication mechanisms. In Norway, for example, four security levels for authentication and non-repudiation are officially defined, and any use of electronic identification to authorize access to health information is subject to strong security with strong authentication. At level 4, two-factor authentication is required where one factor should be based on qualified certificates.

Authentication can be conducted by using digital signature as the electronic ID, which can be used to log into different systems. For the initial certification and secure distribution of required public-private key pairs, existing and widely accepted solutions for Public Key Infrastructure (PKI) shall be deployed, which is outside the scope of this chapter. On reception of a log in request, the receiving system responses with a random number (nonce) or a string text. Encryption is then carried out on the device of the user who wants to log in using their private key, resulting in a "digital signature". The receiving system then checks this "digital signature" with the user's public key. The private key can be stored in smart cards, key fobs, universal subscriber's identity module (USIM) or any device that has a computer chip. The common technical solution to access the private key is by inserting a card to a card reader and entering a PIN. With key fobs, the user normally has to enter a PIN, and then the device will display a number, also known as Temporary Authorization Number (TAN), which can be used to log in. In order to enable multiple users to use one mobile gateway device (communications device) for sending measurements to back-end servers (hosting various services such as the PHR) as well as for accessing/reading measurement values from those back-end servers, a solution based on digital certificate is proposed to be used as shown in Fig. 5.

Each user of the system needs to identify themselves to the back-end servers hosting various services via the mobile gateway (e.g., tablet, laptop). To achieve this, each user should have their own personal digital certificate. Such a certificate can be issued, e.g., by a health service provider, by a health insurance or by the national health system administration/authorities. It must be certified by a Certification Authority (CA), and it is stored in their personal identification device, such as smartcard or SIM card connected to a smartphone. The application in the gateway device is then responsible to send the user's credentials to the back-end server for authentication. To ensure that both gateway device and server trust each other, 2-way mutual authentication is proposed to be utilized (i.e.,

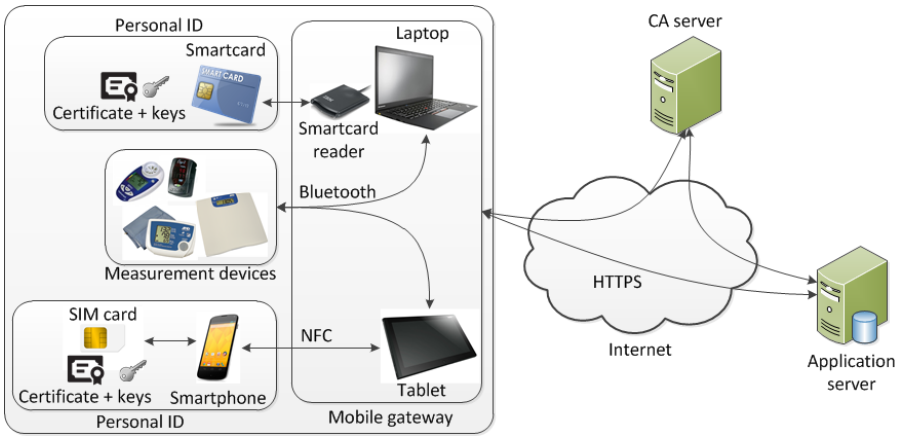

Fig. 5: Proposed architecture for multi-user mHealth environment

user's digital certificate to authenticate the user and server's digital certificate to authenticate the server). A secure connection between the gateway device and the server is then established for transmitting measurements data based on SSL technology.

Reliability

In this section, solution approaches will be described on conceptual level to increase the reliability of the mHealth infrastructure components, in order to safeguard the operation of (potentially) vital monitoring devices and alarm services even in the situation of outages of electrical power, loss of connectivity to communication networks or their complete failure, or malfunction of certain mHealth devices. The solutions address the identified requirements, and focus on the mobility of the patient and the health and care experts, and on the corresponding portability of devices, in particular within the Point-of-Care environment.

Self-Monitoring:

Self-monitoring refers to the identification of failures, in order to trigger applicable recovery or fallback actions, or to initiate alarms to local users or remote support staff. A self-monitoring function can either be deployed on the to-be-monitored device itself, in order to monitor the status of interfaces and SW components on that device, and to trigger a re-initialization or re-start if required. Alternatively, the monitoring function can be deployed on a separate, high-availability device, to avoid the impact of malfunctions on the monitoring functionality itself. However, that requires dedicated interfaces between the monitoring device and the to-be monitored device.

The main risks for the patients in all three user scenarios when being outdoor on the move is the loss of connectivity to the HIS infrastructure, or with one or multiple wireless body sensors. A monitoring function on the "Wearable HUB"

(e.g., a smartphone) or on the "HUB and UI" (e.g., a tablet PC) continuously controls the connectivity with the wearable body sensors and with the HIS infrastructure via mobile communication, such as via a cellular communication network or via a Wireless LAN (WLAN) infrastructure. On detection of a connectivity loss, the monitoring function will initiate a connectivity recovery function that tries to re-establish the connectivity. If connectivity recovery to either the wearable sensor/s or the HIS infrastructure is not possible, the patient will be provided with corresponding information and recommendations, under consideration of their usability and interaction needs.

HW Redundancy:

In order to take care of the availability of essential mHealth solutions also in the case of HW failures, critical components can be duplicated. In case of outage of a component, the stand-by device (so far redundant) with replicated application and service SW takes over the functionalities.

Two modes of operation are proposed: (1) a "master-slave operation", and (2) a "parallel operation" mode. In mode (1), a self-monitoring component (see above) activates a "slave" device on detection of a malfunction of the "master" device. The slave device carries out the same applications and logical functionalities as the master device, and the monitoring function also takes care for the capturing and provisioning of operational status information from the master device, in order to continue the operation on the slave device as seamless as required and possible. In mode (2) the critical SW applications and functionalities are deployed and executed on two identical, separate HW devices in parallel. If one HW device stops working, the other one continues with seamless operation. A monitoring function detects the malfunction of one device, and initiates a notification in order to request a HW replacement.

The utilization of HW redundancy is applicable to all three user scenarios. The communication functionality of a tablet PC can be taken over by a mobile phone or portable embedded device with mobile communication support, in case of failure of the tablet PC. Though the support applications are potentially reduced in functionality and usability on a smaller or even headless (i.e., without display) device, the transmission of potentially vital life sign recordings from the patient to the health & care experts via the HIS infrastructure continues. Wearable sensor devices for the measurement of important health data can be duplicated, in order for the data to be available also in the case one sensor stops working.

Power fallback:

One aspect of the "power-fallback" is the continuation of operation of devices in the patient's point-of-care environment at home in the case of a failure of the public power supply. In this case the role and functionalities of a device with

power supply from the grid, e.g., a stationary “Home-Gateway”, is taken over by a battery-powered device as the “Wearable HUB” (e.g., smartphone) or a “HUB and UI” (e.g., tablet PC). This is of particular relevance for the communication functionality. The detection of the power-failure and the handover to the alternative hardware is supported by the (battery-backed) monitoring function.

Another aspect is the reliability and availability of functionalities of the portable devices the patient has with them when being outdoors on the move. A power-monitoring functionality monitors the power status of the devices (in particular of the communication and application device (e.g., tablet PC), reduces the power consumption at certain charging levels (e.g., by reducing communication frequency or screen brightness), generates power alarms in form of notifications to the patient and to remote personnel in order to request a re-charge, and initiates a handover to a second redundant device that still has power.

Connectivity fallback:

The availability and reliability of the communication functionalities is of essential importance for all user scenarios that include the measuring of vital signs from patients on the move, and the transmission of those data to HIS infrastructure services, from where they are utilized by remote health and care experts or for the information of relatives. Hence, in case of breakdown of one underlying communication service or certain involved connectivity components, the communication continues through another available communication link or technology.

In case the fixed broadband connectivity of a Home-gateway in the patient’s PoC environment stops working, the monitoring function (see above) initiates the handover of the communication to any available portable device with cellular connectivity, such as a smartphone or cellular-enabled tablet PC.

In case the cellular connectivity of the “wearable HUB” (e.g., the smartphone) of the patient stops working due to, e.g., loss of coverage or network failures while the patient is on the move, the monitoring functionality initiates the reconnection to any alternative cellular or WLAN network, or informs the patient about recommended actions.

Capacity Adaptation:

Within the context of reliability of mHealth services there is also the availability of underlying infrastructure components and services. In order to adapt to increasing processing and storage requirements caused by an increasing number of service and infrastructure users, also the corresponding capacities of the involved components have to be adapted. The basic concept is to apply cloud technologies, such as load balancing on virtual servers to infrastructure components as the

proposed Information Integration Platform (IIP). However, the discussion of those technologies is out of the scope of this chapter.

The prototypical verification of the proposed solution concepts is part of ongoing work (see also the outlook section).

Usability

The importance of a user-friendly design needs to be taken into account when developing new mHealth services. The combination of user-specific requirements and limited relative small-screen interfaces as on smartphones creates design challenges in usability, which includes learnability, efficiency and satisfaction as the general requirements described by (Nielsen, 1993). In a systematic approach to design principles, Su et al. showed how a mobile nursing information system can be developed when taking care of the usability aspects and the user's cognitive model, and not only the technology aspects (Su and Liu, 2012).

It will also be important to perform adequately usability testing in a realistic scenario and environment with a high level of realism, as this will influence the actual use, as highlighted by (Svanæs et al., 2010). They have proposed a model for usability tests for mobile health care systems where the physical environment will play an important role, looking at ergonomic aspects such as the ability to have both hands free. Those principles can also be applied to the health and care support for a mHealth patient. How the actual devices and sensors can be used in a daily situation will be of outmost importance for how those systems will be used. This is also according to the Technology Acceptance Model as described by Davis (1989), where the combination of easiness in use and usefulness of the solution can give an indication of future use of a system.

In order for elderly people to become familiar with the usage of new mobile technology solutions, it will be relevant for developers to gain interactive experience of how elderly feel when using the mobile technology. The functions they are provided with should not be limited to assist the user but also to let the user interact with the system, as described by Isaacs et al. when addressing issues of surrounding accessibility to mobile devices and services (Isaacs et al., 2013). Design requirements for mHealth solutions will need to take care of the different users and their needs, with a special focus on the elderly person who is supposed to give inputs from vital signs measurements, understand information and warnings given from sensors and reminder functions, as well as to interact with health care workers and close relatives at distance by video conference and social media solutions.

Traditionally, the patient care and daily support will be the responsibility of the actual hospital, the local doctor (GP) or the municipality home health care services. As the access to a patient's health record normally will be restricted to

health care personnel employed at the actual organization, the case for our mHealth patient will be a seamless health care service across organizational borders. However, several obstacles both or regulatory issues and of technical interoperable issues will be a challenge in defining a reference architecture. The focus on shared access to medical information will be important for inter-organizational collaboration when introducing new care pathways based on the mHealth technology options. McGinn et al. stressed the importance of understanding the user needs and perspectives when implementing multi-organizational care services because of the complexity and focus by different health care professionals (McGinn et al., 2012). Especially, the team communication will require efficient information flow (Kuziemsky et al., 2009, Borycki et al., 2010). However, limited interoperability and inflexible workflow processes were discovered to be major obstacles when introducing new health care services for the community care in Australia (Clark and Lewis, 2012), and this is probably a general problem in most countries. Seamless healthcare will require access to medical information across organizational boundaries when the patient's travel between different health care services will have a need of co-ordinated follow-up, as described in a report from NHS in England (Eason et al., 2012).

Beside the User Interface (UI) and interaction aspects of applications and services the patient (or user in more general terms) is confronted with when using any mHealth device or application. There are aspects in the underlying communication infrastructure related to the distribution of measurements and other patient data to multiple services, which also have a significant impact on the overall usability of mHealth environments.

As stated in the usability requirements above, the patient data measured in the PoC may be needed for more than just one service (e.g., remote health monitoring service, PHR service, hospital EHR service, alarming service, and social media service). In the traditional siloed approach, each measurement device sends its measurements to a specific application running on the mobile gateway device, which then forwards the data to the corresponding back-end server hosting a specific service. The usability of the system is sacrificed since the user has to interact with different applications running on the mobile gateway device, or even with different dedicated devices for each specific application. Furthermore, running many applications on a mobile device will also consume more battery power, which will reduce the lifetime of the device. One solution is to deploy one application on the mobile gateway device which is responsible for handling measurement data from all measurement devices, and sends the data to different services. The drawback of this approach is that the mobile device still needs to send measurement data to multiple destinations (i.e., multiple services), which will also affect the power consumption negatively. To tackle this issue, an Information Integration Platform (IIP) is proposed to act as aggregation and distribu-

tion point for measurement data, so that the mobile device only needs to send the measurements once. The IIP is responsible to deliver the measurement data to services that use it. Publish/subscribe messaging pattern is utilized by the IIP so that different services can subscribe to different measurement data channel and get notified whenever new data is available. Fig. 6 shows the deployment of an IIP within the proposed reference architecture. A more detailed description of the IIP's functionalities is available in (Trinugroho et al., 2013).

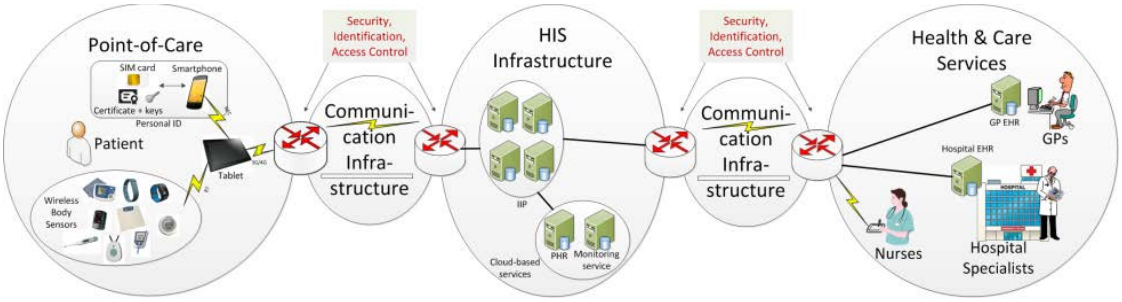

Fig. 6: End-to-End Architecture with Information Integration Platform (IIP).

5 Experiences and Results from Prototypes

Several prototypes have been designed and developed, covering the essentials of the proposed solutions for the mHealth ecosystem. In order to enable measurement data to be reused by different services, the IIP has been developed and deployed in a lab environment. As mobile devices play an important role within the mHealth ecosystem in supporting mobile patient, their lifetime operation can be very crucial for the safety and health of the patient. By utilizing the IIP, which is deployed in the cloud, mobile devices used by the patient only need to send one message for each measurement to the IIP. The IIP is then responsible to distribute this message containing the measured data to different services (e.g., alarming service, remote health monitoring dashboard service, PHR service, and hospital EHR service). This will reduce the mobile devices' power consumption while also eliminating the requirement of the patient to do multiple measurements with different redundant devices for different services, which can be seen as a serious usability drawback. The IIP itself makes use of publish/subscribe messaging pattern which enables various services to subscribe to different data and get notifications whenever new data is available. More detailed functionalities of the IIP are described in a separate article written by the authors in (Trinugroho et al., 2013). Fig. 7 depicts two deployed prototype services, namely remote health monitoring service and SOS service by utilizing the IIP as service broker.

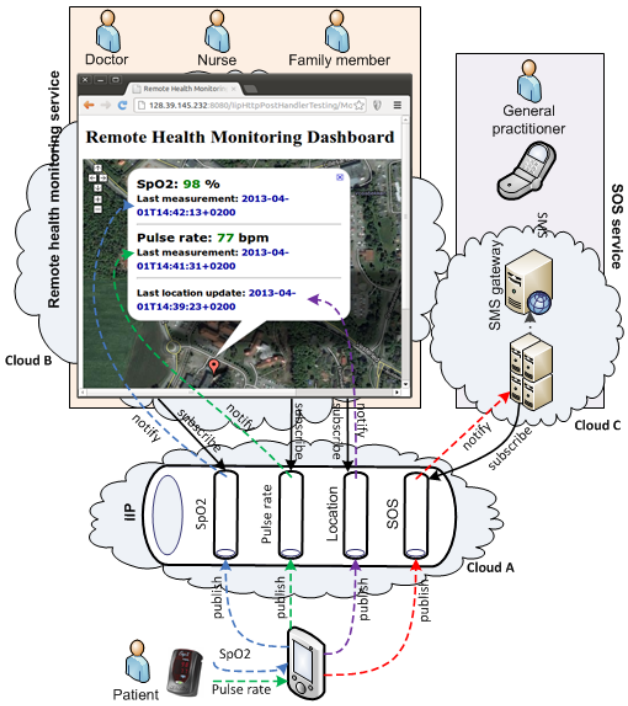

Fig. 7: Remote health monitoring and SOS services through IIP (Trinugroho et al., 2013)

Digital certificates play a central role in Public Key Infrastructure (PKI), deployed for example on electronic ID cards which provide means of proving an identity in electronic transactions (Adams and Lloyd, 1999, Housley and Polk, 2001). It is also used to verify that a public key belongs to a specified identity. A digital certificate is issued by a certification authority (CA), which is a third party entity whom both the user of the certificate and the serving party, such as a Web site, trust. The signature on a certificate is testament by the certificate signer that the identity information and the public key belong together. PKI forms a hierarchy where root CA may issue certificates directly to an entity or delegate this process to subordinate CAs, which results in a chain of certificates. The root CA and the subordinate CAs along the chain must have the trust of the verifiers to verify an end-host certificate. In some cases, the CA incorporates the role of a registration authority (RA). Where a separate RA is used, the RA is a trusted End-Entity certified by the CA, acting as a subordinate server of the CA. The CA can delegate some of its management functions to the RA. For example, the RA may perform personal authentication tasks, report revoked certificates, generate keys, or archive key pairs.

The CA is responsible for issuing and verifying certificates. The CA can be a unit within an organization or a company, but also an independent entity. The CA signs the public key certificate to prevent modification or falsification. The Root CA's certificate forms the root of all certificate validation. The validation of certificates occurs using the appropriate public certificate residing within the root

CA list. When a client has established a trust to a CA, they can trust certificates issued by that CA. The clients are ensured that the certificate is genuine by verifying the signature using the CA's public key. The infrastructure consists of a CA with Certificate Revocation List (CRL) publication and Online Certificate Status Protocol (OCSP). The CRL is a list of revoked certificates, while OCSP is a standard protocol to verify certificates online.

A prototype that enables the mobile patient to do measurements and to send the data to a remote PHR server has also been implemented, incorporating mutual authentication between the mobile device and remote server based on digital certificates to comply with the Norwegian level 4 security requirements. The prototype supports multiple users to use one mobile device, with a simplification that all client certificates are stored in the mobile device itself, and different users (e.g., patients, nurses) have to authenticate themselves to the mobile application by using passwords. The password used for logging in to the mobile application must match the password for the client certificate in order to establish a secure connection. If the password does not match any stored client certificate, the interaction is cancelled. The prototype consists of a server-side and a client-side application. A Web server and the CA are hosted in the server, and the Web server mainly hosts a PHR application with a database. The client-side is an Android application that is responsible for sending measurement data to the server and for displaying a Web page containing information from the server-side PHR application. Both the client and the server have their own certificates issued from the CA. Before any data gets exchanged, a secure connection has to be established.

Fig. 8 shows a sequence diagram of a patient sending a measurement data to the PHR application through a mobile device, and Fig. 9 depicts a sequence diagram of a patient accessing their health record via a mobile device.

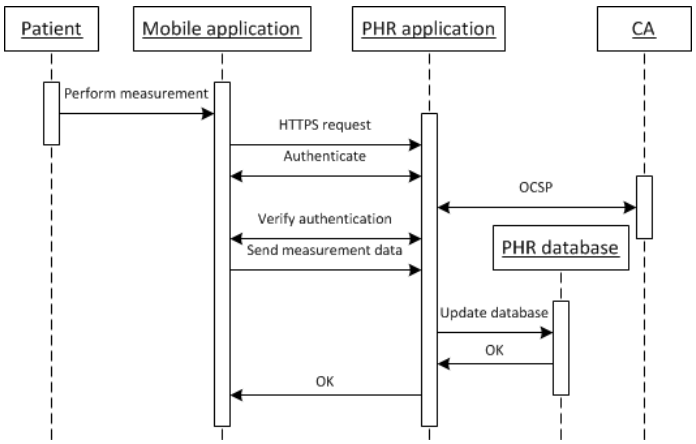

Fig. 8: Sequence diagram of sending measurement data

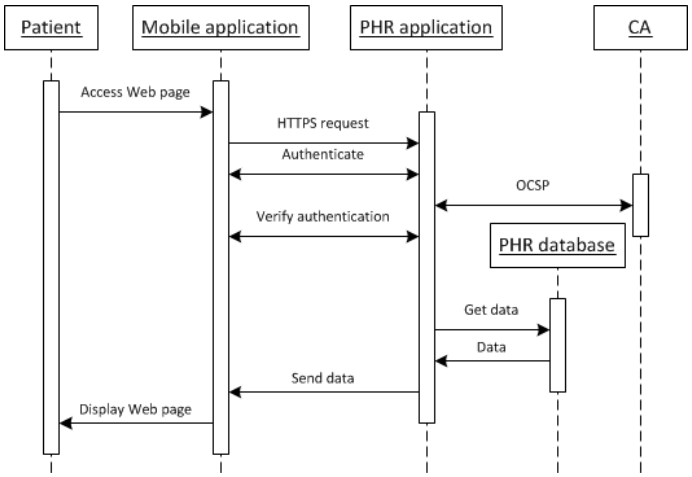

Fig. 9: Sequence diagram of accessing measured data

6 Conclusions

Within this chapter, security, reliability, and usability aspects within mHealth environments have been addressed. Three user scenarios have been described to act as guiding case studies for the analysis of requirements and solutions, and a generic reference architecture for the mHealth ecosystem has been described, encompassing three main entities, namely the point-of-care environment, the HIS infrastructure, and the health and care services. Based on the concrete user scenarios, a requirements analysis has been carried out, determining requirements that general mHealth solutions put on the various components of the mHealth reference architecture, with focus on the main study aspects.

Addressing the requirements, a number of solutions have been proposed, including state-of-the-art solutions, prior-art technologies, and concepts for further study and verification. The proposed solutions have been partly realized and verified as proof-of-concept implementations.

One learning from the realization of the proposed security solutions is the principle trade-off between security and usability. A secure communication channel and a reliable access control and privacy protection are very important for exchanging and storing health-related data, and user authentication is the first and utmost important step. The safer the user authentication process should be, the more authentication factors are required to be used. However, security levels are usually increased in proportion to the increased difficulty level of efforts that the user has to perform, which leads to significant usability drawbacks. Considering disabilities and limitations of typical mHealth user, the level of security has to be compromised with the required ease of use.

Another major result is the developed general reference design, which follows the reference architecture and contains solution components as a portable com-

munication gateway in the PoC environment and the Information Integration Platform (IIP) in the HIS infrastructure, which have been developed using open standard technologies. As a conclusion from the prototyping and verification, we propose to use a general open infrastructure for the development of new mHealth solutions and services, and recommend following the approach selected for the described reference design.

7 Outlook

The currently implemented prototype for the verification of the authentication solution for multiple users using one mobile device to send measurement data to back-end servers is simplified to utilize username and password as credentials, which are then mapped to corresponding digital certificates stored in the mobile device. A dedicated personal identification device is under development, including smartcards and SIM cards. The digital certificates which are issued by the CA are stored in these personal identifiers. The utilization of USIM cards, which carry personal certificates for identification and authentication purposes, is also being studied.

The proposed solution concept for reliability and availability of connectivity including monitoring components is under preparation.

Furthermore, there is an ongoing work on a UI adaptation component to adapt UI and interaction characteristics from the perspective of usability and user needs.

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10 Questions and Answers

(Q1) What are the main scenarios / case studies for mHealth solutions?

(A1) Support for patients in early dementia stage living in their own home; allow patients with chronic diseases to live at their own home and keep mobile as much as they can; "home-based-care" = support the remote treatment of patients at home or on the move to achieve rehabilitation and physical training, to avoid long-term and expensive hospitalization.

(Q2) How can mHealth solutions support the life of patients in an early dementia stadium?

(A2) remind of regular tasks, appointments, medication, etc; support for orientation and positioning, including tracking in case of emergency; keep social contacts and initiate audio-visual-communication.

(Q3) What are the key requirements for mHealth solutions as discussed in this chapter?

(A3) Security (involving access control and privacy protection, based on identification, authentication, authorization); Reliability (including self-monitoring, redundancy/fall-back solutions); Usability (including accessibility).

(Q4) What are the main domains of an end-2-end mHealth reference architecture?

(A4) Point-of-Care environment; Health & Care Services environment; Health Information Services (HIS) environment.

(Q5) How can a patient be reliably identified and authenticated in a mHealth environment in a user-friendly way, i.e., without much user involvement?

(A5) With an electronic, personal user ID, in form of a private, certified key stored on a personal device as a smartcard, key fob, or SIM/USIM card attached to a personal device, such as a smartphone or tablet PC.

(Q6) Why can self-monitoring, application recovery and fallback actions be very important for mHealth services?

(A6) In order to safe-guard the operation of (potentially) vital monitoring devices and alarm services even in the situation of outages of electrical power, loss

of connectivity to communication networks or their complete failure, or malfunction of certain mHealth devices.

(Q7) What are crucial usability aspects for mHealth solutions?

(A7) Adaptation of user interfaces to the needs, limitations, and preferences of patients; adaptation to the specific point-of-care environment and its characteristics with regards to specific medical devices, treatments; compromise between security and usability.

(Q8) What are the common authentication factors and their examples? What are the main advantage and drawback of having multiple authentication factors?

(A8) Something the user knows (e.g., password), something the user possess (e.g., smart card), something the user is or does (e.g., fingerprint). The more authentication factors being used, the more secure a system is. However, multiple authentication factors can lead to usability issues as it becomes more complicated to use the system.

Appendix E

Telemedicine and Cooperative Remote Healthcare Services: COPD Field Trial

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Telemedicine and Cooperative Remote Healthcare Services: COPD Field Trial

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Abstract — **The introduction of sustainable telemedicine solutions throughout Europe requires the development of secure, flexible and expandable systems and the evaluation of their operation in real-world settings such as field trials. This paper describes a system for a remote monitoring and care support field trial with Chronic Obstructive Pulmonary Disease (COPD) patients. By following a user-centred development and Privacy by Design approach, the needs of all involved user groups could be addressed, while fulfilling, at the same time, national requirements with emphasis in security and privacy protection. The solution covers specific applications and services for COPD patients and their remote care takers, but allows the generalization of its applicability to other patient groups.**

Keywords — **eHealth, telemedicine, nursing informatics, Health ICT, system implementation, National Health Policies and Informatics**

Introduction

The average life span of people is increasing [1], leading to a scenario where a high percentage of the world-wide population is affected by ageing-related chronic diseases. For instance, Chronic Obstructive Pulmonary Disease (COPD) will be the fourth most common cause of death by 2030, according to a projection from the World Health Organization [2]. This development leads to the need for patient-centred efficient care solutions that help to keep patients independent as long as possible. At the same time, efficiency is a major challenge for the medical sector. Medical routine supervision of patients with chronic diseases have a high potential for efficiency gains, by giving support to patients in their private homes, while avoiding unnecessary consultations.

In this paper, we present a case study of a field trial system for the secure remote monitoring and support of home-based COPD patients. The scientific scope is the information and communication technologies (ICT) needed for the end-to-end system, including the approach of Privacy by Design (PbD). The study is carried out in 3 phases: (1) initial design, development and test phase (including description of the target telehealth and telecare applications and services, analysis of technical requirements, state-of-the-art systems, and the development of an end-2-end solution; (2) pilot test phase with a small number of test patients, including system tests and refinements; and (3) field trial phase within the FP7 EU project "United4Health" [3]. The structure of this paper follows these phases, and concludes with a brief evaluation and discussion of the solution including an outlook for further research.

1. Target Services and Requirements

Chronically ill patients need frequent monitoring of their health condition and prompt follow-up at the point-of-care. The trial system for the United4Health project will support remote monitoring and follow-up assistance for the patients after being discharged from hospital to their homes, additionally considering the need for a close collaboration of different health care organizations.

The system (see Figure 1 for the reference system overview) will provide the following main services and functionalities:

- Daily measurement of blood oxygen saturation (SpO_2) and pulse.
- Electronic patient questionnaire for daily reporting of COPD symptoms.
- Anonymized and encrypted data transmission to Electronic Health Record (EHR) and Personal Health Record (PHR) systems.

- Telemedicine system for the collaborating healthcare organizations, providing follow-up support with overview of patients' status and access to monitoring data.
- Video consultation and follow-up support between health care staff and patients.

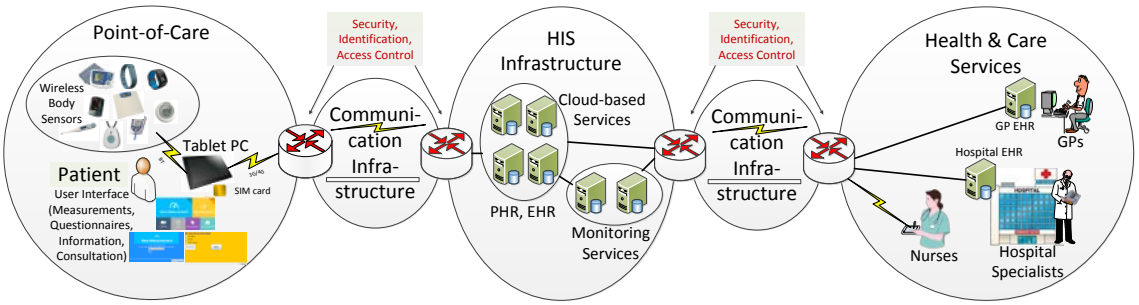

Figure 1: Reference System Overview

2. The Field Trial System

Most emerging telemedicine systems are proprietary, transmitting the information through a dedicated communication gateway device and providing very limited integration of the point-of-care environment with a generic, standard-based HIS infrastructure. The presented trial system widely corresponds to the Continua End-to-End reference architecture [4], while the Continua "WAN device" is separated into a data aggregation component (see the Information Integration Platform (IIP) [5] in the software architecture overview of Figure 2) and a value-adding services component.

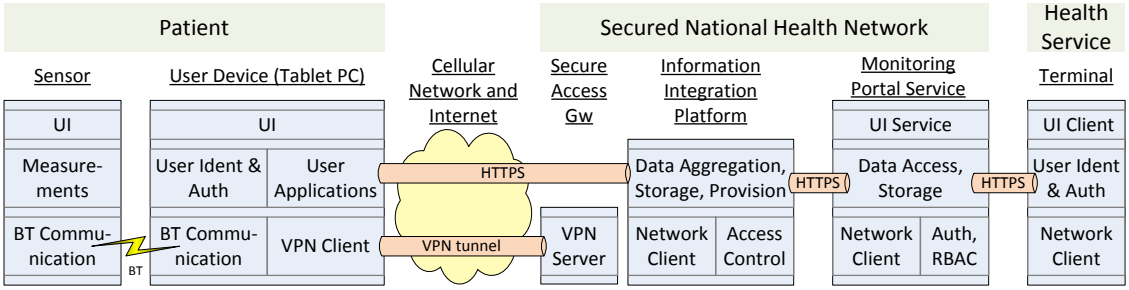

Figure 2: Software Architecture Overview

The solution development has followed a PbD principle, implementing a hierarchical ***security concept***. All data communication between patient's tablet PC and the Secured National Health Network takes place through an encrypted VPN tunnel in the Cellular Network and Internet infrastructure. The transmission of user data from the tablet PC (sensor measurements and questionnaire answers) to an IIP is additionally encrypted by utilizing HTTPS. The Monitoring Portal

Service accesses the patient data provided by the IIP also via HTTPS, and provides an encrypted monitoring UI to various Care Service providers. Patients identify and authenticate themselves through the tablet's user applications. Privacy protection is achieved by an anonymized identifier for the patient data. Any health care professionals identify and authenticate themselves towards the portal service, to provide Role Based Access Control (RBAC) to the patient data. The access of different services to the IIP is controlled by an identity-based Discretionary Access Control (DAC).

The development of application and service UIs has followed a ***user-centred design*** (UCD) process. Relevant user groups have been involved as "co-designers" in the iterative interaction design, implementation and testing of patient applications on the tablet PC as well as the monitoring services for care professionals.

Aiming for ***Interoperability and Integration*** with legacy HIS components, the implementation of the communication solution for the system components utilizes open Internet standards, e.g. HTTP(S) protocol and RESTful Web Service interfaces to IIP. The medical sensor devices are certified by the Continua Alliance to allow an easy integration of the Bluetooth communication protocol with the tablet PC. The implementation of the tablet PC software in Java provides platform portability.

3. Discussion, Conclusion and Outlook

The presented system has been designed for sustainability in a phased approach and deployment in the secured National Health Network infrastructure. It is being used in this national network until summer 2015 as a field trial system involving up to 200 patients, representing the Norwegian contribution of the EU FP7 project United4Health [3]. To our knowledge, similar national solutions in other countries do not fulfil the security requirements for the deployment in the Norwegian Health Network. The scope of the trial covers the technical feasibility of the system, usability aspects for patients and care professionals, suitability for the collaboration of care providers, and care efficacy for the patients. Corresponding research results are separately presented. The architecture follows the Continua reference architecture [4] with an implementation that can be easily adapted for patients with other (chronic) diseases. The xHRN interface for integration with standard-based EHR systems is an ongoing work.

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Appendix F

End-to-end Security and Privacy Protection for Co-operative Access to Health and Care Data in a Telehealth Trial System for Remote Supervision of COPD-Patients

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End-to-end Security and Privacy Protection for Co-operative Access to Health and Care Data in a Telehealth Trial System for Remote Supervision of COPD-Patients

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Abstract — **The security and privacy of personal, health-related data in emerging telehealth and telecare systems is crucial, in particular under consideration of additional requirements. On the one hand optimal usability of the devices and applications provided for the monitoring of the health condition is desirable for the supervised patient. On the other side the different health and care organizations require co-operative access to the common infrastructure for storage, transmission and provision of the data from the patients.**

In this paper we analyse the different types of security related issues and requirements of the telehealth trial system developed for a Norwegian implementation of the EU funded United4Health project, and describe a solution concept for functionalities and policies addressing those requirements. Identified design limitations of the security concept and initial results from the trial operation are discussed.

The paper concludes with the general relevance of the proposed security concept also for telehealth systems for remote monitoring of other patient groups by potentially other types of services, and an outlook on expected infrastructure evolutions and corresponding security considerations.

Keywords — **Security, privacy, telehealth, telecare, EHR, NHN, cloud, health information technology**

Introduction

The amount of personal, health related data that are collected, transmitted, stored, processed, and provided by data systems connected to the Internet (or in the *Cloud*), is strongly increasing (as indicated e.g. by the increasing adoption of EHR systems [1]).

On the one hand this is driven by telehealth and telecare systems for professional health and care service providers, which typically support the remote supervision of home-based patients. As the average life span of people is increasing, an increased percentage of the worldwide population is affected by ageing-related chronic diseases [2]. Chronic Obstructive Pulmonary Disease (COPD), for example, will be the fourth most common cause of death by 2030, according to a projection from the World Health Organization, only behind ischemic heart disease, cerebrovascular disease, and HIV/AIDS [3, 4]. It will be the fifth most common cause of chronic disability worldwide by 2020 [5]. In order to keep such patients independent and autonomous within their own living environment as long as possible, patient-centric and efficient supervision and care solutions are needed. And in order to secure the future of health and care systems around the globe, such solutions must provide the best balance between high-quality medical support for individual patients and cost for the society. Medical routine supervision and remote follow-up of patients with chronic diseases is one area that has a high potential for efficiency gains, by giving optimal personalized support to patients within their own private environment, while avoiding unnecessary consultations [6].

On the other hand, commercial, cloud based services for end consumers (as e.g. Apple Health, Fitbit, Jawbone UP, Nike FuelBand, Polar, Samsung, Sony; see [7]) are getting momentum. Such services allow to collect certain health and fitness related data (as typically pulse / heart rate, motion / activity, body temperature, blood pressure, etc.) and to illustrate those on gadgets (as SmartPhones, SmartWatches, etc.) and on corresponding vendor-specific Web-based portals.

Personal medical data about health and care conditions are privacy-critical on the one hand, and a functioning health information service infrastructure as a whole is of potentially life-critical relevance on the other hand. Due to that, there are a number of security aspects to be considered when collecting, accessing, transmitting, and providing different types of information via the distributed components of the health infrastructure.

The general focus of this paper is on the privacy protection of patient data within the components of the end-to-end infrastructure of a telehealth and telecare sys-

tem. The security aspects to be considered when developing of a security concept for the Information and Communication Technology (ICT) solution are manifold:

- The *patient* (or in general the supervised person) must be reliably authenticated.
- The devices (as e.g. dedicated sensors) for the acquisition of medical, health and care related information from the patient must be reliably authenticated.
- The communication between the measurement devices (sensors) and the patient application device (e.g. a tablet-PC) must take place via a secure connection.
- A clearly defined *relation management* must be in place between the patient, the patient application device, and the measurement devices, in order to reliably relate the personal data from the patient (as sensor measurements or other data gathered via the patient application device) to the corresponding patient.
- The access of the patient to the patient application device must be authorized.
- The access of the patient application device (and the applications running on it respectively) to the communication infrastructure must be controlled.
- The transmission of data between the patient application device and any Electronic Health Record (EHR) or Personal Health Record (PHR) service component in the health information infrastructure must be secured (encrypted).
- The access (e.g. from any telehealth or care service provider) to any personal patient data in the health information infrastructure (i.e. stored and processed in any EHR or PHR system) must be controlled.
- If components in a dedicated national health network as the Norwegian Health Network (NHN, [8]) infrastructure are involved, specific authentication and authorization rules for access control might apply.
- The communication between the information access devices of telehealth and other medical and care service providers and the EHR or PHR systems in the health information infrastructure (as in a NHN) must be secured (encrypted).

As basis for a more detailed analysis of security related requirements, and for the development and discussion of a security concept, we look at the telehealth trial system developed for the EU-funded project “UNIversal solutions in TElemedi-

cine Deployment for European HEALTH care" (United4Health, or just U4H), and especially at the solution developed for the specific Norwegian requirements [9]. The aim to support a close cooperation of professional health and care providers from different organizations, and to involve even informal care providers as relatives, puts specific requirements on the system, in particular with respect to the security of the patient data. Another focus point for the development and evaluation of the U4H trial system has been the usability of applications and services for the different involved user groups (namely patients and care providers), and we address also the specific impacts of security mechanisms on the usability in this paper.

Within the following *Materials and Methods* section we will give a short overview of the U4H trial system and its main use cases. As part of that we will provide a detailed analysis of the security-related requirements within the different architectural domains of the end-to-end (e2e) system. In the *Results* section we will explain the security concept, which has been implemented in the U4H trial system. In the *Discussion* section we will then look at covered security requirements and potential security limitations, and address improvement potential with regards to usability. In the *Conclusions* we will explain the general relevance of the security concept (proposed for the ongoing U4H trial system) for other telehealth and telecare services for the collection and communication of health data.

Materials and Methods

Figure 1 shows the systems architecture of the U4H trial system with its main domains, the Point-of-Care (PoC) environment of the patient, the Health Information Services (HIS) infrastructure, and the infrastructure for the Health and Care Sources, i.e. the different sources of health and care services.

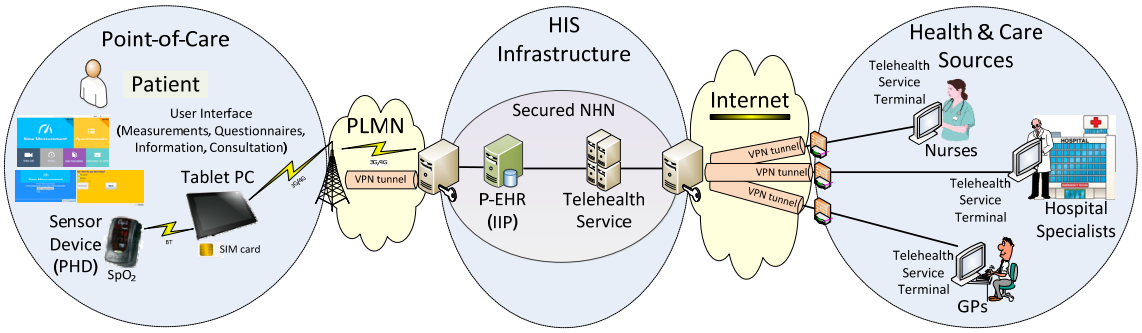

Figure 1- Architecture overview of United4Health telehealth trial system for COPD patients

The U4H Trial System

The overall purpose of the U4H trial system is the remote supervision and follow-up support for COPD patients in their home after being discharged from hospital, following a stationary treatment. We will subsequently explain shortly the main functionalities of the system along the different system domains.

Point-of-Care:

A software application on a tablet-PC supports the patient to carry out daily (at least) measurements of his pulse and blood oxygen level (SpO_2). The SpO_2 sensor device communicates the measurement values through a wireless Bluetooth (BT) connection to the tablet-PC. Additionally, the breathing quality of the patient can be measured with a Spirometer device.

The patient application on the tablet-PC provides furthermore a user interface (UI) with questionnaire forms for the daily reporting of COPD-symptoms of the patient.

The data (SpO_2 values, optionally Spirometer values, questionnaire answers) are stored in a local database on the tablet-PC. From there they are used for an information UI for the patient, and are transmitted to the HIS infrastructure.

Within the U4H field trial, each COPD-patient uses the tablet-PC for a temporary period of one month. After that period the device is provided to another patient participating in the field trial.

Health Information Services Infrastructure:

The data from all remotely supervised patients are transmitted and stored in a personal electronic health record system (P-EHR). A dedicated telehealth service provides a Web-based information portal for telehealth and care service providers. This service takes the patient data from the P-EHR system, evaluates the data according to “red (critical) – yellow (attention) – green (normal)” conditions (“Triage”), and provides overview pages with the triage-results of all supervised patients, as well as detailed condition pages with all information from a specific patient, collected during the supervision period.

Health and Care Sources:

Health and care professionals from different organizations have collaborative access to the telehealth data (i.e. measurements and questionnaire answers) from patients they are responsible for. This includes specially trained telehealth nurses (potentially located in dedicated telehealth center facilities), medical specialists in the hospital where the patients have been treated before discharge, and also general practitioners (GPs) that take care for the ambulatory care of the patients.

With a telehealth service terminal the health and care service providers get access to the Web-portal containing the overview of patients' status and the history of detailed monitoring data, provided by the telehealth service in the HIS infrastructure.

The U4H trial system also supports video consultation between the patient and the health and care service providers for the remote check-up and follow-up support. The security of the video consultation system is not considered in this paper.

Information flow through the U4H system

When a patient answers the daily questionnaire on COPD-symptoms on the tablet-PC, the answer-values are stored on the tablet-PC, together with an identifier of the patient and the date/time when the questionnaire took place (Figure 2).

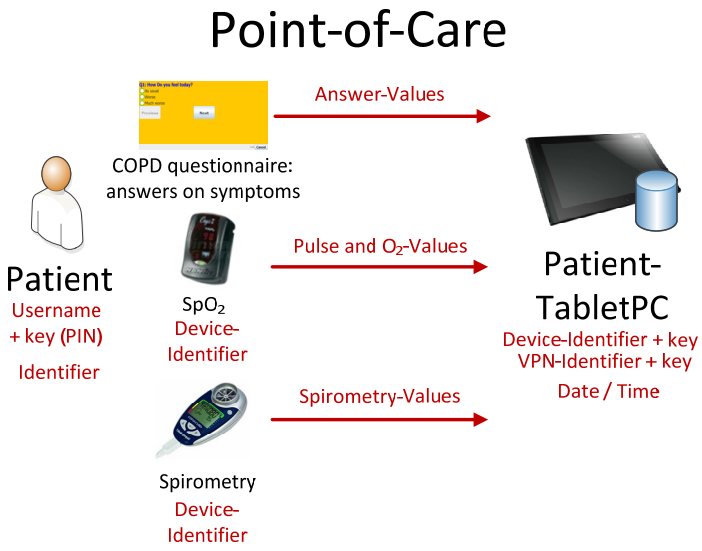

Figure 2- Information Flow in the Point-of-Care

Similarly, pulse and O_2-values from a pulse-oximetry measurement or the measurement-values from a spirometer-measurement are transmitted to the patient-tablet-PC, and are stored there together with the patient-identifier and the date/time of the measurement.

The patient-related information from each distributed patient-tablet-PC is transmitted to a Personal Electronic Health Record (P-EHR) system in the Health Information Service infrastructure (Figure 3). This information includes a patient-identifier, the answer-values from the COPD-symptoms-questionnaires, the pulse- and O_2-measurements-values, and the spirometry-measurements-values, all combined with the date/time of their acquisition, and the device-identifier of

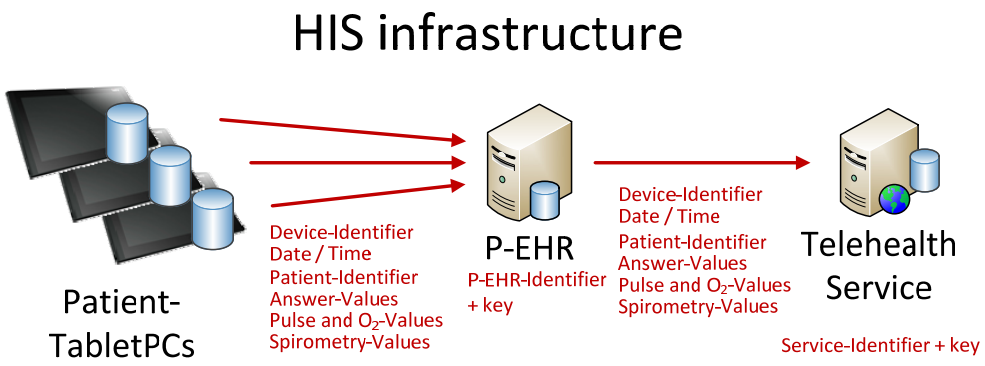

Figure 3- Information flow through the HIS Infrastructure

the patient-tablet-PC that was used for the acquisition of the information. In the P-EHR service the data is stored in a database, and is made available to the telehealth service.

The telehealth service is the central Web-based access point for the questionnaire and measurement data from all supervised COPD-patients. Also the results from the Triage-evaluation, carried out by the telehealth service and using the raw patient data, are provided via this Web-portal (Figure 4).

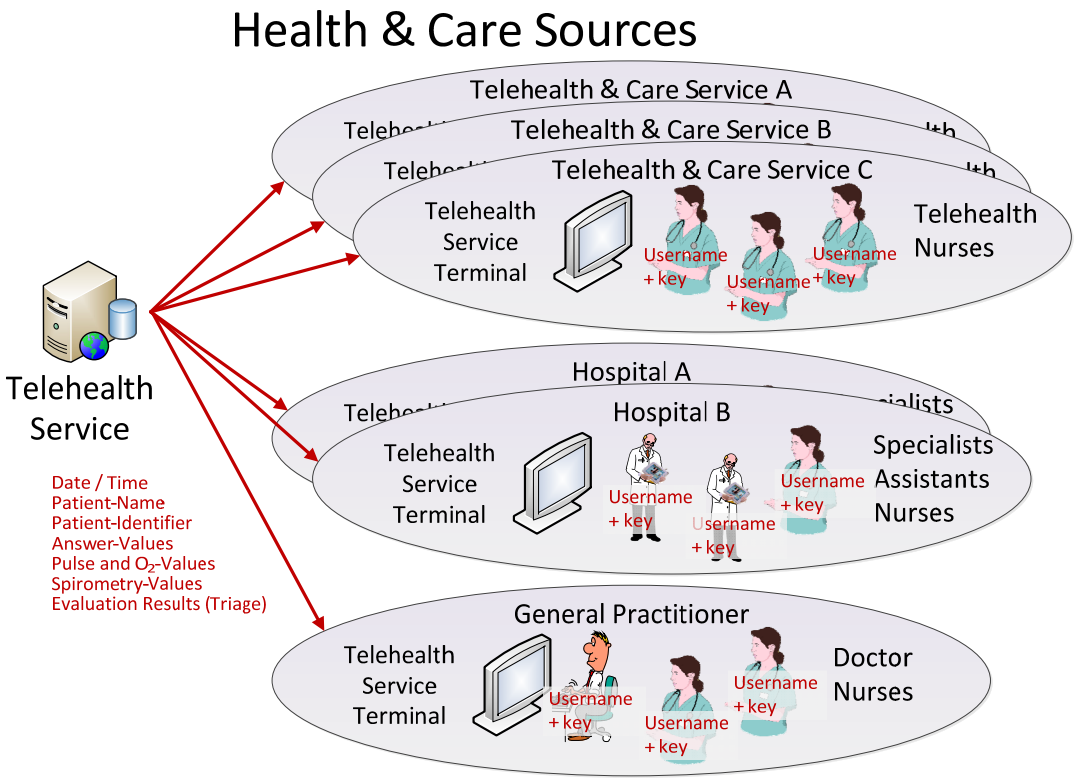

Figure 4- Information Flow to the Health & Care Sources

Different telehealth & care services, hospitals and also general practitioners use telehealth service terminals, which are shared by all staff of the corresponding institution. For example, all telehealth nurses of a telehealth & care service organization might share one terminal, the staff of a specific hospital (or a department respectively), or the staff of a GP office.

Analysis of Security Requirements

The fundamental objective of computer security is to protect the confidentiality, integrity and availability of the data and services of the system looked at [10].

Within this paper we focus in particular on the confidentiality of the patient data when being gathered, stored and communicated through the ICT infrastructure of the U4H trial system. Hence, we address the e2e confidentiality of the patient data from the point-of-care to the health and care service providers. Besides the confidentiality (as basis for the patients' privacy protection) we also address the system integrity.

Potential threats within the different domains of the U4H e2e system and requirements for corresponding countermeasures are identified in Table 1, Table 2 and Table 3 below.

Further security-relevant requirements, as the availability of the ICT system components for any U4H services, and a thorough analysis of possible attacks and risks, are not within the scope of this paper.

Table 1 - Threats and Requirements in Point-of-Care

# no	Threat	Requirement
Req1	Confidentiality threat: wrong person gets access to patient data (e.g. when tablet-PC is handed over from one patient to another)	Access control = authentication and authorization of patient to telehealth applications and personal data
Req2	Misuse of sensor device interface of patient-tablet-PC, to get access to data and services	Secure authentication of sensor device(s) and secure connection to tablet-PC
Req3	Unintended use of applications and services on patient-tablet-PC for purposes not related to telehealth supervision (e.g. installation of any software, access to Internet, etc.)	Patient is authorized for access to a secured desktop environment on the tablet-PC only, that contains the telehealth applications and services, and personal data

Req4	Physical or mental limitations or disabilities of patient limiting the intended use for remote supervision	Enable a high level of usability, in particular of any security related functionalities

Table 2 - Threats and Requirements in the HIS Infrastructure

# no	Threat	Requirement
Req5	Confidentiality threat: unintended access to personal patient data at transmission from patient-tablet-PC to P-EHR system	Encryption of communication between patient-tablet-PC and P-EHR system
Req6	Confidentiality or integrity threat: Misuse of patient-tablet-PC interface of P-EHR system, to get unintended access to data and services or to send false data	Access control = authentication and authorization of patient-tablet-PC at the P-EHR system
Req7	Confidentiality threat: Misuse of service interface of P-EHR system, to get unintended access to data and services	Access control = authentication and authorization of telehealth service at the P-EHR system
Req8	Confidentiality threat: unintended access to personal patient data at transmission from P-EHR system to telehealth service	Encryption of communication between P-EHR system and telehealth service
Req9	Confidentiality or integrity threat: Misuse of P-EHR system interface of telehealth service system, to get unintended access to data and services or to send false data	Access control = authentication and authorization of P-EHR system at the telehealth service
Req10	Compromise national laws and policies for information security ensuring interoperability of services and systems for exchange and storage of health and care data	Enforcement of rules for the deployment of the P-EHR and telehealth service systems within the NHN infrastructure (Code of Conduct, [11], e.g. storage of personal health data within national boundaries of Norway)

Req11	Availability threat: unavailability of patient data when inter-changed between different EHR systems	Unique Patient-Identifier to be used in all EHR- and service systems (cooperating in the HIS infrastructure)

Table 3 - Threats and Requirements at Health & Care Sources

# no	Threat	Requirement
Req12	Confidentiality threat: wrong person gets access to patient data through the telehealth service Web-portal	Access control = authentication of individual person at any cooperating health and care service provider (i.e. medical specialists, GPs, nurses, assistants, etc.) and authorization to access personal patient data only as required for their responsibilities towards the patient
Req13	Confidentiality threat: unintended access to personal patient data at transmission from telehealth service to telehealth service terminal at health care service provider	Encryption of communication between telehealth service and telehealth service terminal

Related Work

According to a report on e-health strategies published in January 2011 by the European Commission (referred from [12]), trust in eHealth systems by both citizens and professionals had been identified as one of, if not the key challenge in all countries. Privacy had been recognized as the most sensitive aspect of eHealth records systems.

Due to their high importance, significant efforts have been put into research studies of different security and privacy aspects of eHealth systems.

Fernández-Alemán et al [13] have carried out a systematic literature review of articles dealing with the security and privacy of EHR systems, most of them addressing standards or regulations related to the privacy and security of EHR data.

Kaletsch and Sunyaev [14] have examined a theoretical foundation of Personal Health Records (PHR) for the deployment in a Cloud environment. Along a few case studies the top-threats for patient's privacy have been identified.

Zhang and Liu [15] proposed a reference model for EHR security, focusing on EHR sharing and integration in healthcare clouds. The model has not been proven in a test or trial system.

Goldman and Hudson [16] study consumer-focused Internet services for online-access and distribution of health information. One finding is, although the Internet appears to offer anonymity and a safe place to seek and share information (what obviously attracts many health care consumers), that many eHealth business models depend on identifying and tracking users for different purposes.

Terry and Francis [17] argue, that acceptance from patients and physicians is the initial requirement for the nationwide transition to EHRs, which depends at the forefront on privacy and confidentiality concerns. They propose an autonomy-based EHR system, giving the patients full control over personal information.

Kluge [18] addresses the risk management of patient health data under consideration of international and global interoperability, and calls for "professional health information organizations", that should lead the development and harmonization of security protocols, and of principles for the certification.

Results

The analysis of security requirements and potential threats has resulted in a security concept and corresponding mechanisms, which we have deployed along the different components in all domains of the U4H trial system.

Point-of-Care Security

Req1 + Req4

At the start of the patient device (switch-on of the tablet-PC), the telehealth application for remote supervision starts automatically, and the patient has to authenticate himself towards his user account with a personal identification number (PIN) assigned to his user name (=account name). Discretionary Access Control (DAC) is carried out, based on the authenticated identity of the patient. All personal data, including all sensor measurements and questionnaire answers, are stored in a database located within the user account of the patient (and are transmitted to the P-EHR system in the HIS infrastructure). When the telehealth supervision of the patient comes to an end, the user account of that patient, including the database with any personal data, is deleted by an administrator, before the tablet-PC is being prepared for another patient.

To improve the usability, the PIN is only 4 digits long. Also it is known to the telehealth nurses, that are in charge for that patient, so that they can remind it to

the patient on demand via phone or video conference, e.g. in case the patient has forgotten the PIN.

Req2

Only sensor devices following the Continua alliance specification are supported for the measurements. The communication with the patient-tablet-PC device goes via Bluetooth (BT). The one-time link configuration between the sensor device and the tablet-PC requires a specific Bluetooth device PIN, which has to be configured in the tablet-PC by an administrator. For that a specific administrator account is configured in the tablet-PC, requiring a corresponding administrator password for authentication. Other devices than the linked sensor devices cannot communicate with the tablet-PC.

Req3

A secured desktop environment[1] is installed within the Windows operating system of the patient-tablet-PC, which only contains the applications required for the telehealth supervision of the patient. That environment is automatically started when the tablet-PC is switched on, and prevents the patient (or anyone else) from using unauthorised resources. Only a secret key sequence, known to the administrator, allows switching to the Windows desktop environment.

Health Information Services Infrastructure

Req5

For the communication of the patient-tablet-PC through a public land mobile network (PLMN) infrastructure with the P-EHR system deployed within the National Health Network (NHN) infrastructure, a multi-layered security concept has been developed. For the U4H trial an Information Integration Platform (IIP, [19]) has been utilised as implementation of the P-EHR system.

On link layer, a Virtual Private Network (VPN) tunnel is established between the mobile broadband communication module of the patient-tablet-PC device and a secure access gateway at the NHN[2]. Using the VPN-Identifier of the patient-tablet-PC (refer to Figure 2) and a corresponding symmetric key, stored in the

[1] For the U4H trial system, the "Secure Exam Browser (SEB)" (http://sourceforge.net/projects/seb/, free under GPL license) is used. It has been developed as Web-browser-environment to carry out online-exams safely, but allows changing any computer into a secure workstation.

[2] For the U4H trial system, a VPN solution from the Norwegian mobile network operator Telenor is being used, called Mobile Data Access (MDA) (http://www.telenorfusion.no/makeit/communication apis/mobiledataaccess/mdatechnicaldetails.jsp)

tablet-PC and known to the secure access gateway, the tablet-PC device is authenticated to the gateway. Subsequently, bidirectional encryption of all traffic through the underlying PLMN and Internet infrastructure is established.

On application layer, the HTTPS protocol [20] is utilized for the e2e communication between the telehealth application on the patient-tablet-PC and the P-EHR system (IIP) within the VPN infrastructure of the NHN. The device-identifier of the patient-tablet-PC (refer to Figure 2) and a corresponding symmetric key known to the P-EHR system (IIP) is used for authentication, and for the establishment of bidirectional session encryption. By this, the transmission of all personal patient-related data from the telehealth application to the P-EHR system (IIP) is protected. In a potential future real deployment, asymmetric keys could alternatively be used to establish the session encryption, utilizing a Public Key Infrastructure (PKI). In that case, digital certificates would be issued and validated by a Certification Authority (CA) for the authentication of all patient tablet-PCs and for the P-EHR system (IIP).

Req6

As the communication of any client with the P-EHR system (IIP) via the interface for the patient-tablet-PCs is carried out through HTTPS (refer to the security solution for Req5 above), only authorized clients (authenticated by the correct device-identifier + key pair) can communicate with the P-EHR system (IIP). For that, the P-EHR system (IIP) carries our DAC based on the authenticated identifiers of the communication devices.

Req7

Similarly to the communication of patient-tablet-PCs with the P-EHR system (IIP) (refer to Req6), also the communication of any application or service node with the P-EHR system (IIP) utilizes HTTPS. The telehealth service component has to provide the valid service-identifier + key pair (refer to Figure 3) for the authentication towards the P-EHR system (IIP), in order to get authorized for corresponding data access. The DAC mechanism in the P-EHR system uses the authenticated service-identifiers.

In order to protect the privacy of personal patient data stored in the P-EHR system (IIP), an arbitrary patient-identifier is sent from the patient-tablet-PC together with all telehealth data, instead of the patient's name or any identifier that can easily be related to the patient. Only the telehealth service can map the patient-identifier to a specific patient, and hence pseudonymization of the patient data is applied when being communicated from the patient-tablet-PC to the telehealth service, and stored in the P-EHR system (IIP).

Req8

The P-EHR system (IIP) requires communication via HTTPS, in order to authenticate any application or service node, and to authorize incoming requests (refer to Req7). This also establishes bidirectional encryption of the data traffic between the P-EHR system (IIP) and the telehealth service, protecting the data against eavesdropping.

Req9

The HTTPS protocol is used for authentication of the telehealth service to the P-EHR system, and for bidirectional encryption of all messages exchanged between them (refer to Req8). Correspondingly, the P-EHR system uses its P-EHR Identifier + key pair (refer to Figure 3) for the authentication at the telehealth service, and the telehealth service use DAC based on the authenticated P-EHR identifiers to control the access.

Req10

Norway has developed a legally-binding "Code of Conduct for information security in the healthcare and care services sector" [11], defining an information security policy to ensure a secure interoperability of information system from all organizations operating within the National Health Network (NHN).

As the HIS infrastructure components for the U4H trial system, namely the P-EHR system (IIP) and telehealth service, are deployed within the NHN (refer to Figure 1), those components had to be compliant with the code. The code requires (as one example besides many other rules), that the information system components for the storage of any personal health-related data have to be physically installed on Norwegian territory. This excludes for example cloud-based solutions relying on storage systems being located outside Norway.

Req11

A unique patient-identifier, to be defined for all patient devices (as the U4H patient-tablet-PCs), is crucial for the availability of patient data when being interchanged between cooperating EHR systems and health and care service systems (as the U4H telehealth service) within the HIS infrastructure (see Figure 3).

Such an identifier should be anonymized from other public known identifiers (as the patient name or the social security number), to protect the privacy of the patient data within the EHR systems (see also Req7). The mapping of that anonymous patient-identifier to a specific patient should only be technically available for the patient devices and the health and care services.

Health and Care Sources

Req12

The efficient and secure access to health and care related data from the remotely supervised patient is crucial for the cooperative approach of the U4H trial system. In order to achieve that, a Role-Based Access Control (RBAC) [21] approach has been chosen. Each individual health and care service provider staff uses the telehealth service terminal to authenticate her-/ himself at the common (i.e. shared by all health and care sources organizations) Web-portal of the telehealth service with her / his username + key pair (refer to Figure 4). Based on their authentication, the individual service providers are grouped according to their organization or institution, and get authorized to access personal data of those patients that are assigned for supervision by that organization.

A more detailed definition of access groups also allows distinguishing between specific access rights of different groups within each organization. For example, authenticated doctors can be authorized to perform different operations on the patient data than assistants or nurses.

Req13

The communication between the P-EHR system (IIP) and the telehealth service is secured by using the HTTPS protocol (refer to Req8 and Req9 above). Now, HTTPS is not used for client authentication and access control of the telehealth service terminals (which is done by RBAC at the telehealth service), but only for encryption of all messages between the telehealth service and each telehealth service terminal.

Discussion

The requirements towards the security policies and functionalities of the telehealth e2e system for the U4H trial have been addressed in the system development as described within this document. Compared to most other related work (see above) about security and privacy of eHealth systems and EHR data, we have followed a more practical approach towards the implementation of the proposed security concept. The trial operation will also be analysed with respect to security limitations or issues in the design, implementation or operation of the system.

During the design and development of the U4H trial system, which has followed a User-Centered Design (UCD) approach [22], the dependencies between security and usability became obvious. Usability is critical in particular for patients with physical or mental disabilities or limitations. Long (and presumably more

secure) passwords are subject to be forgotten, or are problematic to be entered on the touch screen of a tablet-device for people with motoric difficulties. For telehealth services providers, as the nurses in the U4H telemedicine central (and also for other health and care sources), the efficiency of the system in the daily usage is crucial. The telehealth service terminal is shared by potentially many individual persons within one organization (as a telemedicine central), and the authentication and authorization procedure must not limit the timely access to potentially life-relevant information from supervised patients. Other methods, as e.g. biometric authentication or the use of personal SmartCards, or other devices, as mobile phones supporting RFID technology [23] or NFC technology [24] for authentication, are subject to be integrated and tested in evolutions of the current trial system.

With regards to the general information architecture of the system, other alternatives would have been possible when it comes to the storage, transmission and processing of the patient-related information. Two potential extremes would have been to (1) collect, store and process all information in the PoC environment, e.g. on the patient's tablet-PC, or to (2) transmit all information directly to the Health & Care Sources (Figure 4), and to store and process it there. The main requirement of the telehealth system is to provide the different, collaborating health and care services with secure and efficient access to the patient information. In case of alternative (1), each telehealth service terminal would need e2e on-demand access to the patient-related information on a specific tablet-PC in the PoC environment. This would not be efficient for various reasons, as the unsynchronized data collection by the patient and the information request by the health and care service provider, due to the complex addressing of the data on each distributed patient-tablet-PC, and due to the risk of a specific tablet-PC lacking connectivity or just being switched-off when the health and care service provider requests information from that specific tablet-PC. The required robustness of the system makes it necessary to cope with a (temporary) loss of connectivity, and to retransmit any new patient-related information as soon as connectivity is recovered. Furthermore, the patient application on the tablet-PC shall provide autonomous recommendations to the patient in case of critical conditions, also when communication is not possible. Those requirements need the data to be stored and evaluated also on the tablet-PC, which is not the case in the alternative (2).

Alternative (2) would allow e2e security, i.e. the transmission of encrypted patient-related information from the patient-tablet-PC to the health service provider. In that case, each of the co-operating health service provider devices / applications would have to carry out the evaluation and decision support separately, and the data and information from the patient would either have to be forwarded from one service to another, or would have to be transmitted again, e2e from the pa-

tient-tablet-PC to the next health care service(s). Also, the patient-related data and information would not be available for other services in the national health network infrastructure if desired. For those reasons we have chosen a Services Oriented Architecture (SOA) approach with a cloud-technology-based infrastructure in the national health network, consisting of the P-EHR system (IIP) and the Telehealth Service, which provides a central, secure, Web-based access for the cooperating health and care sources. The e2e security in the proposed architecture is realized as secure chain of a few communication legs (Figure 4).

We have not carried out a formal study of vulnerabilities and potential attacks, nor a risk analysis, as this paper focusses on the initial security requirements and the corresponding system design and policies.

Further security related requirements, and also potential vulnerabilities and attacks, will arise with the integration of the P-EHR system (IIP) with other EHR systems or healthcare service components within the NHN, following the goal of system cooperation and integration. The P-EHR system (IIP) interface for the communication with the telehealth service via HTTPS provides for an easy and secure integration also with other services, though the content format of the messages transmitted securely via that interface will have to be adapted to the target system.

The patient-tablet-PC device for the U4H trial is provided and maintained by IT administrators of the trial partners, ensuring compliance with security policies in terms of software installation and configuration. In the deployment of real telehealth systems for large numbers of patients, this might lead to scalability-challenges related to the operation and maintenance (O&M) of the system. Such challenges can e.g. be the manual administration of patient accounts (refer to Req1 above), or the one-time connection of BT sensor devices to each patient tablet (refer to Req2). In future telehealth and telecare systems, it will be desired that also freely-available, off-the-shelf consumer devices can be utilized. In that case, the patients will have to install provided software on their tablet-PCs, or use the by default installed browser application. This bears the risk that - intended or unintended - malicious code gets installed in the patient device. That can potentially open a back-door into a secured national health network. It is therefore necessary to make precautions in the HIS infrastructure, to protect against potential vulnerabilities or attacks from patient devices. One potential option is to incorporate security precautions together with the patients' user credentials into a certified, secured app that would allow the patients to use their own device (as e.g. their personal smartphone). From the HIS infrastructure perspective only such a certified app would be required, instead of a defined and pre-configured mobile medical device.

Conclusion

The proposed security concept fulfils the identified security requirements for the U4H trial system. The system for the U4H trial, which is planned to run until summer 2016, has been developed according to the proposed security concept. The trial will help to identify potential security limitations and vulnerabilities, and further usability limitations (in particular related to security functionalities and policies) might be identified and utilized for improvements of the security concept.

Although the security concept and implementation has been developed for a specific trial system, the use cases and corresponding requirements of the telehealth services for remote patient supervision that are subject of the U4H project, represent typical characteristics of telehealth services. For that reason, the proposed security concept and the results and findings from the trial operation are also applicable for telehealth services for other patient groups, involving potentially other measurement devices, other questionnaires, other patient device types, and also other health and care service providers.

Emerging consumer market devices and applications for the collection of fitness and health related data, and for the transmission, evaluation and illustration on Web-portals, provided by cloud-based services, have similar security requirements as the studied telehealth service within the public health infrastructure. Consequently, the proposed security concept and trial results are also applicable for that type of services.

Security-related usability improvements can be expected from authentication mechanisms for patients and healthcare personal making use of biometric or Internet-of-Things (IoT) technologies (using RFID or NFC), and are subject for further studies.

Further impacts on the security requirements will arise from the expected integration of consumer health devices and services with the public telehealth services, and from the increased integration and cooperation of EHR systems for various health and care services within the public HIS infrastructure.

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Appendix G

Future Telehealth and Telecare Reference Design based on IoT Technologies: From Remote Monitoring to Smart Collaborative Services with Decision Support

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Future Telehealth and Telecare Reference Design based on IoT Technologies: From Remote Monitoring to Smart Collaborative Services with Decision Support

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Abstract — **The demographic changes are producing ageing societies across the world, resulting in greater demands on the health and care systems due to age-related disabilities and chronic diseases. Efficient telehealth and telecare services are needed to control the corresponding expenditures, by supporting increased collaboration between different professional and involving informal health care providers, and by empowering the patients to manage their health and well-being.**

Emerging trial systems for remote patient monitoring present preliminary solutions not exempt of certain limitations. We propose a future eHealth reference system architecture and core components, aiming at secure, smarter and more collaborative telehealth and telecare services. The implicit cooperation between the so-far separated domains of consumer well-being services and public telehealth and telecare services will be beneficial for all parties.

Keywords — **eHealth; health informatics; telehealth; telecare; Internet of Things; ontologies; EHR; distributed decision support.**

Introduction

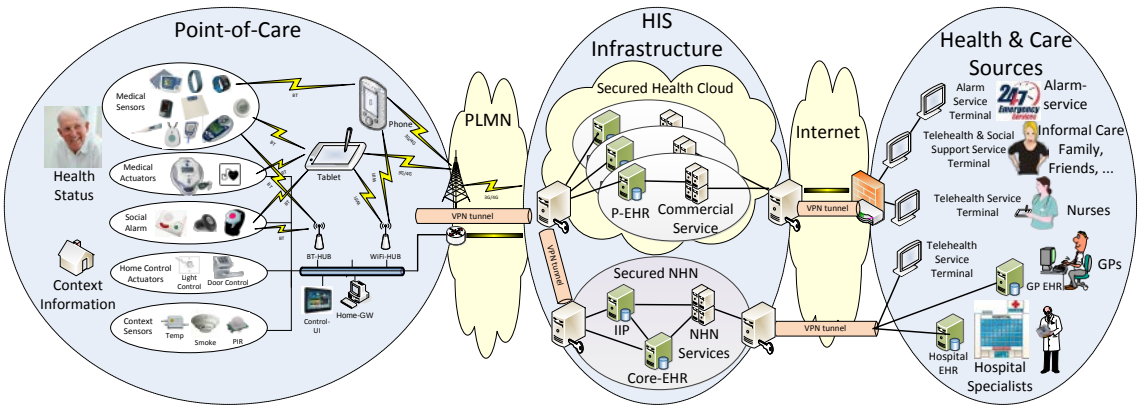
An increased efficiency of the development, operation and utilization of telehealth solutions requires a smarter and adaptive device platform for data collection and communication in the point-of-care, distributed reasoning and decision support, and a secure storage and provisioning infrastructure. This has to support the cooperative access to health data and information (Core-EHR, P-EHR, other records) for professional and informal health and care providers, enforcing also privacy protection and access control.

Methods

For the EU FP7 project United4Health a trial system for remote monitoring of COPD patients at home has been developed and deployed in the secured Norwegian National Health Network (NHN). The solution provides routine measurements and questionnaires for the patient, and a secure and collaborative provisioning of the results to professional health care sources via an Information Integration Platform (IIP) and a dedicated NHN telehealth Web portal service.

Results

The result is a Secured Health Cloud infrastructure for commercial well-being, health and care services, complementing the NHN infrastructure on top of a common authentication and access control system as part of the overall Health Information System (HIS) infrastructure. The proposed point-of-care device platform will be personalizable for the patients' needs, utlizing smart sensors and ontologies for the individual data and as basis for adaptable, remotely manageable software modules for distributed decision support and user interaction.



Conclusions

The proposed reference architecture provides the basis for secure collaboration between commercial, professional and informal health and care sources, enabling personalized, smarter, and more efficient health and care services.

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Appendix H

Reference Design for Smart Collaborative Telehealth and Telecare Services Based on IoT Technologies

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Abstract — **The demographic development shows aging societies throughout the globe, leading to higher demands on the health and care systems due to age-related disabilities, chronic diseases, etc. Telehealth and telecare services for more efficient support of health and care providers are needed, which can be significantly improved by the continuous technological developments in areas such as sensor devices, Internet of Things (IoT), cloud services, and data analysis.**

This paper addresses the potential of selected emerging technologies to make eHealth systems smarter, more collaborative and more efficient. As a result of the analysis of the most promising technological trends, characteristics of future telehealth and telecare services are derived, requirements are identified, and a future eHealth reference design is proposed.

Keywords — **eHealth; health informatics; telehealth; secure health cloud architecture; decision support**

I. INTRODUCTION

All around the globe the population aged 60 or over is growing rapidly [1], and is expected to increase from 841 million people in 2013 to about 2 billion in 2050. This fact challenges current health and care systems [2], particularly owing to patients with functional limitations, disabilities, and with an increased demand for long-term care for chronic diseases related to longer life expectancy. Higher demands on long-term care and the general economic pressure to control health care expenditures require efficient utilization of medical technologies and increased collaboration within the professional health care sector. Furthermore, the involvement of informal care provided at patient's home by family members, friends and voluntary organizations has to be intensified [3], with new useful alternatives such as supporting remote care through information and communication technologies.

This paper addresses future telehealth and telecare services for smart and efficient medical routine supervision of patients within their own private environment, aiming at better health and quality of life. Emerging telehealth and telecare systems reveal certain limitations of today's technologies. In order to overcome them, a way forward towards future integrated and collaborative telehealth and telecare services is described, addressing the cooperation of commercial cloud-based fitness and wellbeing services with the public health and care infrastructures. A reference design for their accomplishment is presented, with special attention on upcoming technologies from the Internet of Things (IoT), data ontologies from Semantic Sensor Networks (SSN), Artificial Intelligence (AI) and Decision Support Systems (DSS). While the initial focus of the reference design is on professional health care services, it will also allow involving and supporting non-professional informal sources of long-term care. A high-level overview of the reference system for the discussed services is illustrated in Fig. 1, consisting of three main system domains (see Table I) with components from a variety of eHealth stakeholders.

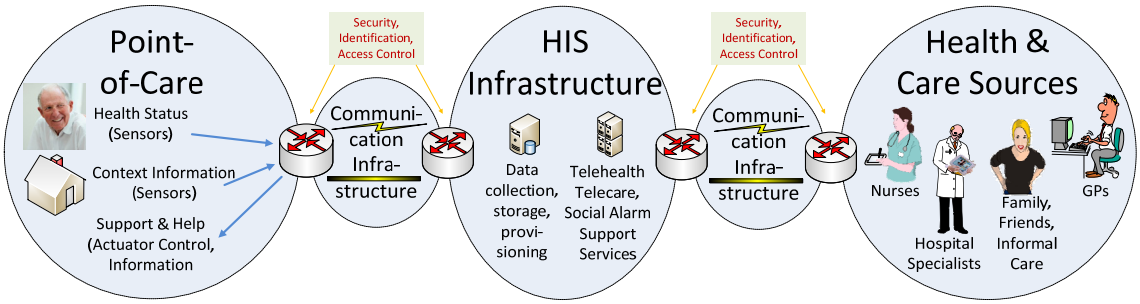

Fig. 1. Reference System for Telehealth and Telecare Services

TABLE I. TELEHEALTH AND TELECARE REFERENCE SYSTEM DOMAINS

Point-of-Care (PoC) Environment
Information about health status of patients and their context (e.g. location, room temperature) shall be gathered and made available for health and care service providers through a health information service (HIS) infrastructure.
Patients shall receive information and support from remote service providers, as well as from family members, friends, and other voluntary sources of care.
Health Information Services (HIS) Infrastructure
Data from patients are securely aggregated, stored, and made available.
Service logic and user interfaces of dedicated tele-health, telecare and social alarm services for the provision of controlled centralized access to required patient data and value added information for the distributed health and care sources.
Health & Care Sources
Nurses, general practitioners (GPs), medical specialists in hospitals, and providers of informal care as family members of patients and voluntary care providers, need efficient and collaborative access to information from their patients, allowing to carry out routine supervision remotely, provide information and remote health and care support.

II. TECHNOLOGICAL TRENDS

In this section, an overview of technological trends is given that have the potential to strengthen the characteristics and capabilities of future telehealth and telecare services.

As indicated by sociological trends, the ageing societies demand more flexible, efficient and intelligent solutions for telehealth and telecare services. Today's solutions and services do not sufficiently provide a number of required service characteristics, or have significant limitations. The trends in the following technological areas show high potential to strengthen the technological foundation for future services.

A. Internet of Things (IoT); Smart Sensors; Machine-to-Machine (M2M) Communication

- Paradigm for the integration of several technologies and communications solutions: radio frequency identification (RFID) and tracking technologies, wired and wireless sensor and actuator networks, enhanced communication protocols (shared with the Next Generation Internet), and distributed intelligence for smart objects [4], in particular for the healthcare application domain.
- Smart Sensors: transition of once-inert objects into embedded sensor-laden intelligent devices, analysing and mining their raw data to abstract, more valuable information, being connected to the Internet via heterogeneous access networks, and communicating directly with other system components (M2M) [5].

B. Ontologies and Semantic Sensor Networks (SSN)

- SSN ontology [6]: designed to describe sensors and sensor observations; applied to achieve a standard way of representing sensor data, and to support extensive reasoning together with supplied meta data.

C. Cloud Technologies; Big Data; Artificial Intelligence (AI); Decision Support Systems (DSS); Machine Learning; SOA

- Uptake of Electronic Health Records (EHRs) in clinical environments generates massive data sets ("Big Data"), expanding the capacity to generate new knowledge, helping with knowledge dissemination, and allowing a transformation of health care by delivering information directly to patients [7].
- Research efforts and development investments on AI and machine learning have created a broad theoretical knowledge base, and powerful commercial AI computing platforms as, e.g., Watson from IBM [8], targeting in particular the potential for health care.

III. POSITION

As discussed in previous sections, the increasing demand for technology support for long-term home care with smart and efficient telehealth and telecare solutions cannot be fully satisfied by today's solutions. The utilization of emerging technologies will increase the potential and technical capabilities to develop solutions in the future that can address the needs of all user groups involved. Following, the main characteristics and the technical requirements framework of services are described that overcome today's limitations and can be expected to be introduced in the near future. Finally, a reference system architecture is proposed for the accomplishment of the foreseen services.

A. Future Telehealth and Telecare Services

Service Characteristics
Patients are equipped with imperceptible wearable or implanted sensors, that provide information about their medical condition.
Patients are surrounded by or equipped with actuators, remotely controlled by nurses and doctors or supported by an AI system with configurable level of autonomy. By that they positively influence the patients' medical condition or give other type of on-site support (e.g. medicine dispenser, first-aid robot, cardiac pacemaker, insulin dispenser, breathing control, …).
Patients and medical professionals are not limited to specific vendors or products, but can select from a range of standards-based, certified products according to the individual health care support requirements.
Patients do not actively have to identify and authenticate themselves with user names, passwords, PINs, etc.
Appliances in the PoC give autonomous advice to patients based on data from specific medical sensors (in particular when devices loose connection to HIS).
Patients are not in charge of updating status of sensor and actuator devices (e.g., wireless charging, PV).
Advises and information for patients are presented in an easy-to-use and accessibility-adapted way (e.g., touch screen devices, voice communication, gesture recognition).
Patients are motivated to physical exercise for improved rehabilitation and long-term care by sharing data with relatives and informal care providers via social media.
Information from PoC (e.g., health / medical data, questionnaires, alarms) is securely transmitted in real-time into health information systems.
Telehealth, telecare and social communication services (e.g., alarms, video consultations) provide access to EHR and P-EHR data, to value-added information and to diagnosis and decision support, using all relevant patient data from the health information systems, and supporting the collaboration between the different health and care sources in charge.

The following technical requirement domains have to be considered in the design and implementation of the future telehealth and telecare services and their supporting infrastructure components.

Requirements Framework
Flexibility/Integration, Expandability, Scalability
A health care solution must be able to handle expected growth in patient number, services and devices.
Security and Privacy, Authentication, Access Control
The solution must be trustworthy and allow for implementing complex, distributed security policies and rules.
Interoperability and Interworking
The solution shall enable interactions with other national and international service domains.
Usability (patients, medical professionals, informal care)
End-user relevance and intuitive handling will increase user acceptance and error free handling.
Reliability, Robustness, Availability
People's lives and health require a solution with high dependability and low risk of failure.

B. Future Reference Design

The proposed reference design addresses the scenario for healthcare services in 2020-2030, and considers the utilization of selected emerging technologies. An overview of the underlying system architecture is illustrated in Fig. 2, containing the core components involved in the design of the future services.

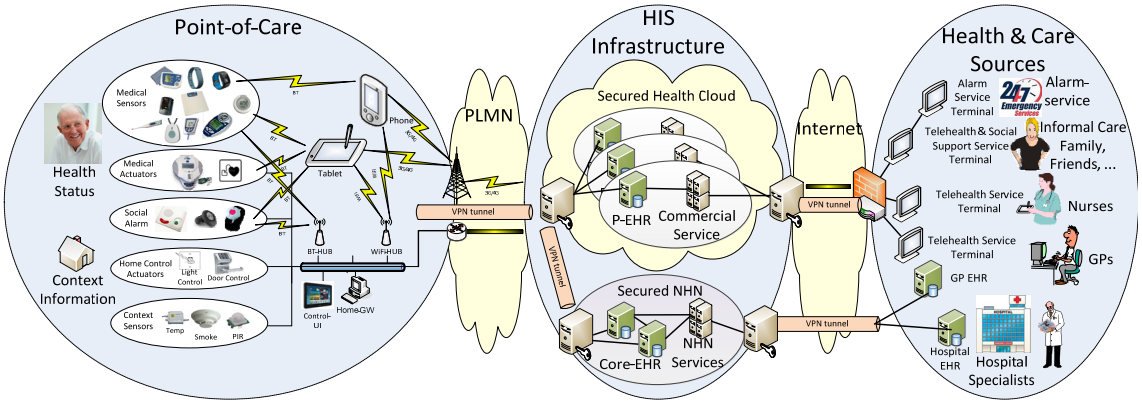

Fig. 2. System Architecture for Future Telehealth and Telecare Services

1) Point-of-Care

The central component of the Point-of-Care (PoC) environment is the patient device, which carries out the user interaction logic and provides the graphical UI for the patient, takes care for the communication with sensors and actuators in the PoC environment, and serves as communication gateway with the HIS infrastructure. The proposed functional architecture of the PoC device is shown in Fig. 3. Sensors for patients' health status and context information from the PoC as well as actuators for care support and home control are connected through device-specific smart sensor adapters and handlers. These software modules support the applicable connectivity and communication protocols, can evaluate the sensor data (e.g., by rule-based reasoning) to trigger certain events or produce value-added information, and can be added to the PoC device software on demand. The sensor adapters and handlers forward the data and value added information to the common data integration and exchange module (CDIEM). The underlying database is based on the World Wide Web Consortium (W3C) semantic sensor network (SSN) ontology standard [6], which allows smart evaluation and reasoning based on data semantics, and flexible extension of the database with regards to new sensor or actuator parameters. The CDIEM also provides a subscribe-notification-based exchange of data: any software module carrying out a specific functional logic subscribes to new needed data (utilizing the data semantics), and feeds the results of its operation back into the CDIEM. The layer of software modules for specific functionalities and use cases include a generic

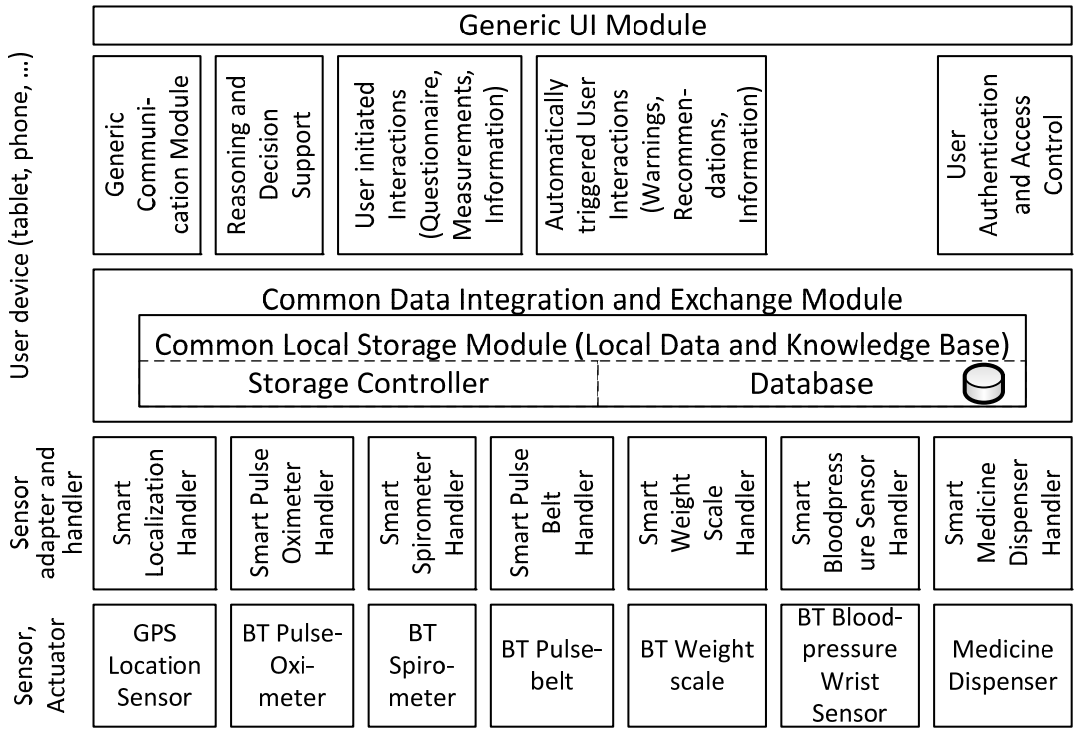

Fig. 3. Software Architecture Overview of PoC Device

communication module for the exchange of data with the HIS Infrastructure through a VPN link, a user authentication and access control module, and various modules for user interaction use cases. Besides the data storage module, the reasoning and decision support is another central component of the PoC device software. This provides for complex evaluation logic involving any of the data and information available in the local storage, and can trigger events as alarm notifications to remote care sources (via the CDIEM and the communication module), and can autonomously support the patient via the CDIEM and dedicated user information and interaction modules. By using ontology technology, sensor observations together with other patient history information (e.g., diagnosis) make rule based reasoning and machine learning possible. Additionally, the use of ontologies will improve semantic interoperability and integration. A generic UI module provides the means to realize all user interactions through the service UI in a flexible and modular way.

2) Health Information Services (HIS) Infrastructure

Besides the secured National Health Network (NHN) infrastructure, containing Core-EHR systems and services for the public health sector (as in particular, for the access to and exchange of EHRs), the proposed future HIS infrastructure is extended with a Secured Health Cloud. Based on a common IT infrastructure using cloud technologies, a multitude of services can be hosted and facilitated by dedicated P-EHR systems. The services are operated by commercial service providers as, e.g., social alarm support, telecare providers and commercial vendors of gadgets and services for the online management of health and fitness information. Data in any P-EHR originating from any PoC can be utilized by the public NHN services via secure (authenticated and authorized) access, to extend the available health and context data in the Core-EHR with additional health and context information. Furthermore, each service provider in the secured health cloud uses the P-EHR data from “its“ patients and customers for its individual services.

3) Health & Care Sources

A central aspect of the proposed secured health cloud is a common security framework: health and care sources (such as social alarm and informal care service providers, nurses, but also GPs and hospital specialists), can securely utilize the telehealth and telecare services provided (possibly as Web-based information portals) in the secured health cloud through a common authentication and authorization system, allowing both secure and flexible collaboration. Public healthcare sources as GPs and hospital staff can securely access EHR data from Core-EHR systems in the NHN, and directly from different P-EHR systems in the secured health cloud via an encrypted link and the com-mon access control.

IV. Discussion

The strengths of the proposed reference design for future telehealth and telecare services are manifold. The modular SW architecture allows to flexibly integrate new sensor and actuator devices via dedicated handler modules, which support specific communication technologies, and support intelligence on sensor level ("SmartSensors"). The event-based (subscribe, publish, notify) data exchange on top of a central data storage supports the integration of software modules for new use cases and functionalities. Furthermore, a reasoning and decision support component operating directly on top of the central data storage allows for complex evaluation tasks of patients' health and context data, leading e.g. to fast emergency notifications, and autonomous patient support.

The secure interconnection of the two HIS domains – "Secured NHN" for the public health system, and "Secured Health Cloud" for commercial service providers – is the basis to make data from the patients' PoC available for more efficient public health services in a secure and privacy-protecting way, while securing a closer collaboration between all health and care sources. The compliance with the right standards by the P-EHR systems (as Continua Health Alliance, HL7 and CEN/ISO EN13606) will be key to enable the described exchange of data.

V. Conclusion and Outlook

The proposed reference design shows how emerging technologies can help to boost the development of eHealth service infrastructures and future telehealth and telecare services using them. The development of a proof-of-concept prototype system (ongoing by end of 2015) includes a more detailed elaboration of the security system for the secured health cloud, as well as details of the standards to be considered for the P-EHR systems and their accessibility. Taking the prototype a step further towards a trial system will allow to carry out research about the social acceptance and usability of the described future telehealth services, and further technological details of the future infrastructure.

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Appendix I

The EU-project United4Health: Results and Experiences from Automatic Health Status Assessment in a Norwegian Telemedicine Trial System

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The EU-project United4Health: Results and Experiences from Automatic Health Status Assessment in a Norwegian Telemedicine Trial System

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Abstract

***Introduction* — Patients with chronic obstructive pulmonary disease require help in daily life situations to increase their individual perception of security, especially under worsened medical conditions. Unnecessary hospital (re-)admissions and home visits by doctors or nurses shall be avoided. This study evaluates the results from a two-year telemedicine field trial for automatic health status assessment based on remote monitoring and analysis of a long time series of vital signs data from patients at home over periods of weeks or months.**

***Methods* — After discharge from hospital treatment for acute exacerbations, 94 patients were recruited for follow-up by the trial system. The system supported daily measurements of pulse and transdermal peripheral capillary oxygen saturation at patients' homes, a symptom-specific questionnaire, and provided nurses trained to use telemedicine ("telenurses") with an automatically generated health status overview of all monitored patients. A colour code (green/yellow/red) indicated whether the patient was stable or had a notable deterioration, while red alerts highlighted those in most urgent need of follow-up. The telenurses could manually overwrite the status level based on the patients' conditions observed through video consultation.**

***Results* — Health status evaluation in 4970 telemonitor datasets were assessed retrospectively. The automatic health status determination (subgroup of 33 patients) showed green status at 46% of the days during a one-month monitoring period, 28% yellow status, and 19% red status (no data reported at 7% of the days). The telenurses manually downrated approximately 10% of the red or yellow alerts.**

***Discussion* — The evaluation of the defined real-time health status assessment algorithms, which involve static rules with personally adapted elements, shows limitations to adapt long-term home monitoring with adequate interpretation of day-today changes in the patient's condition. Thus, due to the given sensitivity and specificity of such algorithms, it seems challenging to avoid false high alerts.**

***Keywords* — COPD, decision-support techniques, telehealth, remote patient monitoring, personalised health status assessment algorithms, triage.**

1 Introduction

The remote home monitoring of patients with chronic diseases has been a topic of many research projects [1-4]. The main goals in these studies have been to help patients in daily life situations, to increase their individual perception of security even under worsened medical conditions, to reduce home visits by doctors or nurses, and to avoid unnecessary hospital admissions and readmissions.

The analysis of long time-series of vital signs data from patients at home over periods of weeks or months is both a new opportunity as well as a new challenge for healthcare services, and differs from traditional monitoring procedures in a hospital ward or under emergency conditions. While classic triage procedures such as "trauma triage", "emergency triage" or "emergency department (ED) triage" [5, 6] are defined as "the process of classifying patients according to injury severity and determining the priority for further treatment", the long-term follow-up of patients with chronic diseases has to adapt the treatment and medication to the long-term telemonitoring perception and short-term changes of the condition of the individual patient and the corresponding needs for support and intervention. To avoid confusion between the objectives of clinical "ED triage" and those of the long-term monitoring and decision support for treatment and follow-up prioritization of home-based patients, the terms "health status level assessment" and "health status score" will be used in this study.

Difficulties arise in the determination of actual algorithms for automatic health status score calculations, and in the definition of cut-off values for the different reported modalities to trigger the correctly colour-coded alert level for such remote home monitoring situations.

In a review of 20 studies for predictive algorithms for the early prediction of chronic obstructive pulmonary disease (COPD) exacerbations to support clinical decisions of home telemonitoring, Sanchez-Morillo et al. concluded that "models with good clinical reliability have yet to be defined", and that "novel predictors need to be identified".[7] In the UK, 12 telehealth systems were analysed for their use of information exchange between patients and healthcare professionals.[8] Data analysis methods with predefined algorithms to be configured by the health professionals were implemented in 11 of the systems. In four of the investigated systems, a colour-coded format was used to indicate the severity of the patients' status and the priority of support and follow-up; at the same time, occasionally false positive and false negative alerts were encountered.

For detection of day-to-day variations of the patient's condition, it is not possible to use retrospective methods; thus, methods for automated calculations of individual threshold values will be necessary to develop. But there seems to be a gap in the knowledge on how patients in their daily routines use sensors for telemonitoring, and which indicators might be used in which way for triggering alerts that should, in turn, lead to appropriate levels of responses.[9]

The results of this study should help to answer the following research questions:

> ***RQ 1.*** *Do the implemented health assessment algorithms provide the required adaptation of health status levels and corresponding alerts for treatment and follow-up needs to the individual medical condition of each COPD patient?*
>
> ***RQ 2.*** *What recommendations can be given for improved cut-off values and algorithms, or for procedures to define or calculate appropriate values?*

2 Methods

For the Norwegian trial in the EU-funded project United4Health (U4H),[10, 11] a solution was developed for COPD patients at home, involving a tablet personal computer (PC) application to collect and transmit monitoring data, and a video conferencing tool to get support from one of eight nurses trained to use telemedicine ("telenurse") at a telemedical centre.[12-14] They were instructed to report their health symptoms daily (the patients were asked to send their measurement data/symptom questionnaires in the morning, since COPD usually has the highest symptom load at that time of day), followed up by a video consultation where a telenurse explained necessary actions like changes in inhalation therapy or the start of antibiotic or corticosteroid treatment,or both, if a worsened situation was encountered. (The telemedicine system for the collection and assessment of remote monitoring data was available 24/7. The support service by the telenurses was only available during office hours of the telemedical centre (Monday–Friday 8:00–15:00; Saturday 8:00–12:00). Automatic alerts were only followed-up during office hours, and patients were told to call their general practitioners (GPs) or emergency services if they needed help outside office hours.) The health status assessment included measurements of the transdermal, peripheral capillary oxygen saturation (SpO_2) of the blood, and the heart rate measured with a pulse oximeter connected via Bluetooth to the tablet PC, and information about subjective symptoms observed by the patient, as gathered through a daily electronic questionnaire (Table 1). Peak Expiratory Flow (PEF) measurements were skipped from the method section by the U4H consortium since clinicians judged PEF to be

unreliable during a COPD exacerbation (PEF is the maximal flow (or speed) achieved during the maximally forced expiration initiated at full inspiration). Reported data were instantly evaluated automatically when received from the patient, using an algorithm to create a colour code that provided the nurse with a quick overview of the current patient condition.[15]

Table 1: Daily Questionnaire

Q_i	Question	Possible answers
Q_1	How do you feel today?	As usual Worse Much worse
Q_2	How is your breathing today?	As usual Worse Much worse
Q_3	How is your amount of sputum today?	As usual Worse Much worse
Q_4	What is the colour of your sputum today?	No sputum / Clear / White Yellow / Green / Brown
Q_5	Are you using rescue medication / nebulizer or oxygen today?	No, I am not using them today. As usual More than usual Much more than usual
Q_6	Have you started up with additional antibiotics after last discharge?	No / I have finished. Yes – Apocillin / Penicillin Yes – Imacillin / Amoxicillin Yes – Ciproxin Yes – Azitromax Yes - Other
Q_7	Have you started up with new Prednisolon after last discharge?	No. Yes – 20 mg Yes – 30 mg Yes – 40mg Yes - Other

Patients hospitalised for exacerbation of COPD (according to the Global Strategy for Diagnosis, Management and Prevention of Obstructive Lung Disease) were considered for inclusion at the time of discharge from the

pulmonary department at Sørlandet Hospital HF in Kristiansand. The exclusion criteria comprised patients that did not want or could not sign the informed consent form, were not able to or did not want to use the telemedicine system, were in problematic clinical or social circumstances, or were discharged to a locality that either had no mobile broadband data coverage or could not be reached by the telemonitoring team. A trained nurse instructed the patient in how to use the telehealth solution, and the first measurements of pulse and SpO_2 were recorded and used as reference values for the assessment of following day-to-day monitoring data. Baseline data were collected by the hospital staff at discharge.

All data measured and reported by the patients with their tablet PC application were consecutively uploaded to a secured data server at the telemedical centre, where the health status levels were automatically calculated with a specific algorithm. The United4Health protocol defined cut-off values for a "red" alert status based on already existing empirical algorithms used in several centres in the UK. For the Norwegian trial, cut-off values for a ''yellow'' health status were added to the clinical protocol by the study clinician (co-author of this paper) to increase the sensitivity of the system and the patients' safety as an early warning indicator of a ''notable'' health condition deterioration.

Green: The patient is in a stable or improved clinical condition with unchanged medication. The self-reported health symptoms are unchanged or improved compared to the previous day. The reported pulse-oximetry measurements are within an acceptable range compared to individual reference values.

Yellow: The patient is in a condition that needs special attention. If the pulse-oximetry measurements, or at least one reported symptom, indicate notable deterioration since the previous day or the hospital discharge, respectively, a yellow alert is triggered. These cut-offs were: an increase in pulse of >10 bpm, a reduction in SpO_2 of 4-5%, an answer to question 1, 2, 3 or 4 defined as "worse", or question 5 answered with "more than usual" (Table 1).

Red: The patient is in a critical condition. The pulse-oximetry measurements or the self-reported symptoms indicate significant deterioration since the previous day or hospital discharge, respectively; that is, an increase in pulse of >15 bpm, a pulse >120 beats/min or <50 beats/min, an oxygen saturation that is ≥6% lower than the reference value, or Q5 answered with ''much more than usual''.

Following the trial protocol, a daily teleconsultation took place with all patients during the (typically) first 14 days of trial participation (*High Level of Telemonitoring Service phase*). For the next 14 days (*Reduced Level of Telemonitoring Service phase*), the daily measurements and symptoms

reporting were continued, but a video consultation would only be conducted in the case of a deteriorated health condition, indicated by *yellow* or *red* status alert. After approximately one month the equipment should be returned to the hospital, but the patients could call the telemedical centre to discuss their condition with the trained nurses at any time during the opening hours for the next 11 months (*Low Level of Telemonitoring Service phase*). If recommended by a doctor, the High or Reduced Level of Telemonitoring Service phases could be prolonged, resulting in situations where patients could keep the equipment at home, to be used in cases needed. After the teleconsultation, the telenurses could manually overwrite (i.e. increase or decrease) the automatically calculated health status assessment levels, based on their experience with the health condition of each individual patient, or following a discussion with the patient's GP.

To investigate the obtained accuracy of the automatic health status assessment algorithms and the reasons for any manual overwrites, we have analysed the monitoring datasets from the clinical trial, with the aim of defining recommendations for improved algorithms for automatic calculations of a health status score. The datasets were de-identified and exported from the telemedicine system to Excel spreadsheets for the evaluation of the health level status assessment in this study.

Ethical considerations

This study was approved by the Norwegian Centre for Research Data (project number: 35356). All participants received oral and written information about the project and confidential treatment of the collected data. Participation was voluntary and participants could withdraw at any time without reason. All participants signed up explicit written consent.

3 Results

During a period of two years, from May 2014 until April 2016, a total of 94 patients with COPD were recruited for the telemonitoring trial. (The trial system had been in operation until June 2016, but monitoring data and automatic assessments after April 2016 could not be considered for this study.) The baseline data are listed in Table 2. Approximately 2%, 19%, 32%, and 44% were in COPD stage I, II, III, and IV, respectively.

The planned participation duration of each patient in the trial according to the clinical trial protocol was 30 days after discharge from hospital, but with wide possibilities for personal adaption as recommended by the doctors, leading to

some earlier drop-outs, and some cases of significant longer participation. Approximately 10% of the patients were readmitted to hospital and thus had 2–3 additional periods of telemonitoring.

Table 2: Baseline Data of Patients included in Telemonitoring Trial

	Male (n=48)		Female (n=46)		Total (n=94)	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age	70.7	9.4	67.6	8.8	69.2	9.2
FEV1 in % (predicted)	38.2	17	38.1	12.5	38.1	14.8

SD: standard deviation

Two thirds of the patients had a prolonged use of the telemonitoring services beyond the planned 30 days, and more than a quarter kept the equipment and reported monitoring data for more than 90 days. Approximately one third of the patients were defined as drop-out before the end of the planned period for different reasons (e.g. some of them encountered difficulties with bad quality in the video consultations due to poor mobile data coverage). The number of days included in the telemonitoring trial (taken from the last day of monitoring data reported to the telehealth system) varied from 1 to more than 365 (Figure 1), and the overall average duration of participation in the telemonitoring services was 70 days.

In total, 4970 datasets were analysed for this study received by the telehealth system, each containing a pair of pulse oximetry measurements (pulse and SpO_2), a set of answers to the daily questionnaire, or a combination of both. There could be multiple datasets for one patient for one day; for example, in case the measurement or the questionnaire had been executed and transmitted multiple times, or as a consequence of suggested repeated monitoring during a deterioration. For the health status level assessment, the first reported data of the day is used, as the result potentially triggers an alert to the telenurses for required follow-up support or treatment.

An overview of the development of the pulse-oximetry data (measurements of pulse and SpO_2) reported by the patients during the first 90 days of their trial involvement is shown in Figure 2. More than two third of the patients that still had the monitoring equipment have sent measurement reports (e.g. 94%, 75%, 63%, and 67% on day 1, 30, 60 and 90, respectively).

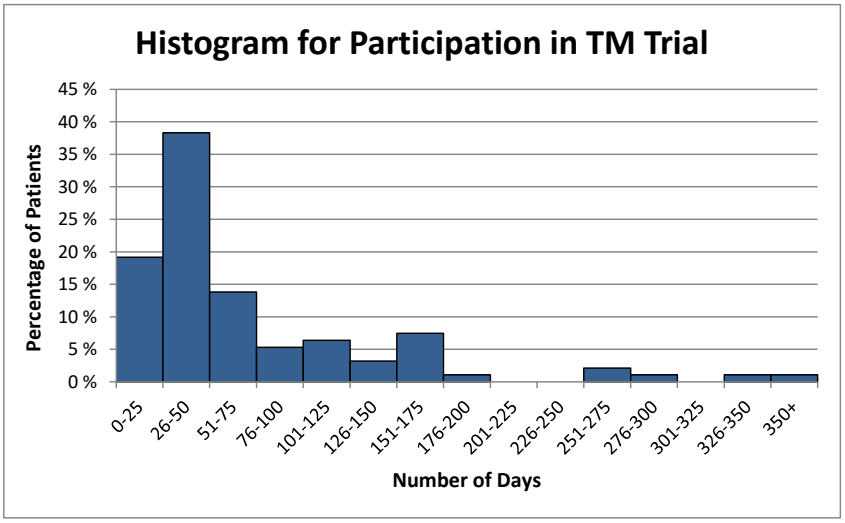

Figure 1: Histogram of Participation Duration [number of days] in TM Trial (n=94).

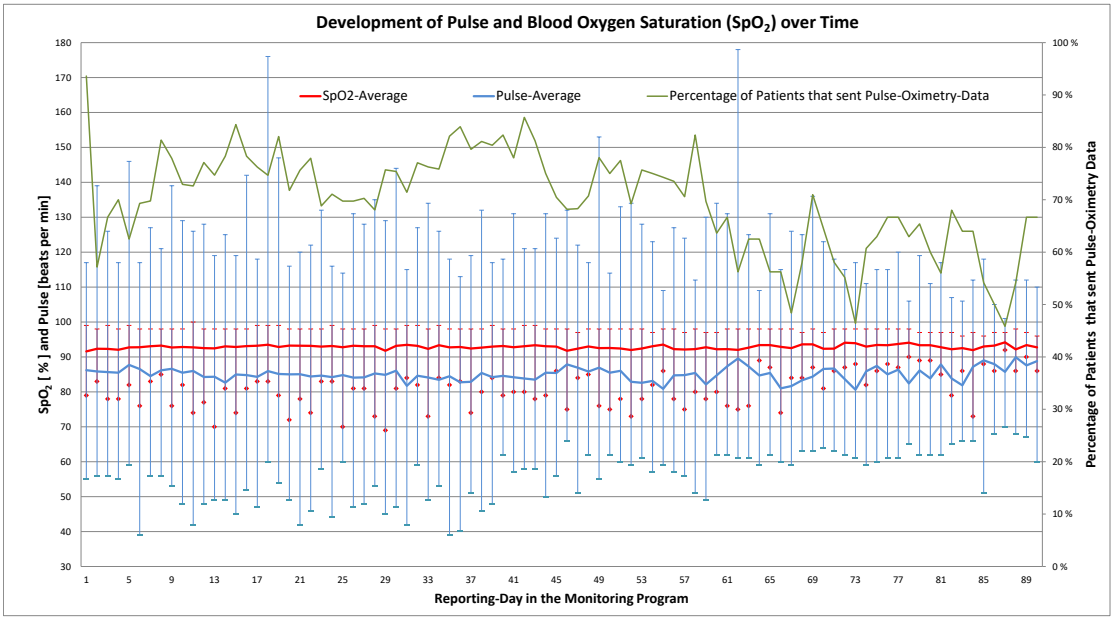

Figure 2: Development of reported Pulse and Blood-Oxygen Saturation (SpO_2) (n=94).

[Percentage of patients that sent measurement report (green line, right y-axis); Average pulse and SpO_2 values (calculated each day from all received patient reports) together with their min and max values (blue and red line respectively, scale of left y-axis for both parameters).]

The average daily reporting rate is illustrated in Figure 3. As long as the patients had the monitoring equipment, they used it on average for at least 70% of the days (Monday–Friday) to send monitoring data. They sent pulse-

oximetry measurements at an average of 75% of the days during the first 30 days, and daily questionnaires 84% of the days. During the 90-day period, monitoring data were sent at two thirds of the days (i.e. at 60 days in average).

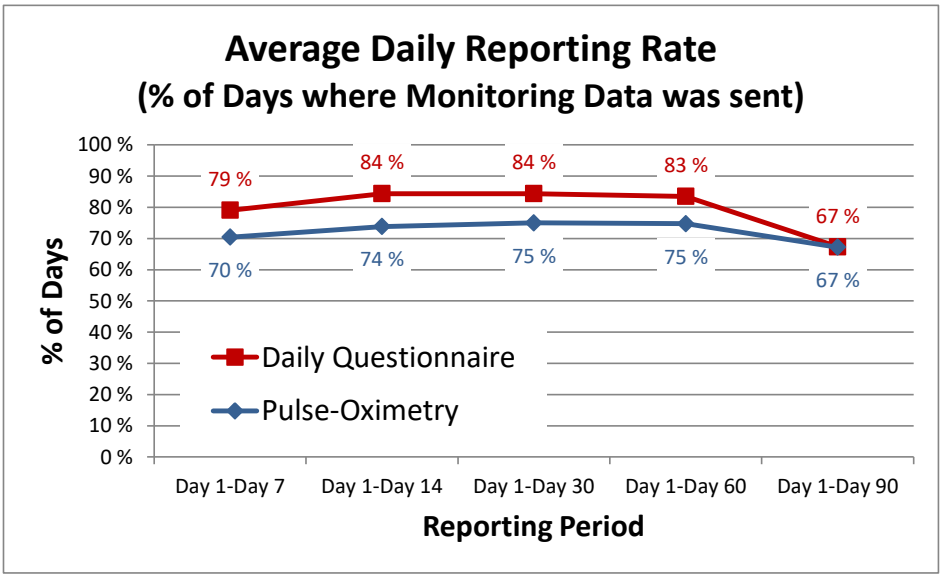

Figure 3: Average Reporting Rate (n=94).
[% of days during first 7, 14, 30, 60 and 90 days when monitoring data was reported.]

For the accuracy analysis of the health status assessment algorithm we have selected a subgroup of 33 patients (i.e. 35% of the total of 94 patients), that have reported pulse oximetry measurements and/or answers to the daily questionnaire on a minimum of 25 days during the first 30 days of participation in the telemonitoring trial.

The automatic health status level categorisation into ‘‘*green*’’, ‘‘*yellow*’’, and ‘‘*red*’’ alerts were assessed *before* they were analysed and possibly overwritten by the telenurses. Monitoring 33 patients over 30 days corresponds to a total of 990 ‘‘patient-reporting days’’, of which we received 928 reported datasets (94%). In total, 460 patient-reporting days (46%) were assessed as ‘‘*green*’’ level (indicating a stable condition of the patient on that day), 275 (28%) as ‘‘*yellow*’’ (alerting the nurse of a notable condition), and 193 (19%) as ‘‘*red*’’ level. The frequency of each health status level (averaged over all patients and all days of the considered periods) is illustrated in Figure 4.

In total, 101 assessments (i.e. 10% of all 990 ‘‘patient days’’) were modified manually by the telenurses, 81% were unchanged, and 9% were incomprehensible to assess due to lack of reported data. An overview of the type of the adjustments and the reasons is given in Table 3: if the reported data,

such as a pulse value, caused a red or yellow alert, and the telenurse adjusted the corresponding initial health status assessment level following the video consultation, because the health condition was actually not critical, the health status level was lowered to yellow or green, respectively, and the data was counted as ‘‘initial pulse assessment too high’’.

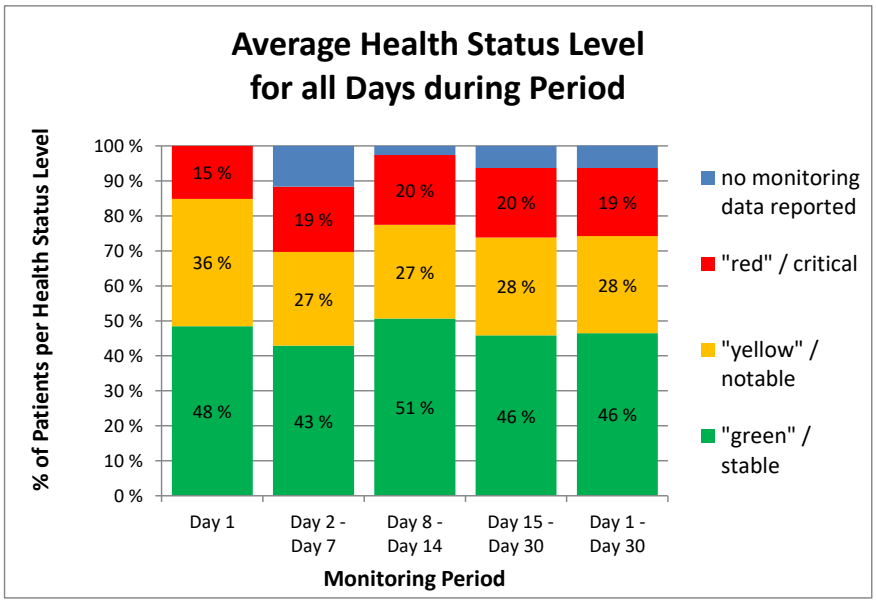

Figure 4: Unadjusted Average Health Status Level during selected Monitoring Periods (n=33).

In total, 10% of the calculated health status levels were downrated and thus could be judged as false positive if the reclassification at the telemedical central, including manual overwrites by the telehealth nurses, was considered correct. Of those, pulse assessment (42%) and daily questionnaire assessment (39%) were the main reasons for too-high assessment-level calculation.

4 Discussion

The examined trial system facilitates the remote monitoring of home-based COPD patients and the provision of decision-support information for the prioritisation of follow-up support and treatment by telenurses in a telemedical centre, in cooperation with GPs and medical specialists in hospitals. Changes of certain monitoring data from one day to the next are important to identify notable or even critical exacerbations.

Table 3: Analysis of Manual Overwrites of Health Status Level Assessment

Type of Adaptation (related to all Assessments)			Reasons for Adaptation (related to Overwrites)	
false-high	red to yellow	2.7 %	Pulse-Assessm. too high	41.6 %
	yellow to green	5.3 %	SpO_2-Assessm. too high	4.0 %
	red to green	1.7 %	Pulse- and SpO_2-Assessm. too high	3.0 %
			Daily Quest.-Assessm. too high	38.6 %
			Pulse- and Daily Quest.-Assessm. too high	7.9 %
	Sum	9.7 %	Sum	95.0 %
false-low	green to yellow	0.4 %		
	yellow to red	0.1 %		
	green to red	0.0 %		
	Sum	0.5 %	All initial assessment levels too low	5.0 %
Total		10.2 %	Total	100 %

Patients reported monitoring data regularly every weekday and partially beyond that during the weekend. Technical problems or difficulties to use the equipment for collecting or sending the data could obviously be avoided by involving the patients in a user-centred design process.[12] A potential reason for incomplete reporting data (in particular, in the case of long-term routine monitoring) was a good individual perceived health condition, leading to a lower support need and the impetus to report health data. Hence, the lack of monitoring data does not necessarily indicate a bad or even alert condition, but may indicate the opposite; that is, a stable or improved health status. However, with the current algorithms of the telehealth service these aspects are difficult to interpret. If the overall health condition of a patient is unknown or unstable, the lack of monitoring data should preferably trigger an alert to follow-up with a remote check-up of the patient (e.g. by phone or video call) or with a reminder to send monitoring data. If a patient condition is known and overall stable, the lack of data for one or a few days can be treated differently, usually assuming no significant changes in the health condition. This, in turn, requires a system that can ascertain the behavioural characteristics of a patient, and that can identify a good, healthy, stable condition and distinguish that from a condition in deterioration.

The health status of the monitored patients is – on average – quite constant during the trial period. The measured pulse oximetry data (Figure 2) does not show significant mean changes during the first 90 days, while extreme values (as extreme high, low pulse or very low SpO_2 measurements) become less frequent with increasing monitoring duration (i.e. beyond day 60). The clinical expectation here would be an increased SpO_2 and reduced pulse over time due to improved clinical conditions during monitoring. Certainly, the reduced number of participating patients causes a selection bias here that cannot be corrected and may explain why values (Figure 2) seem stable. Thus, patients that experience an improved condition may, to a larger degree, drop out of monitoring compared to those who are deteriorating or experience continued exacerbation. Beyond day 70, however, the number of higher maximum values of the score increases, indicating a ‘‘worse’’ or even ‘‘much worse’’ subjective health perception of some patients, most likely also influenced by a selection bias of those with a more chronically unstable condition.

The assessment of the pulse and especially the SpO_2 measurements was of essential importance for the monitoring of the COPD status. The introduction of a ‘‘yellow alert’’ allowed the nurses to detect early deteriorations of COPD that, assuming sound handling, could avoid more serious deteriorations and unnecessary hospitalisations. In the PROMETE study[4] a three-colour traffic light system was used, but only the red alert was related to the patient’s measurements.

The manual overwriting of the automatic health status level assessment by the telenurses resulted in adjusted health status levels. The analysis of the adjustments (Table 3: Analysis of Manual Overwrites of Health Status Level AssessmentTable 3) shows, that approximately one in 10 of all assessment levels were set lower by the nurses, and mainly from ‘‘yellow’’ to ‘‘green’’. In most of these cases, either the initial assessments of the measured pulse values were too high, or of single items of the daily questionnaire. The cut-offs had been defined accurately according to general clinical knowledge and the U4H trial protocol, and provided adaptation to the patients’ condition through individual reference values taken on the day of discharge from the hospital. However, high pulse could be detected if the patient had been in activity just before monitoring the pulse. In such cases, a retest of the pulse after 5–10 min (e.g. during a video consultation) often showed a lower pulse so that the initial red alert was adapted to yellow, and yellow to green. Thus, the automatic assessment by the telehealth service based on generic, static cut-off values might be too sensitive and not sufficiently personalised for each individual patient, causing unnecessary warnings or alerts. In a COPD pilot monitoring study, Velardo et al.[2] used multivariate analyses and non-parametric density

estimation techniques for calculations of the actual threshold values. Shah et al.[3] found (in the same pilot study) advantages of including respiratory rate as a predictor in the multivariate approach, giving improved estimations for personalised alerts. Farmer et al.[1] used a 95th centile as the alert threshold for heart rate and oxygen saturation, and Segrelles Calvo et al.[4] calculated an average value over measurements from the first three consecutive days as baseline for the calculation of deviations causing alerts.

Improved algorithms for automatic calculations of a health status score will be of importance for the routine use of telehealth solutions to support the self-management of patients with COPD. Improved algorithms are also relevant in systems for telenurses to assist patients with correct medical advises. An approach for ongoing research work would be the utilisation of smart, self-learning systems with artificial intelligence (AI) technologies. The development of appropriate machine learning algorithms and corresponding real-time data evaluation systems requires more clinical data.

Related studies evaluating the clinical outcome of the interventions by the telenurses triggered by the alerts during this trial are under publication.

5 Conclusions and Lessons Learned

The automatic, computer-based assessment of monitoring data from home-living COPD patients, as explored in this trial system, utilises algorithms and rules that depend on cut-off values for certain measurements or self-reported parameters, thereby reflecting the health condition of the patients. As such algorithms and rules look at the day-today development and changes of the reported data to identify notable or critical abnormalities, the accuracy and reliability of the health status assessments depend highly on the continuous reporting of the required parameters by patients, at least on a daily or more frequent, regular basis. This study reveals that there were no technical problems or usability challenges causing significant interruptions of the self-reporting of monitoring data by the patients, but that a stable and improving subjective health and well-being status could lead to a reduced motivation to regularly report health data.

Furthermore, the cut-off values defining certain health status levels are crucial for the accuracy of the health status assessment, and thus for the quality of the rule-based analysis. The results from the trial system show that static, generic cut-off values, as used, for example, for emergency medicine triage, are sufficient to trigger emergency alerts, while they do not support decisions by telenurses with high accuracy and reliability. Instead, cut-off values must be personalised to the individual health condition and common levels of health

parameters. Predetermined, personally adapted cut-off values defined at the beginning of a telehealth monitoring period of a patient might not adapt sufficiently with the dynamic general health condition of a patient. The results from the tested algorithms are not sufficient to provide for reliable (avoiding false-negative) and efficient (avoiding false-positive) alerts. More personalised, adaptive, and intelligent assessments are needed.

The tested telehealth trial system has shown strengths and advantages in the patient interaction, data collection, timely, reliable, and safe transmission of monitoring data, and the interaction with health professionals. Ongoing research work will combine, test, and evaluate this in combination with smarter, AI-based assessment and decision-support algorithms.

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7 Declaration of conflicting interests

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Appendix J

Telemedicine Trial System for Personalized Follow-up Support of Patients with Chronic Obstructive Pulmonary Disease (COPD) - Results and Experiences from Health Status Assessment and Risk Estimation Algorithms

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Internal report of the Center for eHealth and Healthcare Technologies at the University of Agder, Grimstad, Norway, August 2016.

Telemedicine Trial System for Personalized Follow-up Support of Patients with Chronic Obstructive Pulmonary Disease (COPD) - Results and Experiences from Health Status Assessment and Risk Estimation Algorithms

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Highlights —

- **Monitoring of 94 COPD patients, 70 days (average), 75% daily reporting completeness**
- **Evaluation of automatic health assessment of multiple patient-reported modalities**
- **10% of calculated health status scores overwritten manually, mainly as false-high**
- **Static rules and cut-off values not sufficient for reliable and efficient follow**

***Objective* — The use of telemedicine systems by patients reporting vital signs measurements and other health-related data from their home is evolving and has been studied and published by many research projects. In such a scenario, the reported data are received at a telemedical centre, where trained nurses follow up on the actual patient's condition and initiate necessary interventions. In some systems a color-coded assessment algorithm (called triage in medical vocabulary) is implemented in order to determine fluctuations and exacerbations of patients' conditions and to provide the healthcare staff with necessary alerts and information to support the prioritization of individually adapted support actions or interventions.**

Based on data reported by COPD patients with a pilot system developed for the EU-funded research project United4Health in South-Norway [7], we analyze on the one hand the reporting behaviour of the patients and their health status development during the trial participation, and on the other hand how the nurses at the telemedical centre utilized and adjusted the automatic health status assessment of those data. The evaluation of different assessment algorithms is expected to allow recommendations for future methods, together with improved cut-off values for warnings and alarms when actions are needed.

***Methods* — Patients were recruited to use a telemedicine monitoring solution for a defined period of 30 days after discharge from hospital treatment for acute exacerbations. For the first two weeks, they were instructed to report daily measurements of pulse and transdermal peripheral capillary oxygen saturation (SpO_2), in addition to a symptom specific questionnaire. Based on reported data, the telemedicine system determined a color-coded health status level for each reporting patient for that day. The calculation algorithms used defined cut-off values, as absolute generic as well as individual personalized values. Nurses at the telemedical centre, re-sponsible for the patient monitoring, got instantly an overview of all monitored patients, sequenced with red alerts for the most critical patients. In individual cases they could manually overwrite the assessment level, assigning a different colour code according to the patient's condition observed through a video or telephony consultation.**

***Results* — The evaluation of 4970 datasets from 94 tele-monitoring patient interventions provided insights in the long-term reporting behaviour: during the mean trial participation duration of 70 days, the average daily reporting completeness was around 75%-80%, while only around 25% of the patients reported every day during the first week and less than 10% during the whole first 30 days. The automatic health status assessment, done by the combinatorial fusion and evaluation of the reported pulse-oximetry values and subjective answers to a symptom specific questionnaire, showed stable conditions during about 50% of the whole monitoring period, about 30% notable conditions, but also 20% of alerts of critical conditions. The analysis of the manual ad-**

justments of the automatic health status assessment by the telehealth nurses revealed the frequency of about 10% and also reasons for the adjustments. Alternative assessment algorithms were compared in retrospective calculations.

***Conclusion* — The evaluation and comparison of different health status assessment algorithms to be used for the real-time calculation of color-coded health status assessments levels for the decision support of telehealth nurses allows recommendations for alternative assessment algorithms and for procedures for the determination of cut-off values. It also revealed that the sensitivity and specificity of such algorithms should be challenged in future studies.**

***Keywords* — COPD; Decision Support Techniques; Telehealth; Remote Monitoring; Personalized Health Status Assessment Algorithms; Triage**

1 Introduction

1.1 Aim of the Study

Remote home monitoring of patients with chronic diseases has been a topic of many research projects [1-6], where the main goals were to help patients in daily life situations, to increase their individual perception of security even under worsened medical conditions, to reduce home visits by doctors or nurses, and to avoid unnecessary hospital admissions and readmissions. For the EU-funded project United4Health [7], a solution was developed that utilized video communication technology to support patients at home with medical advice from a trained nurse at a centralized telemedical centre in order to take necessary actions like changes in inhalation therapy or start of antibiotic treatment. The actual interventions to be proposed by the nurse depended on the medical condition of the patient, as assessed by the data reported by the patient. These data included measurements of the transdermal, peripheral capillary oxygen saturation of the blood (SpO_2), the heart rate, and information about the patient's subjectively observed symptoms, as gathered through a daily questionnaire. The reported data from the patient were instantly evaluated automatically by a health status assessment algorithm, creating a colour code that provided the nurse with a quick overview of the actual patient condition. On daily basis the patient's reported condition would be followed by a video consultation.

The analysis of long time-series of vital signs data from patients at home over periods of weeks or months is both a new opportunity as well as a new challenge for healthcare services, and differs from traditional monitoring procedures in a hospital ward or under emergency conditions. While typically triage (also called "trauma triage", "emergency triage" or "emergency department (ED) triage", [8] [9]) is defined as "the process of classifying patients according to injury severity and determining the priority for further treatment", the long-term follow-up of patients with chronic diseases has to adapt the treatment and medication to the long-term development and short-term changes of the condition of the individual patient and the corresponding needs for support and intervention. In order to avoid confusion between the objectives of clinical "ED triage" and of the long-term monitoring and decision support for treatment and follow-up prioritization of home-based patients, the terms "*health status level assessment*" and "*health status score calculation*", respectively, will be used in this study.

The main objective of the EU-funded United4Health project was to gain insights in challenges and obstacles when deploying new telehealth solutions at broad scale in a sustainable way, and how those services can be adopted to existing

routines and health care procedures. An important aspect of the routine procedures was the self-reporting of the actual condition and the use of the provided telemedical equipment by the patients. The South-Norway Site of the United4Health project has developed a solution for remote home monitoring of home-based COPD patients, where the patients used a tablet PC device and a pulse-oximeter for their measurements and daily self-reporting to a database securely stored within the Norwegian National Health Network. To this the doctors at the hospital (COPD Specialist Services), the inter-organizational telehealth centre operated by the municipality health care services (secondary health care level) and the local doctors (General Practitioners, GPs) had access. The solution is further described in this paper.

Difficulties arise in the determination of actual algorithms for automatic health status score calculations, and in the definition of cut-off values for the different reported modalities in order to trigger the correct colour-coded alarm-level for such remote home monitoring situations. For the trial system a dedicated assessment algorithm was defined by the consortium in the clinical protocol, utilizing the combinatorial fusion of multiple modalities. Based on experiences from 94 patients included in the clinical trials, the trained nurses at the telemedical centre in many cases had to manually override the automatically calculated health status colour code. In order to investigate the reasons for those manual overrides, we have investigated nearly 5000 datasets, with the aim of defining recommendations for improved algorithms for automatic calculations of a health status score. Such improvements will be of importance for routinely use of self-management and telehealth solutions for patients with COPD (and also other chronical diseases), and are relevant also in decision support systems that give telemedicine nurses a more reliable tool helping them in giving the patients correct medical advises.

In our study, we explain and retrospectively evaluate algorithms for the automatic calculation of an individual COPD health status score applicable for self-reported multi-modal patient health-status data. The first algorithm is implemented according to a defined clinical protocol where cut-off values are defined according to best clinical practice. The obtained accuracy of this and two additionally proposed alternative algorithms is evaluated retrospectively with data from the clinical trial by comparing the calculated health status levels with the manual override actions made by the nurses. The number of patients included in this sub-group study (33) and the length of the considered monitoring period (first 30 days) is comparable to the studies of Velardo [4] and Segrelles-Calvo [6] (see more details in scientific background below). In addition to common clinical practice, we introduce a “yellow” health status level in our clinical trial protocol

as an early warning indicator of a “notable” health condition, and evaluate the impact on the monitoring routines.

The results of this study should help to answer the following *research questions*:

RQ 1. Do the data collection, transmission, and evaluation algorithms of the analysed telemonitoring service provide decision support information for the monitoring health and care professionals in a manner as they need it to provide reliable and efficient health and care follow-up for the remotely monitored COPD patients, according to their individually reported multimodal conditions and the corresponding support needed?

RQ 2. Do the implemented health assessment algorithms provide the required adaptation of health status levels and corresponding alerts for treatment and follow-up needs to the individual medical condition of each patient?

RQ 3. Are the used cut-off values for the determination of the actual health status level of each patient along the different reported modalities appropriate for the decision support and prioritization of follow-up actions? What recommendations can be given for improved cut-off values and algorithms, or for procedures to define or calculate appropriate values?

1.2 Scientific Background

Chronic Obtrusive Pulmonary Disease (COPD) encounters for reoccurring emergency admissions, and is projected by the World Health Organization (WHO) to become one of the four leading causes of death worldwide by 2030 [10]. Telehealth solutions are expected to help patients with chronic conditions in their daily life, to manage a worsened condition without the need of emergency hospital care. Results from the “Whole System Demonstrator” (see [1]) showed that telehealth follow-up of patients with chronic conditions resulted in lower mortality and lower emergency admission rates, compared to a control group in a clustered randomized control study. Odeh et al. investigated a Telemedicine Service for patients with COPD and heart failure [2], which was provided for 36 months to 48 patients, and led to the clinical outcome of reduced acute and emergency visits including reduced hospital admissions due to all causes by 13%. It is anticipated that patients’ daily self-reported symptoms correlate with patient deterioration [11]. However, patients with chronic diseases can also experience difficulties in using mobile technologies for self-management due to cognitive impairments [12], and careful attention should be paid to the design of such solutions. Liliholt et al. followed the TeleCare North trial in Denmark [13], and found that technical skills and health literacy are no prerequisite for the patients to use the Telekit system for reporting their vital signs measurements.

New eHealth and mobile health (mHealth) telemedicine solutions have evolved over the past years, and according to Hofstede et al. [14] patients have general knowledge of such solutions, but no clear understanding of their advantages. However, almost half of the 400 patients in their telephone survey considered the possibility of taking more responsibility for their own care and self-management. When involving patients in a user-centred design, telehealth solutions for patients with COPD at home can be developed with focus on user-friendly functionalities and interfaces [15]. Nevertheless, Liu et al. have found conflicting evidence in their systematic review [16] that home health monitoring technologies can be of help addressing the patients' condition of COPD, but as telemonitoring interventions are relatively new, the results might have been influenced by usability problems.

In the UK, 12 telehealth systems were analysed for their use of information exchange between patients and health care professionals [17]. Data analysis methods with predefined algorithms to be configured by the health professionals were implemented in 11 of the systems. In four of the investigated systems, a colour-coded format was used to indicate the severity of the patients' status and the priority of support and follow-up; at the same time occasionally false positive and false negative alerts were encountered. An Internet-linked tablet PC for self-reporting of daily symptoms and pulse-oximetry measurements has been studied by Farmer et al. [3]. Their so-called "EDGE platform" gave the clinicians timely and immediately available information without overwhelming flow of data, although no immediate alerts were implemented - the response from the clinician was based on 4-day intervals. The EDGE-platform used a 95th centile as alert threshold for heart rate and oxygen saturation measured with a pulse oximeter and calculated from an initial 6-week period, allowing their web-based system to give valuable tailored alerts for the additional period.

Triage as a method for assessing the severity of injuries was originally developed by Champion et al. for emergency medical care [18]. They described a Triage Index to be used for the determination of injury severity in order to prioritize the acute assessment with available therapeutic resources. Shelton evaluated the use of a 5-level Emergency Severity Index [19] to easier and faster determine the needed care in emergency departments, and the use of triage methods for defining the patients' actual condition has been expanded also for the utilization in telehealth solutions.

Manually entered threshold values for certain measured life signs can be used for generating alerts or calculating a triage colour-code indicating the patient's actual condition. Such threshold values can be given as general recommended fixed limits, or can be manually adjusted to the individual patient needs based on

clinical evaluation. In a COPD pilot monitoring study, Velardo et al. [4] analysed retrospectively an electronic diary questionnaire of 18 patients over a period of six months, with measurements of pulse rate, blood oxygen saturation and respiratory rate. Their data-driven approach focused on automatically generated alerts based on multivariate analyses and non-parametric density estimation technique for calculations of the actual threshold values, and revealed advantages compared to manually alert setting thresholds when they used automated methods. In the same pilot study, Shah et al. found advantages in another retrospective analysis (using the data from the same 18 patients) of including respiratory rate as a predictor in a multivariate approach giving improved estimations as input for a more personalized alerting method [5]. However, they did not collect an objective measure of lung infection, and used the self-reported medication events as exacerbation indicators.

In order to reduce the experienced excessive red alerts and time spent on triage follow-up, Banerjee and Tanner [20] tried different methods for statistical analysis of measurement variations in order to provide a highly sensitive method for defining alert thresholds; however, their method did not include online calculations of thresholds as the method was retrospective.

A home telehealth solution was clinically evaluated by Segrelles-Calvo et al. in the PROMETE study with 60 patients during 7 months [6], where a 3-colour traffic light system was used to receive, monitor, assess and trigger follow-up by clinicians. Only the red “clinic alert” was related to the patient’s measurements, and an average value over the first 3 consecutive days was calculated to be used as baseline for calculations of deviations according to defined percentages for heart rate, O_2-saturation, blood pressure and peak-flow.

In a comparison of two methods for risk stratifications of pulmonary embolism with 168 patients, Nordenholz et al. [21] found that a pulse oximetry cut-off below 92.5% gave a moderately acute identifier of low-risk patients.

For detection of day-to-day variations of the patient’s condition, it is not possible to use retrospective methods; thus methods for automated calculations of individual threshold values will be necessary to develop. But there seems to be a gap in the knowledge on how patients in their daily routines use sensors for telemonitoring, and which indicators might be used in which way for triggering alerts, that should in turn lead to appropriate levels of responses [22]. Furthermore, in a global research agenda for Personalized Telehealth [23], Dinesen et al. have pinpointed the need of innovative data analytics for personalized calculations of the patient’s actual condition.

2 Materials and Methods

The EU-project United4Health [7] (2013-2015) was initiated with the aim of large scale deployment of telehealth services for patients with chronic conditions as COPD, heart failure and diabetics, and a trial system was implemented to study those services at scale and their adoption in routine care. According to the regulations in Norway, patients discharged from acute hospital treatments are transferred to the municipality health and social care services. The telehealth solution was developed to achieve the needed collaborative care across organizational borders, and according to the Norwegian health data security regulations. An overview of the system is illustrated in Figure 1 below.

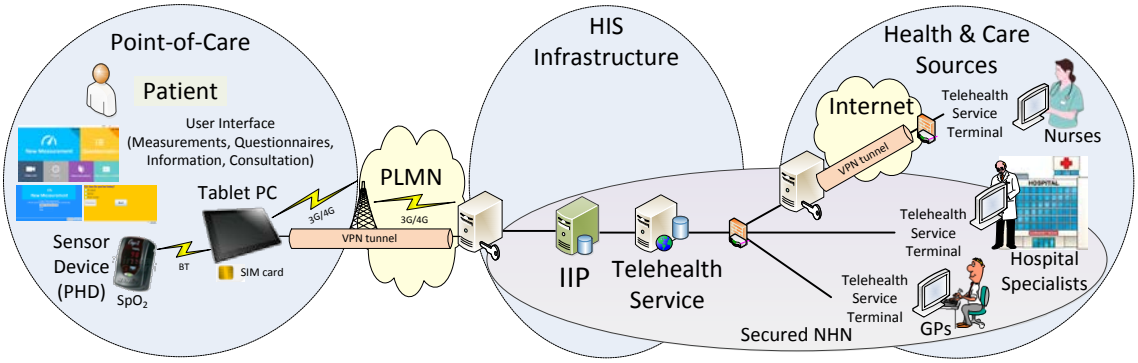

Figure 1: Trial System Overview
(EU project United4Health, South-Norwegian pilot site)

In the following we explain the use case scenario and requirements for the remote monitoring and follow-up support of home-based COPD patients as realized by the trial system. Furthermore, we briefly describe the main components along the major domains of the system, which are required to assess, transmit, evaluate and provide information from the Point-of-Care (typically the patient's home), via the Health Information Service (HIS) infrastructure, to the Health & Care Sources environment, where the information is utilized by trained nurses, general practitioners (GPs) and medical specialists in hospitals.

2.1 Clinical Protocol for the Trial System

The clinical protocol for this study in South-Norway was developed according to the scientific trial protocol for the United4Health project, as a short-term implementation study of telehealth follow-up after hospital discharge for COPD patients with acute exacerbations. Patients that were hospitalized for exacerbation of COPD according to the Global Strategy for Obstructive Lung Disease (GOLD) were considered for inclusion in the study at the time of discharge from the pulmonary department at Sørlandet Hospital HF in Kristiansand. If they did not want or could not sign the informed consent form, were not able to or did not

want to use the telemedicine system, were in problematic clinical or social circumstances, or were discharged to a locality that either had no mobile broadband data coverage or could not be reached by the telemonitoring team were not considered. A trained nurse instructed the patient to use the telehealth solution, and the first measurements of pulse and SpO_2 were recorded and used as reference values for the assessment of following monitoring data day-to-day. In a dedicated suitcase the necessary equipment was correctly pre-configured for each individual patient, ready to be used when arriving at home.

The patient was instructed to perform a daily measurement of pulse and SpO_2 by use of the pulse oximeter, and in addition to fill in a daily questionnaire, where the patients had to answer seven pre-selected questions on symptoms focusing on general well-being, breath, sputum, sputum colour and use of extra reliever medication/nebulizers, extra oxygen, antibiotics or steroids. A defined timeslot for a daily video consultation with the telemedical centre was negotiated. This procedure was supposed to be followed for the first 14 days as a *High Level of Telemonitoring Service* phase. For the next 14 days, defined as *Reduced Level of Telemonitoring Service* phase, the daily measurements and questioning were continued, but a video consultation would only be conducted if the condition deteriorated. After those phases (30 days in total) the equipment should be returned to the hospital. At any time during the opening hours (Monday – Friday between 08:30h to 15:00h) patients could call the telemedical centre in case they needed to discuss their condition with the trained nurses. This was also the declared procedure after the 30-days-period, and was defined as *Low Level of Telemonitoring Service* phase, to be continued for the next two months through ordinary telephone contact, since the telemedical equipment had been returned.

Based on a doctor's evaluation, the patient could have a prolonged period of *High Level of Telemonitoring Service*, which resulted in a situation where the patient could keep the equipment at home, to be used in cases needed.

Baseline data was collected by the hospital staff at discharge. All data measured and reported by the patients with their tablet PC application was consecutively uploaded to the secured data server at the telemedical centre, where the operator could monitor the reported data of each patient, supported by automatically calculated health status levels. The respiratory nurse specialist at the telemedical centre (*telehealth nurse*) had the possibility to manually override the calculated health status level, if they experienced during a video consultation that the patient's actual condition deviated from the automatic calculations. They could also store a journal note based on their evaluations.

According to the general U4H protocol, the recorded data were assessed with algorithms to calculate the health status level based on the combinatorial fusion

of the reported modalities and defined cut-off values for each modality. The cut-off values were based on already existing empirical algorithms used in several centres in the UK. The Norwegian clinical protocol added “yellow” alert cut-offs to increase the sensitivity of the system to detect early changes of health status. These cut-offs were defined on a purely empirical clinical basis. A “red” alert was notified to the telehealth nurse if the pulse rate was either <50 bpm or >120 bpm, the oxygen saturation had fallen by ≥6% from their discharge baseline, or two of the seven daily questions were out of range (‘worse’ or ‘more than usual’) for two consecutive days. The telehealth nurse would then contact the patient by the secured video call, and follow a telemedical review in order to give adequate advices. Criteria for hospital admissions were to follow local protocols.

According to the Norwegian trial protocol, the following health status levels were defined:

- ***Green***: The patient is in a stable or improved clinical condition with unchanged medication. The reported pulse-oximetry measurements are within an acceptable range compared to individual reference measurements made at discharge from the hospital. The self-reported health symptoms are unchanged compared to the previous day.
- ***Yellow***: The patient is in a condition that needs special attention. If the pulse-oximetry measurements (refer to section 2.2.3.1) or at least one reported symptom (refer to section 2.2.3.3) indicate notable deterioration since the previous day or the hospital discharge respectively, a yellow alert is triggered. These cut-offs were followed:
    - an increase in pulse of >10 bpm, or a reduction in SpO_2 of 4-5%, or
    - an answer to question 1, 2, 3 or 4 defined as “worse”, or question 5 answered with “more than usual”

  This warning threshold was introduced in addition to the U4H protocol to increase sensitivity for early signs of deterioration of COPD.

- ***Red***: The patient is in a critical condition, equivalent to the alert limits defined above. The pulse-oximetry measurements or the self-reported symptoms indicate significant deterioration since the previous day or the hospital discharge respectively.

Section 2.2.3 below provides more details on the implemented algorithms for data evaluation and the determination of the health status levels.

2.2 Realization of Trial System

The main purpose of the trial system was to support the primary care of home-living COPD patients by telehealth nurses. The support allowed to remotely and

continuously monitor the health status of the patient, and to provide decision support information for the follow-up treatment. Furthermore, the system facilitated the inter-organizational cooperation of the telehealth nurses with general practitioners (GPs) and medical specialists in hospitals, by making the patient's monitoring data available for further diagnosis support and treatment recommendations. The telehealth nurses could contact the patient on a regular basis or if required for example to clarify the status and to give immediate support through an integrated video communication service.

In order to make the self-measurement and –reporting process easy and user-friendly, and to avoid difficulties with the operation of the reporting application and measurement equipment, the development of the tablet PC application had followed a User-Centred Design (UCD) approach [15]. Patients were involved since the early development phases in particular in the interaction and the user interface (UI) design, and in iterative testing and refinement. In parallel, telehealth nurses were involved in the development of the Telehealth Service [24]. The studies explain the UCD approach and the usability advances for the different user groups. For the usability evaluation a dedicated usability evaluation infrastructure for eHealth applications and services [25] had been established, in order to support the iterative testing and refinement of the patient application and the telehealth service involving both interacting user groups during the development phase. In a qualitative study of the first 10 patients included in the project, it was found that "the telemedicine intervention contributes to stress reduction caused by illness burden and facilitates living as normally as possible" [26]. A study of Barken et al shows that the patients experienced safety and increased knowledge through the digital dialog with the telehealth nurses enabled by the telehealth system, which indirectly improved their health related quality of live (HQoL), and in term lead to increased mastery and control in managing their disease [27].

2.2.1 Ascertainment of Health Status

For the measurement of pulse and blood oxygen saturation (SpO_2), a fingertip pulse oximeter (model 9560 Onyx II from Nonin Medical Inc.) was utilized as Personal Health Device (PHD). The transmission of the measured data from the PHD to the patient application on the tablet PC is based on Bluetooth communication technology (see also Figure 1), and the key-protected pairing of the PHD with the tablet PC was done when the patient received the equipment. The tablet PC application guided the patient stepwise through the measurement process (refer to [15] for more details about the UI design and interaction flow).

A questionnaire for the self-reporting of COPD-related health symptoms was implemented for the trial system, with seven questions that should be answered

by the patient on a daily basis. The questions Q_i, possible answers, and the corresponding answer values $Ans_i(Q_i)$ are listed in Table 1. Clinical experience from the UK is the basis for this short daily questionnaire, which has been approved by the other clinical experts in the U4H project. These questions have been used in various sites in the UK and are thus empirical more than evidence based.

Table 1: Daily Questionnaire

Q_i	Question	Possible answers	$Ans_i(Q_i)$
Q_1	How do you feel today?	As usual Worse Much worse	2 3 4
Q_2	How is your breathing today?	As usual Worse Much worse	2 3 4
Q_3	How is your amount of sputum today?	As usual Worse Much worse	2 3 4
Q_4	What is the colour of your sputum today?	No sputum / Clear / White Yellow / Green / Brown	2 3
Q_5	Are you using rescue medication / nebulizer or oxygen today?	No, I am not using them today. As usual More than usual Much more than usual	1 2 3 4
Q_6	Have you started up with additional antibiotics after last discharge?	No / I have finished. Yes – Apocillin / Penicillin Yes – Imacillin / Amoxicillin Yes – Ciproxin Yes – Azitromax Yes - Other	0 1 2 3 4 5
Q_7	Have you started up with new Prednisolon after last discharge?	No. Yes – 20 mg Yes – 30 mg Yes – 40mg Yes - Other	0 1 2 3 4

In order to allow for a safe, privacy-protecting transmission, the monitoring data, i.e. questionnaire answers and sensor measurement values, were complemented with a non-public *Patient-Identifier*. This anonymized identifier does not allow identifying a patient directly, and only the Telehealth Service can do the mapping

of the reported data tagged with that identifier to a specific patient. Also the exact *Reporting Date / Time* was added for later evaluation and presentation purposes. Upon successful transmission, the patient was informed accordingly on the application UI by a corresponding success indicator.

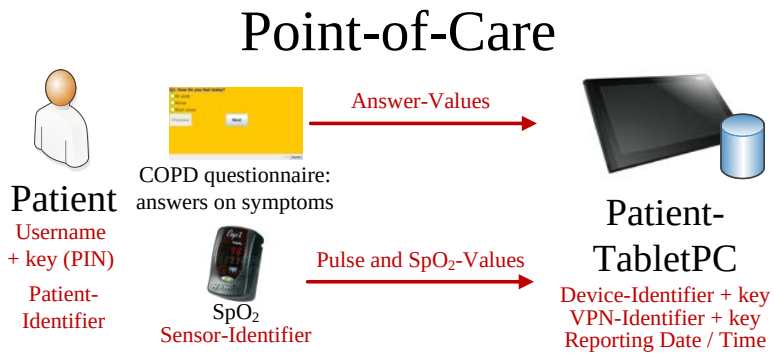

Figure 2: Point-of-Care (PoC) Communication

2.2.2 Transmission of Monitoring Data

A key requirement for the development of the remote monitoring system was the secure, reliable and fast transmission of monitoring data from the patients' tablet PC devices in their Point-of-Care to a Telehealth Service in the HIS Infrastructure (Figure 1). An Information Integration Platform (IIP) [28] was used to aggregate the monitoring data from all patient tablet PC devices, and forwarded it to the Telehealth Service (Figure 3).

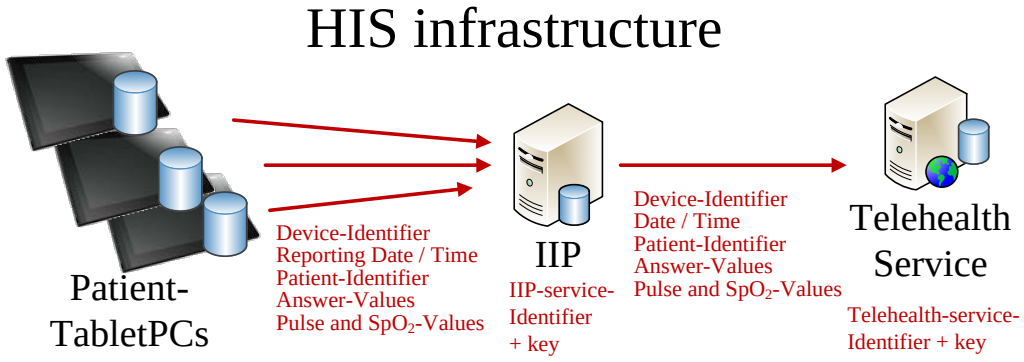

Figure 3: Point-of-Care (PoC) to Health Information Services (HIS) Communication

The IIP (Figure 4) provides safe and efficient means as an *Information Broker* for the distribution of data from many *Information Providers* (which are the patient tablet PCs in the trial system) to multiple *Information Consumers*. In the trial system deployment, the Telehealth Service was the only *Information Consumer*.

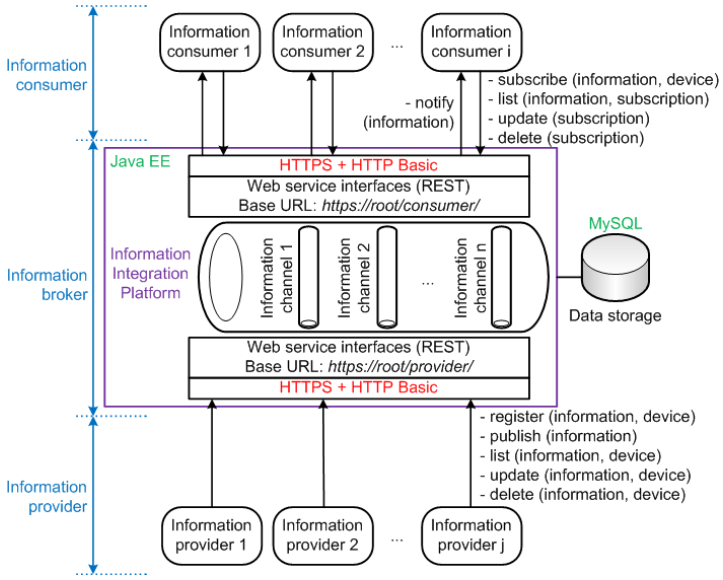

Figure 4: Information Integration Platform (IIP) Overview [28]

For the different types of monitoring data (pulse measurement, SpO_2 measurement, daily COPD questionnaire, and COPD Assessment Tool (CAT), so-called "Information Channels" are defined in the IIP. The details of the information handled in each Information Channel are listed in Table 2-Table 5. This allows for an independent transmission of all types of reporting data.

Table 2: IIP Information Channel for Pulse-Measurements

Information-Channel attribute	Attribute Value	Value Syntax	Description / Note
infoID	info:*********	info:[{0..9}:9]	Unique identifier assigned by system
name	pulse		
description	Pulse-Rate		Pulse rate, measured by patient with pulse sensor device as part of TMon
pmdId	pmd_*******	string	Unique identifier of PMD device
pmdBatteryLevel	[charge level %]	integer	Battery status of PMD device
lastupdateDate	date / time	UTC	Last info-update received by IIP
patientId	*********	[{0..9}:7]	Identifier known by Telehealth-Service
pulse	[pulse-rate]	string	Measured pulse value
dateTime	date / time	UTC	Measurement-Data/Time by tabletPC; e.g. 2015-06-18T17:12:22
ownerUsername	Device-Identifier	tablet_[{0..9}:4]	Own Id for authentication towards IIP
allowedSubscribers	[serviceId1, serviceId2, …]	string	serviceId1=ID of Telehealth-service

The *Information-Channel Attribute* `ownerUsername` is used as identifier for the authentication of the information owner to the IIP. In the trial system, the patient tablet devices are registered with their *Device-Identifiers* as owners of the information channels. The *Patient-Identifier* is transmitted as *Attribute Value* of the attribute `patientId`. The separation of the *Device-Identifier* from the *Patient-Identifier* allows that each patient tablet PC device has to be registered in

the system just once. The *Patient-Identifier* is configured as part of the user account, when a device if provisioned for another patient, and is transmitted together with the monitoring data, to allow the mapping of the data to a specific patient in the Telehealth Service.

Table 3: IIP Information Channel for Blood Oxygen-Saturation-Measurements

Information-Channel attribute	Attribute Value	Value Syntax	Description / Note
infoID	info:*********	info:[{0..9}:9]	Unique identifier assigned by system
name	spo2		
description	Blood Oxygen Saturation		SpO2 value, measured by patient with SpO2 sensor device as part of TMon
pmdId	pmd_*******	string	Unique identifier of PMD device
pmdBatteryLevel	[charge level %]	integer	Battery status of PMD device
lastupdateDate	date / time	UTC	Last info-update received by IIP
patientId	*********	[{0..9}:7]	Identifier known by Telehealth-Service
spo2	[spo2-level]	string	Measured SpO2 value
dateTime	date / time	UTC	Measurement-Data/Time by tabletPC; e.g. 2015-06-18T17:12:22
ownerUsername	Device-Identifier	tablet_[{0..9}:4]	Own Id for authentication towards IIP
allowedSubscribers	[serviceId1, serviceId2, …]	string	serviceId1=ID of Telehealth-service

The IIP allows configuring access rights to each information channel in the information channel attribute `allowedSubscribers`, by stating those services that can subscribe to the information published through the corresponding information channel. Here the Telehealth Service identifier is configured as an `allowedSubscriber` in all information channels for all patient tablet PC devices. No other service (or client) can get access to the "published" monitoring data.

Table 4: IIP Information Channel for Daily COPD Questionnaire Answers

Information-Channel attribute	Attribute Value	Value Syntax	Description / Note
infoID	info:*********	info:[{0..9}:9]	Unique identifier assigned by system
name	DailyInterview		
description	Daily questions on symptoms		7 pre-selected questions on symptoms, answered by patient as part of TMon
lastupdateDate	date / time	UTC	Last info-update received by IIP
patientId	*********	[{0..9}:7]	Identifier known by Telehealth-Service
q_1, q_2, q_3, q_4, q_5, q_6, q_7	[answer-values]	Integer; [{0..5}]	Answer values to questions Q1 – Q7 of daily questionnaire
dateTime	date / time	UTC	Reporting-Data/Time by tabletPC; e.g. 2015-06-18T17:12:22
ownerUsername	Device-Identifier	tablet_[{0..9}:4]	Own Id for authentication towards IIP
allowedSubscribers	[serviceId1, serviceId2, …]	string	serviceId1=ID of Telehealth-service

With the attribute `lastupdateDate` the IIP registers when new monitoring data is received from the corresponding information provider, i.e. from a patient tablet PC. In order to be independent from potential connectivity interruptions of a patient tablet PC device, the actual measurement / reporting date and time of

the patient is separately transmitted in the `dateTime` attribute. Even in the case of a temporary communication interruption the urgency of a potential alert can be determined.

Table 5: IIP Information Channel for CAT-Answers

Information-Channel attribute	Attribute Value	Value Syntax	Description / Note
infoID	info:*********	info:[{0..9}:9]	Unique identifier assigned by system
name	CAT Questionnaire		
description	COPD Assessment Tool		8 standardised questions on COPD assessment of patient
lastupdateDate	date / time	UTC	Last info-update received by IIP
patientId	*********	[{0..9}:7]	Identifier known by Telehealth-Service
q_1, q_2, q_3, q_4, q_5, q_6, q_7, q_8	[answer-values]	Integer; [{0..5}]	Answer values to questions Q1 – Q8 of CAT
dateTime	date / time	UTC	Reporting-Data/Time by tabletPC; e.g. 2015-06-18T17:12:22
ownerUsername	Device-Identifier	tablet_[{0..9}:4]	Own Id for authentication towards IIP
allowedSubscribers	[serviceId1, serviceId2, …]	string	serviceId1=ID of Telehealth-service

The Telehealth Service evaluated the Monitoring Data (refer to section 2.2.3 below) and provided it with additional decision support information to the health & care professionals (telehealth nurses, GPs, and specialists at a hospital) through a Web-based interface to their Telehealth Service Terminals Figure 5.

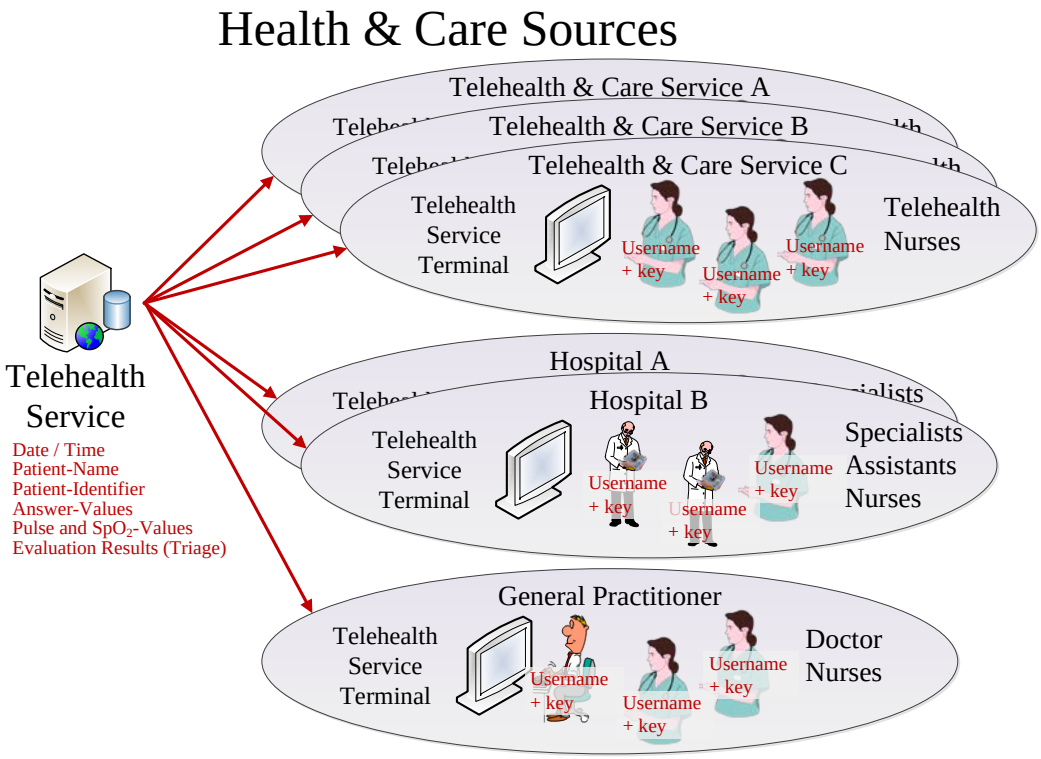

Figure 5: Telehealth Service to Healthcare Providers Communication

For the deployment and operation of services within the secured Norwegian National Health Network (NHN), a "Code of Conduct for information security in the healthcare and care services sector" [29, 30] had to be followed. A dedicated study of "End-to-end Security and Privacy Protection for Co-operative Access to Health and Care Data" had been carried out accompanying the development of the U4H telehealth trial system [31].

2.2.3 Evaluation of Data and Provision of Decision Support Information

The Telehealth Service received, aggregated and evaluated all monitoring data reported by each patient, in order to provide immediate status information as basis for the individual follow-up and treatment by the telehealth nurses and other involved health and care professionals as the patients' GPs and COPD specialist at the hospital. The personalized assessment of the health status of the patient was carried out in terms of three levels, represented by the colour codes green, yellow, and red, and was triggered by the reception of new data from the patient via the IIP. The overall health status score was thereby calculated from the results of the pulse-oximetry assessment and the daily questionnaire assessment, which could be carried out and reported independently by the patient.

2.2.3.1 Assessment of Pulse-Oximetry Measurements

The heart rate / pulse and the oxygen saturation of the blood (SpO_2) were always measured at the same point in time and reported as a value pair. Each value was assessed separately, before a combined health status level was calculated. Crucial for the assessment were cut-off values for both the pulse and the SpO_2 parameters. We have compared the impact of three different algorithms for the definition of cut-off values:

(1) Cut-off value algorithm 1: Cut-off values based on personalized and static reference values, determined at entry-point of the patient in the trial. This is according to the Norwegian clinical trial protocol as described in chapter 2.1.
A reference value both for pulse and for SpO_2 was set for each participating patient by the medical staff at the day of discharge from hospital (day_0), and was stored within the trial system as part of the individual patient profile.

$$SpO_2\_ref = SpO_2(day_0)$$
$$Pulse\_ref = Pulse(day_0)$$

Based on these reference values, the system calculated the following cut-off values:
An oxygen saturation that is ≥6% lower than the reference value is critical = “red level”:

$$SpO_2\_red\text{-}limit = SpO_2\_ref - 6\ [\%]$$

An oxygen saturation that is ≥4% and <6% lower than the reference value is notable = “yellow level”:

$$SpO_2\_yellow\text{-}limit = SpO_2\_ref - 4$$

A pulse higher than 120 beats/min or lower than 50 beats/min is critical = “red level”:

$$Pulse\_red\text{-}limit\_upper = 120\ beats/min$$
$$Pulse\_red\text{-}limit\_lower = 50\ beats/min$$

A pulse that is ≥15 beats/min higher than the reference pulse or the pulse measured on the previous day (day_{i-1}) is critical = “red level”:

$$Pulse\_red\text{-}limit = 15\ beats/min + \min(Pulse\_ref, Pulse(day_{i-1}))$$

A pulse that is ≥10 and <15 beats/min higher than the reference pulse or the pulse measured on the previous day (day_{i-1}) is notable = “yellow level”:

$$Pulse\_yellow\text{-}limit = 10\ beats/min + \min(Pulse\_ref, Pulse(day_{i-1}))$$

These reference and cut-off values have been the basis for the health status assessment in the trial system.

2.2.3.2 Proposed alternative algorithms for health status score calculation

In order to evaluate actual methods in a retrospective analysis comparing specificity and sensitivity, two additional algorithms were derived. The analysis is based on the monitoring data collected in the trial.

(2) Cut-off value algorithm 2: Cut-off values based on personalized and adaptive reference values.
In order to adapt the health status assessment to the changing general health condition of each monitored patient during the involvement in the trial, alternative reference values were calculated as the average of the measurements from the previous three days including today.

$$SpO_2\_ref\_alt_1 = \frac{SpO_2(day_i) + SpO_2(day_{i-1}) + SpO_2(day_{i-2})}{3}$$
$$Pulse\_ref\_alt_1 = \frac{Pulse(day_i) + Pulse(day_{i-1}) + Pulse(day_{i-2})}{3}$$

The calculation of cut-off values based on those reference values followed the same algorithms as above:

$SpO_2\_red\text{-}limit\_alt_1 = SpO_2\_ref\_alt_1 - 6\ [\%]$
$SpO_2\_yellow\text{-}limit\_alt_1 = SpO_2\_ref\_alt_1 - 4\ [\%]$
$Pulse\_red\text{-}limit\_upper = 120\ beats/min$ $Pulse\_red\text{-}limit\_lower = 50\ beats/min$
$Pulse\_red\text{-}limit\_alt_1 = 15\ beats/min + \min(Pulse\_ref\_alt_1, Pulse(day_{i-1}))$
$Pulse\_yellow\text{-}limit\_alt_1 = 10\ beats/min + \min(Pulse\_ref\_alt_1, Pulse(day_{i-1}))$

(3) Cut-off value algorithm 3: Cut-off values based on a mix of personalized and generic, static reference values.
As defined in the assessment protocol of the U4H project, the assessment of the patients' pulse values was based on static and generic, non-personalized cut-off values, while the assessment of the SpO_2 values followed algorithm (2) above utilizing personalized, static reference values determined at discharge from hospital.

$SpO_2\_ref\_alt_2 = SpO_2(day_0)$
$SpO_2\_red\text{-}limit\_alt_2 = SpO_2\_ref\_alt_2 - 6\ [\%]$
$Pulse\_red\text{-}limit\_upper = 120\ beats/min$ $Pulse\_red\text{-}limit\_lower = 50\ beats/min$

The assessment of the pulse-oximetry measurements $SpO_2(day_i)$ and $Pulse(day_i)$ based on those cut-off values has followed the algorithms in Table 6 and Table 7. For cut-off value algorithm 3, only the "green" and the "red" ("alert") health status level were determined.

Table 6: SpO_2 Assessment Level

$SpO_2\_assess\_level(day_i)$	Condition
Critical = "red"	$SpO_2(day_i) <= SpO_2\_red\text{-}limit$
Notable = "yellow"	$SpO_2(day_i) <= SpO_2\_yellow\text{-}limit$
Stable = "green"	$SpO_2(day_i) > SpO_2\_yellow\text{-}limit$

Table 7: Pulse Assessment Level

Pulse_assess_level(day_i)	Condition
Critical = “red”	(Pulse(day_i) >= Pulse_red-limit_upper) ∨ (Pulse(day_i) <= Pulse_red-limit_lower) ∨ (Pulse(day_i) > Pulse_red-limit)
Notable = “yellow”	Pulse(day_i) > Pulse_yellow-limit
Stable = “green”	(Pulse(day_i) > Pulse_red-limit_lower) ∨ (Pulse(day_i) <= Pulse_yellow-limit)

2.2.3.3 Assessment of self-reported health symptoms based on daily questionnaire

Based on the answer values $Ans_n(Q_n, day_i)$ for the questions Q_1 to Q_7 according to Table 1, the assessment of the self-reported health symptoms by the daily questionnaire *Quest_daily_assess_level(day_i)* followed Table 8.

Table 8: Daily Questionnaire Assessment Level

Quest_daily_assess_level(day_i)	Condition
Critical = “red”	($Ans_n(Q_n)$ = 4 for any question $Q_n \in \{Q_1, Q_2, Q_3, Q_4, Q_5\}$) ∨ (($Ans_n(Q_n)$ = 3 for more than 2 questions $Q_n \in \{Q_1, Q_2, Q_3, Q_4, Q_5\}$) ∧ (Quest_Daily_assess_level(day_{i-1}) ϵ {“yellow”, “red”}))
Notable = “yellow”	($Ans_n(Q_n)$ = 3 for any question $Q_n \in \{Q_1, Q_2, Q_3, Q_4, Q_5\}$) ∨ (($Ans_6(Q_6, day_i) > 0$) ∧ ($Ans_6(Q_6, day_{i-1}) > 0$)) ∨ (($Ans_7(Q_7, day_i) > 0$) ∧ ($Ans_7(Q_7, day_{i-1}) > 0$))
Stable = “green”	all other conditions

Furthermore, a Daily Questionnaire Score (DQS) had been calculated as the sum of the answer values to questions Q1 – Q5:

$$\mathrm{DQS}(day_i) = \sum_{n=1}^{5} Ans_n(Q_n, day_i)$$

2.2.3.4 Combined daily personalized health status level

The combined personal health status assessment level *Health_assess_level(day$_i$)* based on the latest reported pulse-oximetry measurements and answers to the daily questionnaire for self-reporting of health symptoms of each day was determined according to Table 9, based on the results in Table 6, Table 7 and Table 8.

Table 9: Combined Daily Health Status Assessment Level

Health_assess_level(day$_i$)	**Condition**	**Note**
Critical = "red"	(SpO_2_assess_level(day$_i$) = "red") OR (Pulse_assess_level(day$_i$) = "red") OR (Quest_daily_assess_level(day$_i$) = "red")	If *any* modality is "red", the overall assessment level is "red"
Notable = "yellow"	(SpO_2_assess_level(day$_i$) = "yellow") OR (Pulse_assess_level(day$_i$) = "yellow") OR (Quest_daily_assess_level(day$_i$) = "yellow")	If *any* modality is "yellow", the overall assessment is "yellow"
Stable = "green"	(SpO_2_assess_level(day$_i$) = "green") AND (Pulse_assess_level(day$_i$) = "green") AND (Quest_daily_assess_level(day$_i$) = "green")	If *all* modalities are "green", the overall assessment is "green"

All monitoring data from each patient was provided to the telehealth nurses and other involved healthcare professionals through a user interface of the Telehealth Service (refer to [24] for more details about the Telehealth Service UI). The outcome of the health status assessment was utilized to support the nurses in the prioritization of the patient follow-up, i.e. the decision about most urgent actions, including the initiation of immediate phone or video calls with patients to check their individual condition and needs, and the involvement of GPs or even emergency support. For that, the data of each monitored patient was highlighted in a patient overview with the colour code representing the overall health status assessment level, utilizing the latest received data of the ongoing day. From the service UI, also details about further previous measurements and questionnaire responses were available for each patient.

3 Results

During the 2 years from May 2014 until April 2016 a total of 94 patients with COPD were recruited for the telemonitoring trial. The baseline data are listed in Table 10, where patients had an average age of 69 years. 18 of those patients (19.1%) had a Degree COPD[1] of 2, 30 (31.9%) had a COPD Degree of 3, and 41 (43.6%) had a COPD Degree of 4, resulting in an average Degree COPD of 3.3, measured according to the Gold COPD scale.

Table 10: Baseline Data of Patients included in Telemonitoring Trial

	Male (n=48)		**Female (n=46)**		**Total (n=94)**	
	Mean	**Std.Dev**	**Mean**	**Std.Dev**	**Mean**	**Std.Dev**
Age	70.7	9.4	67.6	8.8	69.2	9.2
FEV1 in % predicted	38.2	17	38.1	12.5	38.1	14.8

9 of the 94 patients had 2-3 additional periods of telemonitoring after readmissions to hospital treatment, and 67% of the patients had a prolonged use of the telemonitoring services beyond the planned 30 days. 29 patients (31%) were defined as drop-out before end of the planned 30 days' period for different reasons (e.g., some of them encountered difficulties with bad quality in the video consultations due to poor mobile data coverage). 19 patients were readmitted to emergency treatment at hospital or acute care treatment (20.2%). The number of days included in the telemonitoring services (taken from the last day of monitoring data reported to the telehealth service) varied from 1 to more than 365, and the actual frequency distribution of the percentage of patients (related to the overall number of 94) over the number of days included is depicted in Figure 6 below.

In total, we have analysed 4970 datasets for this study received by the telehealth service, each containing a pair of pulse-oximetry measurements (pulse and SpO_2), or a set of answers to the daily questionnaire, or a combination of those. Each dataset originates from one patient, and is tagged with an (anonymized) patient identifier and the date and time when the monitoring data was collected (i.e. when the measurement was done or the daily questionnaire answered)[2].

[1] "Degree COPD" is defined according to the COPD stages 1(mild), 2 (moderate), 3 (severe) and 4 (very severe)

[2] This date and time of monitoring can be different from the date/time of transmission from the patient tablet PC device or the reception of the data at the telehealth service in the HIS infrastructure. In case of connectivity problems of the patient tablet PC device, the data is stored and transmitter as soon as connectivity is established again. For the health status assessment, the date/time of monitoring is crucial (not the date/time of reception by the telehealth service).

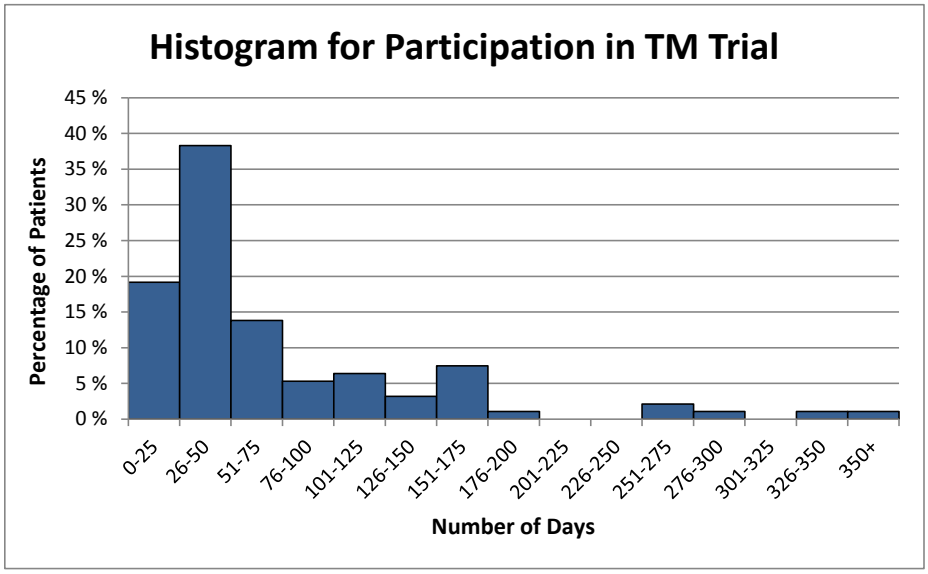

Figure 6: Histogram of Participation Duration [number of days] in TM Trial

There could be multiple datasets for one patient for one day, e.g. in case the measurement or the questionnaire had been executed and transmitted multiple times. For the health status level assessment, the first reported data of the day is used, as the result potentially triggers an alert to the telehealth nurses for required follow-up support or treatment.

An overview of the development of the pulse-oximetry data (measurements of pulse and SpO_2) reported by the patients during the first 90 days of their trial involvement is shown in Figure 7. Between 88 of all 94 equipped patients on day 1 (94%) and 16 of 24 patients still equipped on day 90 (67%) have sent measurement reports (green line, right y-axis). On day 30, 65 patients still had the equipment and 49 sent measurements (75%), and 21 of 33 equipped patients (63%) reported on day 60. For each reporting day the average pulse and SpO_2 values (calculated from all received patient reports) together with their min and max values are plotted (blue and red line respectively, left y-axis and scale for both parameters).

Analogue the development of the self-reported health symptoms, taken from the received daily questionnaire responses of the patients during the first 90 days of their involvement in the monitoring program, is shown in Figure 8.

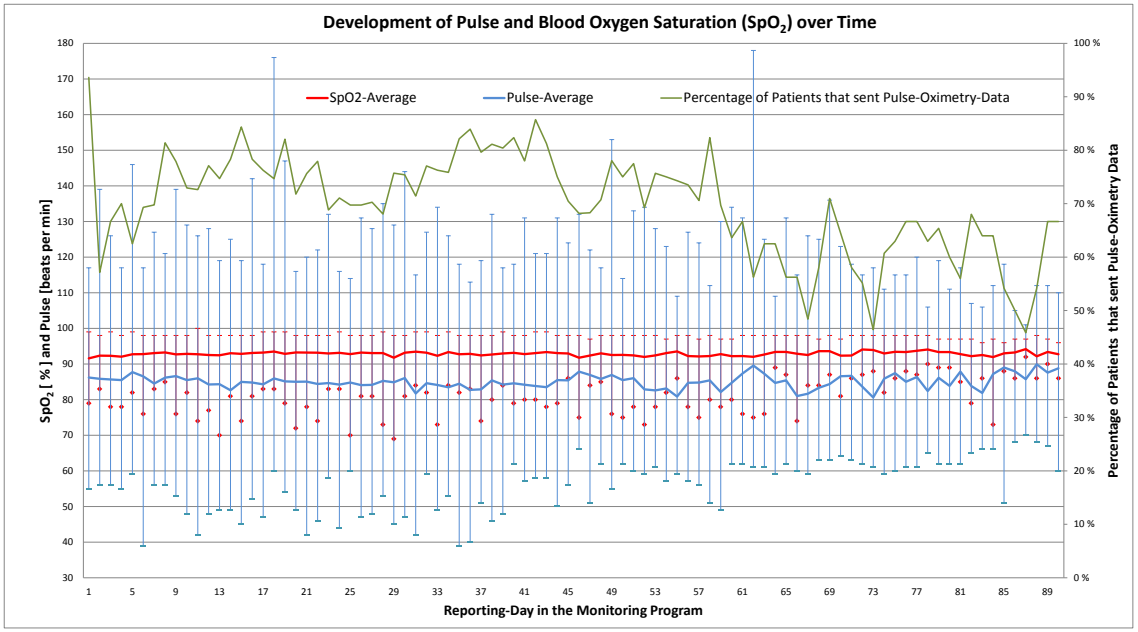

Figure 7: Development of reported Pulse and Blood-Oxygen Saturation (SpO_2)

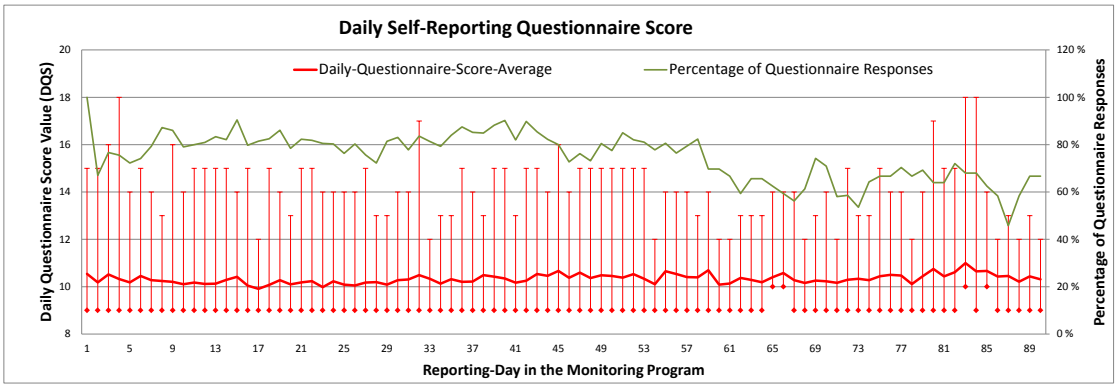

Figure 8: Development of Daily Self-Reporting Questionnaire Score

It contains for each trial-day the average of all received Daily Questionnaire Score values (DQS, see 2.2.3.3), as well as the min (lowest = “best” possible value is 9) and max (highest = “worst” possible value is 19) of all responses from that day. Also the percentage of patients that have sent questionnaire responses on each reporting-day is plotted (green line, right y-axis), in relation to the number of patients who still are equipped with the tablet device. While on the first day, all 94 patients equipped with the tablet device sent a questionnaire response, only 54 of 65 patients (83%) sent a response on day 30, 23 of 33 (70%) on day 60, and 16 of 24 (67%) on day 90, respectively.

The overall average duration of participation in the telemonitoring services was 70 days, with a little difference between the last day of pulse-oximetry reporting (70.1) and the reporting of daily questionnaire answers (70.4). Figure 9 illustrates the percentage of patients (from the 94 patients starting on day 1) participating for at least 7, 14, 30, 60, and 90 days, respectively, in the telemonitoring services.

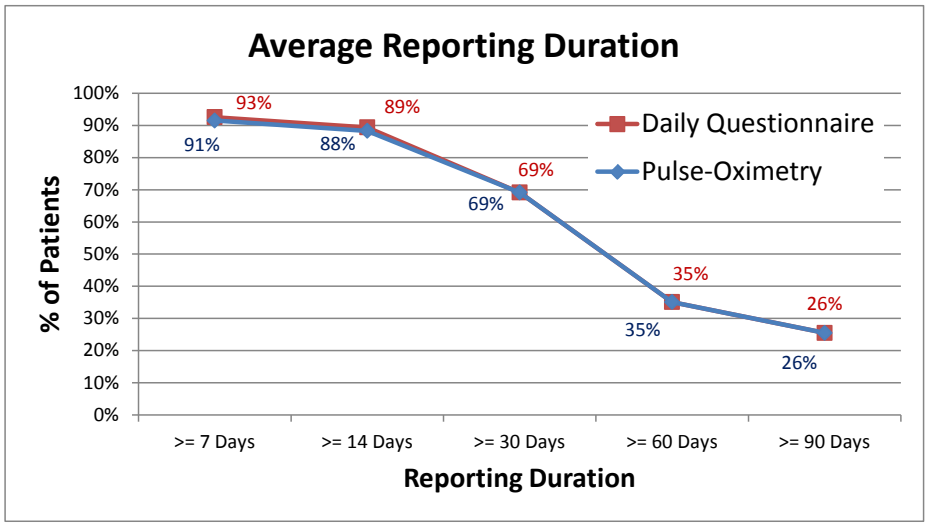

Figure 9: Involvement Duration in TM Services

Another perspective on the utilization of the telemonitoring services is the completeness of the reporting, i.e. the ratio of patients with telemedical equipment that regularly send measurements and questionnaire answers. Figure 10 shows the percentage of patients that report continuously every day for the first 7, 14, 30, 60, and 90 days, respectively, both for the daily questionnaire and the pulse-oximetry data.

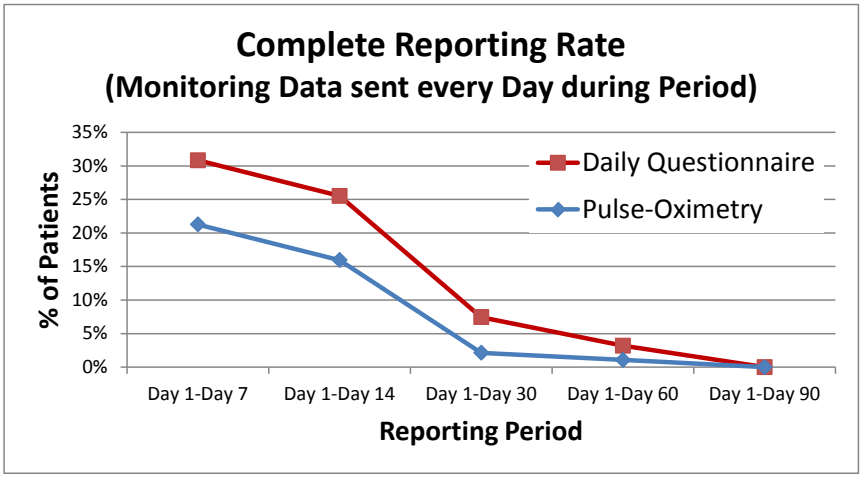

Figure 10: Rate of Complete Reporting

The corresponding average daily reporting rate, i.e. the average percentage of days of the considered periods when monitoring data (pulse-oximetry measurements and daily questionnaire answers) have actually been sent, is illustrated in Figure 11. An average of 75% of days of the period "Day 1 to Day 30" for example means that the patients have sent reports in average on 22.5 days of the 30-days-period, and 67% of the days in period "Day 1 to Day 90" correspond to an average of 60 days reported during the 90 days period.

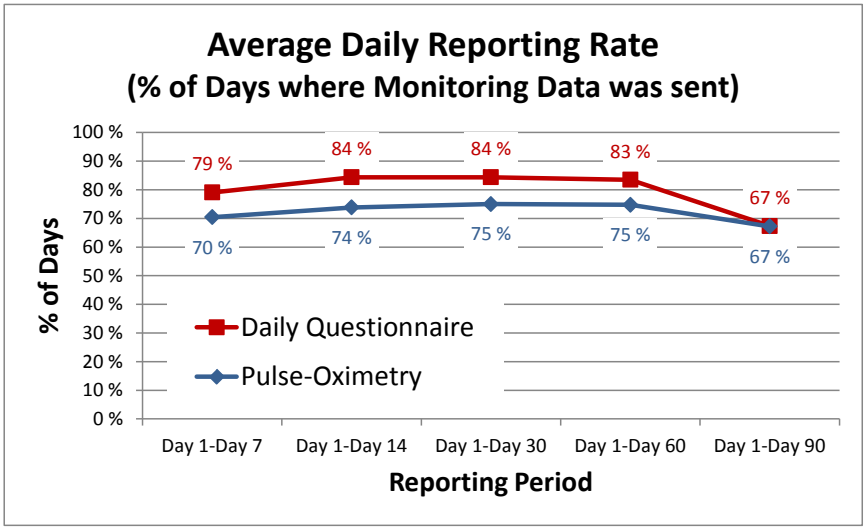

Figure 11: Average Reporting Rate [% of Days reported]

For the analysis of the health status assessment algorithms we have selected a sub-group of 33 patients (i.e. 35% of the total of 94 patients), that have reported pulse-oximetry measurements and/or answers to the daily questionnaire on a minimum of 25 days during the first 30 days, i.e. during the *High* and the *Reduced Level of Telemonitoring Service* phases.

First, the health status level categorisation according to 'green, yellow, and red' alerts, were assessed before they were analysed and possibly overwritten by the telehealth nurses. Monitoring 33 patients over 30 days corresponds to a total of 990 "patient-reporting-days", of which we received 928 reported datasets (94%), while on a total of 62 days individual patients didn't report. In total, 460 patient-reporting-days (46%) were assessed with "green" level (indicating a stable condition of the patient on that day), 275 (28%) with "yellow" (alerting the nurse of a notable condition), and 193 (19%) with "red" level. The frequency of each health status level (averaged over all patients and all days of the considered periods) is illustrated in Figure 12.

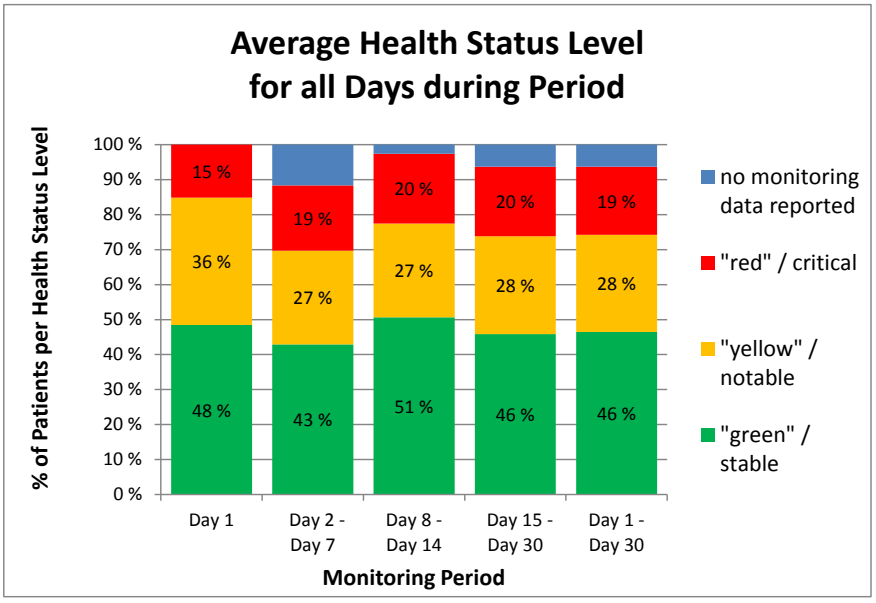

Figure 12: Unadjusted Average Health Status Level during selected Monitoring Periods

The telehealth nurses could then manually overwrite the automatically-calculated health status assessment levels, based on their experience with the health condition of each individual patient, or following a phone or video consultation. This results in the distribution of health status levels as illustrated in Figure 13.

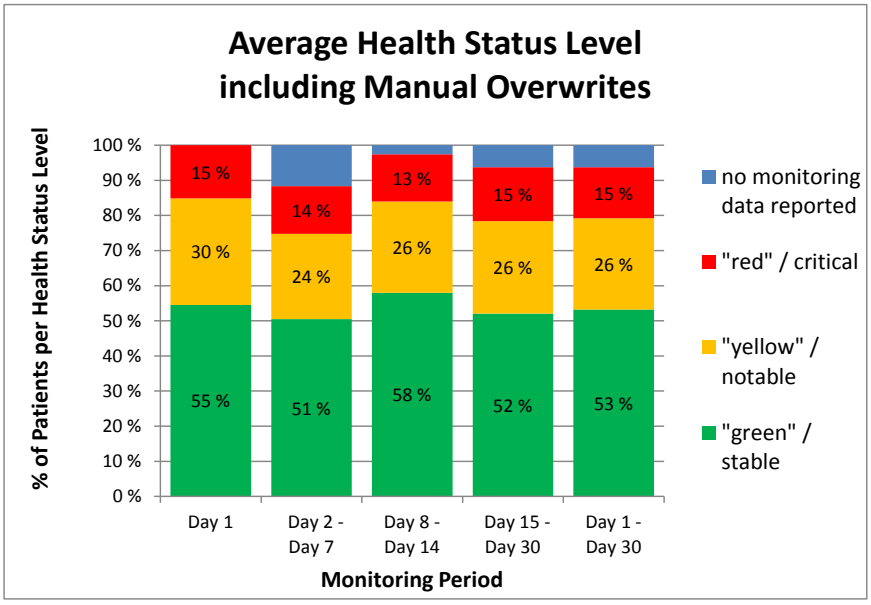

Figure 13: Adjusted Average Health Status Level including Manual Overwrites by Telehealth Nurses

In total 101 assessments, i.e. 10.2% of all 990 “patient-days” were modified manually, 80.8% were unchanged, and 9% were impossible to assess due to lack of reported data. An overview of the type of the adaptation and the reason (looking at initial and adapted health status assessment levels) is given in Table 11.

Table 11: Analysis of Manual Overwrites of Health Status Level Assessment with Algorithm Alternative 1

Type of Adaptation (related to all Assessments)			Reasons for Adaptation (related to Overwrites)	
false-high	red to yellow	2.7 %	Pulse-Assessm. too high	41.6 %
	yellow to green	5.3 %	SpO_2-Assessm. too high	4.0 %
	red to green	1.7 %	Pulse- and SpO_2-Assessm. too high	3.0 %
			Daily Quest.-Assessm. too high	38.6 %
			Pulse- and Daily Quest.-Assessm. too high	7.9 %
	Sum	9.7 %	Sum	95.0 %
false-low	green to yellow	0.4 %		
	yellow to red	0.1 %		
	green to red	0.0 %		
	Sum	0.5 %	All initial Assessm. Levels too low	5.0 %
Total		10.2 %	Total	100 %

Resulting from our retrospective analysis of 928 reported datasets, the impacts of new reference- and corresponding cut-off values for the assessment of the pulse-oximetry data according to “cut-off value algorithm 2” (see section 2.2.3.1 above) are shown in Table 12. We have calculated the health status levels based on the new cut-off values, and have compared those (analogue to the process above) with the final assessment of the trial system including the health status levels overwritten by the telehealth nurses. Hence, we analyse the adjustments that would be required to reach the final, adjusted assessment (Figure 13) from the assessment calculated with the alternative algorithm. In total 190 new assessments (corresponding to 19.2% of all 990 considered “patient-days”) would be different from the adjusted assessments, 71.8% would be the same, and 9% of the data were not reported.

Table 12: Impact of Alternative Cut-off Values for Pulse-Oximetry Assessment with Algorithm Alternative 2

Type of required Adaptation (related to all Assessments)			Reasons for required Adaptation (related to Number of Differences)	
false-high	red to yellow	0.9 %	Pulse-Assessm. too high	10.0 %
	yellow to green	5.3 %	SpO_2-Assessm. too high	1.1 %
	red to green	0.7 %	Daily Quest.-Assessm. too high	23.2 %
			Pulse- and Daily Quest. Assessm. too high	1.6 %
	Sum	6.9 %	Sum	35.8 %
false-low	green to yellow	4.8 %		
	yellow to red	3.8 %		
	green to red	3.6 %		
	Sum	12.3 %	All new Assessm. Levels too low	64.2 %
Total		19.2 %	Total	100 %

While the percentage of false-high assessments (6.9%) is lower than the percentage of health status levels reduced manually by the telehealth nurses (9.7%, see Table 11), the ratio of health status levels that are false-low has risen from 0.5% to 12.3%.

The alternative “algorithm 3” for the determination of cut-off values (see 2.2.3.1) only considers the “green” and the “red” health status assessment levels. By far most of the reported data assessed as “yellow” according to the final evaluation by the trial system and the adaptations by the telehealth nurses would be assessed as “green” if algorithm 3 would be used. In total 320 assessments (corresponding to 32.5% of all 990 considered “patient-days”) would be different from the initial assessments by alternative 1, and 58.5% would be unchanged. 30.7% of all assessments would be lower than the otherwise “yellow” or “red” evaluated monitoring data, making this assessment algorithm less sensitive with a higher risk to miss potentially critical conditions of patients, i.e. of “false-low” evaluations. More details of the impacts of the “assessment and cut-off value algorithm 3” are provided in Table 13.

Table 13: Impact of Alternative Assessment Algorithm 3

Type of required Adaptation (related to all Assessments)			Reasons for required Adaptation (related to Number of Differences)	
false-high	red to yellow	1.1 %	Pulse-Assessm. too high	3.1 %
	yellow to green	0.0 %	SpO_2-Assessm. too high	1.2 %
	red to green	0.7 %	Daily Quest.-Assessm. too high	1.2 %
	Sum	1.8 %	Sum	5.6 %
false-low	green to yellow	24.4 %		
	yellow to red	0.0 %		
	green to red	6.3 %		
	Sum	30.7 %	All new Assessm. Levels too low	94.4 %
Total		32.5 %	Total	100%

4 Discussion

The examined trial system facilitates the remote monitoring of home-based COPD-patients and the provision of decision support information for the prioritization of follow-up support and treatment by telehealth nurses in a telemedical centre, in cooperation with GPs and medical specialists in hospitals. The development of the self-reporting application for the patients (section 2.2.1) and the telehealth service for the provision of monitoring data and decision support information for the healthcare professionals (section 2.2.3) has followed a User-Centred Design approach, aiming at high usability of the user-interaction and user-friendly user interfaces, which has been evaluated in separate studies [15, 24]. The active participation in the trial and utilization of the equipment for continuous and regular, daily reporting of pulse-oximetry measurements and health symptoms by patients is important for the reliable, automatic health assessment by the telehealth system and the implemented rule-based assessment algorithms with its underlying cut-off values. Changes of certain monitoring data from one day to the next are important to identify notable or even critical exacerbations.

The participation duration in the trial, determined by the availability of the monitoring and self-reporting equipment for the patients and the – at least occasional – reporting of data, can be seen in Figure 9: around 90% of the recruited patients send reports at least during the first 14 days (*High Level of Telemonitoring Service* phase), more than 70% of the patients still participate the trial during the *Reduced Level of Telemonitoring Service* phase, and

approximately 25% have kept the equipment and reported monitoring data for more than 90 days. As long as the patients have the monitoring equipment, they use it on average for at least 2/3rd of the days to send monitoring data (Figure 11). The self-reporting of health symptoms along the daily questionnaire was reported to be less complex than obtaining the pulse-oximetry measurements. But then, just a few patients send complete, daily monitoring data (Figure 10): even during the first 14 days (*High Level of Telemonitoring Service* phase), just 16% send pulse-oximetry measurements every day, and 25% use the daily questionnaire day-to-day.

There are various reasons for the limited completeness of the reporting of monitoring data: as mentioned, technical problems or difficulties to use the equipment can distract the patients from collecting or sending the data. On the other side, the better a patient subjectively feels, the lower would be the need to report data about the condition. Hence, the lack of monitoring data does not necessarily indicate a bad or even alert condition, but may indicate the opposite, i.e. a stable health status. However, with the algorithms of the telehealth service, this is not possible to interpret, since patient data is necessary for such assessments. As long as the overall health condition of a patient is unknown or unstable, the lack of monitoring data should rather trigger an alert to follow-up with a remote check-up of the patient (e.g. by phone or video call) or with a reminder to send monitoring data. In case a patient condition is known and overall stable – as often the case in long-term monitoring of patients with chronic disease - the lack of data for one or a few days can be treated differently, usually assuming no significant changes of the health condition. This in turn requires a system that can learn behavioural characteristics of a patient, and that can identify a good, healthy, stable condition and distinguish that from a condition in deterioration.

The health status of the monitored patients is – on average – quite constant during the trial period. The measured pulse-oximetry data (Figure 7) does not show significant mean changes during the first 90 days, while extreme values (as extreme high or low pulse or very low SpO_2 measurements) become less frequent with increasing monitoring duration, i.e. beyond day 60. Certainly, the reduced number of participating patients causes a selection bias here that not can be corrected. Such bias is also influenced by the likely drop in daily registration among those with an improved condition. Further, the average score value from the daily self-reporting questionnaire of health symptoms (Figure 8) shows a quite low average figure during the whole first 90 monitoring days, reflecting a stable and confident subjective health status. Beyond day 70 the number of higher maximum values of the score increases though, indicating a “worse” or even “much worse” subjective health perception of some patients, most likely

also influenced by a selection bias of those with a more chronically unstable condition.

The automatically calculated health status level (Figure 12) confirms this observation: the percentage of the selected 33 patients that are assessed as “stable”, “notable” and “critical”, averaged over all days of different considered monitoring periods within the first 30 days of the trial participation, is more or less constant, with nearly 50% of the assessments being “green”, around 30% being “yellow”, and just around 20% being “red”.

Algorithm 1 (refer to section 2.2.3.1) provides adaptation of cut-off values to the patients’ condition through individual reference values and includes a “yellow” warning level for increased sensitivity of the assessment. The manual overwriting of the automatic health status level assessment by the telehealth nurses resulted in the new health status level distribution illustrated in Figure 13. The analysis of the modifications (Table 11) shows, that about 10% of the assessment levels were set lower by the nurses, mainly from “yellow” to “green”, and that in most cases either the assessments of the measured pulse values were too high, or the single items of the daily questionnaire. That means, that in relation to the modified assessment of the health status by the nurses, the automatic assessment by the telehealth service might be too sensitive, causing a number of unnecessary warnings or alerts.

Alternative algorithm 2 for the determination of cut-off values (see section 2.2.3.1) is an attempt to adapt the cut-off values more to the individual and slowly changing health status of each individual patient, while still identifying critical conditions. We have assessed the monitoring data from the same 33 selected patients again retrospectively, and compared the results with the assessment following algorithm 1 including overwrites by the telehealth nurses. As seen in Table 12, the number of “false-high” assessments is reduced compared to the modifications made manually in the previous algorithm (down to < 7%), in particular the previously too sensitive assessment of pulse values is down to 10%. On the other side, the reduced sensitivity, following the dynamically-adapting cut-off values, lead to an increased number of assessments with a lower health status as previously (12%), which could include false-low assessments. The retrospective calculation of health status levels does not consider though whether the lower-than-before assessed monitoring data reflect a critical condition, which would have been adapted by the nurses correspondingly.

The alternative algorithm 3 considers only the “green” and the “red” assessment levels, and a static, generic cut-off value for pulse measurements, similar as used in Emergency Triage. This assessment of the monitoring data with “alternative 3” cut-offs leads to redefined alerts in more than 32% of all cases, mostly due to

false-low redefinitions. In relation to the adjusted assessment (Figure 13), 242 of the previous 257 yellow assessments (24.4% of all assessments) and 62 of the previous 144 “red” assessments (6.3% of all) were redefined as “green” (Table 13). This indicates that static and generic, non-personalized cut-off values may come along with reduced sensitivity and a higher risk of false-low assessments.

There is one major objection to our above statements: The final, readjusted, colour-based alert decision by the telehealth nurse is considered the gold standard for our conclusions and hence as a qualitatively correct medical decision. That might not be the case. The challenge for future research is to define a more reliable, medical parameter as the gold standard for such research.

5 Conclusions, Outlook, “Lessons Learned”

The automatic, computer-based assessment of monitoring data from home-living patients with chronic diseases, as explored in this trial system, utilizes algorithms and rules that depend on cut-off values for certain measures or self-reported parameters, thereby reflecting the health condition of the patients. As such algorithms and rules look at the day-to-day development and changes of the reported data in order to identify notable or critical abnormalities, the accuracy and reliability of the health status assessments depend highly on continuous reporting of the required parameters by the patients, at least on a daily or more frequent, regular basis. As this trial has revealed, there are different reasons causing short or longer interruptions of the self-reporting of monitoring data. On the one hand, technical problems or usability challenges with the provided monitoring and reporting equipment can prevent the patients from sending the monitoring data. On the other hand, a stable and improving subjective health and well-being status can also make patients forget the importance or relevance of reporting health data.

Another critical aspect for the accuracy of the health status assessments is the determination of cut-off values that define certain health status levels, and that thus are crucial for the rule-based assessment. The results from the trial system have shown, that static, generic cut-off values, as used for example for emergency medicine triage, are sufficient to trigger emergency alerts, while they do not support decisions by telehealth nurses (and also for GPs and medical specialists) with high accuracy and reliability. Instead, cut-off values have to be personalized according to the individual health condition and common levels of health parameters. Predetermined, personally adapted cut-off values defined at the beginning of a telehealth monitoring period of a patient, might not adapt sufficiently with the dynamic general health condition of a patient. With “alternative algorithm 2” a more dynamically adaptive determination of cut-off

values has been evaluated, which should be tested in future prospective trials focusing on accuracy and reliability of the health status assessment and on a proper definition of a gold standard to test sensitivity and specificity against. The results from the so far tested algorithms are not satisfactory enough to provide for reliable (avoiding false-negative) and also efficient (avoiding false-positive) alerts.

Health status assessment and decision support systems which are based on more or less static rules, algorithms and cut-off values have significant limitations, especially regarding the analysis of data from patients with multiple morbidities. Long-term monitoring of patients with multiple morbidities requires analysis of more health parameters, which can vary from patient to patient and have complex interaction and dependencies between each other. Therefore, more personalized, adaptive and intelligent assessments are needed. An approach of ongoing research work is the utilization of smart, self-learning systems with artificial intelligence (AI) technologies. Machine learning technologies allow to automatically retrieve knowledge from reported and even not-reported data, leading to risk estimations and determination of health trends based on statistical probabilities. The development of appropriate machine learning algorithms and corresponding real-time data evaluation systems requires more clinical data. The tested telehealth trial system has shown strengths and advantages in the patient interaction, data collection, timely, reliable and safe transmission of monitoring data, and the interaction with health professionals. Ongoing research work will combine, test and evaluate this in combination with smarter, AI-based assessment and decision support algorithms.

While the focus of this study has been on medical informatics perspective of the calculation of decision support information, advantages for remotely monitored patients (for example reduced stress level and improved well-being while living at home [26], increased mastery and control in managing their disease [27]) and for the telehealth service providers (for example reduced on-site visits by home nurses and less hospital readmissions) can be expected, and are subject of further ongoing studies about the medical and operational efficiency. As soon as more reliable analysis and risk detection algorithms are in place, specialized nurses at telehealth services can be relieved from the continuous long-term remote patient monitoring, which can be provided by automatic feedback and advice systems instead.

6 Authors' contributions

Martin Gerdes: technical lead of pilot system development for acquisition of data; conception of study and drafting of article, with focus on “Materials and Methods”, presentation of data, discussion of results, and conclusions; finalization and submission of article

Frode Gallefoss: medical lead of pilot study design; supervision of trial execution; analysis and interpretation of data; revising and approval of article with focus on medical background, presentation of results, discussion and conclusion

Rune W. Fensli: technical and scientific lead of pilot system development; drafting and revising of article with focus on scientific background, analysis and interpretation of results, and conclusions; approval of article

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8 Statement on conflicts of interest

The authors have been involved in the co-design processes for developing the telemedicine solution used in the South-Norway trial of the United4Health project.

There are no other conflicts of interests.

9 Summary table

Existing knowledge on remote monitoring and health status assessment:

- Methods from Emergency Department triage assessment have been adopted in some telemedicine systems, where patient-measurements are used for medical decision support and alert notifications, but the specificity and reliability is not known.
- However, long time-series of patient-measurements of vital signs parameters is different from a snap-shot measurement in an emergency situation, and actual algorithms have in some papers been evaluated according to retrospective analysis.
- It is supposed that patients can use new telemedicine systems, as long as the systems are designed in a user-friendly way, and technical skills and health literacy are no prerequisite for the patients' vital signs measurements on daily bases at home for long-term.

What this study added to our knowledge:

- In this paper, we have presented our experience from a clinical trial with COPD patients reporting daily measurements of SpO_2 and pulse together with a symptom specific questionnaire, indicating that patients for several reasons will not conduct health status reports to the telehealth system each and every day.
- In a detailed evaluation of a sub-group of 33 patients reporting 924 datasets, the telehealth nurse has overwritten the automatically calculated health status score in 10.2% of the cases, with 9.7% turning out as false high, indicating that the algorithm used in the clinical trial has weaknesses that should be improved.
- Actual algorithms to calculate a health status score need to be adaptive to individual tailored long-time changes; however, there is a lack of golden standards to compare actual methods and algorithms for their specificity and reliability.
- Future research should try to evaluate smart self-learning systems with artificial intelligence, and define methods for evaluation of the reliability and specificity against a golden standard for health status level assessment.

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Appendix K

Conceptualization of a Personalized eCoach for Wellness Promotion

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***Abstract* — Evidence-based health promotion programs implement clinical practice guidelines built upon results of clinical trials with a definite number of participants, collected during a specific period of time. Wearable technologies allow for continuous observation of wellness parameters of multiple citizens, combined with monitoring of activities and context parameters involved in citizens' wellness. A statistical inference model can describe the relation between multidimensional activities and context parameters, the wellness of an individual and a comparable reference group, utilizing machine learning techniques and knowledge from continuous observations of multiple citizens.**

This paper presents a holistic concept of a coach system, namely eCoach, that combines specialized medical evidence available from randomized control trials, with individual and reference knowledge to create and reinforce wellness-based recommendations. The eCoach adapts these recommendations in a continuous personalized coaching dialog addressing citizen's needs and preferences.

***Keywords* — eCoach, holistic observation, personalized recommendations, reinforcement, HCI personalization, machine learning, Big Data, AI**

INTRODUCTION

The expected inversion of the age pyramid [37] comes along with an increase of functional limitations, disabilities, and demand for long-term care of chronic diseases, challenging current health and care systems [7]. For the professional healthcare sector the higher demands on long-term care and the general economic pressure to control health care expenditures means a rising requirement for efficient utilization of health information technologies and increased cross-border collaboration. Self-monitoring and self-management of fitness parameters have become popular because of the provided information about individual health and wellness status. There is also an increasing amount of data produced by younger generations born into the "Internet Age". This particular group of technology users is used to smartphones, wearable Internet-of-Things (IoT) devices and cloud-services, which allow them to use data associated to their life-style. Both trends, a socio-economic need for a stronger citizen involvement in management of their health and disease, and readiness for understanding and control of their health and lifestyle, raise the demand for personalized wellness promotion. In this line, the health sector provides information to formal and informal healthcare providers and individual healthcare receivers with information about health status, diagnoses and recommendations for interventions. However, there are still various limitations in this flow of information:

- Emerging commercial solutions to collect health, wellness and context related data (e.g. FitBit fitness wristbands, Empatica E4 wristband, Apple Watch and Health App, etc.) typically upload data through non-open cloud services. Such data is not available to formal health and care service providers through services and applications in the public health information systems. Wellness evaluation approaches of these solutions have limited validity [19], and activity and lifestyle recommendations are typically not quality-assured based on clinical evidence.
- Clinical decision support systems (CDSS) have a clinical focus, and provide decision support for healthcare professionals. However, these systems do not always include patients in their design which generally hinders patients and other citizens from understanding and correctly using such systems.
- Telehealth systems for remote patient monitoring (RPM) provide support to patients for assessment and reporting of health parameters. These systems provide remote monitoring support for healthcare professionals with the evaluation of the reported parameters and decision support for the follow-up of patients. However, RPM systems do not generally provide information and recommendations directly to patients.

Artificial Intelligence (AI) enables technological evolutions and innovations in the healthcare sector, that are already utilized in medical research for analysis of

clinical data, for support of diagnoses and treatment plans in clinical decision support systems. Potential can also be envisioned in a decentralized provisioning of healthcare, which may have significant advantages, e.g., for the quality of life of home-living elderly people.

In this paper, we propose the conceptualization of a *personalized AI-driven electronic coach (eCoach)* for *health and wellness promotion* (Figure 1). The goal is to provide citizens with personalized information and recommendations for their health and wellness education and self-management through a continuous personalized dialog.

For the purpose of explaining the eCoach, we use the following denotations:

Wellness Status: continuous holistic observation and assessment of functional and physiological wellness parameters, cognitive and mental parameters, social wellbeing parameters and spiritual faith.

Activities: observation and assessment of holistic activities and actions performed by the citizen, as e.g., physical activities, nutrition and medication.

Context: influencing factors, e.g., time, location, environmental conditions, climate and weather conditions.

Recommendations: multimodal recommendations regarding behavioral and contextual aspects to motivate for changes of activities, or to change contextual conditions.

The eCoach will continuously assess citizen's activities and wellness status, and provide personalized recommendations. The AI-driven eCoach determines recommendations from reference knowledge (i.e., from clinical practices guide-

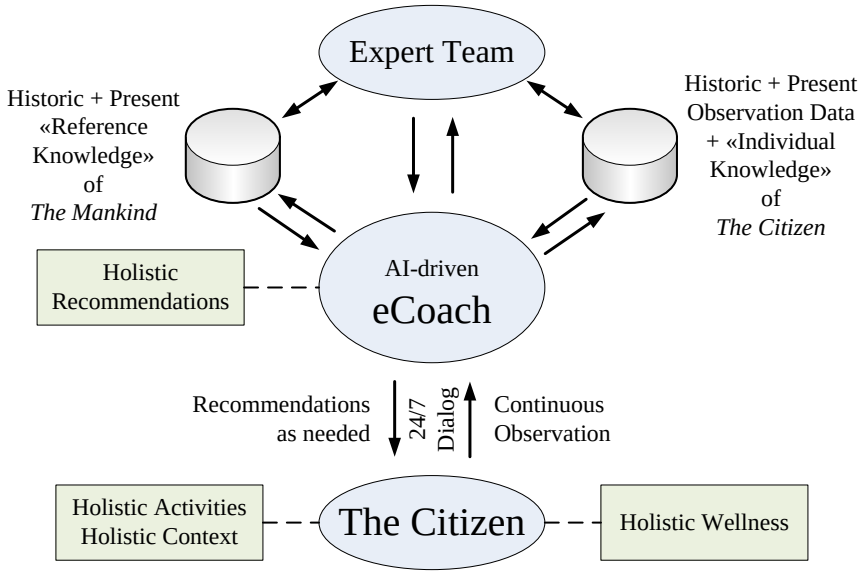

Figure 1: Purpose of the eCoach

lines (CPAs), that are based on medical evidence and are turned into computer-interpretable guidelines (CIGs), and from historic and present observations of others), and from reinforced knowledge about optimal activities and interventions for an individual citizen.

The *Expert Team* of medical and healthcare specialists supports the development, training, validation and operation of the eCoach, and receives decision support information about monitored citizens. In the following discussion, we focus mainly on the recommendations provided to citizens as the primary eCoach users. The Research Background following this introduction provides background information related to the proposed eCoach concept from the fields of Human-Computer Interaction (HCI), Holistic Wellness Assessment, Data Collection and Transmission, and Artificial Intelligence (AI) technologies for healthcare and wellness management. The Solution Requirements Outline explains the general approach of the eCoach concept and requirements for the realization, describes the HCI personalization and provides details about the wellness management process from a technological perspective. We also explain main aspects for the realization, validation and evaluation of the eCoach. The Discussion explains advantages of the eCoach at a conceptual level compared to existing solutions, and improvements for eCoach users. We conclude with a summary of the characteristics and advantages of the proposed eCoach.

RESEARCH BACKGROUND

Human-Computer Interaction (HCI)

The development of an eCoach places end-user at the center. Methods such as user-centered design, participatory design or co-design turn end-user into active contributors of the technology design process, evaluation and outcome. The eCoach applies a holistic approach that implies the analysis of four dimensions of the human being: physiological, cognitive, mental and social. Ultimately, the eCoaching outcome will result in customized advises and invitations for action specifically targeting human physical activity, clinical interventions and context. In this regard, time and space are two critical components of the inclusion of a human user. Thus, one of the core elements is the personalization of the coaching. The eCoach should be able to adapt also the type of interaction with each user, appropriate to the personal, technical and clinical circumstances concurrent to the eCoaching process. Aspects such as usability, accessibility and interaction design are part of the Human-Computer Interaction (HCI) that addresses how users use, access and interact with technology. The usability component will address the ease-of-use of the interface; the accessibility component will address the adaptation of the eCoach to the range of abilities and disabilities of user. Visually disabled users and patients with chronic diseases, for

example, present different challenges for designing the interaction, user interface and access to information.

Wellness Assessment

Researchers have described their views on *Wellness* as a "holistic complex concept that is affected by several internal and external factors and parameters". The World Health Organization (WHO) has defined *Wellness* as "the optimal state of health of individuals and groups. There are two main concerns: the realization of the fullest potential of an individual physically, psychologically, socially, spiritually and economically, and the fulfilment of one's role expectations in the family, community, place of worship, workplace and other settings" [33]. *Health* has traditionally focused on the individual in relation to illness status, and also a newer WHO definition of *health* as "physical, mental and social well-being" [6] focusses on the individual's health perception as assessed by questionnaires and its functional and bodily reserves as measured by physical means.

Quality of life has been defined as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" [28]. Compared to other health-related concepts, such as *health quality-of-life* (H-QoL), *wellness* looks at both individual dimensions as well as dimensions of the integration of the individual in its environment. In line with this, Hoyman has described the *human health* as a "multi-dimensional unity, involving the whole person in his total environment", and has suggested a wellness model consisting of four inseparable dimensions: physical fitness/well-being, mental and cognitive health, social well-being, and spiritual faith [15].

To observe and quantify wellness at a single point of time or the change over a period of time by a cohort of sample parameters, Rachele et al. provide an overview of a variety of instruments for the unidimensional and multidimensional measurement and assessment of wellness, along various wellness models [29]. Demiris, Thompson et al. have studied a holistic approach and a framework for the technology enhanced assessment of older adults' wellness [10, 35], informed by Hoyman's wellness model [15]. Study participants expressed the desire to understand their own wellness information more in depth, and showed interest in specific programmatic activities around promoting wellness, and wanted to know what they could specifically do to improve or prevent decline a specific need or area. They found that their framework of informatics based wellness assessment could support a holistic view of older adults' needs, facilitate decision making, links between formal and informal caregiving networks, and could lead to identification of early trends and patterns.

Data Collection and Transmission

Internet of Things (IoT) technologies are applicable to the health sector for the collection and transmission of observation data from citizens' point-of-care (PoC) to a central services infrastructure [14]. Specific solutions have been proposed, e.g. by Paschou et al., for metrics and methods for an efficient data transfer in combination with a Health-IoT [22]. Amin et al. presented a device independent Data Curation Framework (DCF) that accumulated sensory data from multimodal sources in real time [4]. The DCF allowed the creation of a context-rich lifelog as basis for multidimensional insights into user activities and behaviours. This enabled the DCF to support data-driven knowledge-generation, and descriptive and predictive analytics. Rawassizadeh et al. focussed on smartwatches as platform for context sensing and context analysis, and proposed an energy-efficient, generic, integrated framework for continuous sensing and prediction on small wearable devices [30].

Artificial Intelligence (AI) technologies for Healthcare and Wellness Management

The increasing deployment of IoT-systems for the collection and transmission of healthcare-related data in Electronic Health Record (EHR) systems leads to a rapidly expanding amount of data. Converting this *Big Data* into information and knowledge has manifold potential to improve the quality and efficiency of health care delivery [21]. *Big Data* processing expands the capacity to generate new knowledge for the healthcare sector from clinical studies and historic patient journals, and it can help with the dissemination and utilization of the knowledge in the field for diagnostic reasoning by physicians. Clinical decisions often rely on the experience of decision makers to interpret presented information, following an intuitive approach [8]. The individual experience can be extended by a decision support system based on knowledge from historic and long-term continuous monitoring. Such systems can also empower patients by delivering information directly to them (and to citizens in general), allowing them to play a more active role in their personal wellness management.

A key for dealing with the large information sets and hence for the realization of the potential of Big Data is the advances in analytic techniques in Computer Science, especially in machine learning. The analysis of Big Data leads to information and knowledge about the *context* of the citizen, and allows to provide *context-aware* healthcare services [26]. *Context reasoning* (or inferencing) techniques can be classified into supervised learning, unsupervised learning, rules, fuzzy logic, ontological reasoning and probabilistic reasoning [26]. These techniques can be utilized to provide diagnosis support for medical professionals, to dynamically adapt healthcare workflows to patient's condition, and to provide recommendations and decision support information for interventions and behavioral aspects.

The interaction of citizen's wellness with a dynamic contextual environment and multimodal individual activities as considered by the eCoach has analogies with *Reinforcement Learning* [16]. This describes the problem faced by an agent that learns behavior through trial-and-error interactions with a dynamic environment. The three most important distinguishing features of the reinforcement learning problem are being a closed-loop in an essential way, not having direct instructions as to what actions to take, and where the consequences of actions, including reward signals, play out over extended time periods.

Existing *Clinical Decision Support Systems (CDSS)* are computer-based decision-making systems to analyze and diagnose medical problems and diseases, and aid in treatment guidelines [2, 39]. Methods have been developed and validated for representation of medical knowledge and inference under uncertainties [18]. An important basis for computer-assisted diagnosis (CAD) and decision support for treatment plan are computer-interpretable guidelines (CIGs) [25]. CIGs are formalized clinical practice guidelines (CPGs). CDSSs are generally not designed for real-time evaluation of observations, diagnosis and decision support recommendation in telehealth settings for remote monitoring and for end-user coaching.

Bayesian Network Modelling is an AI-technology which is in particular useful for the evaluation and assessment of heterogeneous observations with uncertain and complex dependencies as required for the eCoach concept. It has been validated for the reasoning of data from sensors and humans in pervasive health monitoring settings [24, 38]. Furthermore, technologies for the recognition of activities of daily living (ADLs) and the corresponding wellness assessment have been presented [34].

Deep Information Understanding and Reasoning is another AI-technology, that has validated advantages for the mining of knowledge from structured and unstructured data records, in particular from medical records [1]. The generation of reference knowledge and the multidimensional classification of the information is an essential prerequisite for the determination of personalized recommendations by the eCoach.

Recommender Systems cover content-based, collaborative, or hybrid recommendation methods [3]. The consideration of user preferences in content-based recommendations and of recommendations for other people with a similar profile in collaborative recommendations presents similarities with the eCoach goals.

Existing solutions for wellness promotion

Mining Minds is a novel digital framework for personalized healthcare and wellness support [5]. It models daily life events using heterogeneous input

sources and provides personalized services to enhance human life style through customized and personalized user interfaces capturing user preferences, platform usage and user's contextual information. It aims for user engagement and provides services in terms of a virtual caregiver.

The cognitive computing system *Watson* from IBM has proven strengths in natural language processing and the learning from structured and unstructured data. This is used for example in clinical research to determine knowledge for diagnosis and treatment support from the automated analysis of large amounts of unstructured health records. A number of case studies illustrate how Watson is used for support of healthcare services provisioning, in particular in cancer treatment [11, 19].

SOLUTION REQUIREMENTS OUTLINE

We will identify the main requirements of the eCoach along the description of a user scenario.

User Scenario: Wellness Management

The eCoach will involve citizens in their management of wellness and disease, with positive impacts on their perceived quality-of-life. Following, we present a description of how the health management of an older patient would look like without an eCoach.

Biography: Anna Katarina (AK) is an 80-year-old lady who lives in a small town in a Scandinavian country. She widowed 2 years ago. AK has one daughter who lives 600km away.

Health condition: AK was recently diagnosed with chronic obstructive pulmonary disease (COPD), and with potential diabetes risk. AK has also sporadic episodes of mild depression. In addition, she has started to have some random memory losses although she has not told anybody, yet, because she is unsure whether she suffers from them.

Interaction with Technology: AK has had to learn how to daily check her glucose and oxygen saturation (SpO_2) levels, pulse, and other related measures to monitor her health.

Interaction with National Health System: AK visits her general practitioner once a month and the hospital once a year. The distance from AK's home to the nearest health care facility in the municipality is around 90 minutes by car, and around 150 to the hospital.

Traditional Statuses Assessment: AK's health status will be intermittently assessed based on the frequency of established visits to her GP and hospital, unless otherwise indicated by emergency episodes. Cognitive and mental status

will be established by default as sufficient for her age and conditions, unless otherwise reported by specialized or primary health services. Social condition will be only intermittently assessed by municipal services.

Conceptualization of eCoach

The proposed conceptualization outlines *How* to personalize the coaching HCI, the observation and analysis process for the determination of *What* to coach, and the *validation approach* of the eCoach in the field.

The eCoach continuously estimates wellness trends and risks by utilizing medical evidence as well as historic knowledge about the impacts of activities and context parameters on the individual citizen and on a reference group. It determines the best activities and context changes to achieve the wellness goals, and gives corresponding coaching recommendations and suggestions in real-time through a personalized human-machine interface (HMI).

Interaction Requirements

The interaction between the eCoach and the coached person pursues three main goals: accessibility of the interaction, personalization of the communication modality, and adaptation of the system to the coached person's needs. For the accessibility of the interaction, different options addressing the HCI are already available in the literature, such as haptic interaction in virtual environments [31] or everyday interactions [20], voice-command [27], speech for low-literacy users [32], context-aware augmented reality [13] and adaptive text for disabled users [12].

Several options will be available for the personalization of the communication modality. The goal is to offer a range of possibilities to adapt the communication to individual's condition and context of the interaction. These include but may not be limited to: text, voice, sonified touch, olfactory or projected. In addition, the adaptation will take into consideration educational level regarding general knowledge and technology use, such as literacy and eLiteracy. Finally, the observations and recommendations will be carried out seamlessly, with minimal and customizable human intervention. This means that the coached person will select the degree of automatization of the decisions made by the eCoach, ranging from human-in-the-loop [17] to totally automated [9].

Technology Requirements

The proposed process of continuous wellness management, inspired by reinforcement learning [16], is illustrated in Figure 2.

Citizens' User Profile:

The citizens' user profile is the basis to relate their individual observations to clinical practice guidelines and knowledge obtained from reference groups of "similar citizens", to consider individual wellness goals and preferences, and to

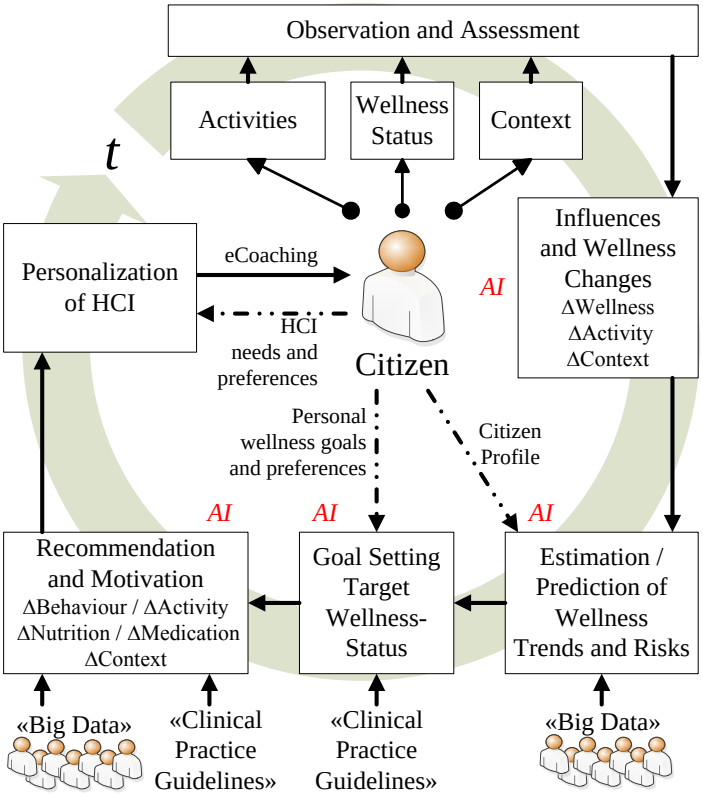

Figure 2: Continuous Process of Wellness Management

personalize the HCI to individual usability needs and preferences. The profile contains various characteristics, e.g., age, gender, geographical context (nationality, region, location, etc.), social context (e.g., married, family, etc.), general wellness status (e.g., known disease and health risks, blind/deaf, high blood pressure, allergies). Correspondingly, citizens are classified according to various parameters of affiliation, such as social affiliation, geographical affiliation, etc.

Observation & Assessment

The starting point for the development of a system for the automatic determination of optimal interventions to improve any individual's **wellness** from a holistic viewpoint requires a *model* for the description and evaluation of wellness, performed activities and interventions, and citizen's context.

The proposed observation and quantification covers the wellness assessment following Hoyman's wellness model [15], performed activities and interventions, and context parameters (Table 1). The measurement and quantification of the wellness status includes functional and physiological parameters, cognitive and mental parameters, social wellbeing parameters, and spiritual faith. The list of parameters in Table 1 is not exhaustive. Measurements of objective parameters are conducted for example with imperceptible wearable or implanted sensors,

	Observations and Assessments
Functional / Physiological Parameters	Health-related Wellness Medical Data: Pulse, Blood Pressure, Blood Oxygen Saturation, Blood Glucose, Weight, Heart Activity, etc. Musculoskeletal Parameters Activities of Daily Living
Cognitive / Mental Parameters	Speed of Processing and Response Time Working Memory; Task Shifting; Planning Mood Assessment and Determination Relation to Activities, Context, etc. (Music, Movie, …)
Social Well-being	Social Support and Integration Social Networks and Communication Activity
Spiri-tual Faith	Spiritual Perspectives (Sense of Purpose, Meaning of Life, Awareness of Inner Peace, Harmony, Hopefulness, Compassion for Others
Context Parameters	Time, Location Geographic Context (country, region, climate, weather, a.o.) Environmental Context (air quality, dust, smog, humidity, a.o.) Social Context (age, family status, …)
Activi-ties	Physical Activities Performed Nutrition, Food & Drinking Medication taken

Table 1: Holistic Observation

while subjective symptoms can be collected with standardized or widely adopted assessment tools.

In order to be able to understand and influence the impact of the multidimensional activities of the individual citizens on their wellness, our proposed eCoach concept also includes the measurement and quantification of holistic **activities**. The holistic perspective on activities includes (among others) physical activities, nutrition, and medication. This also allows distinguishing between the actually performed and the recommended activities and interventions, in order to consider the differences and respond, for example, to known phenomena as wrong medication. There is a potential overlap of the monitoring of activities with the assessment of functional and physiological

parameters of the wellness status, such as the ones associated to activities of daily living (ADLs).

Besides fundamental **context** parameters as the time when and the location where a citizen carried out a wellness observation, further parameters as the geographical and the environmental context have an immediate or a long-term impact on the wellness status. In order to follow changes of the wellness status and influences over time, the observation should be continuously performed. This means carrying out periodic assessments or measurements on daily or more frequent level, or continuing measurements of periods of time.

Influences and Wellness Changes

Based on continuous observation, the eCoach determines the changes of the wellness status (ΔHealth) of citizens. It correlates these changes with those particular activities that are different from the normal activities (ΔActivity), and with any changes of context parameters (ΔContext). This leads to knowledge about the influence of activities, interventions, and context changes on the wellness status of citizen.

The observation of many citizens leads to reference knowledge about the statistical dependencies between changes of observed activities, context parameters, and changes of wellness parameters (see Figure 1).

Estimation / Prediction of Wellness Trends and Risks

Based on the continuous observations of individual citizens' wellness status over a certain period of time, potential wellness trends in terms of risks and improvements and their likelihood in a certain future period of time are determined. The historic knowledge about dependencies between wellness changes and influences (see above) of an individual citizen and reference knowledge from other citizens with a similar profile are used as input for applicable AI-technologies.

Goal Setting of Target Wellness-Status

The eCoach calculates a target wellness status for one (or different) defined point(s) in time in the future in terms of specific goals for selected wellness parameters. The determination of the target parameters and the goal setting considers the calculated wellness trend (see above) and the most critical wellness parameter(s), relevant clinical practice guidelines (CPGs), and personal wellness goals and preferences of a citizen.

Personalized Recommendations and Motivation

Personalized recommendations address the question "How can the individual wellness be improved from an observed holistic wellness-state A to a target wellness-state B with specific activities, interventions and context changes?". The determination of recommendations utilizes medical evidence (clinical

practice guidelines), and individual and reference knowledge about the impact of activities and changes of context parameters on certain wellness parameters. Similar to the estimation and prediction of trends and risks, the eCoach finds those activities and context changes that are expected to have the best influence to achieve the defined target wellness parameter(s) (see above). The recommendations follow (analogue to the observations) a holistic approach, and include behavioral aspects (as physical activities, smoking, etc.), nutrition (change of type and amount of food), medication (in terms of type and dosages), and changes of context parameters (as change of room temperature, improvement of the air quality, avoiding smog, etc.). Personalized recommendations can be either "direct" activities, interventions and context changes, or "indirect" suggestions for actions and activities, that motivate a citizen for desired behavior changes. These recommendations are forwarded to the personalized HCI dialog, and the process continues with the reinforcement of the coaching by the observation and assessment of the actually performed activities and their effects on the wellness status.

Validation of the eCoach in the Field

The proposed eCoach concept will not be realized as a single application or service, but as a system of integrated components, spanning from end-user devices and applications for the interaction with the coached citizens, to infrastructure components for data communication, aggregation, and evaluation for knowledge generation and determination of recommendations. Correspondingly, the technological verification has to incorporate each system component and the overall integrated system. From a HCI-perspective, the achievement of the overall goal of the eCoach has to be verified. This includes (beyond others) studies of the impacts of the eCoach on the wellness and subjective quality-of-life of the coached persons, acceptance and usability aspects of the eCoach, efficiency gains of healthcare providers, and benefits for the health system and the society.

DISCUSSION

Case Study with Wearables

A digital health study [23] had exemplary demonstrated the potential of wearables to provide actionable health information. Wearables were used by healthy citizens for continuous observations of basic life signs, and basic learning techniques allowed learning the set of "standard" values for each individual participant. Utilizing the continuous measurements, algorithms could detect abnormalities, and recommended a medical examination even before participants had notable illness symptoms.

The proposed eCoach concept has a number of potential advantages:

- The eCoach can predict trends and the risk potential for further development of certain wellness parameters by utilizing individual and reference knowledge from continuous observation over longer periods of time to support diagnosis.
- Based on the estimated likelihood for a certain diagnosis, the eCoach can combine reference knowledge (based on clinical evidence) with knowledge aggregated from other citizens with a similar profile to determine what activity or change of context is recommended (in terms of the highest likelihood for a positive influence on the health status).
- Individual preferences for wellness and quality-of-life goals, such as a target fitness status, may be considered for individual recommendations.
- Utilizing continuous long-term observation of an individual citizen, the eCoach learns what multidimensional activities and context changes have positive (and negative) influences on the wellness of this person and, through it, adapt individual recommendations.

Case Study for Monitoring of COPD Patients

Current telehealth solutions for chronic obstructive pulmonary disease (COPD) patients (exemplary we look at a recent test system developed for a field trial in South-Norway in the EU-FP7 project United4Health [36]) can monitor daily glucose and SpO_2 levels, pulse, and other related symptoms to monitor patients' health at home, and send alerts to nurses at a telehealth center when the data indicates alert conditions based on existing and generalized knowledge. However, the system is not linked to an exercise eCoach that is aware of patients' condition, especially not of any lifestyle preferences as outdoor activities, etc. Any slight change of context parameters as the condition in the air and environmental quality may have a profound impact on a patient's COPD condition. Using the proposed eCoach, the patient's physiological parameters (e.g., heart rate, SpO_2 level, galvanic skin response, breathing rate) can be monitored in real-time while she/he exercises, making sure that any positive and negative changes are recorded. Based on the location-enhanced data from aggregated or community-based samples, the eCoach will be able to predict and pre-warn whether a patient should exercise at a particular time in a particular place. Using historical symptoms-related physiological data from a patient, the eCoach may improve the accuracy of the prediction and tailor the warning and recommendations accordingly. Moreover, as the data is triangulated with clinical data, observations, and recommendations, the eCoach can further improve the quality of the recommendations, based on expert's feedback and diagnosis. Other lifestyle behavior including smoking, alcohol consumption and dietary intake can be monitored as part of the multidimensional activities profile of a patient. This

ensures that exercise is not seen as the only (isolated) cause of symptoms, as they would have indirect/direct and short and long term impacts before, during or after the exercise. Location awareness and tracking of the patient's changes of environment should also include the monitoring of indoor and outdoor conditions (e.g., temperature and humidity) and air pollution's sources (e.g., pollens and dust) to create a more localized view of the context parameters.

The eCoach observation data over time will be aggregated for an individual and across all patients to improve the machine learning accuracy and to reinforce personalized recommendations. This allows avoiding two significant limitations of the decision support approaches of current telehealth systems for remote patient monitoring:

- The evaluation algorithms for monitoring data typically consider one-time data, i.e., only the latest reported observation data. Changes of certain wellness parameters over time and hence trends of the overall wellness status are not calculated.
- The decision support algorithms for the detection of serious or critical health conditions are often based on static rules and generic thresholds/cut-off values, with limited personalization according to individual health characteristics. This can lead to reduced accuracy and reliability of the triggered alerts.

User Scenario Revisited: Wellness Management Advantages with an eCoach

The eCoach has the potential to meaningfully involve citizens in their management of wellness and disease, with positive impacts on their perceived quality-of-life. We revisit the user scenario of an older patient previously described, but this time with the inclusion of the eCoach proposed in this paper.

Health Management supported by an eCoach

Interaction with Technology: AK will be explained when necessary and in an understandable and accessible way how to daily check her glucose and SpO_2 levels, pulse, and other related measures to monitor her health, with a comprehensible explanation of the results and the impact in her health.

Interaction with National Health System: AK's visits to her general practitioner will be on demand of the health professionals who are alerted by anomalies or risks in her daily health condition reports. Many of the visits will be virtually made, with the possibility to travel to specialized care facilities only when justified. In addition, new evidence-based practice coming from similar patient groups or disease conditions will be applied when suitable.

Traditional Statuses Assessment: AK's health status will be continuously assessed by the eCoach, alerting, warning or communicating any finding or risks detected in AK's individual health status. The detection system will be based on

individual health status compared with evidence and clinically available evolution of patient groups with similar condition/s. The cognitive and mental status will be continuously assessed by the eCoach, with the same type of assessment and alert system as for the physiological health status. The social condition will be also registered in the system and monitored based on preferences and clinical advice. Finally, the interaction of these four components will be a central part of the system, taking into account the correlation and causality between them (e.g., influence of cognitive and mental cognition on somatic diseases and vice versa).

Complementing existing solutions

Mining Minds intends to complement the role of specialists by intelligent monitoring and smart coaching mechanisms. Through an advanced rule authoring tool the specialists handle the creation and management of health and wellness knowledge, hosted in knowledge bases. The evaluation of the services supported by Mining Minds requires feedback from the users. A feedback analysis component utilizes sources as explicit feedback provided by the user and implicit feedback obtained from the user behavioral responses.

The proposed eCoach can complement the Mining Minds framework by utilizing the concept of reinforcement learning, i.e. the utilization of automatically derived knowledge about the impact of (multimodal) activity and context changes on the wellness status ("Influences and Wellness Changes" component in Figure 2). The eCoach utilizes this individual knowledge together with reference knowledge for the automatic determination of multimodal recommendations under consideration of personal preferences and wellness goals.

IBM Watson started targeting specialized healthcare fields, specifically cancer research, extending also to other areas. The focus is on utilization of AI for clinical research, i.e., the generation of knowledge from analyzing structured and unstructured clinical data. The proposed eCoach requires this type of reference knowledge, and complements the determination of recommendations for treatments and multimodal activities with personalized preferences and optimal impacts. These recommendations are at the same time reinforced from the continuous observation and exploration of individual wellness status, activities and context that are not categorized as stored clinical data. The cognitive capabilities of Watson may potentially complement the personalization of the interaction with the coached user and the specialists with natural language and talk.

CONCLUSIONS

The proposed eCoach concept outlines the future citizen-centric eHealth services that integrate wellness management. This integration involves the development and adoption of technologies and innovations for continuous observations and data aggregation with health-IoT technologies. These technologies would include AI techniques for knowledge generation targeting evidence- and observation-based wellness support.

The main aspects of the eCoach include the reinforcement of individual recommendations based on the continuous observation of performed activities, context changes, impacts on the wellness status, and the underlying holistic approach for observation and assessment. These potentially allow for advantages on the personalization of coaching recommendations determined by computers to the specific needs of an individual coached human. In particular, the eCoach can support telehealth and remote patient monitoring (RPM) services with evaluation of observation data and the automatic provision of personalized support recommendations. A significant advantage is the ability to cover routine monitoring and 24/7 service availability for patients and healthcare providers.

Medical and healthcare experts will have the fundamental role in the eCoach-enabled system for citizen-centered wellness management to support the development, training, validation, and continuous refinement of the eCoach system components. Routine monitoring, checkup and diagnostics can be done by an eCoach, and the healthcare professionals will be able to focus on cases where direct contact with the patients is needed.

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