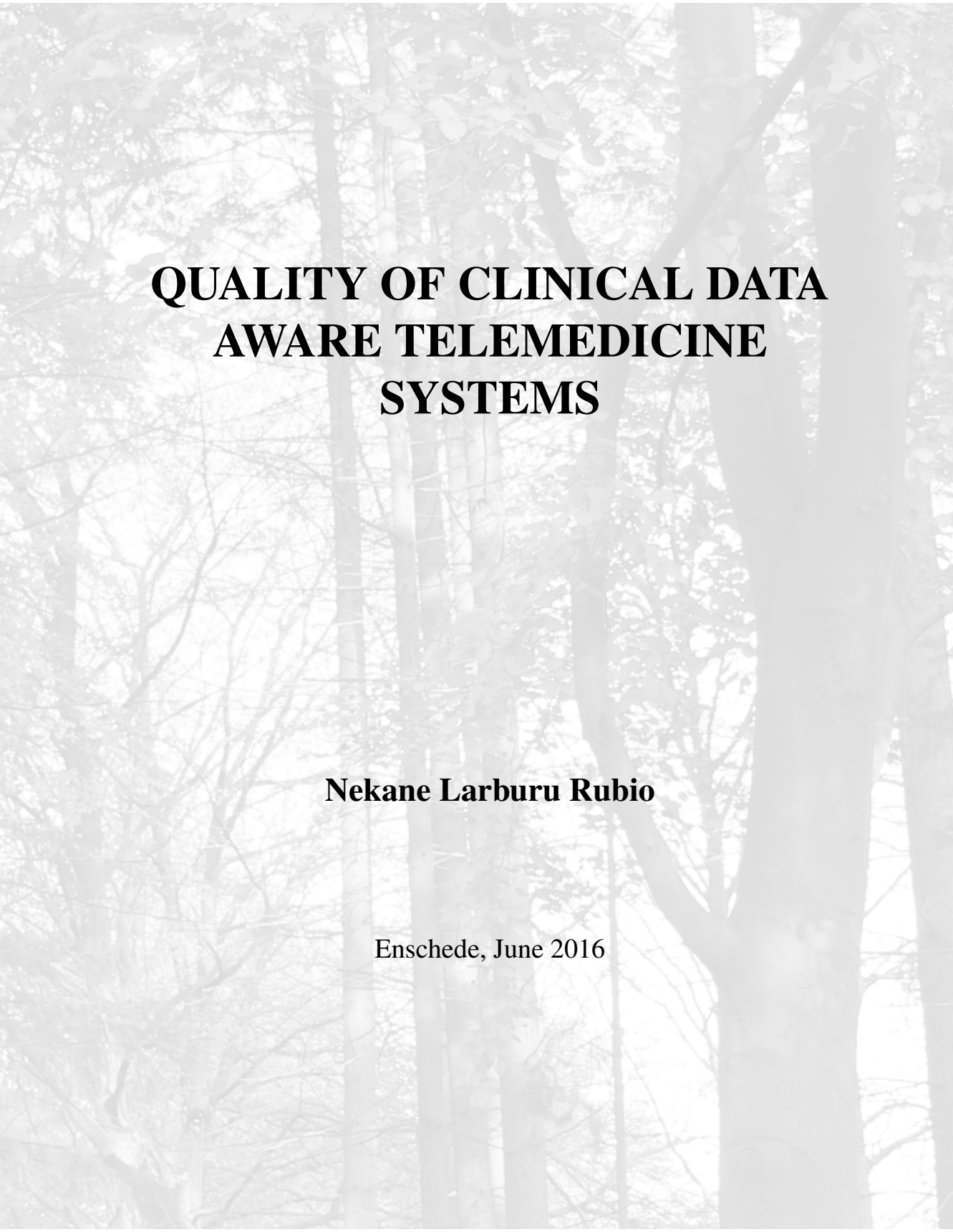

QUALITY OF CLINICAL DATA AWARE TELEMEDICINE SYSTEMS

Nekane Larburu Rubio

Enschede, June 2016

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ABSTRACT

Healthcare services have been evolving continuously owing to new demands caused by demographic and lifestyle changes. The advancements in information and communication technology (ICT) have propelled the development of new healthcare systems that can fulfil these demands. One of the key developments in this field is in the form of telemedicine systems, which aims to reliably deliver remote healthcare to patients through information exchange across distances.

This research is conducted in the context of ambulatory patient treatment guidance where a patient can receive remote treatment that is compliant with the current care-plan, without the presence of his/her doctor, with the aid of a telemedicine system. In order to provide treatment guidance that complies with healthcare procedures, telemedicine systems may apply clinical guidelines. Additionally, the ICT of these telemedicine systems enables the acquisition of patient clinical data. Hence, the clinical guidelines, in combination with ubiquitously acquired patient clinical data, may result in a personalized treatment guidance that will provide the necessary remote treatment to the patient without the need of a practitioner.

Although telemedicine systems have demonstrated the ability to fulfil some of the current healthcare needs, they still have some pitfalls. A major pitfall is the potential variation in the technological context caused by ICT disruptions (e.g. weak data transmission signals). This may lead to degradation of Quality-of-clinical-Data (QoD) and can negatively impact the healthcare service provided by these systems. Therefore, if the degraded clinical data does not fulfil the medical quality requirements, the treatment guidance quality may be 'unreliable' and can potentially put a patient's safety at risk. Hence, the performance of the ICT resources (referred to as the technological context) plays a vital role

in providing reliable patient treatment.

This research explores the impact of technological context on QoD and the effect of degraded QoD on the treatment. It provides insights into the development process of integrating QoD-awareness in telemedicine systems which will help to preserve treatment quality and patient safety even during QoD degradation. Firstly, this thesis presents a QoD-framework ontology that is based on the conceptualization of the technological-context and clinical-context. Secondly, it specifies a QoD-aware telemedicine system architecture which is based on successive refinement of the functional requirements.

- The QoD-framework ontology represents the knowledge of the QoD-aware telemedicine system. This ontology consists of two parts: **(1)** the technological domain ontology, which comprises the Quality-of-Service information of ICT and its relation with QoD; **(2)** the clinical domain ontology, which comprises the information regarding the relations between QoD and treatment abstractions. In this way, we facilitate the development of the knowledge-base for the QoD-aware telemedicine system. Additionally, we show how to augment a clinical guideline with QoD-aware treatment adaptation mechanisms in order to prevent potential risk situations.
- The presented QoD-aware telemedicine system architecture is decomposed into different levels of abstraction in order to cover the details of the system components and their interactions. For that, we first identify the functional requirements of the system at different levels. In addition, we address the design of QoD Broker which is the system component that computes QoD information, and hence, a core component of this research.

The prototype of the QoD-aware telemedicine system has been implemented in a European project called MobiGuide. The prototype comprises the QoD-Broker component and the clinical decision support system, which integrates the QoD-based treatment adaptation mechanism. The QoD Broker provides useful QoD information, while the QoD-based treatment adaptation mechanism preserves the patient's safety during technological disruptions.

Functional and clinical validation of the proposed QoD-aware telemedicine system involves seven validation activities which have been conducted during different phases of this research. Each of these validation activities looks into different aspects of the system, which are covered in this thesis.

This research stresses the positive influence of QoD-awareness integration in healthcare systems. In particular, it addresses QoD-awareness in telemedicine systems for ambulatory patient guidance. The results of the validation activities advocate the integration of QoD-awareness in telemedicine systems as a basis for treatment adaptation mechanisms in order to guarantee system reliability and patient safety.

SAMENVATTING

Gezondheidsdiensten ontwikkelen zich voortdurend onder invloed van nieuwe eisen gerelateerd aan demografische en veranderingen in levensstijl. De snelle vooruitgang in de informatie- en communicatietechnologie (ICT) heeft de ontwikkeling van nieuwe medische systemen die aan deze eisen kunnen voldoen mogelijk gemaakt en bespoedigd. Een van de belangrijkste ontwikkelingen op dit gebied betreft de telegeneeskunde systemen , die gericht zijn op het betrouwbaar leveren van zorg op afstand aan patiënten via de uitwisseling van informatie uit verschillende bronnen en de interpretatie van deze informatie in hun context.

Het in dit proefschrift beschreven onderzoek is uitgevoerd in het kader van de ambulante patiënt behandeling en begeleiding , waarbij een patiënt op afstand met behulp van een telegeneeskunde systeem een behandeling krijgt die voldoet aan het met de behandelaar opgesteld zorgplan, zonder de fysiek aanwezigheid van zijn / haar arts.

Om te voorzien in een behandeling en begeleiding die voldoet aan de procedures in de gezondheidszorg, is het van belang dat de telegeneeskunde systemen bestaande klinische richtlijnen kunnen toepassen. De ICT in deze telegeneeskunde systemen maakt het dan bovendien mogelijk om persoonlijke klinische patiëntgegevens te verkrijgen en te combineren met dergelijke generieke richtlijnen. Op deze manier zal een gepersonaliseerde begeleiding van de behandeling van de patiënt op afstand mogelijk worden zonder voortdurende tussenkomst van een arts.

Hoewel is aangetoond dat dergelijke telegeneeskunde systemen een deel van de huidige medische zorg goed kunnen ondersteunen, hebben ze nog een aantal tekortkomingen. Een belangrijk probleem is de variatie van de technologisch context door technische verstoringen (bijv. zwakke datatransmissie

signalen of fouten in de signalen afkomstig van sensoren). Dit kan leiden tot vermindering van de kwaliteit van de klinische-data (QoD) met negatieve gevolgen voor de kwaliteit van de diensten; de gegeven adviezen inzake de behandeling worden mogelijk onbetrouwbaar en daardoor kan zelfs de veiligheid van de patiënt in het geding komen. Vandaar dat de prestaties van de ICT-middelen (aangeduid als de technologische context) een cruciale rol spelen bij de hoogwaardige en betrouwbare behandeling van de patiënt.
Het onderzoek in dit proefschrift gaat over de impact van technologische context op QoD en het effect van verminderde QoD op de patiënt behandeling. Het beoogt inzicht te geven in de ontwikkeling van telegeneeskunde systemen die QoD-bewust zijn en die helpen om de kwaliteit van behandeling en de veiligheid van de patiënt te behouden, zelfs tijdens periodes van verminderde QoD.
Het proefschrift presenteert een QoD ontologie die gebaseerd is op de conceptualisering van technologische context en klinische context. De QoD ontologie vertegenwoordigt de kennis van QoD-bewuste telegeneeskunde systemen. De ontologie bestaat uit twee delen : (1) de technologische domein ontologie die de kennis over de relatie tussen Quality-of-Service-informatie van ICT componenten en QoD omvat en (2) de klinische domein ontologie die de kennis met betrekking tot de relatie tussen QoD en behandelingsabstracties omvat . Op deze manier faciliteren we de ontwikkeling van de kennisbasis voor QoD-bewuste telegeneeskunde systemen. Bovendien presenteert het proefschrift een methode om klinische richtlijnen te verbeteren door deze uit te breiden met QoD-bewuste behandelingsaanpassingen om zodoende risicovolle situaties voor patiënten te voorkomen.
Het proefschrift presenteert daarnaast de architectuur van QoD-bewuste telegeneeskunde systemen. Deze architectuur beschrijft de systeemcomponenten en hun interacties op verschillende abstractieniveaus. Eerst vertalen we de functionele eisen aan het systeem stapsgewijs in systeemcomponenten die samen het totaalsysteem vormen. Dan detailleren we een van de systeemcomponenten, namelijk de QoD Broker. Dit is de systeemcomponent die QoD informatie berekent, en dus een essentieel onderdeel vormt van het onderzoek. In het Europese project MobiGuide is de architectuur van QoD-bewuste telegeneeskunde systemen geïmplementeerd door middel van een prototype. Het prototype omvat de QoD Broker en een systeem voor de ondersteuning van klinische besluitvorming. Dit laatste systeem integreert het QoD-gebaseerde mechanisme voor behandelingsaanpassing. De QoD Broker biedt nuttige QoD informatie, terwijl het QoD-gebaseerde mechanisme voor behandelingsaan-

passing de veiligheid van de patiënt verzekert tijdens technologische verstoringen.
Functionele en klinische validatie van de voorgestelde architectuur voor QoD-bewuste telegeneeskunde systemen omvat zeven validatie-activiteiten die tijdens de verschillende fasen van het onderzoek zijn uitgevoerd. De validatie-activiteiten richten zich op verschillende aspecten van het systeem, welke worden behandeld in dit proefschrift.
Dit onderzoek benadrukt dat technisch geneeskundige systemen voor de gezondheidszorg rekening moeten houden met QoD. Het onderzoek richt zich In het bijzonder op de ontwikkeling van QoD-bewuste telegeneeskunde systemen voor de begeleiding van ambulante patiënten. De resultaten van de validatie activiteiten pleiten voor de integratie van QoD-bewustzijn in telegeneeskunde systemen als basis voor de behandelingsaanpassing om de betrouwbaarheid van het systeem en de veiligheid van de patiënt te garanderen.

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Nekane Larburu Rubio

CONTENTS

Abstract **iii**

Samenvatting **vi**

List of Figures **xviii**

List of Tables **xxii**

List of Acronyms **xxvii**

1 Introduction **1**

1.1 Background 2

1.2 Problem Analysis 3

1.3 Objectives and Research Questions 7

1.4 Research Scope 8

1.5 Domain of Discourse: Mobile Patient Guidance 9

1.6 Approach 10

1.7 Structure 12

2 State-of-the-Art in QoD-Awareness for Healthcare Systems **15**

2.1 Information Technology in Healthcare 15

2.2 Uncertainty in Healthcare 19

2.3 Conclusions 25

3 Research Design Approach 27
3.1 Research Design Concepts 27
3.2 Requirements Elicitation Method 28
3.3 Context Layering Technique 32
3.4 Application of the Approach 39

4 QoD-Framework Ontology 43
4.1 Background 43
4.2 Towards a Stratified QoD Ontology 45
4.3 QoD-Framework Ontology Application 51
4.4 Discussion 52

5 Quality of Clinical Data Aware Guidelines for Decision Support Systems in Telemedicine 55
5.1 Problem Analysis 56
5.2 QoD-Aware CIG Development Method 58
5.3 Case Study 65
5.4 Conclusions 72

6 Quality of Clinical Data Aware Telemedicine System Architecture 75
6.1 Approach 75
6.2 Telemedicine System Architecture Overview 79
6.3 Mobile and Back-End Subsystems Architecture 84
6.4 Mobile Patient Guidance System Architecture 90
6.5 Back-End Guidance System Architecture 101
6.6 Implementation in MobiGuide 106
6.7 Conclusions 110

7 The QoD Broker 113
7.1 QoD Broker Architecture 113

7.2 QoD Dimensions 119
7.3 QoD Management Techniques 124
7.4 QoD Management Techniques in MobiGuide 137
7.5 Discussion 139

8 Validation **141**
8.1 Validation Approach 141
8.2 Involving Medical Practitioners in the Requirements Elicitation Process 147
8.3 Involving Medical Practitioners in the QoD-Framework Ontology design 150
8.4 Involving Medical Practitioners in the Augmented QoD-Aware Guideline Design 152
8.5 Use Prototype in Test Scenario 153
8.6 Ask Experts about Expected Effects of Solution 163
8.7 Test Prototype with Healthy Volunteers 170
8.8 Test Prototype with Patients 173
8.9 Discussion 179

9 Conclusions **181**
9.1 Reflection on the Research Questions 181
9.2 Research Contributions 183
9.3 Generalization of QoD-Awareness in Other Domains 184
9.4 Directions for Future Research 186

Appendix A iPACT'-FICS' in the Atrial Fibrillation (AF) case **191**
A.1 iPACT' 191
A.2 Medical Scenario (iPACT' Scenario) 194
A.3 FICS' 196
A.4 Merged Scenario (iPACT'-FICS' Scenario) 198

Appendix B Abbreviations, Terms and Notations for the Architec-

ture Description **201**

B.1 Abbreviations Used in the Messages Exchanged Between System Components 201

B.2 Terms 201

B.3 Notations 202

Appendix C MobiGuide Implemented Interactions - Mobile BAN **203**

Appendix D MobiGuide Implemented Interactions - Back End **207**

Appendix E MobiGuide - Complete Questionnaires **209**

E.1 Questionnaire for AF patients 209

E.2 Questionnaire for GDM patients 212

E.3 Questionnaire for Medical Practitioners 214

Bibliography **219**

List of My Publications **233**

List of Figures

1.1 Causal Loop Diagram between quality of data (QoD), Strength of Recommendation (SoR) and Risk of Treatment (RoT) . . . 7
1.2 Engineering Cycle . . . 8
1.3 Approach . . . 10
1.4 Thesis Structure . . . 14

2.1 Pervasive Healthcare and Telemedicine . . . 18
2.2 The Evidence Based Medicine Pyramid [1] . . . 18

3.1 iPACT-FICS Requirements Elicitation Method [2] . . . 31
3.2 Example of heart rate ranges of the physical exercise treatment, specifying the target HR (THR) and the range for each of the phases: target training (TT), warming up (WU), cool down (CD) and pre- and post-exercise (Pre, Post) . . . 33
3.3 Context layering technique representation: (a) Functional relation between clinical abstractions (ca), clinical variables (cv) and technological variables (tv) with technological resources (TR); (b) Non-functional relation of QoD and QoS relation.[2] 34
3.4 mHR-THR clinical abstraction of AF physical exercise treatment during target training phase, and specification of mHR in the target training range (Range_{TT}) and specification of the target HR (THR) for target training (THR_{TT}), warming up (THR_{WU}), cool down (THR_{CD}) and maximum HR (HR_{max}) . . . 36

3.5 Example application of the context layering technique for: (a) Functional relation; (b) Non-functional relation of QoD and QoS relation 37
3.6 The result of the RE method and context layering technique . . 40

4.1 QoD-Framework Ontology Overview [3] 46
4.2 High level design of the QoD-aware telemedicine system with QoD-Framework ontology formalized in the Context Customized CIG (CCC) and QoD Manifesto [3] 53

5.1 Graphical representation of QoD vs. RoT relation for QoD-unaware guidelines 57
5.2 Graphical representation of QoD vs. RoT relation for QoD-aware guidelines 57
5.3 QoD-aware CIG development method 59
5.4 Example of a section of the GDM guideline formalization [4] . 61
5.5 Example of a section of the GDM guideline customization . . 63
5.6 Physical exercise treatment workflow diagram 68
5.7 QoD check and data check workflow diagram for AF physical exercise treatment 69
5.8 QoD_{INIT} workflow diagram for AF physical exercise treatment 70
5.9 Data workflow diagram representation of Blood Glucose Monitoring in the GDM guideline 71
5.10 Graphical representation of the main features to provide optimal decisions following the Evidence Based Medicine principle [5] 73

6.1 Overview of the QoD-aware telemedicine system 79
6.2 Sequence diagram of the QoD-aware telemedicine system and its users 83
6.3 An example of the sequence diagram of the QoD-aware telemedicine system and its users 83
6.4 Distributed telemedicine system: mobile patient guidance system and the back-end guidance system 85

6.5 Sequence diagram between back-end guidance system and mobile patient guidance system 86
6.6 Simplified example of the sequence diagram between back-end guidance system and mobile patient guidance system . . . 87
6.7 Mobile patient guidance system components 90
6.8 Activity diagram 1 of the communication between the components of the mobile patient guidance system 95
6.9 Time sequence diagram corresponding to use case 1 97
6.10 Concrete communication example corresponding to use case 1 97
6.11 Activity diagram 2 of the communication between the components of the mobile patient guidance system 98
6.12 Time sequence diagram corresponding to use case 2 99
6.13 Concrete communication example corresponding to use case 2 101
6.14 Back-end guidance system components and their interaction . 101
6.15 Activity diagram describing the communication between the components of the back-end guidance system 105
6.16 Time sequence diagram corresponding to use case 3 106
6.17 Example projection [6] 110

7.1 QoD Broker components and their interactions 114
7.2 Activity diagram of the communication between the QoD Broker components 117
7.3 Time sequence diagram corresponding to use case 4 (QoD Broker) 119
7.4 Simplified representation of the relation between QoD (of data) and QoS (of technological resource) 124
7.5 Extended representation of the relation between QoD (of data) and QoS (of technological resources) 125
7.6 AF algorithm's Se and Sp relation to input data's SNR [7] . . . 127
7.7 Example of the QoD grades in an observational window 133
7.8 Example of monitored HR, it's overall QoD and the temporal abstraction QoD performed in MG 138

8.1 Top-level design cycle and nested problem solving 142
8.2 Visualization of manually entered Blood Glucose measurement 155
8.3 Data workflow diagram of Blood Glucose Monitoring in the GDM guideline with the representation of the impact of BG QoD in the CDSS (BG Check) 156
8.4 *Top:* Noise and Activity levels used for HR QoD computation; *Middle:* HR; and *Bottom:* QoD and temporal abstraction QoD_{out} 157
8.5 QoD check and data check workflow diagram for AF physical exercise treatment 158
8.6 QoD_{INIT} workflow diagram for AF physical exercise treatment 160
8.7 Example of the presentation for the semi-structure interview . 163
8.8 Pre-pilot testing phase iterative steps [8] 171

LIST OF TABLES

2.1 Criteria for assigning grade of evidence [9] 22
2.2 Determinants of strength of recommendation [10] 23

4.1 Example of the technological resources in a technological context 49
4.2 Example of resource qualifying parameters of each technological resource 49
4.3 Example of a clinical variable and its associated QoD values . 49
4.4 Example of the treatment adaptation 51

5.1 Example of a section of the GDM guideline personalization: BG monitoring times 65
5.2 Stages of the physical exercise and the specifications 67

6.1 Comparison between Non QoD-aware and QoD-aware with a use case 80
6.2 Service description of the QoD-aware telemedicine system . . 81
6.3 System-User interactions 82
6.4 Service description of the mobile patient guidance and the back-end guidance subsystems 84
6.5 Interactions between the mobile and the back-end subsystems 86
6.6 Description of the mobile patient guidance components 91

6.7 Interactions between the components of the mobile patient guidance system 93
6.8 Abbreviation of the components and activities of activity diagram 1 and activity diagram 2 94
6.9 Use case 1 96
6.10 Use case 2 100
6.11 Description of the back-end guidance system components . . 102
6.12 Interactions between the components in the back-end guidance system 103
6.13 Abbreviation of components and activities of activity diagram 3 104
6.14 Use case 3 105

7.1 QoD Broker components 115
7.2 QoD Broker subcomponents' interaction description 116
7.3 Abbreviation of components and activities of activity diagram 4 117
7.4 Use case 4 - QoD Broker 118
7.5 Mapping between selected QoD dimensions and QoD dimensions from literature [11] 123
7.6 Example of a stratification model for HR_{mon} accuracy 128
7.7 Example of the QoD output from 6 samples on the observation window of Figure 7.7 133
7.8 Example of the QoD temporal abstraction 134

8.1 Validation Activities 143
8.2 Single case mechanisms test within MobiGuide 161
8.3 Semi-structured interviews response for effectiveness (Perceived Usefulness) 166
8.4 Semi-structured interviews response for user-control 167
8.5 Semi-structured interviews response for safety 168
8.6 Semi-structured interviews response for ethics 168
8.7 Semi-structured interviews response for expectations 169
8.8 Participants and number of questions presented to each group . 174

8.9 AF patients' questions and answers after the pilot study 176
8.10 GDM patients' questions and answers after the pilot study . . 176
8.11 Medical domain experts' questions and answers after the pilot study 176

A.1 Description of the iPACT' elements for the AF scenario . . . 194
A.2 Description of the FICS' elements for the AF scenario 198

B.1 Abbreviations for messages 201
B.2 Notations used in architecture diagrams 202

List of Acronyms

AF Atrial Fibrillation

BAN Body Area Network

BEG Back End Guidance

BP Blood Pressure

BG Blood Glucose

CDSS Clinical Decision Support System

EBM Evidence Based Medicine

ECG Electrocardiogram

EHR Electronic Health Record

EMR Electronic Medical Record

GDM Gestational Diabetes

GUI Graphical User Interface

ICT Information and Communication Technology

INR International Normalized Ratio

HR Heart Rate

MPG Mobile Patient Guidance

PHR Personal Health Record

RCM Resource Configuration Manager

RQP Resource Qualifying Parameter

TRC Technological Recommendation Composer

QoD Quality of clinical Data

QoS Quality of Service

vMR virtual Machine Record

CHAPTER 1

INTRODUCTION

Rapid advancements in information and communication technology (ICT) enable ubiquitous data availability, providing new opportunities to develop pervasive healthcare applications. Pervasive healthcare can be defined as *"healthcare provided to anyone, anytime, and anywhere by removing location, time and other restraints while increasing both its coverage and quality"* [12]. It integrates the capabilities of current and emerging ICT, which includes monitoring, processing and communication resources [13]. These technologies of pervasive healthcare support a wide range of applications and services, including telemedicine systems services, which enable the remote treatment of ambulatory patients.

Healthcare is facing several challenges in the Organization for Economic Cooperation and Development (OECD) countries. The increase of the number of elderly people and chronic disease, accompanied by the healthcare cost increment and lack of sufficient medical domain experts are examples of some of these challenges [14]. Pervasive healthcare aims to overcome these challenges by providing scalable systems, so that human and financial resources are applied more efficiently. But pervasive healthcare and telemedicine systems also bring new challenges in the form of technical obstacles and uncertainties [13]. These systems are data-driven and the data availability for treatment guidance is supported by ICT-based resources, such as monitoring, processing and communication devices. However, technological context variations, which may be characterized by unexpected ICT performance disruptions (weak data transmission signal due to bad weather or noisy signal due to motion artifacts), can lead to clinical data with 'insufficient' quality-of-clinical-data (QoD). Hence,

the usage of clinical data with 'insufficient' QoD (e.g. lack of correct and complete data) can lead to wrong diagnosis and treatment decisions, putting patients' safety at risk.
This thesis proposes a technological-context based QoD framework to facilitate the development of QoD-aware telemedicine systems in pervasive healthcare for ambulatory patients. Such telemedicine systems are able to safely adapt patient treatment guidance according to the varying QoD, which is influenced by the technological-context at hand. This chapter presents the motivation for this research and addresses the main objectives of this work and our approach.
This chapter is organized as follows: Section 1.1 presents the background of this research. Section 1.2 analyzes the existing problem in current healthcare practice. Section 1.3 presents the objectives and research questions of this research. Section 1.4 presents the research design we followed in the study and Section 1.5 addresses the scope of this work. Section 1.6 describes the approach, and finally, Section 1.7 presents the structure of the remaining thesis.

1.1 BACKGROUND

Healthcare aims to cure and improve mental and physical health of people by preventing or treating illness through services offered by health professionals. Additionally, healthcare is continuously evolving due to new demands (e.g. demographic and lifestyle changes) and new capabilities (e.g. advances in healthcare science and practice, and technological support). In order to offer the best available care, medical practice adopts the Evidence-Based-Medicine (EBM) principle. EBM is defined as "*the conscientious, explicit and judicious use of current best evidence in making decisions about care of individual patients*" [15]. The use of EBM by medical practitioners means integrating their individual clinical expertise (i.e. proficiency and judgment acquired through experience and practice) with the best available external clinical evidence from systematic research (e.g. obtained from observational studies, and randomized trials) [15].
However, to provide best care to patients, healthcare has to face several challenges, such as the high cost of healthcare services and lack of human resources. Pervasive healthcare in extramural settings supported by telemedicine systems can mitigate the negative effects of these issues since it allows ambulant (home) care monitoring, which may reduce the cost and requires less human resources. But telemedicine systems need to adopt traditional evidence-

based treatments and support new ambulatory treatments, which are currently feasible due to recent advancements in Information and Communication Technology (ICT). These new treatments have to comply with EBM, and follow medical protocols and medical practitioners' 'way of working' [16] in order to ensure safe and high quality care.
In such a telemedicine system, we can apply an automated guideline-based clinical decision support system (CDSS). A CDSS processes large amounts of clinical data from monitored patients and based on its internal logic (i.e. medical knowledge) it outputs decisions in the form of clinical recommendations. In order to comply with the medical 'way of working', including EBM, the CDSS logic applies evidence-based clinical guidelines. The evidence-based clinical guidelines are consistent with the EBM principles and support medical practitioners in their decision making process for an individual patient in a specific clinical context. These guidelines result from an unbiased and transparent process of systematically using the best clinical research findings of the highest value. They aim to improve quality of care to patients, reduce potential practice variations and reduce healthcare cost [17].

1.2 PROBLEM ANALYSIS

Although pervasive healthcare and telemedicine systems potentially solve many healthcare challenges, they also introduce several new obstacles and uncertainties. For example, the guarantee of 'good quality' clinical data to preserve treatment efficacy and avoid putting patients at risk.
In telemedicine systems we usually follow the MADE model, which stands from Monitoring, Analysis, Decision and Effectuation. As discussed in [18], ICT resources make it possible to *monitor* clinical data at the point of monitoring, *analyze* the data to make abstractions from the low-level concepts, transforming them into more meaningful concepts, making *decisions* on the appropriate plan (i.e. course of action) based on the given clinical data, and finally *effectuate* the plan, with the intention of bringing about a change in the patient's state, whether directly or via changes in the patient's external environment.
In traditional medical practice, performed mainly in intramural hospital settings, clinical data is used in a controlled environment and managed by medical domain experts (e.g. medical doctor or nurses), who usually trust this clinical data. Clinical data is entered manually by qualified medical experts into the system or automatically by using automated medical (monitoring) sys-

tems. Medical systems used in intramural settings have the required quality control entities. Additionally, if medical domain experts observe suspicious clinical data, they ask for additional measurements or tests (e.g. double Blood Pressure measurements). This existing "quality of data control" in traditional medical practice leads to a common assumption that clinical data used for treatment decisions fulfil medical quality requirements, and therefore is considered trustworthy.

1.2.1 QUALITY OF CLINICAL DATA IN PERVASIVE HEALTHCARE

In pervasive healthcare, telemedicine systems monitor, process and communicate clinical data from ambulatory patients by using ICT based technological resources. These technological resources may have undesirable performance variations during runtime (e.g. temporary mobile internet performance degradation). These performance information, or technological information provided by the technological resources represent the technological context. Hence, during runtime, a technological-context exists for each monitored patient, comprising performance variations that potentially affect quality aspects (e.g. data delay, data errors) of provided clinical data. The degraded quality of the clinical data may have an impact on the treatment, even putting patients' safety at risk. Therefore, we define technological context as *the technical information provided by the technological resources that has an impact on the quality of clinical data (QoD) and hence, characterizes patient's treatment* [2, 19]. QoD is a multidimensional concept and although there is not a clear definition of it, we look into QoD from the user's perspective by following [20, 21, 22] studies: *'best' QoD refers to the clinical data that fulfils 'best' the user quality requirements, i.e. the medical quality requirements, and different QoD grades determine to which extent the data fulfills these medical quality requirements* (see Chapter 7).
In pervasive healthcare carried out in an extramural setting, medical practitioners are not in-situ to supervise the usage of the medical devices by an outpatient and hospital quality control entities cannot ensure the telemedicine system's performance. Hence, the quality of clinical data control that exist on in traditional medical practice is usually lacking in extramural pervasive healthcare settings. Hence, due to the common assumption that QoD fulfils the medical quality requirements, during telemedicine system design, technological-context and QoD are not a priory taken into consideration. This may result in technological-context and QoD-unaware (telemedicine) system.

Consequently, medical QoD requirements are not necessarily always met by the data obtained from the system, and clinical decisions based on the data may, therefore, be 'erroneous'. These erroneous decisions can have a negative impact on extramural treatments, potentially putting patients' safety at risk.
Researchers [23, 24, 25, 26, 27] have studied the impact of "Low" QoD on CDSS output decisions and conclude that the CDSS's output may be erroneous. However, these studies fail to provide a complete solution to deal with this negative impact (see Chapter 2). These literature studies refer to CDSS's output as clinical recommendations (decisions) generated to support patients' treatment guidance or medical practitioners' treatment decision making process. Hence, the QoD degradation may degrade treatment's quality, potentially threatening patients' safety. These studies were also performed in intramural (hospital) settings. One can expect that clinical data with "Low" QoD will occur more frequently in extramural settings, which have much less opportunities for "quality controls".

1.2.2 QUALITY OF TREATMENT AND RISK OF TREATMENT

Traditionally a medical practitioner performs the decision making process for clinical treatments in consultation with the patient. Quality of traditional treatments depends on: (1) adherence to evidence based medicine (EBM), which includes the medical practitioner's experience, knowledge and skills, and the adherence to the applied evidence-based treatment [9], and (2) the patient's adherence to his/her treatment [28].
In extramural treatments, medical experts remotely supervise the treatment and intervene whenever necessary. However, treatment guidance is mainly supported by a telemedicine system that consists of ICT resources. Hence, in an extramural context, QoD of patient data becomes essential to provide 'best' possible treatment. Accordingly, clinical data quality, together with adherence to EBM and the patient's adherence to his/her treatment, are treatment quality features. These features are not independent from each other and they have an impact on the quality of treatment. For example, 'best' QoD will not necessarily correspond to a 'best' quality treatment if the patient is not compliant with the treatment protocol.
We define the risk of treatment (RoT) as *the probability that a given treatment guidance causes any harm or inconvenience to the treated patient*. Usually RoT changes inversely to quality of treatment (QoT), which is *the degree of confidence and certainty to provide 'best' treatment to a particular patient*. An

input clinical data with "low" QoD might trigger a 'false' clinical recommendation from the CDSS. This will result in an 'inappropriate' guidance and the RoT might increase. However, in some cases, QoT can be "high" while RoT is also "high". For example, when using experimental medication in a supervised manner to treat a patient's life-threatening disease (e.g. cancer), both RoT (e.g. life-threatening) and QoT (e.g. highly supervise treatment) can be "high". A related concept is Strength of Recommendation (SoR), which is a known concept in multiple evidence-based clinical guideline studies [9, 29, 30, 31]. The Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) healthcare working group defines SoR as follows: "*the strength of a recommendation indicates the extent to which we can be confident that adherence to the recommendation will do more good than harm*" [9].
The relation between Quality of clinical Data (QoD), strength of recommendation (SoR) and risk of treatment (RoT) is depicted in Figure 1.1 using Causal Loop Diagram (CLD) notation [32]. The nodes in this figure represent the variables of interest, i.e. QoD, SoR and RoT, and the directed edges represent a relation between two variables where one variable causes an effect in the other variable. A positive link (indicated with "+") means that the two related variables change in the same direction, and a negative link (indicated with "-") means that two related variables change in opposite directions. We postulate that, if no special measures are taken, the relation between QoD and SoR is characterized by a positive link (if QoD decreases, SoR will also decrease; and if QoD increases, SoR will also increase), and the relation between SoR and RoT is characterized by a negative link (if SoR decreases, RoT will increase; and if SoR increases, RoT will decrease). For example, if the thyroid function data of an atrial fibrillation patient becomes unreliable (QoD decreases), and the medical practitioner still prescribes Amiodarone, this will reduce the strength of this clinical recommendation (SoR decreases) and leads to a risk increment of the treatment due to potential side effects (RoT increases). Notice that the positive or negative links do not imply proportionality of change but only direction (same or opposite).

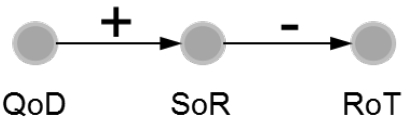


Figure 1.1: Causal Loop Diagram between quality of data (QoD), Strength of Recommendation (SoR) and Risk of Treatment (RoT)

1.3 OBJECTIVES AND RESEARCH QUESTIONS

The generic goal of this research is to study the impact of quality of clinical data (QoD) on healthcare systems and to support researchers and developers in creating QoD-aware pervasive healthcare and telemedicine systems. More specifically, the main objective of this research is to improve the development of telemedicine systems by integrating a QoD-aware infrastructure that:

- computes QoD based on technological-context, one of the main causes of the QoD degradation in telemedicine systems;
- prevents QoD degradation by managing technological resources;
- prevents risks to patient safety due to QoD degradation by incorporating QoD-awareness in the logic for decision-making (clinical guidelines and care giver interface).

Below, we pose a set of research questions to identify and clarify the objectives of this thesis. These questions help to decompose the QoD related problems, found in healthcare systems, to smaller sub-problems. We formulate one research questions, which is decomposed in three sub-questions:

Can QoD-awareness integration improve healthcare systems, in particular telemedicine systems, by preserving system reliability and enhancing (guaranteeing) patient safety when QoD degrades?

- ***How to design a QoD-aware patient guidance (telemedicine) system that preserves the patient's safety when QoD degrades?***
- ***How to develop a conceptual model for Quality-of-Data aware treatment guidance?***
- ***How to include QoD-awareness in executable clinical guidelines?***
- ***What is the architecture of a QoD-aware telemedicine system?***

1.4 RESEARCH SCOPE

In order to develop a QoD-aware telemedicine system, we consider the engineering design cycle presented in software engineering projects [33, 34, 35, 36]. Our study addresses the first three phases of this cycle: the problem investigation, the treatment design and a partial design validation. Notice that the phases presented can be performed concurrently and iteratively (Figure 1.2).

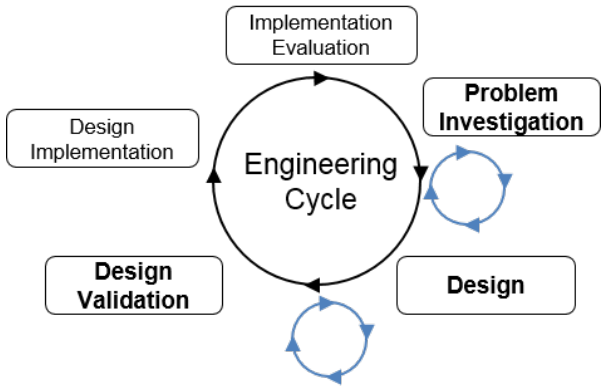


Figure 1.2: Engineering Cycle

We start with the ***problem investigation*** (see Figure 1.2) by examining the potential problem with the clinical data when performance fluctuations in technological resources occur. This phase is conducted in two steps. In the first step we study the problem domain and derived the requirements for evidence-based treatment supported by telemedicine systems. In the second step we identify potential issues that could exist when the clinical data used by telemedicine systems do not fulfil the minimum quality of data requirements. In this phase we also conduct a comprehensive literature study in several areas of relevance for the topic.

Based on the results of the problem investigation we carry out the ***design*** phase of the research (Figure 1.2), which includes several tasks. First, we design an ontology for a conceptual model of QoD. In this phase, we also participated as QoD experts to augment the treatment (guideline) with QoD. This guideline is formalized to be used as a knowledge-base by the telemedicine system. Furthermore, we design the architecture and functionalities of a QoD-aware telemedicine system, and focused on QoD Broker component in charge of QoD management. This architecture is implemented in a telemedicine system prototype.

The ***validation*** of the design prototype is conducted in different stages. First, we conduct several tests by applying Clinical Proof of Concept [37]. Later, the entire system is validated in a real-world setting with healthy subjects and also with patients and domain experts (medical practitioners and nurses) participating in the pilot study.
The scope of our research is limited to these three phases of the engineering cycle and the last two phases, i.e. *"Design implementation"* (transferring a validated result to the market) and *"Implementation evaluation"* (evaluation based on observed performance in real-life practice, e.g. using experience reports) have not been implemented. These phases should be completed if the system is developed for commercial use.

1.5 DOMAIN OF DISCOURSE: MOBILE PATIENT GUIDANCE

The research described in this thesis is part of the European Seventh Frameowrk Program (FP7) project, called MobiGuide (MG) [4]. The MG project aims to develop a mobile patient guidance system. This way the patient can receive remote treatment, without the presence of his/her doctor. MG investigates personalized and context-aware intelligent telemedicine systems for patients with chronic illness. The developed system prototype supports two medical cases: atrial fibrillation - under the cardiology healthcare environment, and gestational diabetes mellitus - under the endocrinology healthcare environment. It addresses the impact of patients' personal and technological-context (e.g. patient marital status, mobile phone coverage, battery power) on pervasive treatments. The technological-context affects the quality of clinical treatment, and therefore, the technological-context is addressed in terms of QoD.
This technological-context and QoD-awareness in pervasive healthcare and telemedicine applications is the focus of this research. In particular, we target telemedicine applications based on clinical decision support systems. Below, we address the main reasons why we consider pervasive healthcare and telemedicine a valid application domain:

- *Data impact on pervasive healthcare and telemedicine:* Pervasive healthcare and telemedicine applications are sustainable due to the ubiquitous data availability. However, 'poor' QoD may lead to useless data for these applications. Therefore, consideration of QoD is necessary for these healthcare systems to provide safe care to patients.
- *Specific quality requirements:* Healthcare has strict procedures and requirements. Therefore, healthcare applications (e.g. telemedicine ap-

plication) need to provide QoD that fulfills the medical quality requirements to ensure treatments efficacy and patients safety.

- *Socioeconomic reasons:* Pervasive healthcare and telemedicine systems may be a solution to prevent the high costs and high demand of medical practitioners in societies where the percentage of aging people and chronic diseases is increasing. However, pervasive healthcare and telemedicine still have challenges to overcome, including those that are addressed in this study, such as the impact of unexpected ICT disruptions and degraded clinical data quality.

1.6 APPROACH

Figure 1.3 presents the approach adopted in this research. The rounded rectangles on top depict the main phases in the research. The square rectangles depict research activities, the results of which can be used in follow-up research. The direct arrows represent a result/input relation between the research activities. The approach applied in this research is divided in five main phases.

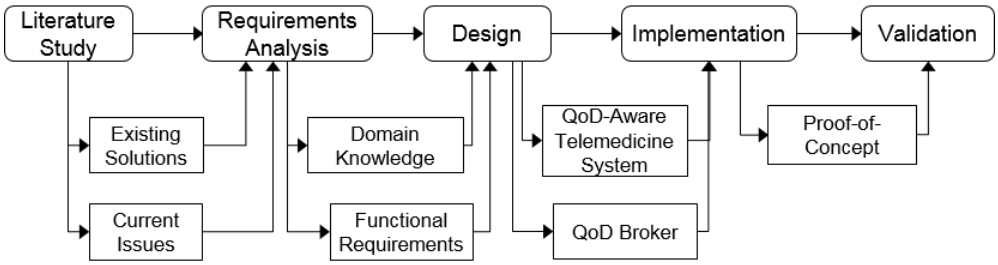


Figure 1.3: Approach

The first phase is the *Literature Study* that consists of presenting:

- *Existing Solutions:* Describes the state-of-the-art in healthcare advancements and addresses some of the solutions proposed in other studies.

- *Current Issues:* Addresses some of the problems that healthcare is facing and provides the background information that has motivate this study.

The second phase is the *Requirements Analysis* for QoD-awareness inclusion in telemedicine. It includes the following:

- *Domain Knowledge:* It supports the specification of the relation between technological-context parameters (i.e. quality of service of ICT that has an impact on QoD) and treatment-context (i.e. mechanism to adapt the treatment when QoD does not fulfil the medical requirements) to integrate QoD-awareness in telemedicine systems. This relation is the ground for QoD-Framework ontology.

- *Functional Requirements:* Identifies the user-system interactions based on the medical activities described in the scenario. These interactions are used to define the QoD-aware telemedicine system functional requirements.

The third phase is the *design* of the QoD-Aware Telemedicine System and QoD Broker, which enables the QoD-awareness in the telemedicine system. As discussed, this research has been conducted in a context of the MobiGuide project, and hence, the design choices are the following:

- Develop an intelligent guideline-based clinical decision support system.

- Focus on pervasive ambulatory treatments.

- Focus on QoD variations caused by technological-context.

The design includes:

- *QoD-aware telemedicine system* design that ensures patient's safety when QoD degrades

  - Guideline: Development of an executable QoD-aware clinical guideline that considers treatment adaptation mechanisms to provide QoD-aware safe treatment guidance
  - Architecture: Decomposition of the system in different levels of abstraction based on the functional requirements

- *QoD Broker subsystem* architecture that enables the QoD-awareness in the system

  - Architecture: Decomposition of QoD Broker in subcomponents based on the functional requirements

  - Functionalities: Functionalities, which address how the QoD Broker subcomponents operate in order to fulfill the user requirements.

The fourth phase is the *implementation* of the QoD-aware telemedicine system prototype. The prototype is a *proof-of-concept* (see Figure 1.4).
The *validation* is the final phase to verify the design requirements and demonstrate the usefulness of the QoD-awareness in telemedicine system. Additionally, this step embraces the validation of intermediate results that were essential for the development of our architecture. Specifically, we want to validate the step from stakeholder goals to system requirements (i.e. the requirements elicitation method) and the interpretation of this requirements into the QoD-framework ontology and the formalization of a QoD-aware clinical guideline.

1.7 STRUCTURE

The structure of this thesis reflects the previously discussed approach. Figure 1.4 correlates the structure of this thesis with the adopted approach. The remainder of this thesis is structured as follows:

- **Chapter 2** presents the state-of-the-art in healthcare, including the healthcare uncertainties addressed in some of the studies, which are related with quality of data and context-awareness. Additionally, we also present missing factors which have contributed to led to the focus of this research.
- **Chapter 3** introduces the requirements elicitation method and the context layering technique, which are the tools to build the conceptual model of QoD (ontology) and define the functional requirements of the QoD-aware telemedicine system and QoD Broker.
- **Chapter 4** presents the QoD-framework ontology that results from the requirements elicitation method and the context layering technique presented in Chapter 3.
- **Chapter 5** describes the process to develop an executable QoD-aware computer interpretable clinical guideline used by the clinical decision support system (CDSS).
- **Chapter 6** presents the overall architecture of the QoD-aware telemedicine system prototype. This includes the specification of the required components to build the QoD-aware telemedicine system.

- **Chapter 7** presents the design of the QoD Broker component architecture and the detailed explanation of each of its functionalities.
- **Chapter 8** presents the validation of the proposed system design and determines whether QoD-aware telemedicine systems would contribute to stakeholders goals.
- **Chapter 9** evaluates the results of this research and lists various directions for future work.

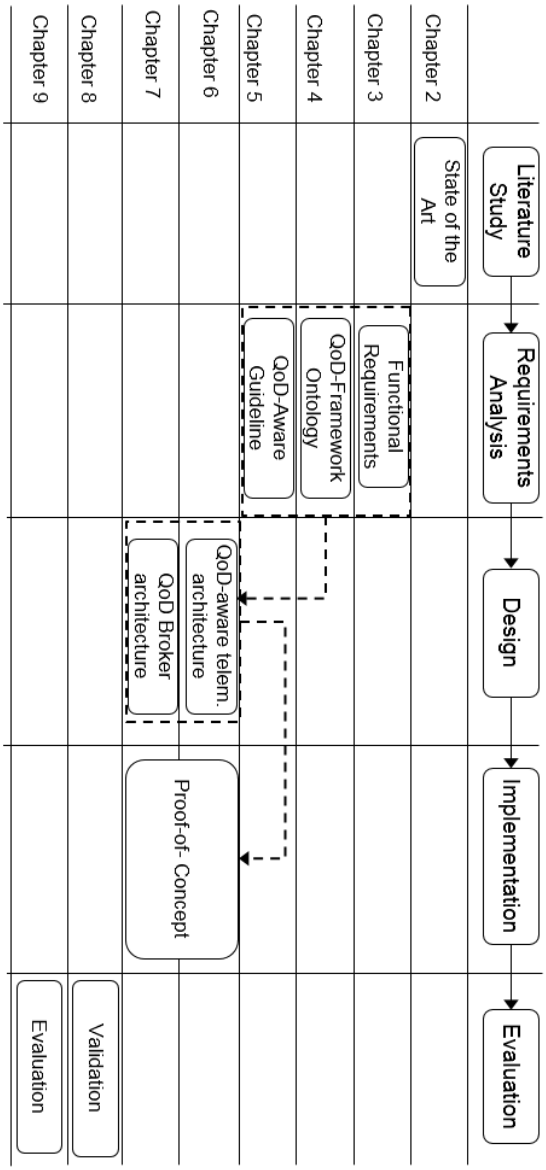


Figure 1.4: Thesis Structure

CHAPTER 2

STATE-OF-THE-ART IN QOD-AWARENESS FOR HEALTHCARE SYSTEMS

This chapter discusses the state-of-the-art on the most relevant topics for this study, which are the evolvement of healthcare towards telemedicine systems and the role of QoD on such systems. Other chapters will include additional state-of-the-art information related to the topic discussed in each chapter.
The chapter is organized as follows: Section 2.1 presents a general overview of healthcare systems' evolution towards pervasive healthcare systems, telemedine systems and guideline based clinical-decision support systems. We also define pervasive healthcare and telemedicine in order to understand the relation between both domains. Section 2.2 defines technological-context and QoD, and discusses relevant studies in the domain of 'context-awareness' and QoD. Additionally, it brings up studies that examine the impact of technological-context and QoD on healthcare and decision support systems. Finally, Section 2.3 provides an assessment of some of the current solutions described in these studies. We also discuss the gaps and pitfalls of some of these solutions, which are the motivation for this research.

2.1 INFORMATION TECHNOLOGY IN HEALTHCARE

Medicine is the science and art of healing that involves a variety of healthcare practices, such as diagnosis, treatment and prevention of diseases in human beings. Healthcare has been evolving throughout history. From prehistoric medicine that incorporated natural sources (e.g. plants), to Egyptian medicine that performed surgeries since 2750 BCE, to Mesopotamian medicine, Indian

medicine etc. [38].
Two of the major challenges faced by current healthcare are: **1)** to prevent the rapid increase of **cost** for caring (due to the increasing number of elderly population, increased occurrences of chronic diseases brought about by lifestyle changes, and the shortage of medical domain experts) and **2)** to provide the 'best' available care based on **evidence-based-medicine** (EBM), which is defined as *"the conscientious, explicit and judicious use of current best evidence in making decision about care of individual patients"* [15]. EBM involves the integration of individual clinical expertise (i.e. proficiency and judgment acquired through experience and practice) with the best available external clinical evidence from systematic research (obtained from observational studies, randomized trials) [15].
In order to adopt EBM principle, medical practitioners apply evidence-based clinical guidelines. As defined by the Institute of Medicine, clinical guidelines are *"systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."* [24].

2.1.1 PERVASIVE HEALTHCARE VS. TELEMEDICINE

Varshney [12] defines **pervasive healthcare** in simple terms as: "*healthcare to anyone, anytime, and anywhere by removing locational, time and other restraints while increasing both the coverage and quality of healthcare*". Mihailidis and Bardram [39] define 'Pervasive Healthcare' as *"the application of pervasive computing in healthcare"*.
We used the definition provided in [40]: *"Pervasive healthcare may be defined from two perspectives: first, as the application of pervasive computing—or ubiquitous computing, proactive computing, ambient intelligence—technologies for healthcare, health, and wellness management; second, as making healthcare available everywhere, anytime—pervasively. Essentially, pervasive healthcare addresses those technologies and concepts that integrate healthcare more seamlessly to our everyday life, wherever we are"*.
In order to define **telemedicine**, we use Craig's [41] definition: "*telemedicine is the delivery of health care and the exchange of health-care information across distances. It is not a technology or a separate or new branch of medicine. Telemedicine episodes may be classified on the basis of: 1) the interaction between the client and the expert (i.e. real-time or prerecorded), and 2) the type of information being transmitted (e.g. text, audio, video).*"

Both pervasive healthcare and telemedicine aim to overcome the challenges faced by modern-day healthcare. The researchers in the area of pervasive healthcare [12, 39] believe that pervasive healthcare is a solution to many existing challenges that current and future healthcare systems face. Similarly, telemedicine domain experts [41] claim that telemedicine is the solution to make high-quality healthcare available to all.

Both domains are closely related and we find that researchers, sometimes, may use it interchangeably. Nevertheless, we believe that the empowerment of patients to take more responsibility for their own health is more stressed in pervasive healthcare than in telemedicine. Bardram [14], an expert in the pervasive healthcare domain, claims that the approach is to move from a centralized model, with highly specialized medical professionals inside hospitals who treat ill patients, to a much more decentralized model where people themselves are active participants in caring for their own well-being. Although this decentralized model may be present also in telemedicine, telemedicine focuses more on making medicine more accessible for every person, at anytime and anyplace. In [14], the differences between pervasive healthcare and telemedicine were also more clear by the fact that pervasive healthcare is able to study and foster patient self-consciousness in his or her own care. Hence, pervasive healthcare may involve medical domain experts, patients or healthy subjects who aim to improve their health condition, or a combination of those. In contrast, we consider that telemedicine *always requires* the involvement of medical practitioners. This way they can treat ambulatory patients by using electronic communications that enable the treatment execution no matter the location of patient and medical practitioners.

In [13], Varshney also discusses that pervasive healthcare systems support wide range of applications and services including telemedicine systems, patient monitoring, location-based medical services, emergency response and management, pervasive access to the medical data, personalized monitoring and lifestyle incentive management. We can argue that some of the services listed, such as personalized monitoring, are also addressed in telemedicine system. However, we can see that pervasive healthcare may imply a wider range of services, including the ones without medical practitioners involvement, and hence, we agree that pervasive healthcare is a broader domain than telemedicine (Figure 2.1).

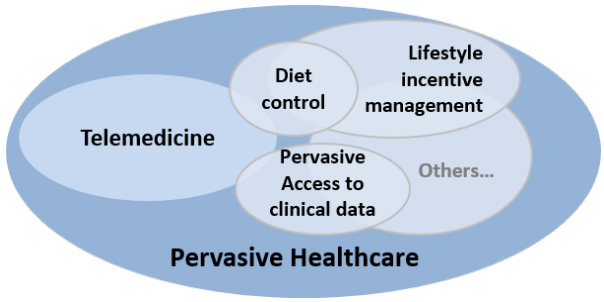


Figure 2.1: Pervasive Healthcare and Telemedicine

2.1.2 CLINICAL GUIDELINES IN HEALTHCARE SYSTEMS

As discussed in Section 2.1.1, in order to provide the 'best care' we need to adapt traditional EBM principles and hence, follow medical protocols and medical practitioners' 'way of working'. To develop such a telemedicine system, the system must formalize evidence-based clinical guidelines. These clinical guidelines are based upon the best available research evidence and practice experience, and the quality of evidence is grated according to the type of evidence (see Figure 2.2). The concise medical instructions that guidelines provide are based on several features, such as clinical test results and clinical data [42].

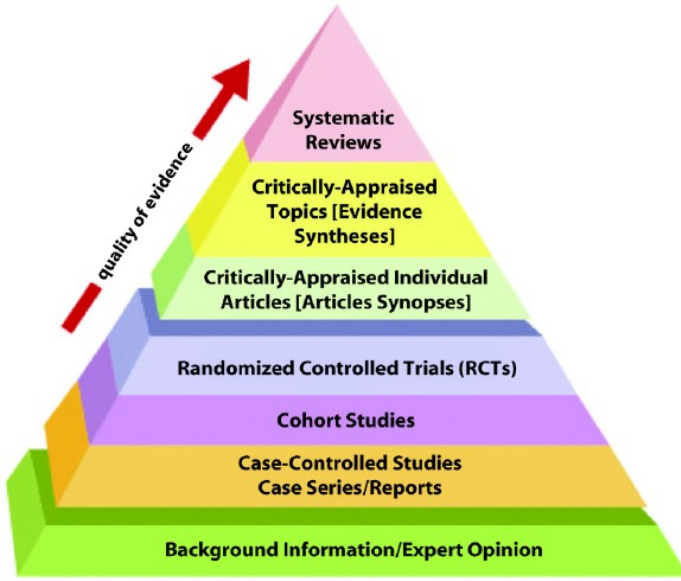


Figure 2.2: The Evidence Based Medicine Pyramid [1]

The potential of clinical guidelines is also being exploited in medical artificial intelligence and in medical decision making. For that, clinical guidelines are formalized into a computer interpretable guideline (CIG). The CIG can be applied in systems such as a clinical decision support system (CDSS), which can interpret and execute these guidelines. In this research study, we apply a CDSS integrated in a telemedicine system that uses the guidelines as the CDSS knowledge-base [6, 43]. Typically, this guideline-based CDSS analyzes the clinical data from different sources and applies the guideline to provide decisions by means of, for example, clinical recommendations. These recommendations aim to guide ambulatory patients or support medical practitioners in their decision making process. Hence, the guideline-based CDSS are integrated in hospital servers or mobile devices to support physicians in their daily practice and ambulatory patients in their daily life.

2.2 UNCERTAINTY IN HEALTHCARE

Uncertainty is a situation in which something is not known or unsure. Hence, in medicine, uncertainty in the patient clinical data, results etc. may have an impact on decisions with respect to patient's treatment. As discussed in Section 2.1, we build the link between both technological-context and QoD, and we address the impact of technological context in healthcare systems in terms of QoD. Current formalized clinical guidelines, used as knowledge for CDSS, do not explicitly address quality of clinical data used for treatment decisions and their effects on the treatment. Nevertheless, medical reasoning systems, such as CDSS and their applied clinical guidelines, face uncertainty [44]. As discussed by Kong et al. [45] uncertainty exists in almost every stage of a clinical making processes and the sources of uncertainties are diverse: patients who cannot describe their symptoms or how they feel, medical domain experts who cannot exactly explain what they observe or clinical data that may contain some degree of error. One of the main challenges is how to handle such uncertainties so that the guidelines, and ultimately the CDSS integrated in telemedicine systems, can provide correct and reliable diagnosis and treatment decisions.

In this thesis we address a specific source of uncertainty, namely the quality of clinical data (QoD), which depends on variability in performance of technological resources (i.e. monitoring, processing and communication devices). We are interested in how to rationally handle these uncertainties so that a CDSS can provide correct and reliable treatment decisions in the form

of recommendations to the medical practitioner and patient. As discussed in Chapter 1, the general public as well as medical domain experts (e.g. nurses & medical practitioners) tend to believe that technological resources, used within controlled medical environments (e.g. hospitals), always comply with healthcare efficiency, quality, safety, and reduced cost [32]. Medical domain experts have been educated to keep an eye on the technological resources and their output data to intervene (e.g. repeat a test) when required. However, most of the medical domain experts do not consider potential disruptions that technological resources (used in telemedicine settings) might have. Therefore, they (wrongly) take for granted that similar procedures will guarantee 'good' QoD in extramural settings.
In the following subsections, we first define technological context and quality-of-clinical-data. Next, we discuss how quality is being studied in the clinical domain, and finally, we address research studies that address the impact of quality of data in healthcare and other domains.

2.2.1 DEFINITIONS OF TECHNOLOGICAL CONTEXT AND QUALITY-OF-CLINICAL-DATA

Context-aware systems offer personalized services to its users based on their context [46]. Dey [47] defines context as follows: *"Context is any information that can be used to characterize the situation of an entity. An entity is a person, place, or object that is considered relevant to the interaction between a user and an application, including the user and applications themselves."*
We are focused on patient treatment, contrary to entities in general, and we address technological context and it's influence on QoD. Therefore, instead of the broad meaning given to context, in this research study we define **technological-context** as: *"technical information provided by a collection of technological (i.e. ICT) resources that may have an impact on the quality of clinical data, characterizing the patients treatment"*.
In order to define QoD, we look at it from the user's perspective by following Wang et al. [21]: *"best QoD refers to the clinical data that fulfills best the user quality requirements, i.e. the medical quality requirements, and QoD grades determine to which extent the data fulfills these medical quality requirements"*. This is in alignment with Tayi et al. [48], who use the term "fitness for use" to define data quality and express that data quality is relative to its usage. Furthermore, we will look into the multidimensionality of QoD since QoD could be studied from different aspects. This is further discussed in Chapter 7, where we present three approaches to select the appropriate QoD

dimensions and how these are applied in our research study (Section 7.2.1).

2.2.2 QUALITY OF EVIDENCE AND STRENGTH OF RECOMMENDATION

'Quality' as a concept is addressed in multiple healthcare and clinical guideline studies, but, generally, these studies do not explicitly address quality of clinical data. The healthcare working group, named Grades of Recommendation, Assessment, Development, and Evaluation (GRADE), investigates **Quality of Evidence** (QoE) and the **Strength of Recommendation** (SoR) in clinical guidelines [9, 10, 29, 31]. Hence, GRADE group studies the factors that may have an impact on healthcare quality, specially regarding clinical guidelines.
GRADE defines QoE and SoR as follows: *"evidence indicates the extent to which we can be confident that an estimate of effect is correct; the strength of a recommendation indicates the extent to which we can be confident that adherence to the recommendation will do more good than harm"* [9]. GRADE presents a system to grade QoE in four grades: "High" or A, "Medium" or B, "Low" or C, and "Very Low" or D [10]. This group also defines factors that may decrease QoE, such as study limitations, inconsistency of results, indirectness of evidence, imprecision and reporting bias in the guideline (Table 2.1).
Besides, GRADE determines SoR as 'strong' or '2' and 'weak' or '1' [10] and also discusses other factors, besides QoE, that can influence SoR, like uncertainty or variability in clinical data values [10] (as shown in Table 2.2).
According to GRADE [9], *"**Recommendations**, or their strength, are likely to differ in settings where regular monitoring of the intensity of anticoagulation is **available** and settings where it is not."* Availability, defined as *'ready to be used'*, could be one aspect of QoD, also addressed in the QoD related literature [20, 49]. We consider the term *"recommendation"* as a suggestion or message given to the medical domain experts or patients to guide them during their treatment. *"Strength"* is a quality attribute of the recommendations that might affect the risk of the treatment. Hence, we can extrapolate this concept and rephrase this statement of GRADE as follows: *"**Treatments**, or their risk, are likely to differ in settings where **quality of clinical data** is sufficient and settings where it is not"*. However, GRADE studies do not present a method to preserve either SoR or the risk of the treatment when QoD does not fulfil medical requirements, which is the aim of our research study.

Type of evidence
Randomized trial = high Observational study = low Any other evidence = very low
Decrease grade if:
• Serious (-1) or very serious (-2) limitation to study quality • Important inconsistency (-1) • Some (-1) or major (-2) uncertainty about directness • Imprecise or sparse data (-1) • High probability of reporting bias (-1)
Increase grade if:
• Strong evidence of association - significant relative risk of > 2 (< 0.5) based on consistent evidence from two or more observational studies, with no plausible confounders (+1) • Very strong evidence of association - significant relative risk of > 5 (< 0.2) based on direct evidence with no major threats to validity (+2) • Evidence of a dose response gradient (+1) • All plausible confounders would have reduced the effect (+1)

Table 2.1: Criteria for assigning grade of evidence [9]

2.2.3 RESEARCH STUDIES ON IMPACT OF QUALITY OF DATA

Several studies [23, 25, 50, 51, 52, 53] address the negative impact of "low" quality of input clinical data on CDSS's output quality. Most of these studies are performed in intramural hospital settings and they address "near line" medical records stored in clinical databases. However, the effect of QoD can be generalized to all clinical data used as input to the CDSS, including monitored real-time "online" clinical data which is increasingly being used in pervasive healthcare treatments.
Hasan [50] analyzes and proves the negative effect that quality degradation of "near line" medical registries data has on CDSS output accuracy, where accuracy is considered a quality attribute [20, 49]. In order to minimize the effect that "poor" QoD has on the CDSS output quality, he presents the following as future work: 1) data-cleanup strategies, 2) controls, and 3) improved medical process design. He defines control as *"any procedure, either electronic or human, that can be used to verify the accuracy or completeness of patient data in order to prevent inaccurate medical decisions"*. Accordingly, his future control strategy is aligned with our approach of using computed QoD to build a QoD-aware CDSS based telemedicine system to prevent low quality ('weak') recommendations.

Factor	Comment
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Costs (resource allocation)	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted

Table 2.2: Determinants of strength of recommendation [10]

McCormack et al. [25] study medical domain experts' perception on the effect of electronic patient clinical data quality on a CDSS. The starting point of [25] is that a CDSS depends on a foundation of "high" quality clinical data and they conclude that medical experts understand the problem that "low" QoD might affect the CDSS output.
Additionally, Berner, in [23, 51], presents the effect that quality of medical records have on accuracy of clinical recommendations provided by the CDSS. He concludes that, in order to output accurate information (i.e., treatment guidance or decision support recommendations), a CDSS must process clinical data of "high" QoD. Similar to Hasan's study, Berner emphasizes the importance to monitor the quality of clinical data, provided as input to the CDSS, and to address the encountered problems, such as the treatment risk increment.
Fisher el al. [52] explore the use of data quality information by decision makers and conclude that experienced decision makers make use of this data quality information and adapt their decisions to provide best output. However, Fisher et al. investigate the phenomena in a broad setting, not specifically in a medical setting, and target humans as decision makers and not automated decision support systems.
Similarly, Cowie et al. [54] present a QoD model for mobile decision to better support the decision making process, if the human user is aware of the quality of the data used in deriving the decision. However, Cowie's study is not related to the healthcare domain, but addresses mobile decision support for normal day-to-day life situations (e.g. traveling). Besides, it does not augment the decision support knowledge so that the automated decision support adapts

it's decision to provide the best recommendation to the user. Instead, it is the human user who needs to interpret the visually represented QoD to determine the best possible decision.
Others [45, 55, 56, 57] present the impact of ICT-based technological resources may have on QoD used in home healthcare services and pervasive healthcare systems. For example, Vavilis et al. [55] present a semi-automated approach for assessing the quality of medical measurements in order to support medical practitioners in their decision making process. Additionally, similar to Cowie's approach, they also present the QoD information to medical practitioners. However, neither the potential negative consequences of QoD on treatments, nor methodologies to augment decision support knowledge with QoD-awareness mechanisms are studied in these approaches. In [57], Sriram et al. identifies the key challenges involved ensuring (and assessing) QoD, but they do not address a method to overcome the potential problems that occur in pervasive healthcare systems when QoD degradation is unavoidable.
Other researchers focus on the study of data quality [49, 58, 59], quality of service (QoS) [60], quality of context (QoC) [61] and quality of experience (QoE) [62]. QoS usually refers to the quality of the ITC resources used to provide the data (e.g. loss ration, delay). QoC is closely related to quality of sensor data used to collect context data. QoE is the subjective perception of the users on the service provided. These studies, including the cited quality of data studies, are mainly focused on the factors that influence the quality of data, service, context or experience respectively, and the dimensions or indicators required to assess this quality. But they do not provide a clear method to integrate QoD, QoS, QoC or QoE in the application domain, so that the application domain can benefit from this information (e.g. adapt the service).
Finally, the European Union (EU) has recently shown concern regarding data quality in mHealth applications [53, 63]. They report that *"Ensuring quality of the data that health apps collect and process is also essential for linking applications to electronic health records and for their effective uptake in clinical practice."* Hence, the EU is studying how to develop guidelines that can assess the validity and reliability of the data that health applications collect and process. One of their concerns is how the technological resources, such as ubiquitous and flexible networks, influence the mHealth apps [53, 63]. So, they consider technological context as one of the potential cause of QoD degradation, which is aligned with our work.

2.3 CONCLUSIONS

The research studies discussed in this chapter address potential negative effects of clinical data quality on healthcare environments. However, they do not propose a method to incorporate QoD-awareness in telemedicine systems that preserve treatment effectiveness and prevent potential situations that may put a patient's safety at risk. Additionally, there is not a method to design QoD-aware telemedicine system that follows EBM principles.
In this thesis, we aim to fill the gaps that have not been covered by these studies, and develop a method to make telemedicine systems QoD-aware in order to maintain treatment efficacy and prevent putting patient's safety at risk.

CHAPTER 3

RESEARCH DESIGN APPROACH

This chapter describes the approach we conduct to designs a QoD-aware telemedicine system.
This chapter is organized as follows. Section 3.1 summarizes our interpretation of the concepts of requirements elicitation, system requirements, system architecture, domain knowledge, and domain ontology, which play an important role in the rest of this chapter. Section 3.2 presents the requirements elicitation method, which is used to acquire the domain knowledge of the relevant stakeholders and to derive the functional requirements on a QoD-aware telemedicine system. Section 3.3 presents our context layering technique, which is used to structure and relate the domain knowledge of the two primary domains, i.e. the application domain (clinical domain) and the technological domain (ICT domain). To conclude, Section 3.4 explains how the requirements elicitation method and the context layering technique are applied in the following chapters to define, respectively, the functional requirements of a QoD-aware telemedicine system and the relevant knowledge on QoD from the clinical and technological domains.

3.1 RESEARCH DESIGN CONCEPTS

Our study of QoD-aware telemedicine systems builds on traditional software engineering methods. We briefly explain our interpretation of several related concepts, which are used in the remaining of this chapter to present our approach that is specialized to deal with the idiosyncrasies of QoD-aware telemedicine systems.

- **Requirements elicitation** is the process of collecting requirements regarding a system (under design). These requirements are usually identified by discussing with the stakeholders (who have an interest in the (future) system) their goals. These goals should be supported by the system. A particular stakeholder is the (end-) user, representing people who will use the functions of the system in their daily practice.

- **System requirements** are the requirements that should be satisfied during system design, i.e. when defining the architecture, components and data for the system.

- **System architecture** is a conceptual model of a system, one that defines the structure, functions and behavior of the system. Often a system architecture is a design artifact, which is used to guide and coordinate the detailed design of the system and to build instances of the system.

- **Domain knowledge** is valid knowledge about an area of human endeavor and it plays key role in the requirements elicitation process. Domain experts are in the best position to express their needs and expectations (and also what they do not need and do not want), and such information can be used to derive system requirements. During the requirements elicitation process, requirements engineers assimilate knowledge from these different domains in order to produce (as complete as possible) a set of system requirements.

- **Domain ontology** is an unambiguous description of domain knowledge, usually through the use of some special (as opposed to natural) language. Having a domain ontology enables the reuse of domain knowledge for different applications, the verification for consistencies, and facilitates the requirements engineer in the process of eliciting the requirements from stakeholders (e.g. medical practitioners).

3.2 REQUIREMENTS ELICITATION METHOD

Requirements elicitation is an essential part of a system development process to successfully derive system requirements by analyzing the needs and goals of the stakeholders. In our research, we study how to design a QoD-aware patient guidance telemedicine system that complies with evidence-based principles. To develop such a system, we first apply a requirements elicitation (RE) method that is not concerned with QoD issues[64]. Next, we refine this

RE method in order to address QoD-awareness in such telemedicine systems.

3.2.1 BACKGROUND OF THE RE METHOD

The applied RE method is based on Benyon and Macaulay [65] and it has been adopted in earlier work [16, 66]. We further developed this method in [64] in order to address the requirements of a mobile patient guidance system that supports evidence-based treatments in an extramural environment (without human medical supervision). There are three main roles involved in this RE method:

- Medical researchers: medical researchers understand the needs of the healthcare system, are familiar with ICT and have medical knowledge. Therefore, they are in a position to specify the requirements of an envisioned system from the clinical perspective. However, as discussed in [64], medical researchers seldom take part in the RE process. In their absence, we propose to replace this role by a team of medical practitioners and requirements engineers. Medical practitioners may have time constraints, but have the medical expertise and ideas for new treatments. Requirements engineers with knowledge of ICT and available time need to take the role of "medical assistant". For that, these engineers need to undertake studies across their disciplinary boundary to enable effective collaboration with the medical practitioners [64].

- ICT experts: ICT experts understand the technological domain and the available ICT that could be used to develop the envisioned system. Hence, they are capable to develop solutions for the application domain problems.

- Requirements engineers: Requirements engineers must become familiar with both the application and the technological domain, in order to derive requirements that make sense in the application domain and that are feasible in the technological domain. Often, their role is close to ICT experts role and, therefore, in the described RE method ICT domains experts role is taken by requirements engineers. Usually, they do not have extended medical background, but are able to determine the system requirements from a technical perspective.

The applied RE method has two stages: 1) the first stage, where the **clinical oriented user activities** are the focus; 2) the second stage, where the

user-system interactions are the focus [64]. Both stages are merged when a consensus is reached between medical researchers (or a team of medical practitioners and "medical assistants") and requirements engineers.

1. In the first stage of the applied RE method, medical researchers develop an **iPACT** (medical) scenario from a clinical perspective. iPACT describes the ***i**ntention* of the envisioned system (e.g. supporting outpatients' treatment guidance) by ***P**eople* who directly interact with this system (e.g. the end-users) and their treatment related **A**ctivities (e.g. a walking physical exercise) in a particular ***C**ontext* (e.g. an outdoors exercise activity) supported by ***T**echnology* (e.g. the envisioned mobile patient guidance system). iPACT is used by medical researchers to build a medical scenario from a user's perspective, describing the thread of main activities for the patient treatment prescribed by the medical practitioner using the system. In this RE method, medical researchers describe an iPACT scenario in an *"ideal"* situation by assuming that the applied technology performs adequately and the quality of the measured and processed clinical data fulfills the treatment requirements.

2. In the second stage, the requirements engineers analyze the user-system interactions required to complement the first stage medical scenario and extend the scenario with **FICS** elements. FICS stands for ***F**unctionality* of the intended telemedicine system, user-system ***I**nteractions*, ***C**ontent* of these interactions, and the intended system's ***S**ervices* which are constituted by the interactions [64]. This stage is conducted by requirements engineers, as shown in Figure 3.1. Requirements engineers propose FICS elements that can support the iPACT activities. The FICS analysis is concluded by adding the user-envisioned system interactions to the iPACT scenario, called the iPACT-FICS scenario (see Appendix A).

To reach consensus on the final content of the iPACT-FICS scenario, the medical researchers and requirements engineers conduct a "handshake protocol". First, medical researchers study the iPACT-FICS scenario and, if necessary, make modifications. These modifications have to be approved by the requirements engineers. This is an iterative process and it stops when a common agreement between both sides is reached (Figure 3.1).

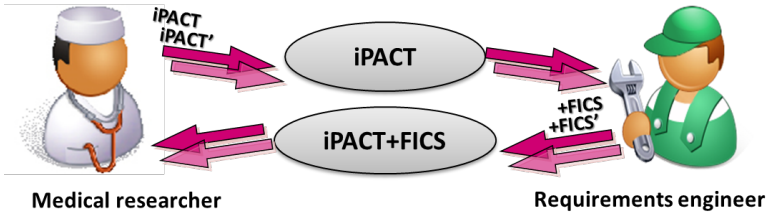


Figure 3.1: iPACT-FICS Requirements Elicitation Method [2]

3.2.2 RE METHOD FOR QOD-AWARENESS

This research study focuses on QoD from the telemedicine system's technological context point of view (see Chapter 1). Therefore, in order to comprise QoD-awareness in a telemedicine system, we refine the iPACT-FICS RE method.

In the previous RE method, the envisioned system is a telemedicine system assumed to perform without disruptions of technological resources (*Ideal Case*). Hence, the system's technological context is such that clinical requirements are always fulfilled (technological context variations are absent or so small that they do not impact clinical data quality).

In this RE method, we focus on the technological resources' disruptions (*Non-Ideal Case*), which lead to a new system's technological context (iPA<u>C</u>T). This new technological context may have an impact on patient treatment. Therefore, we introduce a QoD-aware telemedicine system as the selected technology (iPAC<u>T</u>). Additionally, we make medical researchers aware of the potential technological disruptions that can occur. Next, medical researchers determine how to adapt patient treatment activities (iP<u>A</u>CT), by taking precautionary measures to ensure patient safety. Therefore, this results in new iPACT' elements (and medical scenarios) where the intention (<u>i</u>PACT) of the envisioned system and the people (i<u>P</u>ACT) involved in the scenario remain the same, but the context (iPA<u>C</u>T), the activities (iP<u>A</u>CT) and the technology (iPAC<u>T</u>) differ. Consequently, the FICS elements, which describe the user-system interactions needed for the activities described in the iPACT scenario, may also differ. As a result, we obtain a new augmented iPACT'- FICS' scenario (see Figure 3.1), which enhances ("guarantees") patient safety when technological disruptions occur.

In the *Ideal Case*, the context solely considers personal context (e.g. holidays) where no technological disruptions occur. Hence, the envisioned system design and the treatment activities are not affected by technological disruptions.

However, in the *Non-Ideal Case*, the context also addresses technological contexts where technological resources' disruptions may occur (see Appendix A). Consequently, this new context leads to new activities and technology which needs to be technological context-aware in terms of QoD-awareness.
For example, during an outdoor physical exercise treatment, the intention (i) is to support an out-patient's physical exercise treatment guidance and the people (P) is a cardiac out-patient for both the *Ideal Case* and *Non-Ideal Case*. In the *Ideal Case*, the activity (A) is to perform physical exercise in an 'ideal' context (C) with the support of the envisioned telemedicine system technology (T); while in the *Non-Ideal Case*, the context (C) is 'non-ideal'. So the envisioned system is a QoD-aware telemedicine system technology (T), which provides an adapted physical exercise activity (A) that enhances patient safety when the QoD is degraded 'too much'.
In order to represent how we develop the phenomena related to QoD and identify the functional requirements for the design of a QoD-aware telemedicine system, we applied the iPACT'-FICS' analysis into the atrial fibrillation and gestational diabetes medical case studies (empirical approach). In Appendix A, we present an instance of the iPACT'-FICS' analysis for the atrial fibrillation medical case study applied in the MobiGuide (MG) project [4].

3.3 CONTEXT LAYERING TECHNIQUE

The context layering technique supports the study of the conceptual model for QoD-aware treatment guidance. This technique separates both the clinical and the technological contexts, and builds the relations between them. First, we study the functional relation between the concepts of the clinical domain and technological domain. In the second stage, we study the non-functional ('qualitative') relation between these concepts. We refer to the clinical domain as the clinical layer and the technological domain as the technological layer.
In order to illustrate the context layering technique, we provide examples of the concepts used. This research can be tailored to many different healthcare conditions or cases in the medical domain. Here, we give an introduction of one of the case studies used for this research (atrial fibrillation) and introduce one simplified scenario applied in MG.

Example: Physical exercise treatment for Atrial Fibrillation (AF) patients.
AF is a supra-ventricular tachyarrhythmia characterized by uncoordinated atrial activation with consequent deterioration of atrial mechanical function [67]. Stimulants such as caffeine or exercise may precipitate AF [67]. Nev-

ertheless, physical exercise (e.g. walking) treatment usually improves the cardiovascular condition of an AF cardiac patient [68]. For that, we study the adequacy of heart rate control across a full spectrum of activities of patients with persistent or permanent AF. In order to determine the heart rate control for each patient, a cardiologist conducts a supervised stress test, like the treadmill Bruce test [69]. The output of this test will be used by the cardiologist to determine the patient's HR safe low and high boundaries for different phases of the patient outdoor physical exercise: "pre-exercise (rest)", "warming up", "target training", "cool-down", "post-exercise (rest)" (Figure 3.2).

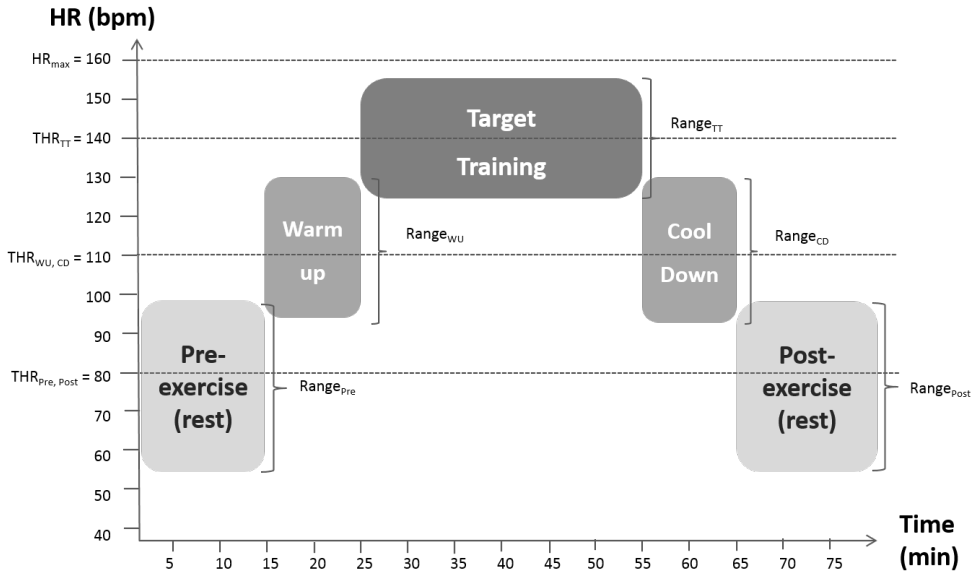


Figure 3.2: Example of heart rate ranges of the physical exercise treatment, specifying the target HR (THR) and the range for each of the phases: target training (TT), warming up (WU), cool down (CD) and pre- and post-exercise (Pre, Post)

3.3.1 FUNCTIONAL RELATION

In this study we use the term functional relation to refer to the relation or dependency that exists between data of the clinical layer and data of the technological layer. Furthermore, we structure data of the clinical layer in terms of **clinical abstractions**, which represent medically meaningful information relevant for clinical treatment decisions. Clinical abstractions are used at the

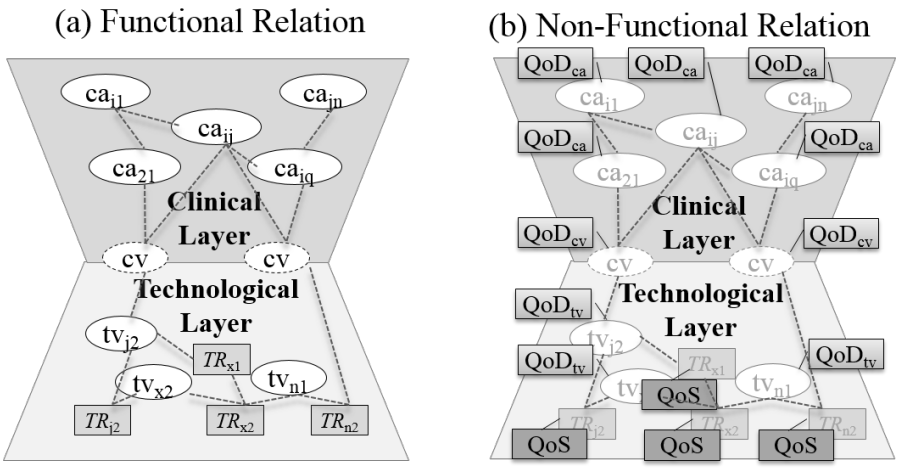


Figure 3.3: Context layering technique representation: (a) Functional relation between clinical abstractions (ca), clinical variables (cv) and technological variables (tv) with technological resources (TR); (b) Non-functional relation of QoD and QoS relation.[2]

point of clinical decision. Similarly, we structure data at the technological layer in terms of **technological variables**, which represent data captured at available points of monitoring of the telemedicine system through technological resources. As an intermediate concept, we use **clinical variables** which are lower level clinical abstractions dependent on the availability of ICT. We distinguish clinical variables from clinical abstractions to build the bridge between the clinical layer and the technological layer. By having these intermediate elements we can have a separation of concerns between the clinical domain and technological domain.
This context layering technique is modeled as an hourglass, as illustrated in Figure 3.3. A large set of clinical abstractions are associated to a small set of clinical variables since multiple clinical abstractions may use same clinical variables. Furthermore, a small set of clinical variables are associated to a large set of technological variables since we need several technological variables to obtain a clinical variable.

Here, we present each of the concepts (clinical abstraction, clinical variables and, technological variables) identified in the functional relation and describe their relationship:

- **Clinical abstraction**

  A clinical abstraction has a context dependent clinical interpretation. Clinical abstractions can be hierarchically related. Higher level clinical abstractions (e.g. physical exercise over-exertion over 30 seconds) are ultimately related to a set of lower level clinical abstractions, i.e. clinical variables (e.g. heart rate (HR)) [54, 70]. A clinical abstraction typically has a temporal dimension, i.e. the abstraction represents a phenomenon with properties that change over time. The context of the phenomenon can be an applied medical protocol or an exerted clinical guideline.

  Example:
  The HR ranges shown in Figure 3.4 together with the monitored HR (mHR) are clinical abstractions in this physical exercise scenario. Their usage guarantees a safe and effective physical training. These abstractions have a temporal dimension: mHR of a patient fluctuates in time within a predetermined range (e.g. 10%) of the Target HR (THR) (Figure 3.4). THR is the clinical abstraction of the maximum HR value (HR_{max}) of a patient, multiplied by an intensity factor (I_{fact}) of the particular patient (with values between (0, 1)).
  During a supervised treadmill physical activity Bruce stress test [69], the cardiologist determines HR_{max} and I_{fact} in order to keep the telemedicine treatment safe and effective in an unsupervised extramural physical exercise environment (Figure 3.2). The HR_{max} can be determined with formulas or by the cardiologist based on the patient condition, and the I_{fact} is determined by the cardiologist based on the patient condition.

  Using a safety margin of Range/2 with respect to THR, with $THR := HR_{\max} \times I_{\text{fact}}$, one can distinguish between three cases when measuring mHR:
  1) over-exertion when $mHR > THR + Range/2$
  2) under-exertion when $mHR < THR - Range/2$
  3) on target when $mHR \in [(THR - Range/2), (THR + Range/2)]$
  The latter case is referred to as the clinical abstraction mHR-THR (Figure 3.5).
  If, during a physical exercise, the clinical abstraction mHR-THR is not observed (mHR is out of the ranges) for a certain specified time (e.g. T = 2 min), an over-exertion or an under-exertion case is triggered. This generates a message to the patient to slow down or to speed up respectively. When mHR is greater than HR_{max}, the precautions delivered should be stronger,

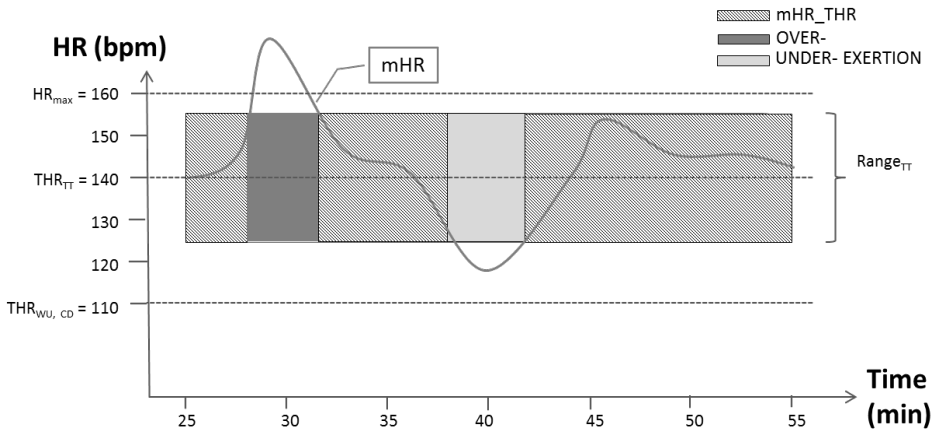


Figure 3.4: mHR-THR clinical abstraction of AF physical exercise treatment during target training phase, and specification of mHR in the target training range (Range_{TT}) and specification of the target HR (THR) for target training (THR_{TT}), warming up (THR_{WU}), cool down (THR_{CD}) and maximum HR (HR_{max})

and the message to the patient may be to stop and rest, or even to call a family member to avoid any potentially risky situations.

- **Clinical Variables**

  Clinical variables are elementary variables which represent a patient's vital signs and some commonly used trend signs known in medicine (e.g. BP, HR). On the one hand, these clinical variables form the lowest level clinical abstractions which are used in the definition of higher level abstractions. On the other hand, these clinical variables result from the technological variables in the technological layer. Therefore, clinical variables act as intermediate elements between high level clinical concepts and data variables at the technological level, as illustrated in Figure 3.5 a.

  Example:
  In the AF physical exercise scenario, the monitored HR (mHR) is used by the mHR-TH clinical abstraction to determine if the patient is over- or under-exercising. Additionally, the mHR is the output of technological resources and, hence, is the outcome of technological variables as discussed next. Therefore, the mHR is a clear example of a clinical variable used to link concepts from the technological and the clinical domain (Figure 3.5 b).

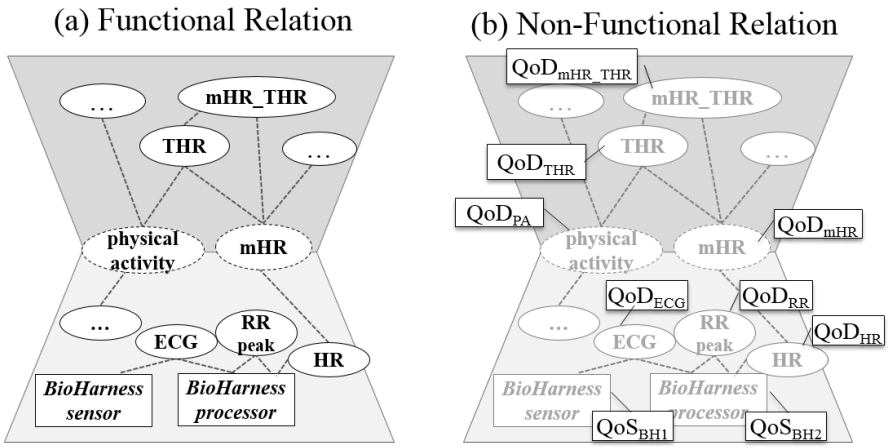


Figure 3.5: Example application of the context layering technique for: (a) Functional relation; (b) Non-functional relation of QoD and QoS relation

- **Technological Variables**

  The technological layer comprises technological variables, which is data data produced by technological resources. It can go through several levels of processing, from 'unprocessed' raw data to structured data, but without human or clinical interpretation. Technological variables are produced (measured) at a point of monitoring, (pre)processed and transferred to the point of decision by technological resources. For example, sensors produce data for the electrocardiogram (ECG) technological variable, which is preprocessed (e.g. RR peaks and HR) and transferred by other technological resources. At the point of decision, technological variables are interpreted as clinical variables, usually represented by the patient's vital-signs, like the mHR (Figure 3.5 a).

  Example:
  In the AF physical exercise treatment case, technological resources provide technological variables at the point of monitoring. The BioHarness sensor [71] measures the patient's electrocardiogram (ECG). The BioHarness processor derives the HR technological variable from the R-R peaks of the measured ECG (Figure 3.5 a). This HR trend sign is wirelessly transmitted; and at the point of decision it is defined as mHR clinical variable, which will be used for treatment purposes.

Figure 3.5 illustrates an example application of the context layering technique

to determine functional and non-fucntional relations. It uses the examples presented in the body text for each concept. The functional relation (Figure 3.5 a) illustrates the relations between different concepts in the clinical and technological layer, which is formalized in an ontology (Chapter 4).
The non-functional relation (Figure 3.5 b) illustrates the relations between the quality attributes of these concepts. In the later examples, we refer to this figure for better understanding.

3.3.2 NON-FUNCTIONAL RELATION

To make the system QoD-aware, we need to determine the qualitative relation between clinical abstractions, clinical variables and technological variables. For this, we first reflect on the quality of service (QoS) of technological resources, which determines the system's technological context and then, we analyze how the QoS contributes to the QoD variations.

- **Quality-of-Service**

  The performance properties of technological resources determine the QoS of these technological resources. We characterize QoS of technological resources with Resource Qualifying Parameters (RQP). RQPs are static, i.e. derived beforehand from the manufacturers' specification of these technological resources, or dynamic, i.e. based on changing values provided by the technological resources during runtime [19].
  These RQPs are the basic elements used to compute QoD by following the algebraic computational models described in Chapter 7. For example, mobile internet connectivity (which affects data availability) and an algorithm's robustness against noise (which affects data accuracy) are RQPs used to compute certain QoD attributes of the data. Furthermore, other factors such as environmental circumstances also contribute to the technological resources' performance and they are modeled as RQPs. For example, the environmental temperature where a measurement is performed may influence the performance of a device affecting the output data quality; or rainy weather conditions can alter the internet connectivity causing data transmission delays or data loss.
  We also investigate the usage of technological resources by the patient since it possibly influences QoD. Therefore, we model user characteristics (e.g. patient education) as RQPs. For example, BP has to be measured by the patient while s/he is sitting in a relaxed condition to provide an accurate

measurement. If the patient is not instructed to perform the measurement correctly (e.g. s/he stands up during the measurement), the QoD of BP value degrades and may not be clinically valid. Another example of a user characteristic is patient trustworthiness. Some patients perform measurements at their convenience in order to produce the clinical data values that they are content with. This has a significant impact on QoD and, therefore, on the patient treatment. Additionally, when data is manually entered, typing errors might occur. Therefore, the trustworthiness of manual input can be considered lower than the trustworthiness of automatic input.

- **Relation between QoS and QoD**

  In our research we first study the relation of QoD when the technological context is compliant with the medical requirements (RE method - *Ideal Case* (Section 3.2)). This means that the QoS of the technological resources must fulfil the requirements to provide 'high' quality data. Accordingly, the QoS requirements of the relevant technological resources are specified in this phase, so that the QoD of technological variables and, as a consequence, the QoD of clinical variables and clinical abstractions fulfil the clinical quality requirements.
  In the revised RE method (*Non-Ideal Case*), the potential technological disruptions that alter the technological context and their potential effects on the QoD are studied. We first analyze the potential malfunctioning of technological resources and their respective QoS values in terms of RQPs. Then, we determine the impact of this QoS on the QoD of the technological variables in the technological layer and the impact of QoD of technological variables on the QoD of clinical variables and, ultimately, on the QoD of clinical abstractions.
  In Chapter 4, we present the QoD-framework ontology, which represents the formalization of this qualitative relation between QoS and QoD by considering both the clinical and the technological layer. In Chapter 5, the process to develop the treatment adaptation mechanisms that ensure the patient's safety (when QoD degrades) are presented.

3.4 APPLICATION OF THE APPROACH

In Chapter 1, we addressed the following design question *"How to design a QoD-aware patient guidance (telemedicine) system that preserves the patient's safety when QoD degrades?"*. The refined RE method and the context layering technique presented in this chapter are applied to develop

a conceptual model for QoD and to identify the functional requirements on a QoD-aware telemedicine system. Hence, they are the tools to answer this research question (Figure 3.6).

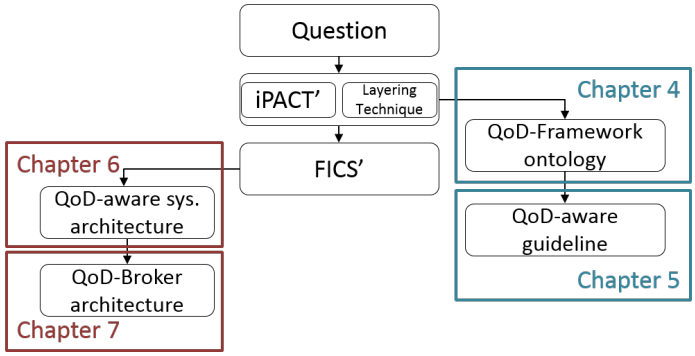


Figure 3.6: The result of the RE method and context layering technique

- The iPACT' analysis of the refined RE method focuses on the QoD-aware treatment guidance activities that will be executed by the patient or/and medical practitioners (who are the end-users of the system) with the usage of the system from a clinical perspective. This corresponds to QoD-aware telemedicine system knowledge represented by the QoD-framework ontology, which is further discussed in Chapter 4. However, in order to develop the QoD-framework ontology, we also developed a tool to link the conceptual and qualitative relation between concepts in the technological context and clinical context. We name this tool a 'context layering technique', since we separate both the technological layer and the clinical layer and address the concepts in each layer with their relation (Section 3.3). The clinical context addresses the treatment related concerns that are described in the clinical guideline. In Chapter 5, we discuss the process of formalizing the QoD-aware clinical guideline in an executable language, so that it can be executed by an autonomous clinical-decision-support-system (Figure 3.6).

- The FICS' elements of the refined RE method describe the user-system interactions and functions. Hence, from the FICS' analysis, we can derive the functional requirements of the QoD-aware telemedicine system.
  In Chapter 6, we first identify the high level functional requirements, which are the starting point for the design of the QoD-aware telemedicine system

architecture. Later, we identify the functional requirements at lower levels of abstraction, which leads to a more detailed system decomposition and description. In Chapter 7, we address the detailed functional requirements of the QoD Broker, which is one of the core components that enables QoD-awareness (Figure 3.6).

CHAPTER 4

QOD-FRAMEWORK ONTOLOGY

Quality of clinical data (QoD) plays an essential role in healthcare management. Therefore, providing a conceptual model of QoD in order to be able to reason about its causes and effects is essential to develop a QoD-aware telemedicine system. Here we present a conceptual model for QoD-aware telemedicine system in the form of an ontology, which is the result of the requirements elicitation (RE) method and the context layering technique presented in Chapter 3. This ontology captures the necessary knowledge for a QoD-aware telemedicine system.
This chapter is organized as follows: Section 4.1 provides background information on ontologies from related research studies. Section 4.2 presents our QoD-framework ontology. Section 4.3 demonstrates the applicability of this ontology in a QoD-aware telemedicine system. Section 4.4 discusses the presented ontology and briefs our conclusions regarding the impact of this ontology in healthcare systems.

4.1 BACKGROUND

As described by Paganelli [72], ontologies may help in:

1. *"specifying contextual knowledge in terms of classes of objects, relationships, and constraints on their properties;*
2. *describing contexts semantically in a way which is independent of programming languages, underlying operating systems, or middleware;*
3. *enabling formal analysis of domain knowledge, i.e. context reasoning*

using first-order logic, or temporal logic;

4. *deriving fresh knowledge and facts through reasoning on context data by using inference engines; and*

5. *enabling knowledge reuse, as ontologies of different domains can be composed and extended with new concepts in order to produce new ontologies without starting from scratch."*

Therefore, in our study we developed a QoD-framework ontology. Our QoD-framework ontology aims to capture the relations between the concepts in the clinical layer (patient treatment context) and the concepts in the technological layer (telemedicine system's technological context). This differs from most state of the art ontologies, which address either clinical guidelines, quality of data, or personal (user) context.
For example, in [72], Paganelli presents a personal context ontology for a specific home care application that supports patients in "alert" situations where patients might require assistance. The context entities include persons (e.g. patient, medical practitioner) and locations (e.g. patient's home and care center). The related context items include information on the patient's biomedical parameters (e.g. vital signs) and home living environment (e.g. temperature). The "alert" situations are attributed to the patient's clinical status (e.g. heart rate out of range) or external environmental situations (e.g. temperature out of range). Other studies address QoD related ontologies, which describe the QoD dimensions [49] that represent different QoD aspects. Moreover, in recent years ontologies have been used to represent clinical guidelines [73, 74]. The usage of clinical guidelines in information systems, such as Clinical Decision Support Systems (CDSS), has contributed to this ontology application. The formalization of a clinical guideline in an ontology supports the implementation of a computer interpretable guideline (CIG), applied in guideline-based CDSS (Section 4.3.2). However, these studies don't merge technological context, clinical data quality and treatment guidance.

4.2 Towards a Stratified QoD Ontology

The telemedicine system's QoD-framework ontology, developed in this research, consists of two parts:

1. the **technical domain ontology**, which captures the knowledge on the technological layer, including the relation between the technological context and the QoD relevant to clinical variables (Section 4.2.1).

2. the **clinical domain ontology**, which captures the knowledge on the clinical layer, including the relation between the QoD and the patient treatment (Section 4.2.2).

As discussed in Section 3.3.1, the clinical variable is the intermediate element that links both domains, and hence, it is part of both domains' ontology (Figure 4.1). Additionally, the clinical variable facilitates the separation of concerns between the clinical layer and the technological layer and enables the development of this distributed ontology.
This QoD-framework ontology has been specified with the Web Ontology Language (OWL) [75]. In Figure 4.1, the OWL ontology is represented by means of Unified Modeling Language (UML) class diagrams. UML classes represent OWL classes, UML class attributes represent OWL datatype properties, and UML associations among classes are used for representing OWL object properties. Figure 4.1 represents the main classes of both the clinical and technological ontology to give the overview of the whole ontology.

4.2.1 Technical Domain Ontology

In the lower part of Figure 4.1 we illustrate the technical domain ontology (high abstraction level), which corresponds to the technical part of the layering technique (Section 3.3) and it is the technical knowledge used by the system.
The technical domain ontology describes the technological context, which is characterized by the performance of the comprising technological resources. The technological resources enable the monitoring of ambulatory patient's vital signs, which leads into clinical data. Hence, the technological context provides clinical data with QoD related information.
As discussed in Section 3.3.2, the performance of each technological resource is determined by its resource qualifying parameters (RQPs). As shown in Figure 4.1, RQPs have a name, type (static or dynamic), a maximum and

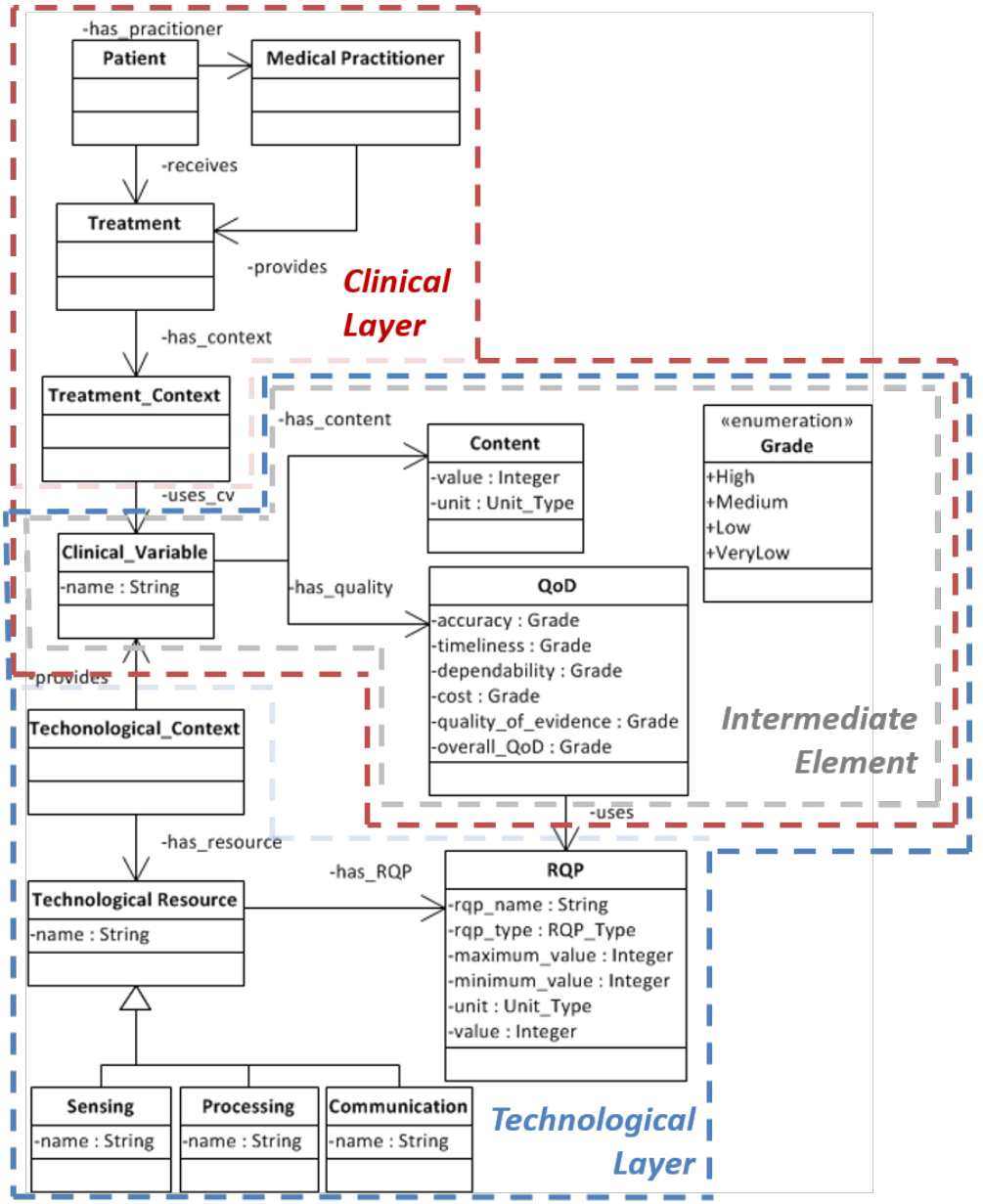


Figure 4.1: QoD-Framework Ontology Overview [3]

minimum value (usually for static RQPs), a unit and a value. Each technological resource can have one or more RQPs and the RQPs are either static or dynamic [19]. Static RQP values are usually provided by the technological resource manufacturer and represent the properties of this resource (or device). For example, the BioHarness manufacturer provides the specification of the system [71], such as the sample frequency of the general log data (e.g. 1 Hz). This information is potentially used to determine the quality of clinical data. Dynamic RQP values are obtained during system execution time and can vary. For example, the battery level of the BioHarness system fluctuates over time.
The RPQs of technological resources are associated with one or more QoD dimension(s) of the provided clinical variables [2, 19]. Accordingly, Figure 4.1 shows that grades for the QoD dimensions of a clinical variable are computed using the associated RQPs. Following the criteria discussed in Chapter 7, we adopt the following five QoD dimensions: Accuracy, Timeliness, Dependability, Cost, and Quality of Evidence, and compute an overall QoD that comprises the five QoD dimensions (Figure 4.1). The QoD dimensions and the overall QoD are graded —High, Medium, Low and Very Low —by using a stratification model (see Chapter 7).
The technological context can vary not only due to the performance variations of the technological resources, but also due to the specific use of these technological resources. In certain scenarios it is possible to choose between alternative technological resources. These alternative resources (e.g. Wi-Fi or 4G connection for data transfer) have the same (abstract) functionality, but different RQP characteristics. Therefore, depending on the chosen technological resource, the RQPs (e.g. subscription cost, transmission delay, and trustworthiness) will differ. Consequently, a different technological context exists that provides the same data but with different QoD grades. These technological resource configuration chains are used to optimize the output data quality [76].
As the focus of the research is the impact of technological context on QoD, we address ICT-based technological resources that influence QoD from the technological context point of view. We exclude other features, such as security and integration features of technological resources. Accordingly, this research classifies the technological resources into three categories: sensing components, processing components and communication components (Table 4.1).

1. *Sensing components* comprise a comprehensive set of data acquisition devices, which provide all relevant "raw" physiological data of a patient

(e.g. an electrocardiogram). These devices are located at the point of monitoring. An instantiation of a sensing component can be the BioHarness sensor system [71] which provides RQPs, such as the battery level and signal to noise ratio (SNR) information (see Table 4.2).

2. *Processing components* comprise algorithms or processes that can analyze and interpret the sensed "raw" data. Usually the output consists of clinical variables or higher level clinical data abstractions. For example, the BioHarness processor is a processing component (Table 4.1). First, it acquires an electrocardiogram signal and detects, for example, the R peaks of the electrocardiogram, which are higher level clinical data abstractions. An accurate 'R peak' detection is essential to derive a trustworthy HR measurement [77]. Hence, it applies signal processing functions to determine the HR or AF episodes. This BioHarness processor can have RQPs, for example, the battery consumption or robustness against noise to detect AF episodes, determined by sensitivity and specificity RQPs (Figure 7.6).

3. *Communication components* are composed of wired and wireless components that enable data transmission between a set of sensing and processing components from the point of monitoring to the point of decision. Wireless communication includes, for example, Bluetooth, Wi-Fi and 4G, and wired communication includes, for example, twisted-pair, cable and fiber-optic communication. RQPs that may characterize the performance of the communication components are the data transmission cost, bandwidth, availability and communication range.

Example:
In the following tables (Table 4.1, Table 4.2, Table 4.3), we present a simplified example of a use case study used in the QoD-aware telemedicine system development.
Table 4.1 presents an example of a technological context, which comprises three technological resources, one for each technological resource type.
Table 4.2 contains the RQP instantiations of each technological resource presented in Table 4.1, which characterize the performance of the technological resources, and consequently the technological context. The instantiations are specified by the RPQ datatype properties. These are some of the RQP instantiations used to compute the grades of the five QoD dimensions and the overall QoD (Table 4.3).

Table 4.3 addresses the heart rate clinical variable, which is the output of the combined use of the technological resources listed in Table 4.1, and its associated QoD information (grades of the five QoD dimensions and the overall QoD).

Class		Individual
Technological Resource	Sensing	BH sensor
	Processing	BH processor
	Communication	Bluetooth

Table 4.1: Example of the technological resources in a technological context

Class	Individual
RQP (BH sensor)	rqp-name: BH-sensor-battery, rqp-type: dynamic, max: 100, min: 0, unit: %, value: 5 rqp-name: BH-sensor-SNR, rqp-type: dynamic, max:30, min:-30, unit: dB, value: 0
RQP (BH processor)	rqp-name: BH-processor-battery, rqp-type: dynamic, max: 100, min: 0, unit: %, value: 86
RQP (Bluetooth)	rqp-name: Bluetooth-range, rqp-type: static, max:10, min: 0, unit: meter, value: - rqp-name: Bluetooth-range-value, rqp-type: static, max: 10, min: 0, unit: meter, value: 5

Table 4.2: Example of resource qualifying parameters of each technological resource

Class	Datatype	Individual
Clinical Variable	Name	heart-rate
Content	value	85
	unit	bpm
QoD	accuracy	low
	timeliness	high
	dependability	very low
	cost	low
	qoEvidence	high
	overallQoD	low

Table 4.3: Example of a clinical variable and its associated QoD values

4.2.2 CLINICAL DOMAIN ONTOLOGY

In the upper part of Figure 4.1, we illustrate the clinical domain ontology (high abstraction level), which correspond to the clinical part of the context layering technique (Section 3.3) and is the clinical knowledge used by the system. Hence, this ontology represents the treatment guidance knowledge.
The clinical domain ontology shows that a patient receives a treatment, and has a medical practitioner, who provides the treatment. The treatment class has a treatment context, which makes use of clinical variables. The QoD of the clinical variables (which are characterized by the underlying technological context) characterize the treatment context. Consequently, the QoD has an impact on the treatment activities, which are adapted based on related medical requirements specified by medical researchers (see Chapter 5).

Example:
We continue with the previous example presented in Section 4.2.1. On the one hand, clinical variables have certain quality grades (Table 4.3), which are based on a specific technological context. On the other hand, a treatment (e.g. a physical exercise treatment) is provided by a medical practitioner (e.g. a cardiologist) to a patient (e.g. a cardiac patient). In an unsupervised outdoor physical exercise treatment context with degraded QoD of the HR clinical variable (Table 4.3), the telemedicine system that guides a cardiac patient must adapt the treatment according to this clinical variable QoD. Hence, the clinical domain ontology integrates the treatment adaptation mechanisms necessitated by degraded QoD, as defined during the RE method.
Table 4.4 presents an example of potential treatment adaptations that are described in the ontology. This adaptation is triggered when the treatment context is characterized by HR clinical data with QoD grades of Table 4.3. As shown in Section 3.3.1, the outdoor physical exercise treatment uses THR clinical abstraction (THR = HR_{max} x I_{fact}) to determine the intensity level of the prescribed physical exercise treatment, based on a measured patient maximum HR (HR_{max}) and an intensity factor (I_{fact}).
As shown in Table 4.4, when the overall QoD of monitored HR is “Low”, the intensity factor used to determine the prescribed physical exercise intensity level is lowered by 10%. Consequently, the QoD-aware telemedicine system ensures that the patient will not be advised to perform a strenuous exercise. Besides, if the overall QoD of the monitored HR is “Very Low”, potentially caused by insufficient HR sensor battery levels (i.e. not able to ensure avail-

Class	Individual	Class	Individual
QoD (overall QoD)	High Medium Low Very Low	Physical exercise treatment adaptation	- $I_{fact} = I_{fact}$ -5% x I_{fact} $I_{fact} = I_{fact}$ -10 x I_{fact} Treatment delay: 1 hour

Table 4.4: Example of the treatment adaptation

able data during the treatment), the system will delay the treatment for 1 hour (e.g. to sufficiently recharge the sensor). For every QoD dimension and every grade, we may have a different treatment adaptation mechanism. In Chapter 7, we describe, in more detail, how we use QoD dimensions and their grades to determine their effects on patient treatment.

4.3 QOD-FRAMEWORK ONTOLOGY APPLICATION

As presented in Chapter 1, this work is being applied in the MobiGuide (MG) European project [4], which aims to develop a QoD-aware patient guidance telemedicine system. The two main software components in charge of the QoD-awareness in the MG system are:

1. The **QoD Broker**, which is a component that translates the technological context information into QoD and aims to preserve (or improve) QoD.

2. The **clinical decision support system (CDSS)**, which uses potentially relevant information, such as the clinical data and its quality, to safely guide patients during their treatment.

Thereby, the QoD-framework ontology presented in Section 4.2 represents the knowledge required by the QoD Broker and the CDSS. This way, the telemedicine system is able to provide QoD-aware treatment that is safe and effective.

4.3.1 QOD BROKER

The QoD Broker computes the QoD dimensions' grades of clinical variables based on acquired technological resources' specific performance information (i.e., RQPs), and by applying computational models described in Section 7.3.1 and [19]. The knowledge used by the QoD Broker is specified in a QoD Manifesto (XML file) and contains the technical domain ontology presented in

Section 4.2.1. Depending on the medical case, the QoD Broker uses a treatment specific QoD Manifesto, so that the computation of QoD corresponds to the requirements defined on each medical case. The QoD Broker sends the computed QoD information to the CDSS, which processes the QoD information together with the clinical data to provide QoD-aware treatment support (Figure 4.2).

4.3.2 CDSS

In the MG telemedicine system, the CDSS uses evidence-based clinical guidelines to provide treatment guidance to the patient. As described by Peleg [78], guideline-based CDSSs need to apply a computer interpretable representation of the clinical knowledge contained in the guidelines; i.e. a computer interpretable guideline (CIG). The presented clinical domain ontology (Section 4.2.2) represents the formalized guideline augmented with technological context information described in terms of QoD. This augmented guideline is known as the Context Customized CIG (CCC) (see Chapter 5). As a result, the CDSS will receive the CCC guideline knowledge, and the output of the CDSS will be a safe QoD-aware treatment guidance (Figure 4.2).

In Chapter 6 and Chapter 7 we describe, in more detail, the CDSS and QoD Broker functionalities, architecture and interactions with the other system components.

4.4 DISCUSSION

The QoD-Framework ontology is the result of applying our RE method together with the context layering technique. This ontology covers both the technological domain knowledge (translation of technological context into QoD) and the clinical domain knowledge (treatment guidance considering QoD information). The separation of knowledge in two domains is necessary since the clinical guideline must not be "polluted" with technological information. The chosen approach also makes it possible to discuss technological context issues in terms of QoD with medical practitioners, who understand this quality concept, without discussing the technical details.
Additionally, we show how the ontology is applied in a real-world telemedicine system that enables safe QoD-aware patient treatment. The technical domain ontology is used by a telemedicine system component in charge of translating the technological context information into QoD information; and the clinical domain ontology is used by a clinical decision support system that

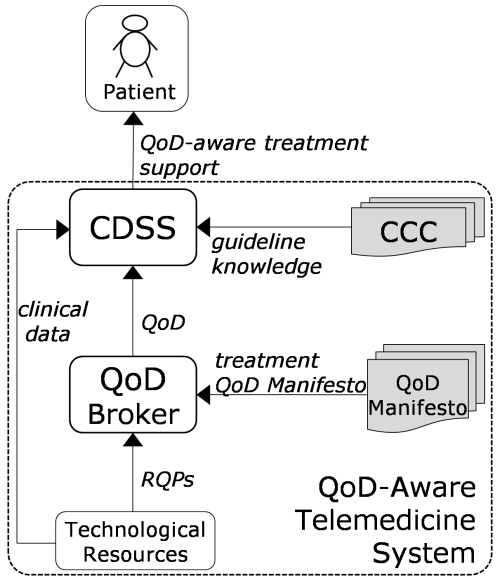


Figure 4.2: High level design of the QoD-aware telemedicine system with QoD-Framework ontology formalized in the Context Customized CIG (CCC) and QoD Manifesto [3]

uses this QoD information, together with the clinical data, to guide patients during the treatment.

We presented one of the use cases of MG [4], where a particular technological context, characterized by the performance of technological resources, leads to a clinical variable quality that affects the treatment (Section 4.2). This use case shows that the approach performs as we expected. The use case also illustrates how the technical domain ontology can be stored in a software agent that outputs QoD and how the clinical domain ontology can be stored in a different software agent that uses QoD and other relevant clinical information (e.g. clinical data) to provide patient treatment guidance. This separation of concerns makes it possible to include additional technological resources information in the QoD Manifesto without the necessity of modifying the CCC. Hence, the QoD-framework ontology positions the clinical domain ontology in the CDSS knowledge-base (i.e. CCC) and the technical domain ontology in the QoD Broker knowledge-base (i.e. QoD Manifesto), avoiding a "polluted" set of clinical guidelines.

In Section 4.3 we have shown that the proposed QoD-framework ontology is feasible to be developed in a QoD-aware telemedicine system. Our vision of

the future is a whole generic healthcare system ontology that addresses QoD, since QoD may have a major effect on patient treatment. Our QoD-framework ontology represents knowledge of a QoD-aware telemedicine system that can be used to support the development of future pervasive healthcare applications that are resilient to technological resources disruptions. The presented ontology is designed to be generic, but does not address some other relevant features, such as personal context and preferences. However, we give room to extend this ontology with other significant features.
In Chapter 8 we discuss the validation activity conducted to validate the ontology in a participatory design setting involving medical practitioners (Section 8.3).

CHAPTER 5

QUALITY OF CLINICAL DATA AWARE GUIDELINES FOR DECISION SUPPORT SYSTEMS IN TELEMEDICINE

As discussed in Chapter 2, several studies address "quality" and "quality of data" as crucial concepts in clinical guidelines and in clinical decision support systems (CDSSs). Generally, a CDSS is assumed to apply the guidelines correctly and use the "best" possible quality of clinical data (QoD) [24]. However, fluctuations in QoD, caused by technological context variations, may result in potentially "wrong" recommendations. As seen in Chapter 2, some studies discuss the potential negative effects of "low" QoD on the output of these systems. Unfortunately, these studies fail to suggest a method that copes with potential negative effects of degraded QoD on the CDSS output.

In this chapter, we propose a QoD-aware CIG development method to prevent "wrong" recommendations and a potential risk increment of patient treatment supported by a guideline-based CDSS. We apply our requirements elicitation method and the context layering technique (see Chapter 3) to determine the impact of QoD on patient treatment. Subsequently, we augment the clinical guidelines with QoD-awareness by including treatment adaptation mechanisms. As a result, we develop a QoD-aware guideline, executed by a CDSS, in the context of telemedicine systems in pervasive healthcare.

The rest of the chapter is organized as follows. Section 5.1 analyses, in detail, the problem that motivated this work. Section 5.2 presents the method we have implemented to achieve our goal. Section 5.3 presents a case study of the applied method and shows the results of the developed prototype using

our method. Finally, Section 5.4 concludes with an overview of the achieved results.

5.1 PROBLEM ANALYSIS

As discussed in Chapter 1, clinical treatments, including the ones described in clinical guidelines, comprise a risk. The ISO 31000 (2009) / ISO Guide 73:2002 defines risk as the *"effect of uncertainty on objectives"*. According to this definition, risk is caused by events whose occurrence and intensity is uncertain (i.e. there is ambiguity or lack of information about these events). It also includes both negative and positive impacts on objectives. We study the risk of treatment (RoT) and define it as "the probability that a given treatment guidance causes harm or inconvenience to the treated patient".
In theory, medical practitioners do not prescribe or conduct a treatment if the risk is above an acceptable risk level (RoT_A). This RoT_A is implicitly determined by the medical practitioner for each patient, disease and treatment option. RoT_A is the threshold for treatment: above this threshold the probability of causing unacceptable harm or inconvenience to the patient is considered "too" high.
In current medical practice, (QoD-unaware) treatment guidelines do not adapt patient treatment based on QoD degradation. However, we cannot always prevent QoD degradation, particularly in pervasive healthcare, where clinical data is vulnerable to technological resource performance variations. Hence, when QoD decreases below an acceptable QoD threshold (QoD_A), the CDSS guideline will provide a potentially "wrong" guidance recommendation. As a consequence, RoT might increase above the RoT_A threshold, putting the patient's safety at risk [9].
Figure 5.1 illustrates a potential relation between QoD and RoT in the case of a QoD-unaware guideline, which is represented with a unique guidance (e.g. G1). For example, if the CDSS guides an AF outpatient during physical exercise treatment while the QoD of the monitored heart rate (mHR) is "Very Low" and the mHR QoD is not taken into account, the clinical recommendation could be "wrong". For example, a decision rule with input mHR that has as a recommendation "increase physical exercise intensity" or "take your anti-coagulant pill". As a result, the risk of treatment increases in terms of probability and impact (e.g. precipitate an AF episode or increased bleeding risk), making the treatment unsafe.

In order to prevent a risk increment above this acceptable range (RoT_A) we

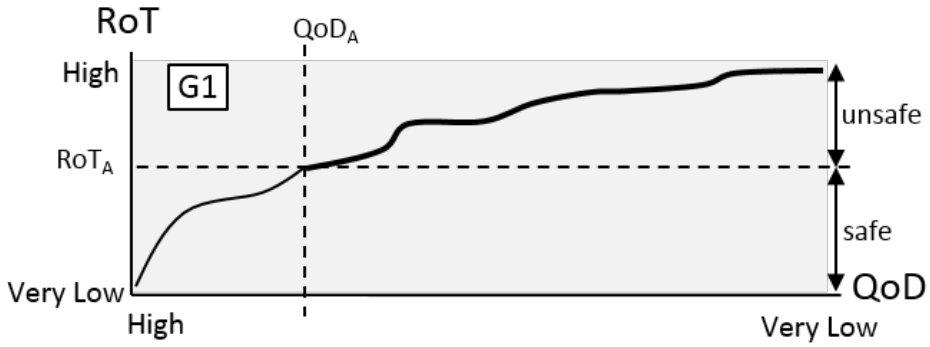


Figure 5.1: Graphical representation of QoD vs. RoT relation for QoD-unaware guidelines

aim to provide different guidance options for different QoD grades. Hence, as shown in Figure 5.2, when the QoD degrades, we apply different guidance options for different QoD grades (G1, G2, G3, G4), which will not output "wrong" recommendations. This will avoid excess risk in treatment above RoT_A and will still maintain a safe level of treatment.

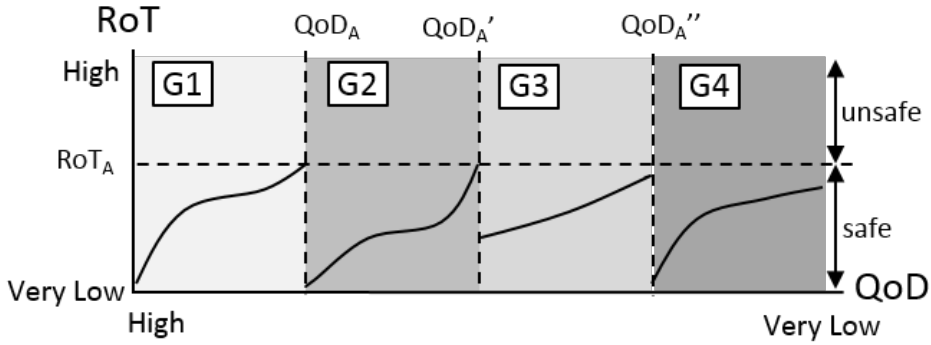


Figure 5.2: Graphical representation of QoD vs. RoT relation for QoD-aware guidelines

For example, when HR QoD decreases below QoD_A (HR QoD = "Very Low"), the adapted treatment recommendation will ensure that the patient is not put at risk ($RoT < RoT_A$) by providing a guidance option (G4) with a QoD-aware CDSS recommendation, e.g. *"Stop the physical exercise"*. Thus, QoD-aware guidelines are used to prevent a treatment risk increment above RoT_A.

Notice that we have not quantified the relation between QoD and RoT. The graphs in Figure 5.1 and Figure 5.2 merely aim to illustrate the nature of the relation between QoD and RoT, based on the discussions we conducted with medical domain experts, in order to understand their implicit knowledge.
This research study applies the GRADE system's approach [30] to rank QoD in four possible grades: "High", "Medium", "Low" and "Very Low" (see Chapter 7). Therefore, Figure 5.2 is represented in four different QoD zones. However, this can be refined with more grades or simplified to have less quality grades.
To develop QoD-aware guidelines, we have developed a method (Section 5.2) that aims to answer the following questions:

1. How do we develop QoD-aware computer-interpretable guidelines that can be executed by the CDSS and lead to "right" (i.e. safe) recommendations in case of degraded QoD?;

2. How do we develop a QoD-aware CDSS that is accepted by medical practitioners?

5.2 QoD-Aware CIG Development Method

Clinical guidelines bring together the best and latest scientifically proven knowledge about how to manage and treat a particular condition. They are developed by panels of top medical experts who review evidence from clinical trials and scientific literature. After a medical consensus is reached, they formalize this evidence-based care into a guideline. Most guidelines are written in a natural language. In order to integrate a guideline into an automated CDSS, a narrative guideline must be formalized in a Computer Interpretable Guideline (CIG).
In this section, we describe the steps required to develop an executable QoD-aware CIG [79] and the implication of involving different domain experts in this development process to reach a clinical consensus on adaptation of treatment in case of degraded QoD (Figure 5.3). First, we discuss the formalization step (Section 5.2.1), followed by a customization step (Section 5.2.2) and a personalization step (Section 5.2.3). These last two steps enable the integration of QoD, context-related information and personalization of guidelines.
The objective is to improve the effectiveness and efficacy of disease management whilst preserving patient safety by adding context-awareness to the guideline and adapting it to the individual patient. At the end of this process

the installation of the guideline is performed in order to start guiding the patient with the support of the telemedicine system (Section 5.2.4).

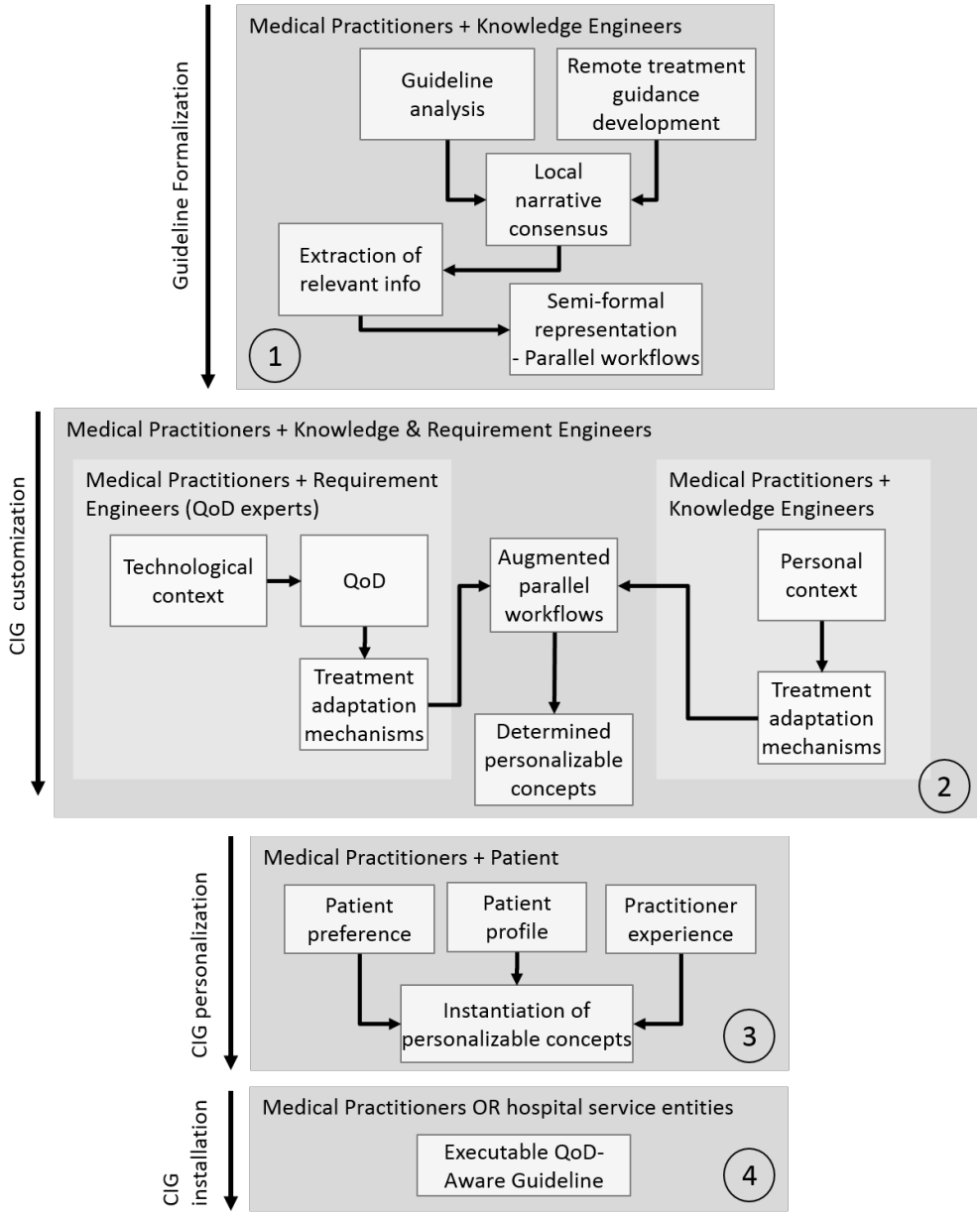


Figure 5.3: QoD-aware CIG development method

5.2.1 GUIDELINE FORMALIZATION

In the guideline formalization step, expert medical practitioners and knowledge engineers collaborate in order to analyze the guideline and develop the remote treatment guidance that must comply with medical protocols and a "way of working" [18, 64].
Based on knowledge acquisition methodologies of [80], the standard guideline is first adapted to local practices and the tacit medical knowledge elicited from narrative text. This results in local narrative consensus, which is then marked up with semantic labels to extract relevant information. CIG modeling languages are similar to traditional workflow languages from the control-flow perspective, but simpler since guidelines can be modeled with a subset of the workflow patterns [16, 18]. As discussed in [81], this labeled, semi-structured text from the guideline of discourse is then converted into a semi-formal representation which (in the MobiGuide project) takes the form of "parallel workflows" (graphical data flow diagrams) representing a sequence of tasks leading to clinical recommendations (Figure 5.3, part 1). These parallel workflows are equivalent to an interpretable version expressed in a textual formal language such as Asbru [16]. Using a selected CIG modeling language (e.g. Asbru), the narrative guideline is modeled *"as is"*, creating a CIG version of the existing guideline.

Example:
The following example sentence (top of Figure 5.4) is extracted from the GDM narrative guideline [82] and it is formalized into a semi-formal representation in the form of parallel workflows (bottom of Figure 5.4). It is a small part of the GDM guideline with a focus on blood glucose (BG) monitoring guidance representation. The following examples in the CIG customization and personalization steps are continuations of this example, to illustrate the overall process of the case.

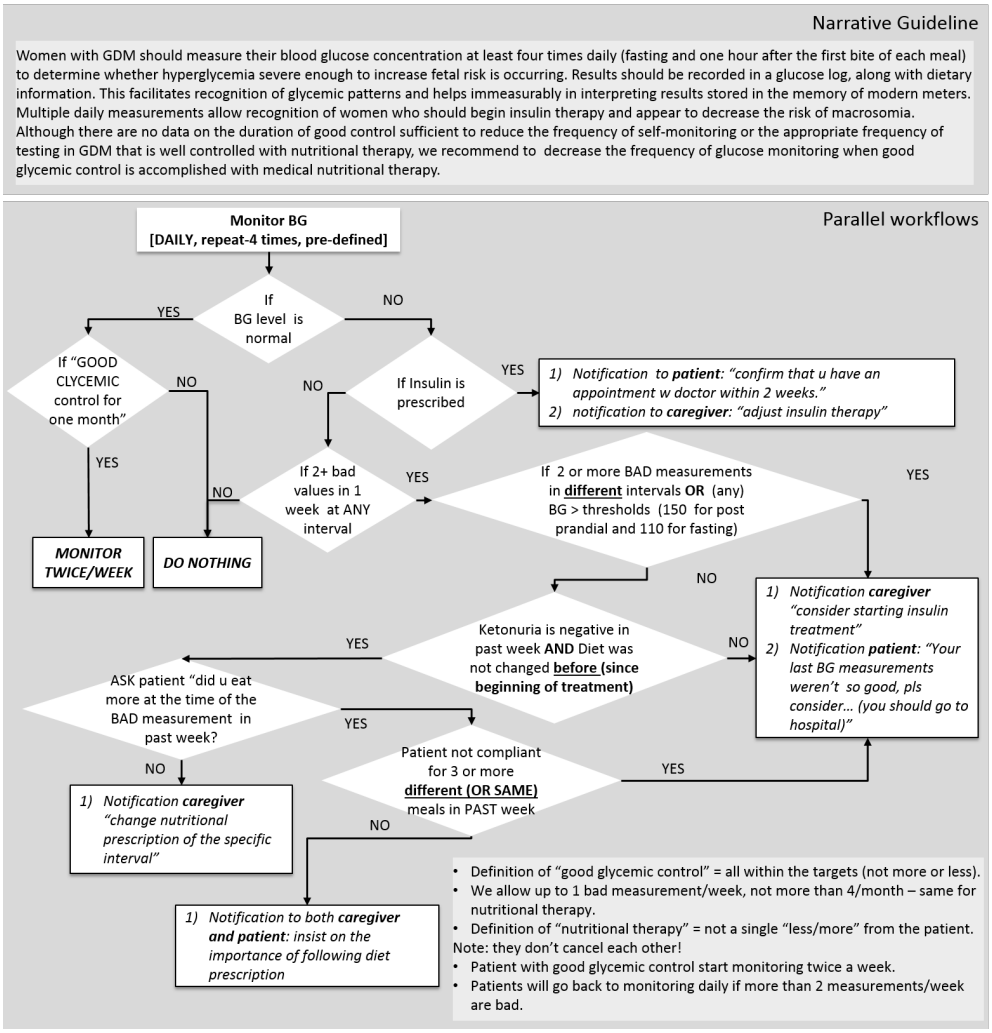


Figure 5.4: Example of a section of the GDM guideline formalization [4]

5.2.2 CIG CUSTOMIZATION

In the CIG customization step, the CIG is extended with the possible contexts that affect patient guidance (Figure 5.3, part 2). These contexts include personal aspects information and technological context information. The personal information contributes to the extension of the clinical context, so that the treatment is personalized. The resulting Context-Customized-CIG (CCC) is induced by either clinical or technological circumstances and it is independent of a specific patient. Different possible generic clinical and technological

circumstances and related parameters are defined, but not the instances of the actual specific patient case and parameters.
As discussed in Chapter 3, the technological context represents the technological resources performance features and has an impact on QoD. Therefore, in the CCC, the technological context information is expressed in terms of QoD (Figure 5.5). In order to adapt the treatment according to QoD, we applied the refined requirements elicitation method [16] and the context layering technique presented in Chapter 3 and [74, 83]. This step is accomplished in several iterations in a collaborative setting involving both medical practitioners and requirements engineers.
Medical practitioners do not analyze specific technological context information, but assess the impact of a specific technological context in terms of QoD variations. Medical practitioners, together with requirement engineers, specify (via semi structured interviews) how the treatment should be adapted to different QoD grades in case the treatment risk is above $\mathrm{RoT_A}$ (see Figure 5.2). As a result, the statements and clinical recommendations that were triggered before by only clinical variables and/or clinical abstractions, will now also be influenced by their associated QoD in order to provide safe recommendations even when QoD degrades. Consequently, not only an *"ideal"* technological context will be addressed in scenarios, but also *"non-ideal"* technological context cases, characterized by degraded QoD.
The customization strategies developed for integration of both personal aspects information and technological context information may require modification of treatment activities by extending the procedural knowledge of the guideline (e.g. change activity from walking to sitting), or the adjustment of parameters of these activities by extending the declarative knowledge of the guideline (e.g. lower the walking activity intensity factor) [6]. Requirements engineers include this information in the parallel workflow representations discussed in Section 5.2.1. The resulting augmented parallel workflows include the impact of personal aspects and technological context on different treatments. As discussed in the validation chapter (Section 8.4), if potential inconsistencies or conflicting conditions are encountered, medical practitioners modify the parallel workflows. Once medical practitioners approve these augmented parallel workflows, they are put in a textual formal language (e.g. Asbru).
The CIG customization step does not include the instantiation of patient specific values. For example, here we consider that a person has a work context, a private life context, and a holiday context. These personal aspects and the

potential treatment adaptation mechanisms, such as medication schedule modification, are defined during customization. During the CIG personalization step, the instantiation of each of these contexts for a particular patient can be determined, e.g. whether the person prefers certain treatment interventions in any of these contexts (Section 5.2.3). Nevertheless, as shown in Figure 5.3 - part 2, before the CIG personalization step is performed, the personalizable concepts are determined and are part of the guideline declarative knowledge. For example, lunch postprandial time, weight and maximum HR.

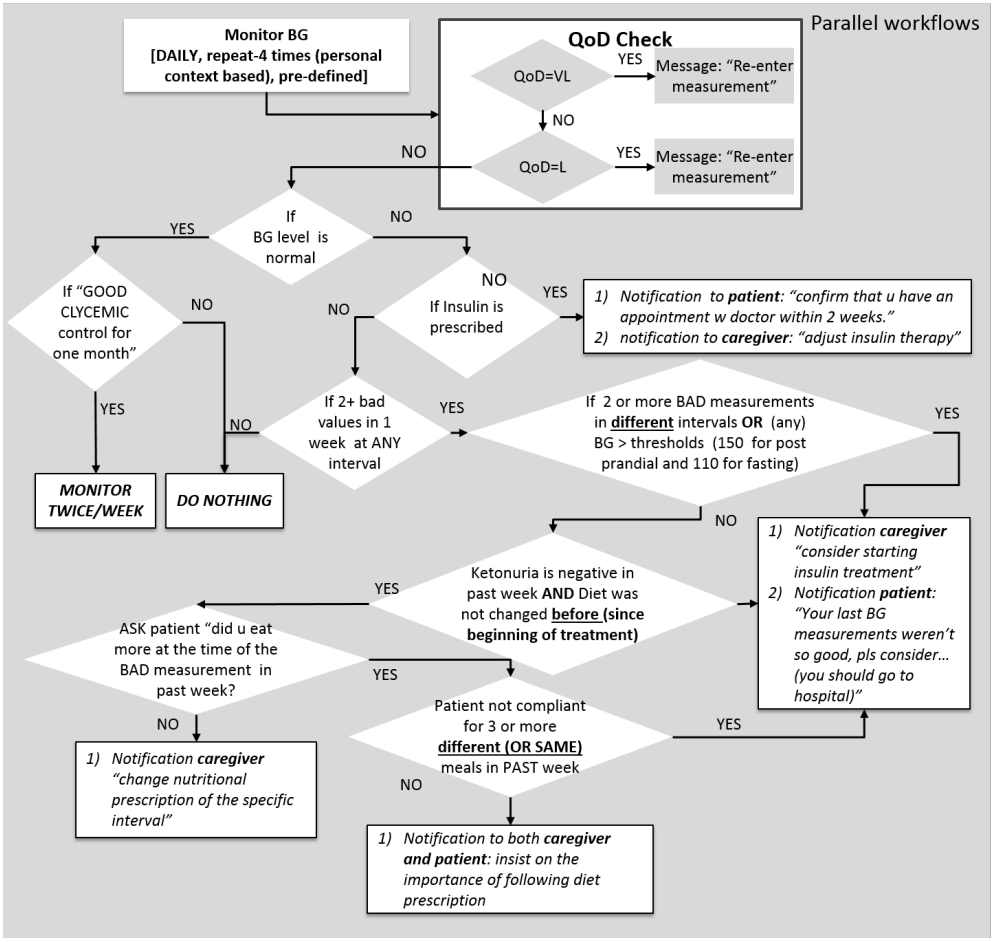


Figure 5.5: Example of a section of the GDM guideline customization

Example:
This example follows the case presented in Section 5.2.1 of the GDM guideline, focused on the BG monitoring guidance. Here, we represent the augmentation of the parallel workflows with technological context and personal aspects information. As illustrated in Figure 5.5, the BG monitoring includes the technological context information by means of QoD: *"if the QoD of BG is Very Low or Low, the patient is asked to re-enter the BG measurement; otherwise, BG levels are checked from a clinical perspective"*. Additionally, in these parallel flowcharts, the BG monitoring timing schedules (4 times) are determined as personalizable values, potentially different in each specific personal case (e.g. "routine context" and "holiday context"), and they are addressed in Section 5.2.3 - Example.

5.2.3 CIG PERSONALIZATION

Following CIG customization, personalization of the CIG takes place during a patient-medical practitioner consultation. In this step, during the consultation, the medical practitioner and the patient instantiate the personalizable concepts together (defined during the CIG customization step). These concepts are specific to the patient's profile (medical condition) and patient's preferences. Hence, medical practitioner experience, the patient's profile (e.g. smoker) and the patient's preferences (e.g. preferred timing of measurements) will be used to instantiate these personalizable concepts (Figure 5.3, part 3). The resulting personalized CIG reflects the real state of the patient and allows him/her to receive decision-support suited for the context, based on the system's knowledge base which contains recommendations approved by medical practitioners. These patient preferences can then be taken into account during CIG execution, enabling personalized recommendations to be delivered at appropriate times.

Example:
This example follows the case presented in Section 5.2.1 and Section 5.2.2 of the GDM guideline, focused on the BG monitoring guidance. As discussed in Section 5.2.2, the BG monitoring timing schedules (4 times) are determined as personalizable values. Hence, during the patient-medical practitioner consultation, the times to get a notification to measure the BG for each context are instantiated (Table 5.1).

Context schedule	Routine context time	Holiday context time
Fasting	7.00 h	9.00 h
Postprandial (breakfast)	8.00 h	10.00 h
Postprandial (lunch)	13.00 h	15.00 h
Postprandial (dinner)	20.00 h	22.00 h

Table 5.1: Example of a section of the GDM guideline personalization: BG monitoring times

5.2.4 CIG INSTALLATION

Once the process of guideline formalization, CIG customization and CIG personalization are completed, the augmented CIG can be executed by the CDSS - Executable QoD-aware guideline (Figure 5.3, part 4). Usually, a medical practitioner or a hospital service entity installs the executable QoD-aware CIG in the system.
During system runtime, incoming data (e.g. patient data from sensors) is annotated with data quality labels by the QoD Broker (see Chapter 6). The CDSS can interpret this data and associated QoD, and link this information to the clinical history of the patient. Thereafter, based on the QoD-aware guideline, the CDSS adapts the recommendations when QoD degrades. Hence, the safety of the patient can be assured even when QoD degrades due to technological context variations.

5.3 CASE STUDY

We study the feasibility and usefulness of our method to augment clinical guidelines with QoD-awareness. We have investigated two specific cases: Atrial Fibrillation (AF) and Gestational Diabetes Mellitus (GDM), where a cardiologist (for AF) and an endocrinologist (for GDM) were involved. AF is a common arrhythmia on which patients complain of palpitations, chest pain, dyspnea, fatigue, lightheadedness, or syncope [67]. GDM is a type of diabetes that occurs in pregnant women and is caused by insulin receptors that fail to function normally [82]. The cardiologist is in charge of the AF guideline and the endocrinologist is in charge of GDM guideline. The successful implementation of the augmented QoD-aware clinical guideline for AF and GDM in the CDSS, incorporating continuous feedback from the two medical practitioners, demonstrates the feasibility and usefulness of the method.
The prototype is part of a larger telemedicine system developed for the MobiGuide (MG) project [4]. This prototype includes existing AF and GDM

guidelines [67, 82] that have been augmented with QoD-awareness. We study the impact of fluctuating QoD of several biosignals on these guidelines, such as Heart Rate (HR) QoD and Blood Pressure (BP) QoD on the AF guideline, and Blood Glucose (BG) QoD and BP QoD on the GDM guideline (see Section 8.5). The prototype implements a QoD-aware guideline-based CDSS and has been tested using several validation activities (Chapter 8).
The following use cases illustrate how QoD is incorporated in an existing AF clinical guideline [67] and in an existing GDM clinical guideline [82].

5.3.1 USE CASE 1: QOD-AWARE AF PHYSICAL EXERCISE TREATMENT

The AF clinical guideline specifies the remote physical exercise treatment, where a patient's HR is being monitored outdoors in order to safely guide the patient. As discussed in Chapter 3, the physical exercise treatment has several stages: "pre-exercise", "warming up" (WU), "target training" (TT), "cool-down" (CD) and "post-exercise". Each of these stages uses clinical abstractions, such as monitored HR (mHR) within a target heart rate (THR) range. THR is the clinical abstraction of the maximum HR value (HR_{max}) of a patient multiplied by an Intensity factor (I_{fact}) with values in the range (0, 1). As discussed in Section 3.3.1, using a safety margin Range/2 with respect to THR, with $THR := HR_{\text{max}} \times I_{\text{fact-pre}}$, one can distinguish between three cases when measuring mHR:
1) over-exertion when $mHR > THR + Range/2$
2) under-exertion when $mHR < THR - Range/2$
3) on target when $mHR \in [(THR - Range/2), (THR + Range/2)]$
The latter case is referred to as the clinical abstraction mHR-THR. These parameters values (HR_{max}, I_{fact}, Range) are patient specific and only the medical practitioner determines these quantities based on the specific patient condition. Each exercise stage has an intensity factor and a range, used to calculate the THR. These values are predetermined by the medical practitioner during patient consultation in the personalization phase and based on the Bruce protocol stress test [69]. The range determines the upper and lower boundaries of each of the physical exercise stages, and could be simplified by using a percentage (e.g. 10%) of THR, and maintained (usually) constant throughout all physical exercise stages. Each exercise stage also has a predetermined duration, set by the practitioner (e.g. 15 minutes).

When mHR is out of the range (over-exertion or under-exertion) for a certain specified time (e.g. T = 2 min), a clinical recommendation (e.g. "slow down"

Stage	THR	I_{fact} (default)	Range	Time
Pre	$HR_{max} \times I_{fact\text{-}pre}$	$I_{fact\text{-}pre}$ = 50%	10%	t-pre: time pre-exercise
WU	$HR_{max} \times I_{fact\text{-}WU}$	$I_{fact\text{-}WU}$ = 50%	10%	t-WU: time warming-up
TT	$HR_{max} \times I_{fact\text{-}TT}$	$I_{fact\text{-}TT}$ = 50%	10%	t-TT: time target-training
CD	$HR_{max} \times I_{fact\text{-}CD}$	$I_{fact\text{-}CD}$ = 50%	10%	t-CD: time cool-down
Post	$HR_{max} \times I_{fact\text{-}post}$	$I_{fact\text{-}post}$ = 50%	10%	t-post: time post-exercise

Table 5.2: Stages of the physical exercise and the specifications

or "speed up") is sent to the patient. The aim of this is to bring the mHR back into the target treatment range, so as to prevent a potential patient risk increment. Figure 5.6 illustrates a simplified version of the workflow diagram of the physical exercise treatment applied in the MG pilot study.

Following the functional requirements of medical practitioners, the MG prototype was designed in a manner that the physical exercise can be initiated and interrupted by the patient or by the system. The patient can press a button ("start exercise", or "stop"), and the system can send a clinical recommendation ("physical exercise treatment recommended", or "stop exercise") to the patient based on the medical prescriptions specified in the personalized guideline.

Once the physical exercise treatment is initiated (by the patient, through pressing the button or after accepting a system-generated exercise treatment recommendation), the system will ask the patient to wear the sensor belt. Once the quality of the initialization clinical data (QoD_{INIT}) is checked (see Use case 2), the pre-exercise phase of the treatment begins. During every exercise phase, the following procedures are followed:

First, the time is set to zero. Notice that in each of the phases the treatment can be interrupted by the autonomous guidance (if clinical or technical problems are detected after the clinical data check or after the QoD check respectively) or by the patient (who wants to stop). If the duration of a phase expires without the treatment being interrupted, the next phase starts. In this case, the treatment stops after the final phase (post-exercise). As discussed in Section 5.2.2, during the CIG customization step we include adaptation mechanisms that cope with degraded QoD. This is handled by the **"QoD Check"** function

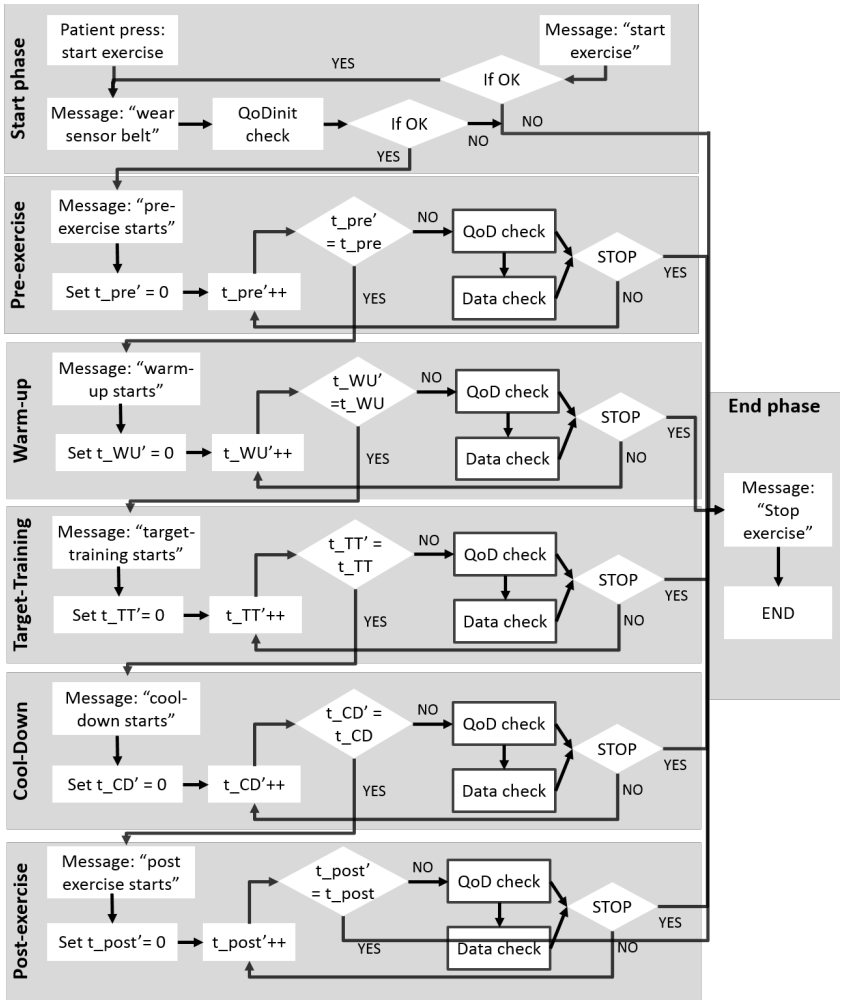


Figure 5.6: Physical exercise treatment workflow diagram

illustrated in Figure 5.6. Figure 5.7 zooms in on the "QoD check" function to illustrate the treatment adaptation mechanism for every QoD grade. Notice that Figure 5.6 does not consider the specific times (e.g. T = 2 min) before a clinical recommendation is provided to the patient (e.g. to stop, to slow down, or to speed up).

As represented in Figure 5.7, during the physical exercise phases the intensity factor, I_{fact}, used by the clinical abstraction mHR-THR is modified based on QoD grades. Typically, I_{fact} is lowered to prevent over-exertion of the patient in case of degraded QoD (e.g. inaccurate mHR data). The possible technolog-

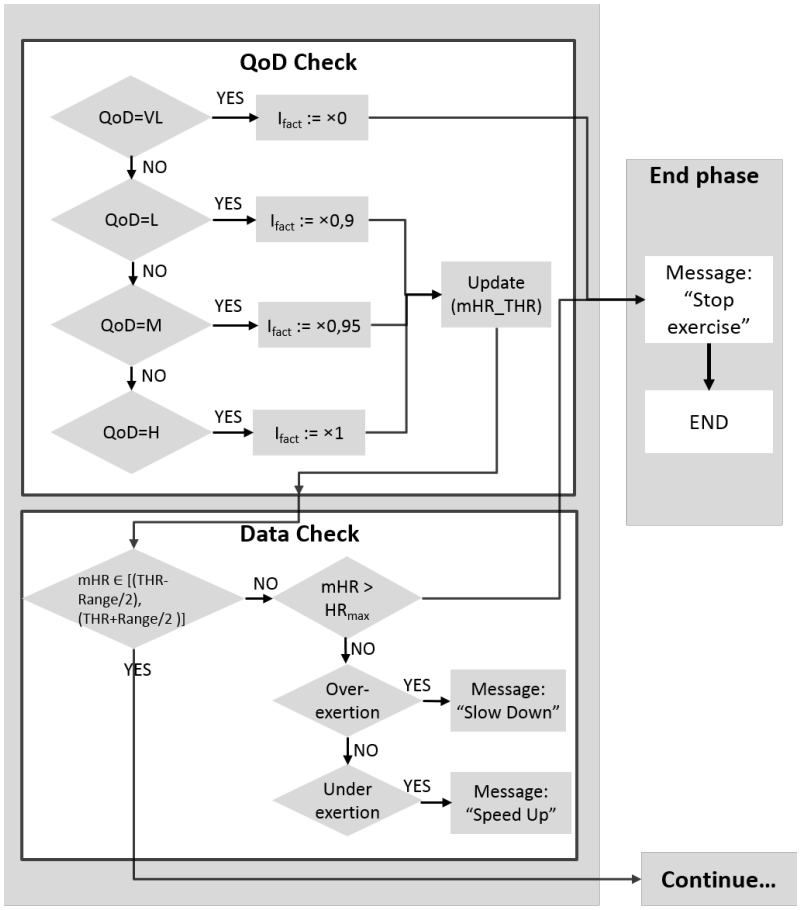


Figure 5.7: QoD check and data check workflow diagram for AF physical exercise treatment

ical contexts are presented to the medical practitioner by means of mHR QoD grades: "High" (H), "Medium" (M), "Low" (L), and "Very Low" (VL). The medical practitioner determines for each case a specific treatment adaptation mechanism. For example, in case QoD=L the physical exercise treatment intensity is reduced (e.g. $I_{fact\text{-}pre} = I_{fact\text{-}pre} \times 90\%$, see Figure 5.7). Accordingly, the THR will be updated, so that the prescribed physical exercise intensity is lower. This way the QoD-aware guidance prevents a "wrong" recommendation to "speed up", which could increase the risk of the treatment. Figure 5.7 does not consider different QoD dimensions, but an overall QoD (see Section 7.3.3).

5.3.2 USE CASE 2: QOD CHECK BEFORE AF PHYSICAL EXERCISE TREATMENT EXECUTION

In some cases, patient treatment requires certain QoD pre-conditions in order to provide data that fulfils the medical quality requirements. These QoD pre-conditions are based on ICT resources' performance. For example, in order to guarantee monitoring HR with "sufficient" QoD during 1 hour outdoor treatment, the HR sensor (e.g. BioHarness [71]) needs to have at least 20% of battery capacity. In case the QoD pre-conditions are not met, the guideline should contain adaptation mechanisms that enhance patient safety (Figure 5.8).
Hence, before the treatment execution starts (e.g. "start phase" in Figure 5.6), the guideline-based CDSS will query an initial clinical data QoD value, QoD_{INIT} (to QoD Broker). This QoD_{INIT} value determines if all ICT resources involved in the treatment satisfy the QoD pre-conditions and are capable of supporting the treatment. As shown in Figure 5.8, if the QoD_{INIT} is NOT "High" (H), the AF physical exercise treatment (from Use case 1) will not be initiated.

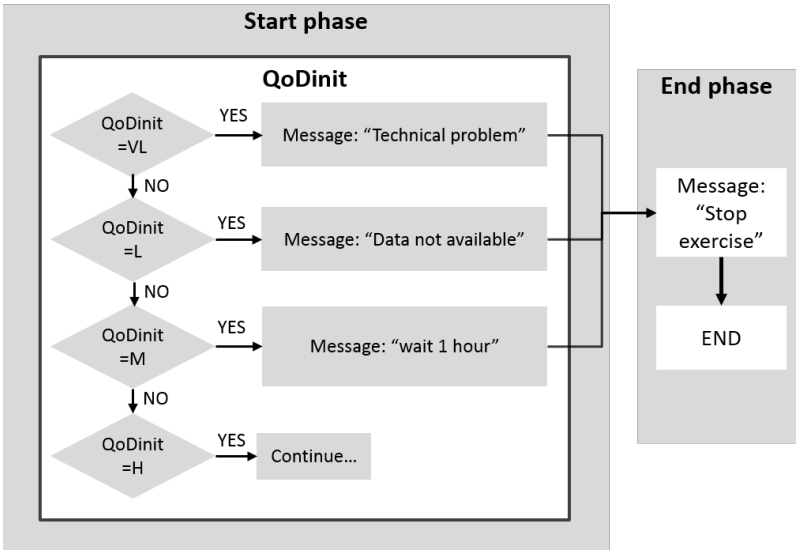


Figure 5.8: QoD_{INIT} workflow diagram for AF physical exercise treatment

5.3.3 USE CASE 3: QOD-AWARE BLOOD GLUCOSE MONITORING, GDM

The existing GDM clinical guideline addresses the Blood Glucose (BG) monitoring treatment [82]. Typically the patient annotates her BG measurements for potential treatment alterations. When using the envisioned telemedicine system, the BG data is inserted automatically or manually into the system. The guideline-based CDSS processes this BG data and, based on its values, determines clinical recommendations for the patient or the endocrinologist.
Nevertheless, in both traditional medical practice and telemedicine practice, QoD might have a significant effect on treatment guidance. In the developed prototype, the main effect implemented in the automated guideline-based CDSS is to "ignore" (i.e. not to consider) BG data that does not fulfil the medical quality requirements (e.g. QoD = "Low" or QoD = "Very Low"). Additionally, the QoD-aware telemedicine system may ask the patient to re-enter the measurement (Figure 5.9).
BG data that fulfils medical quality requirements is used by the guideline-based CDSS to support the medical practitioner in the decision making process (e.g. to adjust the insulin therapy) or autonomously guide the patient during the treatment (e.g. *"Your measurements are fine. You are doing well"*) (Figure 5.9)

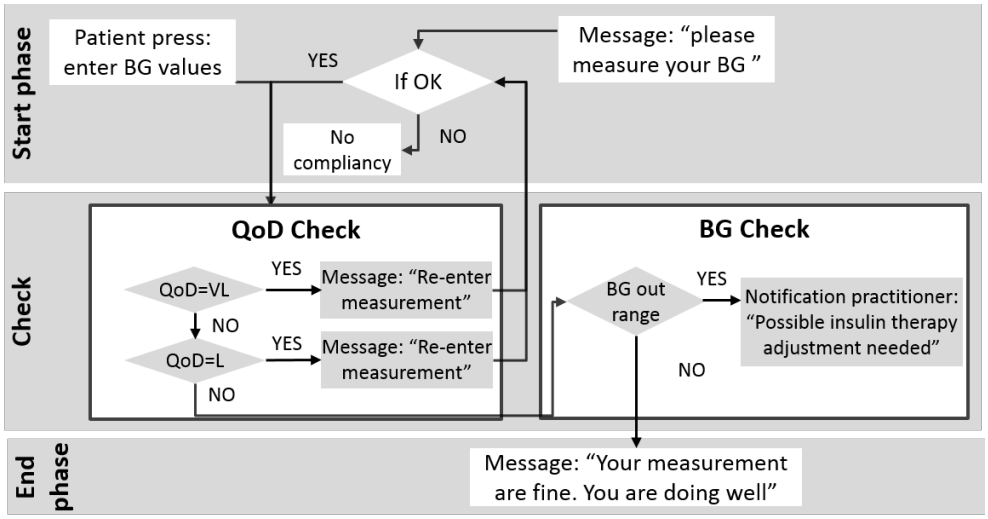


Figure 5.9: Data workflow diagram representation of Blood Glucose Monitoring in the GDM guideline

Notice that this use case is a simplified version of the GDM guideline. The guideline uses the outcome of data mining procedures and temporal abstractions to determine over time if the BG values of the patient are in a safe range or out of the safe range.

5.4 CONCLUSIONS

In this chapter, we proposed a method to build a QoD-aware executable clinical guideline that is applicable in clinical decision support systems and was lacking in previous literature studies. This method has been applied and investigated in two medical cases (AF and GDM) with the cooperation of a cardiologist and an endocrinologist. From the feedback we received from the medical practitioners while conducting the requirements elicitation activities (see Chapter 3), we conclude that the medical practitioners understood, from the beginning, the problem of **1)** "ignoring" QoD in clinical guidelines andf**2)** assuming that QoD always fulfills the medical quality requirements. Through different phases of our design, they validated the treatment guidance adaptation mechanisms (Chapter 8). Besides, they encouraged us to spread this work further to other medical areas. Accordingly, evolving pervasive healthcare can cope with the challenge of providing treatment adaptation mechanisms that preserve treatment quality and prevent risk increment when technological resources performance disruptions occur.
The treatment adaptations based on QoD can be personalized, depending on a patient's condition and preferences, as presented in Section 5.2.3. This QoD-aware treatment personalization should be modifiable by the cardiologist. For example, the treatment adaptation mechanisms for the AF physical exercise treatment should be case-specific:

1. In case we are dealing with a high risk AF patient (potential heart failure during exercise), monitored HR with "low" QoD requires a strong treatment activity modification (e.g. ask the patient to *"stop exercising"*);

2. In case we are dealing with an active "healthy" AF patient, monitored HR with "low" QoD requires a mild treatment modification (e.g. ask the patient to *"slow down"*).

As discussed in [84], EBM is defined as *"the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the*

best available external clinical evidence from systematic research". Figure 5.10 (from [5]) illustrates the crucial role of clinical data to provide optimal decisions. However, we emphasize the role of this clinical data **quality** to provide the optimal decisions.

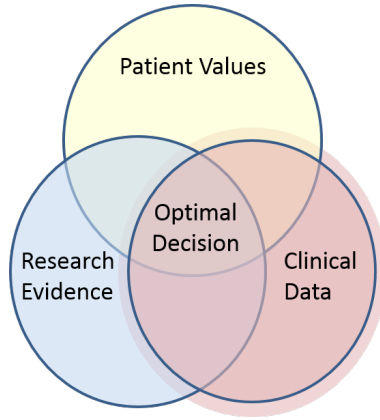


Figure 5.10: Graphical representation of the main features to provide optimal decisions following the Evidence Based Medicine principle [5]

The use of guideline-based CDSS in telemedicine systems will progressively increase, since their aim is to cope with some of the challenges of healthcare: improve the quality of care, reduce unjustified practice variations and reduce healthcare costs [14, 85]. However, diverse studies have already identified that the quality of clinical data from medical registries cannot always be trusted and a CDSS might provide undesirable guidance [24, 26, 42, 78, 86]. Therefore, we propose a method to prevent inappropriate and unsafe treatment guidance recommendations by augmenting the (computer interpretable) clinical guidelines with QoD-awareness.

CHAPTER 6

QUALITY OF CLINICAL DATA AWARE TELEMEDICINE SYSTEM ARCHITECTURE

Having described how to develop a QoD-aware guideline in the previous chapter, this chapter describes the architecture of a generic QoD-aware telemedicine guidance system.
In Section 6.1, we explain the approach that we followed to define the QoD-aware telemedicine system architecture. Section 6.2 describes the high level architecture of the QoD-aware telemedicine system. Section 6.3 presents the decomposition of the system into a mobile and a back-end part. Section 6.4 describes the components of the mobile patient guidance system, and Section 6.5 describes the components of the back-end guidance system. Section 6.6 presents how this QoD-aware telemedicine system architecture has been implemented in MobiGuide and Section 6.7 finalizes the chapter with a conclusion.

6.1 APPROACH

In this section, we first provide some background information on the concept of “system architecture”. Next, we describe the high level functional requirements that resulted from the analysis in Chapter 3, and which lead to a "black-box" system architecture. Thereafter, we describe our approach to decompose blackbox system architecture, and we look into the rationale to further describe this “whitebox” system. The architecture description provided in the following sections constitutes an overview of an entire telemedicine system. However, chapter 7 details one of its subsystems, namely the QoD Broker,

which is the main focus of this research.
In Appendix B, we describe the abbreviations, the glossary of terms and the notations used in the current chapter and in Chapter 7.

6.1.1 BACKGROUND

In order to specify the architecture of a system, we look into the definitions used. ISO/IEC/IEEE 42010 defines architecture as follows: *"an architecture is defined as the fundamental concepts or properties of a system in its environment embodied in its elements, relationships, and in the principles of its design and evolution."* The definition from its predecessor ANSI/IEEE Std. 1471-2000 is more pragmatic: *"architecture is defined as the fundamental organization of a system, embodied in its components, their relationships to each other and the environment, and the principles governing its design and evolution."*
A way to deal with an architecture of a complex system is to decompose the system in different levels of abstraction [87]. Abstraction is the process of addressing the aspects that are relevant at that particular point (in time), while ignoring other aspects which are not (yet) relevant. In this way each level of abstraction covers details of the required system components, and hides the "complexities" that the developer is not (yet) interested in and that may distract him from his current primary goal. Hence, here, we follow this decomposition approach to present the QoD-aware telemedicine system architecture.

6.1.2 HIGH LEVEL FUNCTIONAL REQUIREMENTS

As discussed in Chapter 3, we applied the iPACT'-FICS' requirements elicitation method [64] to identify the (user perspective) functional requirements on QoD-aware telemedicine systems, hereafter collectively referred to as "the system". Here, we present the high level functional requirements, which are derived from the analysis of the FICS' elements presented in Appendix A. The system:

- Shall provide guidance to multiple ambulatory patients simultaneously
- Shall provide QoD-aware guidance information to patient and guidance decision support to the medical practitioner
- Shall store the clinical data (and its QoD), accessible for the patient and medical practitioner
- Shall have an interface to interact with the patient and the medical practitioner

- Shall monitor, process, and transmit patient clinical data
- Shall ensure a safe guidance even when technological context variations (e.g. technological disruptions) occur

These functional requirements lead us to the conclusion that the system will consist of subsystems and components, which can be decompose into different levels of abstraction, as described in the following subsection (Section 6.1.3).

6.1.3 DECOMPOSITION LEVELS

In this research study, we decompose the QoD-aware telemedicine system into three levels of abstraction, namely system level (level 1), subsystem level (level 2) and component level (level 3).

- Level 1: considers the system as a "unified whole"; describes it from the perspective of the system's user who wants to use it for some purpose, and does not consider the internal system design features. The user can be a human or another computer system. In our research, the users of the QoD-aware telemedicine system are humans. This perspective shows "what" behavior the system is capable of offering from an external perspective, often called a "black-box" architecture [88]. This 1st level of abstraction is explained in Section 6.2.

- Level 2: considers the distribution of the system in mobile and back-end (fixed) subsystems. This 2nd level focuses on the functionalities provided to the patient (mobile part) and functionalities provided to the medical practitioners (back-end part), and how the corresponding subsystems interact via a public data communication infrastructure. The architecture describing a system from its internal perspective is often called a "whitebox" architecture [88], and on this level we present the first whitebox architecture design. This 2nd level of abstraction is explained in Section 6.3.

- Level 3: considers the mobile and back-end subsystems as a related group of components; it reveals the internals of each subsystem to show "how" the system is capable of offering services. In this 3rd level of abstraction, we provide the second whitebox architecture, which is addressed in Section 6.4 and Section 6.5. This decomposition level is also the starting point of the implementation process (each of these subsystems can be implemented separately), discussed in Section 6.6.

6.1.4 PERSPECTIVE OF EACH LEVEL OF ABSTRACTION

Based on the ANSI/IEEE Std. 1471-2000 definition of architecture (Section 6.1.1), we identify three perspectives corresponding to our levels of abstraction for the QoD-aware telemedicine system architecture description:

- "...fundamental organization of a system, embodied in its components,..." → Identification of system's functional requirements and its required subsystems and components to fulfill the requirements. In Section 6.1.2 we present the system's high level functional requirements. Later, we cover more detailed functional requirements for each level of abstraction and identify the subsystems and components that correspond to each functional requirement.

- "... their relationship to each other and the environment..." → Specification of the message (information) exchanged between the system vs. end-users (environment) and the system (subsystems and) components. We present a table of the exchanged information between the provider of the message (or data flow) and the user (receiver) of the message (or data flow). This is aligned with the "provider-consumer" paradigm presented in [89].

- "... the principles governing its design and evolution ." → Identification of the protocol which governs the information exchange between the system vs. end-users (environment) and the system (subsystems and) components; "how" (i.e. in which order) are the messages being exchanged. Based on the complexity of this interaction, we explain the protocol in two different ways: (i) if the protocol is simple, we describe it in a time sequence diagram; (ii) if the protocol is complex (i.e., it contains multiple alternatives or conditions, which would require multiple sequence diagrams for its representation), we provide an activity diagram [90] that represents all possible message sequences. Additionally, we describe a use case with a time sequence diagram that corresponds to one possible execution scenario of the protocol.

6.2 TELEMEDICINE SYSTEM ARCHITECTURE OVERVIEW

Figure 6.1 illustrates the black box architecture (*1st level of abstraction*) of the QoD-aware telemedicine system. A generic telemedicine system collects "mobile" patient data from outpatients and patient treatment information from intramural settings (e.g. medical practitioners and hospital). This data and information is processed by the system, resulting in ambulatory treatment guidance information (in the form of recommendations) for the patient and treatment information for the medical practitioners (Figure 6.1).

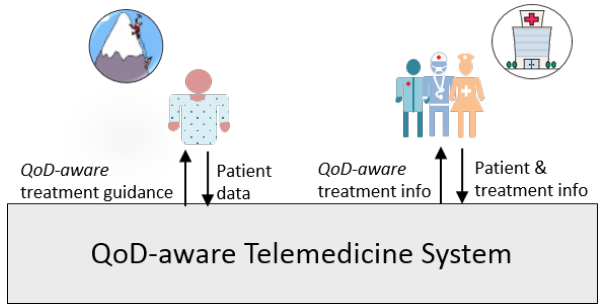


Figure 6.1: Overview of the QoD-aware telemedicine system

Yet, the collected patient clinical data during the system runtime (typically from ICT resources) may not fulfil medical QoD requirements, as discussed in Chapter 1 and Chapter 3. This may lead to a potentially unsafe ambulatory treatment of outpatients. To avoid potentially unsafe treatments, we aim to develop a QoD-aware telemedicine system that computes QoD and adapts patient treatment according to the QoD. Hence, treatment guidance and treatment information, provided by the system, are QoD-aware.
In order to clarify the rationale for incorporating QoD-awareness in telemedicine systems, we describe two potential use cases: a non-QoD-aware use case and QoD-aware use case (Table 6.1).

6.2.1 QOD-AWARE TELEMEDICINE SYSTEM AND ITS END-USERS

The QoD-aware telemedicine system interacts directly with its 'users'. Using the definition of [91], 'users' are the people, groups or companies who will interact with the software and control it directly, and those who will use the products (information, results etc.) of the system (Table 6.2). Besides, they are also stakeholders of the system. The users are grouped based on their roles. In this research we identified two main users and their roles:

NON QoD-aware use case	QoD-aware use case
The patient is performing physical exercise treatment outdoors using the telemedicine system, which processes the patient's clinical data and provides recommendations during the treatment. The HR sensor acquires 'noisy' HR clinical data due to motion artifacts, which shows a low HR value. The CDSS does not distinguish 'noisy' data from 'clean' data, and processes the 'noisy' HR data. The outcome of the CDSS (based on the 'noisy' HR value) is a 'wrong' clinical recommendation to the patient: "increase the physical exercise intensity". This recommendation, triggered by a "low" QoD HR, may put the patient's safety at risk.	*The patient is performing physical exercise treatment outdoors using the QoD-aware telemedicine system, which processes the patient's clinical data, its quality (QoD) and provides QoD-aware recommendations during the treatment. The HR sensor acquires 'noisy' HR clinical data due to motion artifacts, which shows a low HR value. The system computes QoD of HR, so that the CDSS can distinguish 'noisy' data from 'clean' data, and processes the noisy HR data and its QoD. The outcome of the CDSS (based on the 'noisy' HR value and its QoD) is a QoD-aware clinical recommendation to the patient: "stop the physical exercise treatment due to unreliable data". This recommendation, which considers not only the HR, but also its QoD, ensures the patient's safety.*

Table 6.1: Comparison between Non QoD-aware and QoD-aware with a use case

- **Patient**: We define the patient as an external system user, who interacts, while being in a extramural setting (e.g. in his or her own home), with the system in order to be treated by the medical practitioner, who is in a medical setting (e.g. hospital).

- **Medical practitioner**: We define the medical practitioner as an external system user, who interacts with the system in order to provide a personalized evidence-based treatment to his or her patients.

Notice that we could also consider knowledge engineers and system engineers as additional users who interact with the system, with a specific role. A knowledge engineering team is composed of medical practitioners and knowledge engineers, who provide formalized guideline (treatment) knowledge to the system. This knowledge corresponds to the procedural knowledge explained in Chapter 5 and it is integrated in the system (CDSS). As explained in Chapter 5, the suitable guideline (formalized procedural knowledge) for the particular patient is selected by the medical practitioners. Systems engineers provide system control (management) information to the system, so that the QoD-aware telemedicine system can function according the medical requirements.

Components	Description
QoD-aware telemedicine system	A QoD-aware telemedicine system provides mobile ambulatory patient treatment guidance service. It enables medical practitioners to input in the system specific patient and treatment information. Based on this information and patient's clinical data (labeled with QoD) acquired during system runtime, it allows out-patients to receive location-independent QoD-aware treatment. Additionally, it enables medical practitioners to monitor patient progress, while the patient is in the extramural setting.

Table 6.2: Service description of the QoD-aware telemedicine system

However, these users are not further discussed in this chapter since this is out of the scope of our research.

6.2.2 SYSTEM-USER MESSAGE EXCHANGE

In the following table (Table 6.3), we describe the exchanged messages between the QoD-aware telemedicine system and the end-users (i.e. the patient and care practitioners). In this table, the provider represents the entity (human or system) that provides the information, and the user represents the entity (human or system) that acquires the information.

6.2.3 PROTOCOL FOR MESSAGE EXCHANGE

In the sequence diagram of Figure 6.2, we illustrate the protocol for the messages exchanged between the system and the system's users. First, the system receives patient and treatment information from a medical practitioner, who is in charge of enrolling a patient. This information includes the QoD-aware personalized treatment information (guideline) required to guide the patient (see Chapter 5). Once the patient starts using the system, patient data (and QoS data) will be collected by the QoD-aware telemedicine system. Then, the system provides QoD-aware treatment information and QoD-aware treatment guidance to the medical practitioner and patient respectively.

Example: A simplified example of this sequence diagram is shown in Figure 6.3. This figure represents some of the sequences that may occur in the context of an AF patient's physical exercise treatment (see iPACT-FICS scenario in Appendix A). First, the medical practitioner, in charge of treating the patient, will establish the maximum HR recommended for the patient (many other information is hidden in this example). When the patient is perform-

Provider	User	Message name	Description
QoD-aware telemedicine system	Patient	The QoD-aware treatment guidance	Treatment guidance during the ambulatory patient's daily life, which considers the quality of monitored clinical data (QoD) in order to provide reliable guidance that guarantees the patient's safety.
	Medical practitioner	QoD-aware treatment information	Treatment information of the ambulatory patient during his/her daily life, which contains QoD information that represent the quality of the monitored patient clinical data. Hence, the medical practitioner in charge of the treatment can analyze this information, and, if necessary, modify the treatment.
Patient	QoD-aware telemedicine system	Patient data	Autonomously collected clinical data (e.g. vital signs) by the system sensors and devices, and manually inputted data (e.g. treatment responses) into the system.
Medical practitioners	QoD-aware telemedicine system	Patient & treatment information	Personalized patient and treatment (guideline) information (procedural and declarative knowledge), required to provide QoD-aware personalized treatment.

Table 6.3: System-User interactions

ing physical exercise outdoors, the monitored HR data (which includes QoD information of the technological resources being used) is acquired by the system. If the QoD degrades below the medical requirements during the physical exercise, the system will process this data (and its QoD), triggering a notification to the medical practitioner (*"patient HR above limit"*) and to the patient (*"stop physical exercise"*) to ensure patients safety (see Chapter 5).

6.2.4 FUNCTIONAL REQUIREMENTS AND SYSTEM COMPONENTS

This section refines the high level functional requirements, presented in Section 6.1.2, to identify the 2nd level of abstraction subsystems. The system:

RE_{MPG} - Shall acquire patient clinical data and provide autonomous mobile QoD-aware safe guidance, anytime & anywhere, to the ambulatory patient with a wearable system.

RE_{BEG} - Shall process large amounts of data, collected during long periods of

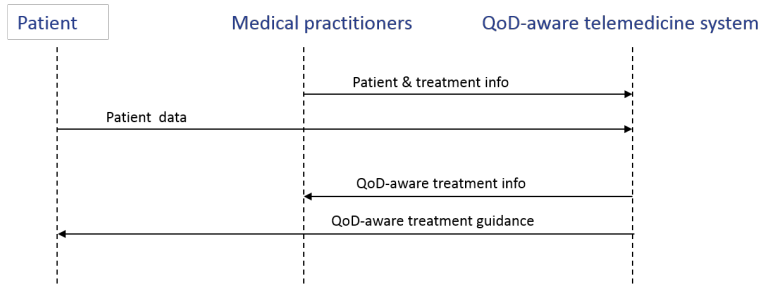


Figure 6.2: Sequence diagram of the QoD-aware telemedicine system and its users

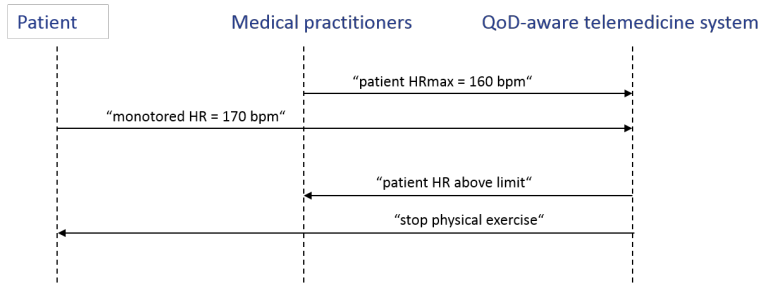


Figure 6.3: An example of the sequence diagram of the QoD-aware telemedicine system and its users

time, to provide personalized (adaptive) guidance to (several) patients (simultaneously); and it shall acquire patient and treatment information and provide guidance information to medical practitioners.

Based on these two functional requirements, we identify two subsystems:

- For RE_{MPG}, we identify the (wearable) **mobile patient guidance (MPG) subsystem**
- For RE_{BEG}, we identify the (powerful) **back-end guidance (BEG) subsystem**

In the following section (Section 6.3), we study these two subsystems and the messages (information) exchanged with their exchange protocols. Thereafter, we identify their functional requirements, which are used for further decomposition of the system architecture.

6.3 MOBILE AND BACK-END SUBSYSTEMS ARCHITECTURE

As discussed in Section 6.2, the presented QoD-aware telemedicine system requires an autonomous mobile guidance subsystem that functions even when a (back-end) server is not available. Otherwise, when, for example, data communication infrastructures are not available, the ambulatory patient would not be able to receive treatment guidance, which may lead to unsafe situations. Nevertheless, the mobile guidance subsystem may have limited capabilities. It needs interaction with a common server that processes data collected during long periods of time and provides personalized clinical guideline information and management services to the medical practitioner. Therefore, the designed system is decomposed in a mobile patient guidance subsystem and a back-end guidance subsystem - *2nd level of abstraction* (Figure 6.4).

6.3.1 SUBSYSTEMS DESCRIPTION

In Table 6.4, we describe the main functions of the mobile patient guidance system and the back-end guidance system:

Components	**Description**
Mobile Patient Guidance	The mobile patient guidance performs real-time high-volume streaming measurements (e.g. vital-signs) and their QoD assessment. Based on the processed data, it provides continuous QoD-aware personalized patient guidance in non-clinically controlled environments, even if the patient is on the go (ambulatory patient). Although, it is independent from the back-end subsystem, (periodically) it acquires updated treatment information from the back-end guidance subsystem to provide up-to-date guidance to the patient. It also provides mobile patient guidance information to the back-end subsystem (e.g. aggregated and summarized information of streaming measurements).
Back-End Guidance	The back-end guidance subsystem acquires the personalized QoD-aware guideline information (procedural and declarative knowledge) from the medical practitioner and enables medical practitioners (in the hospital) to manipulate patient and treatment information. Additionally, it processes large amounts of ambulatory patient clinical data collected during long periods of time (temporal abstraction). This way, it provides 'long-term' personalized clinical guidance information to the mobile patient guidance subsystem.

Table 6.4: Service description of the mobile patient guidance and the back-end guidance subsystems

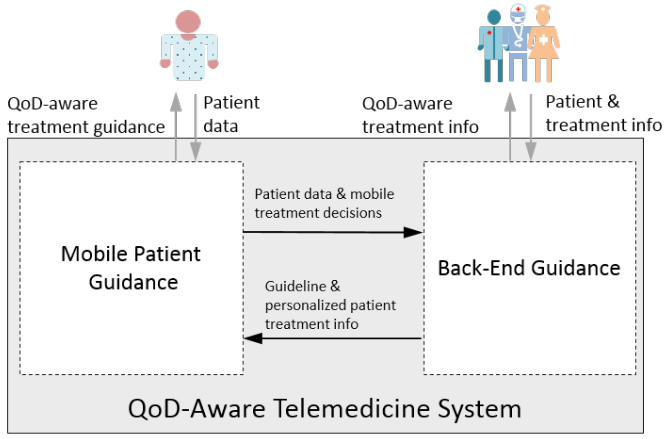


Figure 6.4: Distributed telemedicine system: mobile patient guidance system and the back-end guidance system

6.3.2 MESSAGE EXCHANGE

In Table 6.5, we describe the information exchange between the mobile patient guidance subsystem and the back-end patient guidance subsystem. The interactions between the patient and the QoD-aware telemedicine system (discussed in Section 6.2) are accomplished by the mobile patient guidance subsystem. The interactions between the medical practitioners and the QoD-aware telemedicine system (discussed in Section 6.2.2) are accomplished by the back-end guidance subsystem. However, we do not explicitly address these interactions with the end-users here.

6.3.3 PROTOCOL FOR MESSAGE EXCHANGE

The mobile patient guidance subsystem requires guideline and patient specific treatment information, stored in the back-end, before its execution. Hence, the interaction between these two subsystems is initiated by the back-end guidance subsystem. Once the back-end guidance subsystem provides this information, the mobile patient guidance subsystem can function autonomously. During the mobile patient guidance subsystem's runtime, patient data and mobile treatment decisions are sent to the back-end guidance subsystem, so that long-term data processes (temporal abstractions) are executed. When necessary, and if a network data communication infrastructure is available, the back-end subsystem provides the necessary updated information to the mobile patient guidance subsystem, including information about specific patient treatment changes.

Provider	User	Message name	Description
Mobile Patient Guidance	Back-End Patient Guidance	Patient data and mobile treatment decisions	Monitored and processed patient clinical data with its QoD information (e.g. "BP data and its QoD information") and mobile treatment guidance information (e.g. "non-compliancy to diet").
Back-End Patient Guidance	Mobile Patient Guidance	Guideline and personalized patient treatment info	Guideline information (e.g. IF (HR>HRmax) THEN (stop physical exercise treatment)) and patient specific guideline information (e.g. patient maximum HR = 160 bpm) and long term treatment guidance information (e.g. BP monitor twice a week).

Table 6.5: Interactions between the mobile and the back-end subsystems

In this research, we aim to define the protocols for (ordering) the exchange of the main messages that are required to realize a QoD-aware telemedicine system. Therefore, we do not address other communication tasks that are not the focus of this research study (e.g. initialization and recovery).

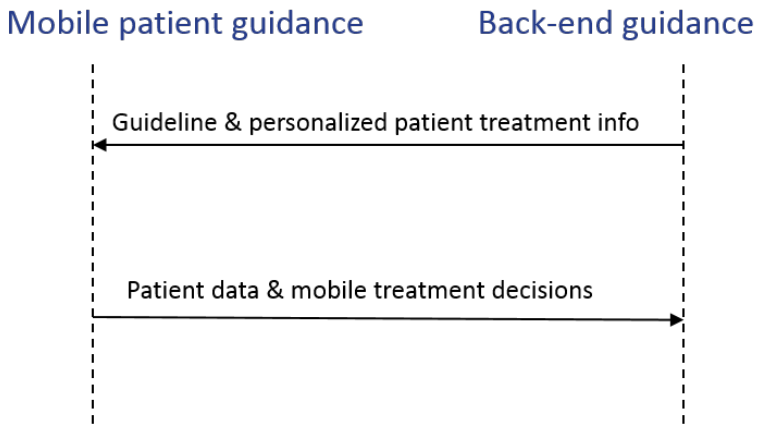


Figure 6.5: Sequence diagram between back-end guidance system and mobile patient guidance system

Example: This example follows the AF patient physical exercise treatment scenario, presented in Section 6.2.3. In Figure 6.6, we show a simplified example of the interaction between the back-end and the mobile guideline subsystems. First, the back-end guidance subsystem provides guideline (procedural) information (e.g. *IF (HR>HRmax) THEN (stop physical exercise treatment)*) and patient specific (declarative) information (e.g. *patient ABC maximum HR = 160 bpm*). The mobile patient guidance subsystem executes the guidance with the information acquired from the back-end while monitoring the patient's vital signs (e.g. HR). Next, it transmits the patient data (e.g. HR = 200 bpm) and mobile decisions (e.g. *physical exercise treatment interrupted*) to the back-end guidance subsystem.

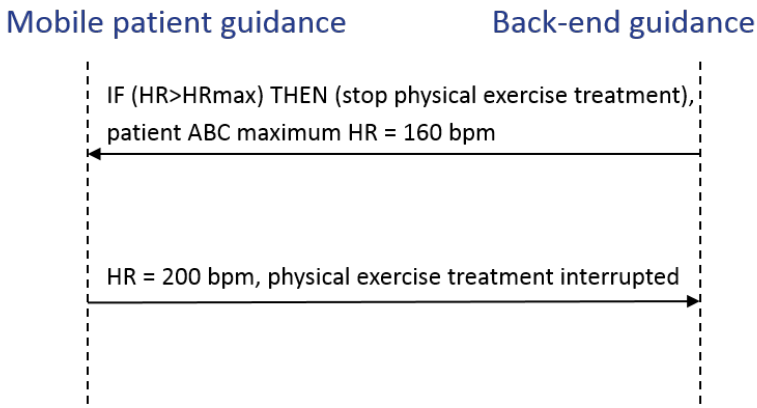


Figure 6.6: Simplified example of the sequence diagram between back-end guidance system and mobile patient guidance system

6.3.4 FUNCTIONAL REQUIREMENTS AND SYSTEM COMPONENTS

Next, we present the functional requirements for the identification of the required components in the next level of abstraction (3rd level of abstraction). Certainly, these functional requirements are also linked to the higher level functional requirements presented in Section 6.1.2 and refine the requirements of Section 6.2.4 (RE_{MPG} and RE_{BEG}). Hence, these requirements are specific for the mobile patient guidance subsystem and the back-end guidance subsystem.

The mobile patient guidance subsystem:

RE_{MPG}_01 - Shall interact with the patient

RE_{MPG}_02 - Shall structure the patient data (integrating the clinical data with its metadata) and store it locally in order to run autonomously

RE_{MPG}_03 - Shall provide guidance to the patient anytime and anywhere (autonomously)

RE_{MPG}_04 - Shall acquire, process and transmit patient clinical data

RE_{MPG}_05 - Shall compute clinical data quality (to enable QoD-aware safe guidance)

In order to fulfil these functional requirements we identify the following components:

- For RE_{MPG}_01, we identify a patient graphical user interface (GUI) component
- For RE_{MPG}_02, we identify a mobile storage component
- For RE_{MPG}_03, we identify a mobile CDSS component
- For RE_{MPG}_04, we identify a ICT resources component
- For RE_{MPG}_05, we identify a QoD Broker component

The back-end guidance subsystem:

RE_{BEG}_01 - Shall interact with the medical practitioner (caregiver)

RE_{BEG}_02 - Shall structure the patient treatment and information introduced by the medical practitioner and store it together with large amounts of mobile patient data (collected during long periods of time)

RE_{BEG}_03 - Shall process large amounts of data in order to provide personal and progressive treatment information to the medical practitioner and to update the system knowledge

To fulfill these back-end guidance functional requirements we identify the following components:

- For RE_{BEG}_01, we identify a caregiver graphical user interface (GUI) component
- For RE_{BEG}_02, we identify a back-end storage component
- For RE_{BEG}_03, we identify a back-end CDSS component

The communication between the mobile patient guidance system and the back-end patient guidance system is accomplished using public networks. The internal mobile components communicate via wireless or wired means. The back-end components are distributed, and therefore, the communication here is hybrid, formed by combining cloud and wired modules.
As listed above, we have identified components with five different functionalities: GUI, data storage, clinical decision support, information and communication technology (ICT) resources and QoD Broker. Based on the functional requirements of each of the systems (mobile or back-end), these functionalities are in both systems or solely in the mobile patient guidance system. The main reasons for having the ICT resources and the QoD Broker functionalities solely in the mobile patient guidance system are described below.

- ICT resources: The ICT resources can be integrated into the the mobile and the back-end subsystems. However, this research focuses on patient real time guidance, and for simplification purposes we have modeled the ICT resources in the mobile system close to the patient. This way it guarantees available data for the mobile CDSS, which can provide patient treatment guidance independent of potential data communication disruptions between the mobile platform and the back-end platform.
- QoD Broker: We could also argue that the QoD Broker could be distributed over the mobile and the back-end. On the one hand, it needs to be part of the mobile patient guidance system to guarantee the autonomous QoD-aware treatment guidance for the ambulatory patient. On the other hand, being part of the back-end guidance system enables the provision of QoD information for the back-end after the data is being communicated from the mobile to the back-end system. However, there are two main reasons that justify the choice of locating the QoD Broker only in the mobile part of the system (Section 6.4):

– The focus of this research is patient guidance, and hence, we focus on computing the QoD of the extramural data, which refers to the clinical data provided by the ICT resources. The ICT resources provide the QoS data for QoD computation and they are designed to be part of the mobile patient guidance system. Hence, the QoD Broker must be physically close to the ICT resources to avoid potential QoS data communication problems.
– QoD Broker has to guarantee the availability of QoD information for patient treatment guidance regardless of the back-end system availability. This patient treatment guidance is provided by the mobile CDSS and it is also located in the mobile patient guidance system.

6.4 MOBILE PATIENT GUIDANCE SYSTEM ARCHITECTURE

In this section we describe the components of the mobile patient guidance system (Figure 6.7), their exchanged messages and the exchange protocol of the messages - *3rd level of abstraction*.

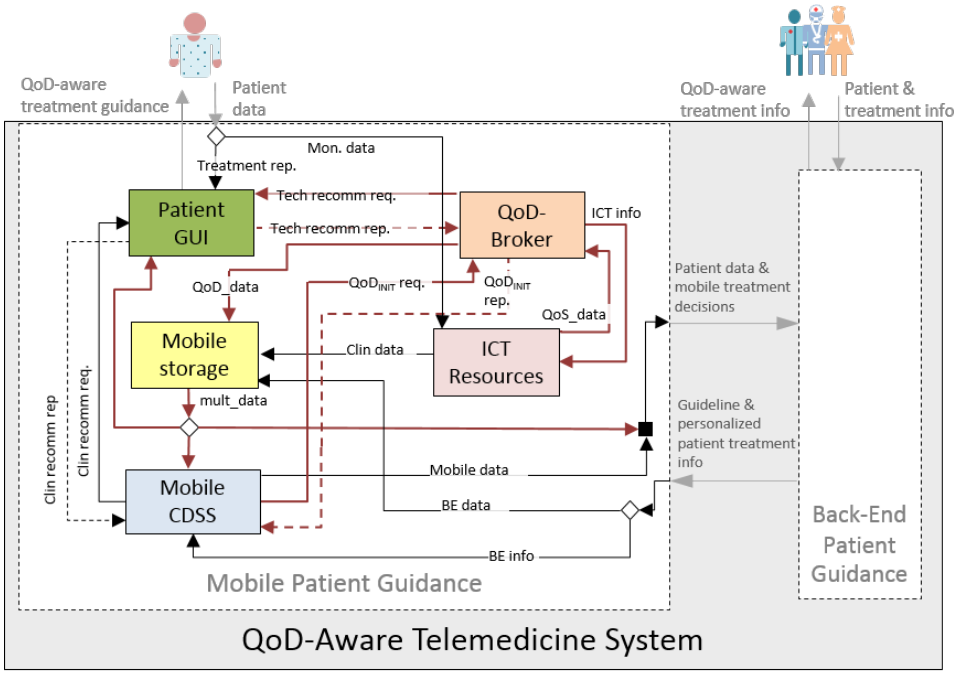


Figure 6.7: Mobile patient guidance system components

Figure 6.7 focuses on the representation of the mobile patient guidance components and their interactions. Notice that the scope of this research is on the QoD-awareness of the telemedicine system. Hence, we emphasize the QoD-awareness related information. See the figure notation in Appendix B.

6.4.1 COMPONENT DESCRIPTION

Table 6.6 describes each of the mobile patient guidance system components.

Components	**Description**
Patient GUI	The patient GUI supports patient-system interaction. It is usually implemented in the patient's smartphone and it provides login and logout services, clinical data visualization services and system-user interaction services. The system-user interaction contains treatment guidance information via clinical and technological recommendations. It also allows the patient to respond to these recommendations.
ICT Resources	The Information and Communication Technology (ICT) resources comprise clinical data monitoring, processing and communication services and ICT resources management services. Hence, it autonomously acquires, processes and transmits patient extramural clinical data and also accepts clinical data manually inserted by the user. Additionally, the ICT resources also comprise a resource configuration manager (RCM), which enables the management of the monitoring, processing and communication resources.
Mobile CDSS	The mobile CDSS provides standalone guideline-based QoD-aware treatment guidance to the ambulatory patient. It acquires all relevant information, such as patient data and treatment knowledge from the back-end, and clinical data and its quality from the mobile storage, in order to provide personalized QoD-aware treatment guidance to a patient.
QoD Broker	The QoD Broker provides QoD-awareness to the whole system by computing QoD and enabling the improvement of QoD with the use of technological recommendations. Hence, if QoD is in risk of degradation and this degradation is avoidable by interrupting or configuring some resource, the QoD Broker will provide a technological recommendation to the patient or to the ICT resource's RCM.
Mobile Storage	The mobile storage provides a data integration service to integrate patient clinical data with its own metadata (e.g. QoD) and local data storage-retrieval services to the rest of the mobile patient guidance components.

Table 6.6: Description of the mobile patient guidance components

6.4.2 MESSAGE EXCHANGE

Table 6.7 provides the description of the messages exchanged between the components of the mobile patient guidance system.

Provider	User	Message name	Description
ICT Resources	Mobile Storage	Clin. data	Ambulatory patient clinical data (e.g. vital signs, manually inputted clinical data) with its identifier (D_{ID}).
	QoD Broker	QoS_data	QoS data of the ICT resources that provide the clinical data with the same data identifier as the clinical data (QoS_{ID}).
Mobile Storage	Mobile DSS, Patient GUI, Back-end[i]	mult_data	The stored clinical data and its corresponding quality information.
Mobile CDSS	Patient GUI	Clinical recomm req.	Treatment guidance information in terms of clinical recommendations for the patient. These recommendations may be just notifications or recommendations which require a response from the patient (e.g. "OK" or "CANCEL").
	QoD Broker	QoD_{INIT} req.	Request for the clinical data quality before the execution of a treatment (treatment initialization) to determine if the treatment is (safely) accomplishable. Hence, in this request it provides (patient specific) declarative treatment information (e.g. prescribed physical exercise treatment duration for the specific patient), which is the contextual information required to determine the QoD.
	Back-end [i]	Mobile_data	Information of treatment decisions taken by the mobile CDSS, so that the back-end is aware of it, can perform further treatment analysis and inform the medical practitioner of any anomaly or change if necessary.
QoD Broker	Mobile Storage	QoD_data	Clinical data quality information (metadata) with the same identifier as the corresponding clinical data stored by the ICT resources for matching purposes (QoD_{ID}).
	Mobile CDSS	QoD_{INIT} rep.	Response of QoD initialization information for a specific treatment initialization.

[i] The back-end guidance system and the patient are not part of the MPG system, but included in this table since they interact with the MPG system components.

	ICT resources	ICT info	Management information for ICT resources (e.g. required to switch of AF detection algorithm) to guarantee 'best' possible performance of essential ICT resources that prevent QoD degradation.
	Patient GUI	Tech recomm req.	Technological recommendations for the patient (e.g. charge the sensor) to prevent QoD degradation. These recommendations may be just notifications or recommendations, which require the response of the patient (e.g. "OK" or "CANCEL").
Patient GUI	Mobile CDSS	Clinical recomm rep.	Patient response to the provided clinical recommendation (e.g. "OK" or "CANCEL").
	QoD Broker	Tech recomm rep.	Patient response to the provided technological recommendation (e.g. "OK" or "CANCEL").
Back-end[i]	Mobile Storage	BE data	It is the patient clinical data stored in the back-end that may be required for the mobile treatment guidance (e.g. patient's medical history).
	Mobile CDSS	BE info	Patient's personalized treatment guidance information, including the prescribed treatment, medication doses, times etc.; and back-end treatment decisions that should be sent to the patient.
Patient[i]	Patient GUI	Treatment rep.	Patient response to treatment guidance provided by the system.
	ICT resources	Mon. Data	Patient clinical data (e.g. vital-signs) acquired by the ICT resources (e.g. sensing components).

Table 6.7: Interactions between the components of the mobile patient guidance system

6.4.3 PROTOCOL FOR MESSAGE EXCHANGE

In order to describe the communication protocol between the mobile patient guidance subcomponents, we present two activity diagrams. These diagrams represent the possible sequences of exchanged messages between the components of the mobile patient guidance systems. Each of the activity diagrams describe part of the communication that correspond to different roles of QoD Broker within the system. Before the communications described in these two activity diagrams starts, the mobile CDSS has to acquire the back-end treatment information and then the mobile storage has to acquire the back-end patient data. This is illustrated in the activity diagram in Section 6.5.3.

6.4.3.1 ACTIVITY DIAGRAM 1

This activity diagram (Figure 6.8) represents part of the activities that occur in the mobile patient guidance system related with QoD awareness. Table 6.8 lists the abbreviations that we use to denote components and activities in the activity diagrams. Some of the activities may take place multiple times, while the other activities are executed just once (see *"_multiple_times"* in Table 6.8).

Component	**Activities**
A Patient GUI	1 Send_Clin_data_multiple_times
B ICT resources	2 Send_QoS_data_multiple_times
C QoD Broker	3 Send_QoD_data_multiple_times
D Mobile Storage	4 Send_Tech_recomm_req
E Mobile CDSS	5 Send_ICT_recomm
	6 Send_Data+QoD
	7 Send_Treatment_guidance
	8 Send_Tech_recomm_rep
	9 Send_Clin_recomm_req
	10 Send_Clin_recomm_rep
	11 Send_QoD_{INIT}_req
	12 Send_QoD_{INIT}_rep

Table 6.8: Abbreviation of the components and activities of activity diagram 1 and activity diagram 2

As shown in Figure 6.8, the communication is started by with the ICT resources. ICT resources acquire patient's clinical data (e.g. vital-signs) and ICT resources performance information (i.e. quality of service information).

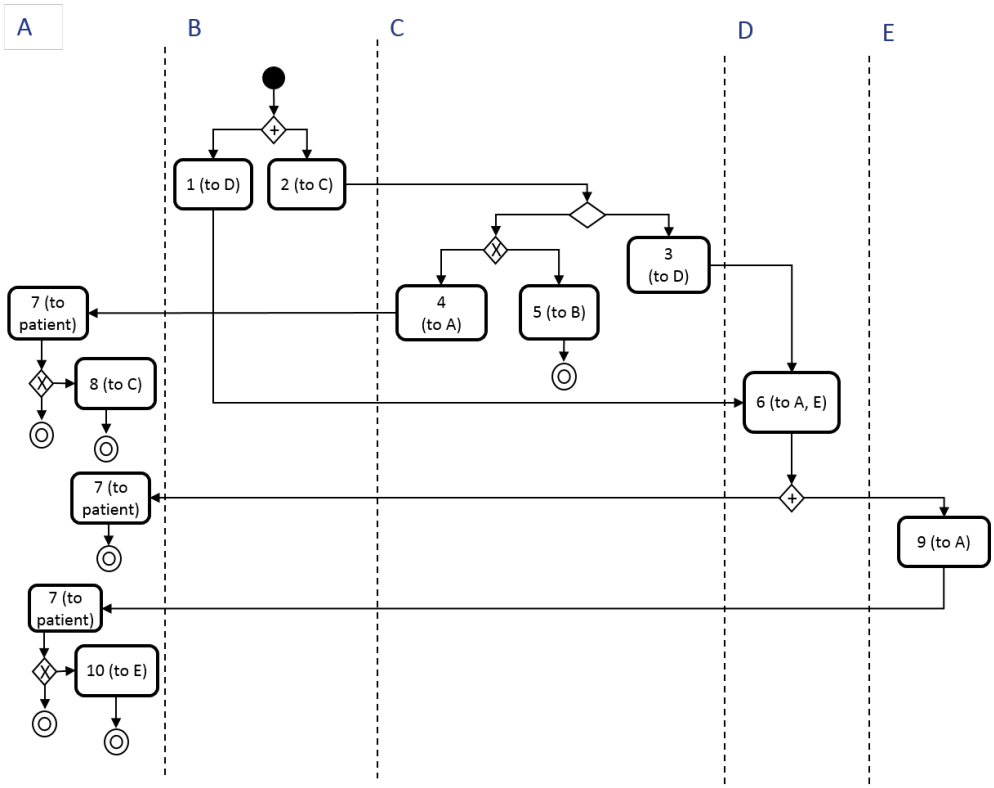


Figure 6.8: Activity diagram 1 of the communication between the components of the mobile patient guidance system

If we are dealing with streaming data, these activities may be executed multiple times. The clinical data is monitored, processed and transferred to the mobile storage. The quality of service (QoS) data is sent to the QoD Broker. The QoD Broker processes the QoS and it provides a recommendation or/and QoD information. The QoD information may be sent multiple times if we are dealing with QoD of streaming data.
There are two types of recommendations provided by the QoD Broker: ICT management recommendations to the ICT resources or technological recommendations to the patient GUI (Figure 6.7). The ICT resources component includes the RCM, which manages the resources. The patient GUI provides the technological recommendation to the patient. If the technological recommendation is just a notification, the activity ends. On the other hand, if the technological recommendation requires a reply, the answer (*"Tech_recomm_rep"*) is sent to QoD Broker, which may use this response for the QoD computation.

The QoD information from the QoD Broker is stored in the mobile storage. The mobile storage integrates both the clinical data and its QoD metadata. It sends this information (*"Data+QoD"*) to the patient GUI and to the mobile CDSS. The CDSS processes this information and, if necessary, provides clinical recommendations to the patient via the patient GUI. If the clinical recommendation is just a notification, then the communication ends. On the other hand, if the clinical recommendation requires a reply, the answer (*"Clin_recomm_rep"*) is sent back to the mobile CDSS.
The use case presented in Table 6.9 and the time sequence diagram of Figure 6.9 are an instance of the activity diagram illustrated in Figure 6.8.

Use Case 1: QoD and technological recommendation provision by QoD Broker	
Brief description	Clinical data is measured and/or processed with low QoD, and measures are taken to improve clinical data quality
Primary actors	QoD Broker, ICT Resources, Mobile CDSS
Secondary actors	Patient GUI and Mobile Storage
Pre-conditions	Mobile CDSS has acquired the Back-End treatment information
Main flow	• ICT resources provide noisy (streaming) clinical data to the mobile storage • ICT resources provide (streaming) QoS data to the QoD Broker; QoD Broker acquires and processes this QoS data, which results in (3) and (4) • QoD Broker computes (streaming) QoD low and provides it to the mobile storage • QoD Broker provides a technological recommendation to the patient via the patient GUI, so that the clinical data QoD is improved • The mobile storage provides the stored (streaming) clinical data and its corresponding (streaming) QoD information to the mobile CDSS • The mobile CDSS processes the (streaming) low quality clinical data and provides a safe (QoD-aware) clinical recommendation to the patient via the GUI • The patient replies to that clinical recommendation via the patient GUI

Table 6.9: Use case 1

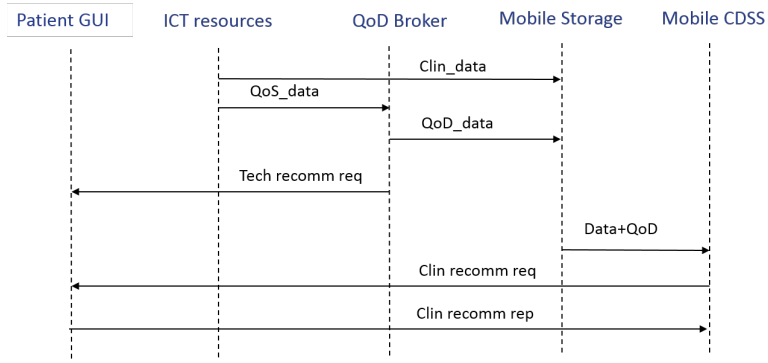


Figure 6.9: Time sequence diagram corresponding to use case 1

Example: This example is addressed in the context of AF physical exercise treatment. First, the ICT resources provide clinical data, which is stored directly in the mobile storage, and QoS data (SNR = 0 dB, which represents a noisy signal), which are processed by the QoD Broker. The resulting QoD information from the QoD Broker is stored in the mobile storage. Additionally, the QoD Broker sends a technological recommendation to the patient via the Patient GUI. The mobile CDSS processes the data and its QoD. Consequently, due to the "low" QoD, will provide a technological recommendation to the patient to "slow down", which is acknowledged by the patient (Figure 6.10).

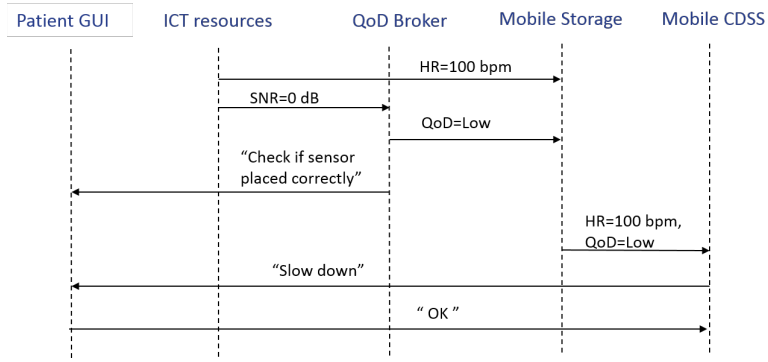


Figure 6.10: Concrete communication example corresponding to use case 1

6.4.3.2 ACTIVITY DIAGRAM 2

The following activity diagram in Figure 6.11 illustrates the other part of the QoD-aware related activities that occur in the mobile patient guidance system. During these activities, the QoD Broker and the mobile CDSS must have QoS data and clinical data respectively. Hence, a precondition for this activity diagram is that the ICT resources activities (i.e. *"Send_QoS_data_multiple_times"* and *"Send_Clin_data_multiple_times"*), presented in the previous activity diagram, are executed beforehand.

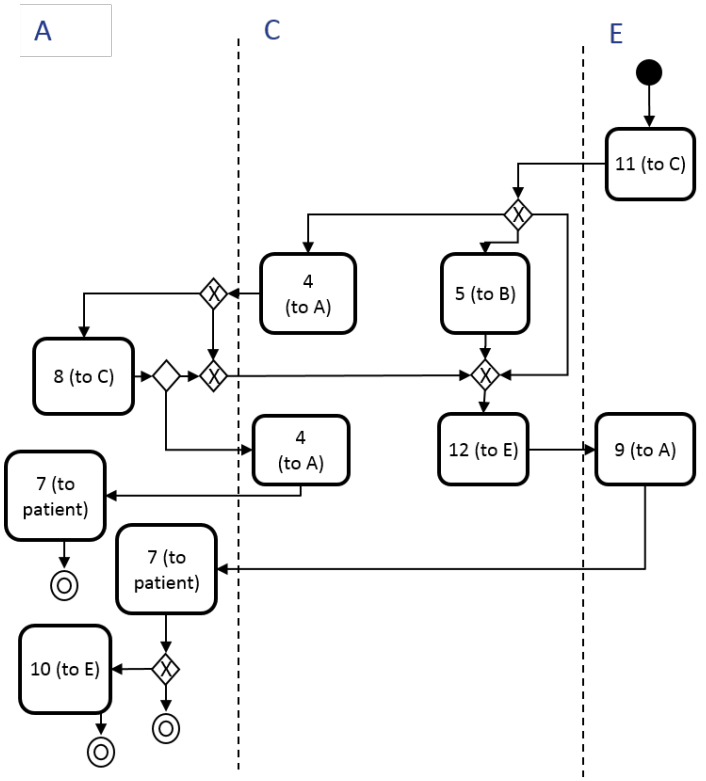


Figure 6.11: Activity diagram 2 of the communication between the components of the mobile patient guidance system

In this activity diagram, the mobile CDSS starts the activity by requesting QoD_{INIT} information from the QoD Broker. The purpose of this request is to identify before the treatment starts whether the ICT resources can guarantee provision of clinical data that fulfils the medical QoD requirements during the treatment (Section 5.3.2).

When this request is sent to QoD Broker, it processes the QoS data and, depending on the ICT resources status, may behave in one of three possible manners (based on criteria used by its internal logic):

1. The QoD Broker provides a technological recommendation (notification or recommendation that requires a response) to the patient (via the patient GUI) to ensure the ICT resources are performing according to the requirements (e.g. "Charge the smartphone battery")

2. It sends an ICT recommendation to the ICT resources' RCM for ICT configuration purposes (e.g. "deactivate AF detection algorithm").

3. It does not provide any recommendation and directly jumps to the next step, which is a QoD_{INIT} response.

Thereafter, the QoD Broker provides a QoD_{INIT} response to the mobile CDSS. This information is processed by the mobile CDSS, which results in a clinical recommendation to the patient GUI and the patient may send a response back to the mobile CDSS.
The use case and time sequence diagram from Table 6.10 and Figure 6.12 represents an instance of the activity diagram illustrated in Figure 6.11.

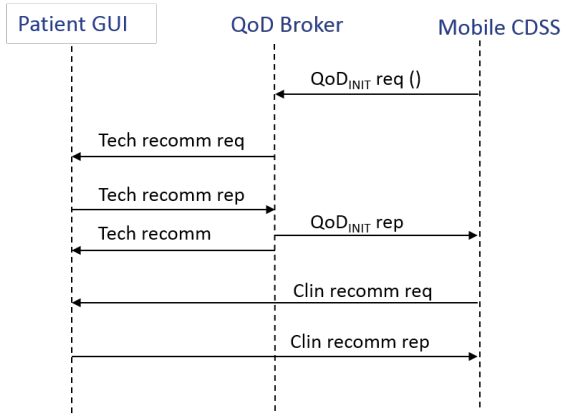


Figure 6.12: Time sequence diagram corresponding to use case 2

Use Case 2: QoD_{INIT} request before the treatment execution	
Brief description	CDSS needs to guarantee QoD status before executing a treatment
Primary actors	QoD Broker, Mobile CDSS
Secondary actors	Patient GUI
Pre-conditions	• Mobile CDSS has acquired the Back-End treatment information • QoD Broker has acquired QoS data from ICT resources
Main flow	• Mobile CDSS requests QoD initialization information from QoD Broker • Based on previously acquired QoS data (e.g. not sufficient bioharness sensor battery for the required treatment), QoD Broker requests a technological recommendation from the patient (e.g. "Did you charge the bioharness sensor recently") • The patient will respond to this recommendation (e.g. "NO") • This information (together with QoS data) is used to provide the QoD initialization information to the mobile CDSS (e.g. "QoD=medium") • And a technological notification (e.g. "charge the Bioharness sensor for 1h") • The mobile CDSS processes this data and provides a clinical recommendation to the patient (e.g. "postpone the physical exercise therapy") • The patient, via the patient GUI, responds to this recommendation (e.g. "OK")

Table 6.10: Use case 2

Example: A simplified example with concrete messages exchanged in this sequence diagram is shown in Figure 6.13. This scenario occurs in the context of an AF physical exercise treatment. First, the mobile CDSS requests QoD_{INIT} information by providing context information with that request: AF medical case, physical activity (PA) treatment, and 60 minutes duration. The QoD Broker processes the QoS data and triggers an alert of no sufficient BioHarness sensor battery to monitor HR. Hence, it asks the patient if the sensor was charge recently ("Did you charge sensor recently?"). The patient replies negatively (with "NO"). The QoD Broker provides the QoD_{INIT} information with quality grade "Low" to the mobile CDSS and sends a technological recommendation to the patient ("Charge sensor for 1 hour"). In parallel, the mobile CDSS processes the QoD_{INIT} information and requests the patient to wait for 1 hour ("Wait 1 hour for physical exercise treatment"), which is acknowledged by the patient (with an "OK").

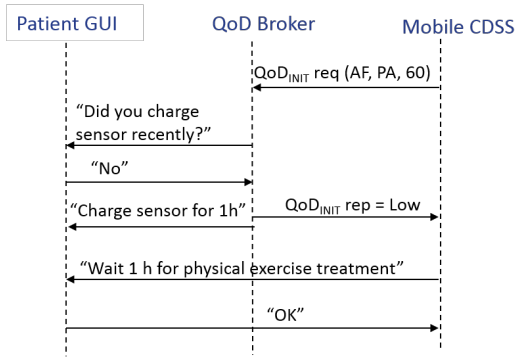


Figure 6.13: Concrete communication example corresponding to use case 2

6.5 BACK-END GUIDANCE SYSTEM ARCHITECTURE

Since this research is focused on QoD-aware treatment guidance for ambulatory patients, the mobile guidance system has one of the main roles in the QoD-awareness provisioning. However, to provide the complete overview of the system, we also provide the description of the back-end guidance system architecture (Figure 6.14). First, we provide the description of the components within the back-end guidance system and then, we present the interaction between these components. Finally, we conclude with describing the required protocol for the exchanged messages - *3rd level of abstraction*.

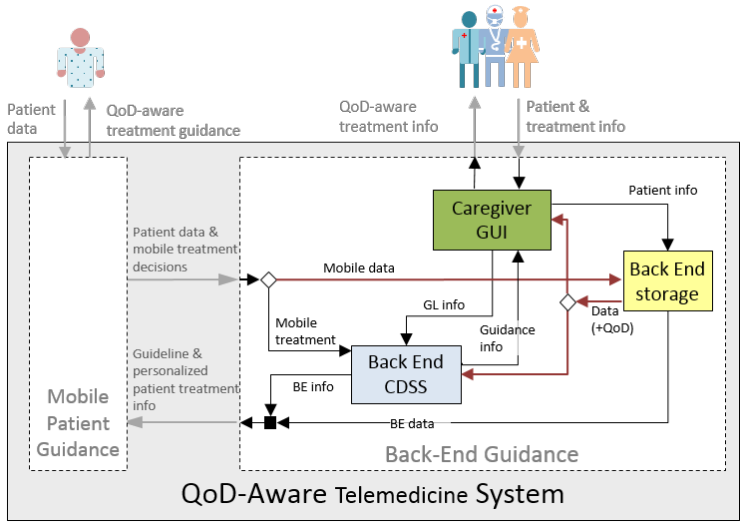


Figure 6.14: Back-end guidance system components and their interaction

6.5.1 COMPONENT DESCRIPTION

As discussed in Section 6.3, the ICT resources and the QoD Broker are not part of the back-end guidance system. The back-end guidance system comprises three components: caregiver GUI, Back-End CDSS and Back-End storage component (Figure 6.14). Table 6.11 provides the description of these components.

Components	Description
Caregiver GUI	The caregiver GUI supports the medical practitioner-system interaction. It is usually implemented in the web server and is accessible from the medical practitioner's computer. It enables the medical practitioner to select the guideline (procedural knowledge) and to integrate patient information (declarative knowledge), so that the system contains the required treatment information. The caregiver GUI is also the interface used to notify the medical practitioner about any relevant patient condition (e.g. patient compliance, glucose level increment during last week etc.) during the ambulatory treatment. It provides the visualization of the clinical data and its QoD, which are stored in the back-end storage. This data visualization supports the medical practitioner in his/her treatment decisions.
Back-end CDSS	The back-end CDSS acquires patient-specific guideline information and personal information (e.g. patient clinical data stored into the back-end storage). Based on this information, it provides guideline-based QoD-aware treatment guidance to the patient by using the mobile patient guidance system (using a projection language [6], Figure 6.17). It also provides treatment guidance information to the care practitioners via the caregiver GUI.
Back-end Storage	The back-end storage integrates the clinical data with its own metadata (e.g. QoD), and provides a data storage-retrieval service to the rest of the back-end components and mobile patient guidance system. We model this back-end storage as an integrated database within the internal hospital electronic health records (EHRs), which stores both the intramural medical records (e.g. patient medical history records), and the ambulatory patient clinical data (extramural records) [92].

Table 6.11: Description of the back-end guidance system components

6.5.2 MESSAGE EXCHANGE

Figure 6.14 illustrates the interactions between the back-end guidance system components. Table 6.12 provides the description of the exchanged information.

Provider	User	Message name	Description
Caregiver GUI	Back-end CDSS	GL info	Patient treatment guideline information (procedural knowledge) required for the execution of the extramural treatment.
	Back-end Storage	Patient Info	Patient personal information (declarative knowledge) entered by the medical practitioner (via the caregiver GUI) during patient consultation.
Back-end CDSS	Caregiver GUI	Guidance info	Treatment guidance information (e.g. treatment recommendation sent to the patient or notifications of possible urgent treatment matters) for the care practitioners via the caregiver GUI.
	Mobile[a]	BE info	Back-end (BE) information (e.g. back-end treatment decisions) for the patient sent via the mobile guidance system.
Back-end Storage	Back-end CDSS, Caregiver GUI	Data(+QoD)	Patient clinical data (e.g. guideline declarative knowledge and monitored clinical data) and its potential QoD information.
	Mobile[a]	BE data	Patient clinical data stored in the back-end system from the caregiver GUI or hospital databases, required in the mobile guidance system.
Mobile[a]	Back-end storage	Mobile data	Extramural patient clinical data (e.g. vital signs and manually input data) and its corresponding QoD information acquired from the mobile guidance system.
	Back-end CDSS	Mobile treatment	Mobile treatment information (e.g. treatment decisions) taken by the mobile CDSS and the patient's responses.

Table 6.12: Interactions between the components in the back-end guidance system

[a]The mobile patient guidance system is not part of the back-end guidance system, but it is included in this table since it interacts with the back-end guidance system components.

6.5.3 PROTOCOL FOR MESSAGE EXCHANGE

In Table 6.12, we provide the description of the information exchanged between the back-end system components. We describe the protocol for these interactions with an activity diagram (Figure 6.15).

6.5.3.1 ACTIVITY DIAGRAM 3

This activity diagram corresponds to the activities handled by the back-end guidance system components.
Table 6.13 lists the abbreviations that we use to denote components and activities in the activity diagram.

Component	**Activities**
A Caregiver GUI	1 Send_Patient_info
B Back-End Storage	2 Send_GL_info
C Back-End CDSS	3 Send_BE_data
	4 Send_Data(+QoD)
	5 Send_Guidance_info
	6 Send_BE_info

Table 6.13: Abbreviation of components and activities of activity diagram 3

This activity diagram describes the following: The medical practitioner selects the appropriate guideline for a specific patient (procedural knowledge) and introduces patient information via the caregiver GUI (declarative knowledge). This patient information is stored in the back-end storage and may be transmitted to the mobile patient guidance system or/and used by the caregiver GUI and the back-end CDSS. Guideline information is sent to the back-end CDSS. Using this guideline information, together with the data from the back-end storage, the CDSS will provide both guidance information to the medical practitioner or/and BE information to the mobile platform for patient guidance purposes.
The use case and time sequence diagram in Table 6.14 and Figure 6.16 represent an instance of the activity diagram illustrated in Figure 6.15.

In this case we do not provide an example since the information shared is extensive and not easy to comprehend. In order to share the QoD-aware treatment guidance information, a projection language is developed [6]. Figure 6.17 shows an example of the projection language.

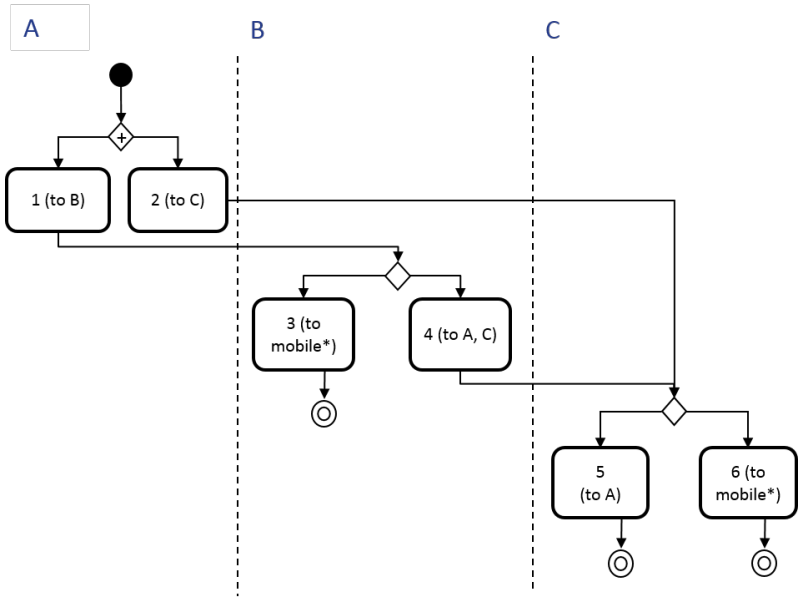


Figure 6.15: Activity diagram describing the communication between the components of the back-end guidance system

Use Case 3: Knowledge and information acquisition	
Brief description	The medical practitioner enrolls a patient and introduces the necessary treatment information into the system and the system provides guidance
Primary actors	Caregiver GUI, Back-end storage, Back-end CDSS
Secondary actors	None
Pre-conditions	None
Main flow	• Caregiver GUI selects guideline (GL) information (procedural knowledge) to be executed for the particular patient, which is processed by the back-end CDSS • Caregiver GUI provides patient information (declarative knowledge) to the back-end storage • The back-end storage provides the stored clinical data (e.g. intramural information and extramural mobile information if already acquired from the mobile patient guidance system) and its potential QoD to the back-end CDSS • The back-end CDSS processes the clinical data and related QoD to provide guidance information to the practitioner via the caregiver GUI

Table 6.14: Use case 3

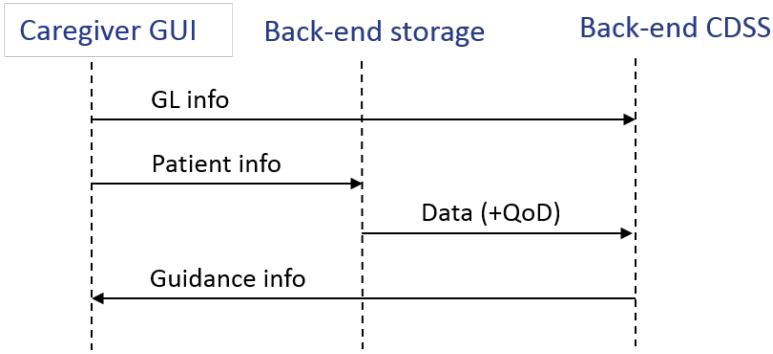


Figure 6.16: Time sequence diagram corresponding to use case 3

6.6 IMPLEMENTATION IN MOBIGUIDE

MobiGuide (MG) presents an opportunity to implement the QoD-aware telemedicine system architecture that is described in this chapter. The central objective of the MG project is "to provide continuous patient guidance in non-clinically controlled environments, even if the patient is on the go (mobile)" [4]. The implementation described in this section is based on the design choices agreed by MG partners.

6.6.1 DATA

One of the challenges in MG was to determine how to communicate between different MG components and their environments (e.g. electronic health records (EHR)). As discussed in [92], semantic interoperability enables meaningful understanding by different systems of all information being transferred among components. It assures global consistency in meaning, a basic requirement to enable better health care and to promote the reuse of clinical data for purposes other than health care, for example clinical research. However, it is difficult to implement, as it requires not only the definition of a common ontology or standard to be used by each of the services and components, but also its implementation separately by each one.
The most extensive project that supports conversions between major international classification systems and records relations among terms in heterogeneous sources is the Unified Medical Language System (UMLS). UMLS is a compendium of many controlled vocabularies in the biomedical sciences. Some examples of the incorporated controlled vocabularies are ICD-10, LOINC, SNOMED CT, and MeSH. Hence, to support this interoperability

in MG, we adopted the virtual Medical Record (vMR) class and the Systematized Nomenclature of MEDicine Terms (SNOMED CT) UMLS standard codes as the logical data model due to its simplicity as well as its expressiveness [92, 93, 94].

6.6.2 MOBILE PATIENT GUIDANCE SYSTEM

Here we describe the mobile patient guidance system implementation choices for data exchanged, interaction protocols and design choices.

- Data:
  To ensure the interoperability between the mobile components, all exchanged patient data is formatted using JavaScript Object Notation (JSON). The dynamic technological information, i.e. Quality of Service (QoS) information, used only by the QoD Broker, will be transmitted using JSON objects. However, this information will not be defined as vMR classes, since it is not medical information.
  The QoD information must be associated to its corresponding clinical data. The association between clinical data and its QoD is not done by using a timestamp, but by using a clinical data ID produced by the GUI. For that, the QoD has an additional parameter ('flag') to indicate if the data is associated to any previously existing data.
- Interaction:
  The communication between different mobile patient guidance system components, in MG implemented by Body Area Network (BAN) components, is handled by the BAN front-end services. In [94] we describe the services offered by the BAN front-end. These are all based on Android services and Android Interface Definition Language (AIDL) descriptions. Here we present the most relevant services provided for the main interactions described in the previous sections.
  The BAN services consist of a data subscription service and a data broadcast service. These services enable data interaction between different mobile components. Each of the components in the mobile patient guidance system can provide its own data using the corresponding identification ID. Other BAN components can subscribe to the data source by using the respective ID. Therefore, when the data is broadcasted from one of the data sources, the subscribed components will receive the data. It essentially works as a data 'push' service, i.e. the data provider sends "fresh" data to the user without waiting for a request from the client

(and not as a data 'pull', i.e. request data, service). In Appendix C we present the methods implemented for the MobiGuide mobile patient guidance system component interactions.

- Design choices:
  There are certain differences between the presented patint guidance system architecture and the system inplemented in MG.
  Firstly, in the generic architecture described in Section 6.6.2 the data integrator in the mobile storage component will associate QoD with the corresponding clinical data using the clinical data's ID. In MG, the mobile storage, and hence, the data integrator, is distributed in each of the components. Hence, the association between clinical data and its QoD information occurs inside each of the components that receive and store the clinical data and its QoD (e.g. mobile CDSS).
  Secondly, the ICT resources are also distributed in MG, unlike the system presented in this chapter. Hence, in order to structure the data into vMR instances, which integrate ID information, we needed another resource. Since the patient GUI is also a clinical data source for manual data input, it was decided that the patient GUI structures the data [95]. Therefore, the clinical data provided by the distributed ICT resources goes through the patient GUI.
  Despite these differences, we can see that the system follows the same principles of QoD-awareness.

6.6.3 BACK-END GUIDANCE SYSTEM

Here we describe the back-end guidance system implementation choices for data exchanged and interaction protocols.

- Data:
  The BAN back-end also follows the vMR class and SNOMED CT UMLS standard codes to support the semantic interoperability. This way, the data is shared between the back-end system and the mobile (front-end) systems.
- Interactions:
  The communication between the back-end guidance system components is handled by the BAN back-end services. These are all based on Web Services using SOAP and WSDL specifications. The main services offered by the BAN back-end are described in Appendix D.

6.6.4 BACK-END GUIDANCE SYSTEM VS. MOBILE PATIENT GUIDANCE SYSTEM

Every patient has a mobile (smartphone) system and a set of ICT resources (e.g. sensors). One of these mobile components is the BAN front-end, which is the counter part of the BAN back-end. In the MG system there is one BAN back-end (back-end guidance system) and multiple BAN front-ends (mobile patient guidance system) components active. The BAN front-end implements functions that enable the MG back-end to securely communicate with components on the patient mobile system and vice-versa. Additionally, the BAN front-end enables internal communication between components of the mobile system. Finally, it provides functions to communicate with sensors, collect data, analyze data, store data and send the data to the BAN back-end [94].
For example, using the BAN front-end messaging service, the data stored in the back-end storage can be retrieved by the mobile patient guidance system components (e.g. implemented by the patient GUI, instead of the mobile storage shown in the architecture). For the system implemented in MG, the data from the mobile components is broadcasted to the back-end data storage (Data Integrator) using the BAN front-end broadcast service.
Furthermore, the MG system uses the BAN message services in order to provide the guideline knowledge (procedural and declarative knowledge) from the back-end CDSS to the mobile CDSS. For that, in MG we developed a common projection language [6]. This projection language was designed to be simple, yet flexible, powerful and generic. The projection language is based on JavaScript for execution using the Rhino scripting engine, which was chosen for its technical suitability: it runs on Android and enables full processing state save/restore by means of its built-in continuation mechanism [6].
Figure 6.17 illustrates an example of a unit projection, which is part of a whole guideline projection [6]. It represents a condition in the GDM guideline (two abnormal blood glucose (BG) measurements within one week), which triggers a recommendation to change the blood glucose measurement schedule when the monitored values, collected during a week (temporal abstraction), are 'correct' (within the regular boundaries).

```
unitProjection("20095","2 abnormal measurements in past week")  annotateTemporal("or", [
"event.getNumber(4985)>=150",
"event.getNumber(4986)>=150",
"event.getNumber(4987)>=150",
"event.getNumber(4988)>=150"
], "abnormalBG", "date"); while (true)  waitTemporalQuery("count >= 2", "abnormalBG", "8
calendardays"); callback("5111", "2 abnormal values in BG were found in your measurements
in the past week, system is calculating another schedule for you");
```

Figure 6.17: Example projection [6]

The *annotateTemporal* statement, used in this example projection, defines the condition under which a record or set of records is annotated with a particular tag. In this case, it tags a set of events as *abnormalBG* if one or more BG measurements, over *150*, occur in one calendar day. The numbers *4985-4988* represent BG measurements at particular times of the day with quality higher than "very low". The wait loop at the bottom waits for at least two *abnormalBGs* to occur within *8 calendardays*, and then sends a callback.
Although not explicitly shown in Figure 6.17, projections may also include details of the clinical effects of QoD. Data with insufficient quality may, for example, be tagged differently by being given a different ID, and may, as a result, trigger different procedures.

6.7 CONCLUSIONS

This chapter covers the generic architecture of a QoD-aware telemedicine system and presents details of the implemented prototype in MobiGuide.
We acknowledge that the current design and prototype has certain limitations and can be improved:

- *Distributed QoD Broker:* In this research we focus on the patient guidance system, and hence, we focus on the QoD awareness in the mobile patient guidance system. However, a QoD-aware telemedicine system may require a QoD Broker on the back-end guidance system's data. This way, the information stored in intramural medical health records and data introduced by medical practitioners, which often do not fulfil the medical quality requirements (e.g. contain errors), will also be QoD-aware.
- *ICT resources prototype optimization:* In the current MG system prototype, ICT resources contain sensors, processors and communication

resources, but do not include any management component (i.e. resource configuration manager (RCM)). Hence, the functionality to manage the ICT resources is not implemented. Besides, similar to the QoD Broker, ICT resources may also need to be modeled into the back-end guidance system's since the back-end also contains data processing and communication components. Furthermore, ICT resources are distributed and a dedicated components, necessary to structure vMR instances, does not exist. Consequently, in the current prototype, the patient GUI is the component in charge of structuring the data into vMR instances.

- *Data input automation:* In the current setting, it is not possible to monitor all clinical data autonomously, i.e. without patient interaction (e.g. diet information). Therefore, in the current design, the patient-user interfaces, necessary to manually input clinical data from the extramural setting, are designed within the ICT monitoring resources. Hence, patient characteristics (e.g. education, age) are considered as QoS data (see Chapter 3) to compute the quality of the manually inputted data. However, the future prototype is expected to be fully automated. Otherwise, due to the complexity of human behavioral features, further study would be necessary to compute the quality of manually inputted data.

CHAPTER 7

THE QOD BROKER

As introduced in Chapter 6, the QoD Broker is the key component that provides QoD-awareness to the whole telemedicine system. In this chapter, we elaborate the design of the QoD Broker. Based on the description of the QoD Broker and its environment, we first identify the functional requirements of QoD Broker. These functional requirements then result in the QoD Broker architecture design, which comprises the description of QoD Broker subcomponents. Thereafter, we present the QoD Broker functionalities that address how the QoD Broker components (inter-)operate in order to fulfil the user requirements.
This chapter is structured as follows: Section 7.1 introduces the white-box architecture of the QoD Broker, describing each of the QoD Broker components and the interactions between them. Section 7.2 addresses the method we used to select the QoD dimensions discussed in this research and provides their definition. Section 7.3 presents the five QoD management techniques we developed using the selected QoD dimensions. Section 7.4 illustrates the implementation of the QoD management techniques in the MobiGuide (MG) project. We conclude this chapter with a discussion about the implemented QoD Broker architecture and functionalities (Section 7.5).

7.1 QOD BROKER ARCHITECTURE

In Chapter 6, we already described the QoD Broker (Section 6.4.1). Here, we refine the RE_{MPG}_05 functional requirement as follows. The QoD Broker:

1. Shall acquire the required QoD management knowledge (i.e. QoD im-

provement and computational rules and algorithms)

2. Shall provide "useful" QoD information

3. Shall provide technological recommendations that enable the improvement of QoD

Based on the described functional requirements, the QoD Broker comprises three main sub-components (Figure 7.1):

- For (1), we identify the ***QoD logic***, which acquires the required QoD management knowledge
- For (2), we identify the ***QoD qualifier***, which provides the useful QoD information
- For (3), we identify the ***Technological recommendation composer***, which provides technological recommendations that enable the improvement of QoD

Following the same approach and structure as in Chapter 6, this section provides the description of QoD Broker components (Section 7.1.1), exchanged messages between QoD Broker components (Section 7.1.2), and the protocol for these exchanged messages (Section 7.1.3).

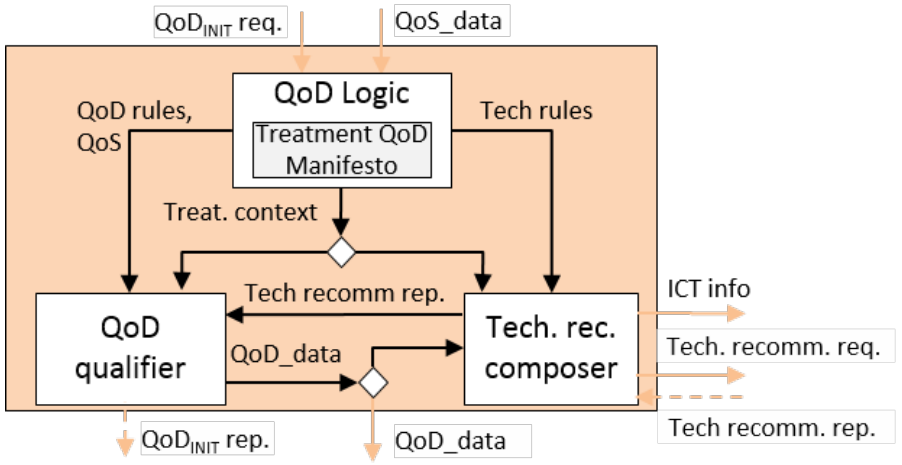


Figure 7.1: QoD Broker components and their interactions

7.1.1 QOD BROKER COMPONENTS DESCRIPTION

In Chapter 6, we described a telemedicine system at three levels of abstraction. Here, we describe the decomposition of the QoD Broker, which corresponds to a 4th decomposition level (Figure 7.1). In Table 7.1, we describe each of the QoD Broker components.

Components	**Description**
QoD Logic	This component hosts all QoD management knowledge (i.e. QoD improvement and computational rules and algorithms) in the treatment QoD manifesto (technological ontology - Section 4.2.1). It receives QoS data (static and dynamic) and QoD_{INIT} requests, which contain the treatment declarative information, used when necessary for QoD computation. It provides the necessary QoD management knowledge and data (QoS) to the other QoD Broker components.
QoD qualifier	It acquires QoD computation knowledge. Using this knowledge, it processes the data (QoS, treatment context) in order to compute QoD information for the specific context.
Technological recommendation composer (TRC)	It acquires QoD improvement knowledge. Using this knowledge, it processes data (QoD, treatment context) in order to compute technological recommendations for the patient or/and ICT information for the RCM.

Table 7.1: QoD Broker components

7.1.2 MESSAGE EXCHANGE

A description of all messages exchanged between the QoD Broker components is provided in Table 7.2.

Provider	User	Message name	Description
QoD logic	QoD qualifier	QoD rules	Quality-of-Data computational rules for each clinical data and treatment context.
		QoS	Quality-of-Service data (Chapter 3) of ICT technological resources (that provide the clinical data), with the same data identifier as the clinical data (QoS_{ID}).
	TRC	Tech rules	Technological recommendations' computation rules considering the clinical data quality, treatment context and the language of the user.
	QoD qualifier, TRC	Treat. context	Treatment declarative knowledge (e.g. 2 h - physical exercise treatment duration) required to compute QoD and provide technological recommendations in the specific context.
QoD qualifier	TRC	QoD data	Computed clinical data QoD that is specific for a context and linked to a clinical data with same identifier (QoD_{ID}). It may trigger a technological recommendation in a specific context.
TRC	QoD qualifier	Tech. recomm. rep.	Technological recommendation reply (from the patient) linked to a specific technological recommendation request. It may be used to better understand the user context and possible causes of degraded QoS for QoD computation purposes.

Table 7.2: QoD Broker subcomponents' interaction description

7.1.3 PROTOCOL FOR MESSAGE EXCHANGE

In order to describe the message exchange protocol between the QoD Broker components, we use an activity diagram (Figure 7.2) using the UML activity diagram notation [90]. This activity diagram (activity diagram 4) characterizes activities that may occur within the QoD Broker. As shown in Table 7.3, the activity diagram includes the "external*" label, which refers to the other telemedicine system components described in Chapter 6, such as the patient GUI or the mobile CDSS.

7.1.3.1 ACTIVITY DIAGRAM 4

In Table 7.3, we provide the letters assigned to each component and the numbers assigned to each activity in the representation of the activity diagram illustrated in Figure 7.2.

Component	Activities
A QoD Logic	1 Send_QoD_Computation_Rules
B QoD Qualifier	2 Send_QoS_information_multiple_times
C TRC	3 Send_Treatment_Context_multiple_times
D External*	4 Send_Tech_Recomm_Composition_Rules
E Mobile CDSS	5 Send_QoD_information_multiple_times
	6 Send_ICT_information
	7 Send_Tech_Recomm_Request
	8 Send_Tech_Recomm_Reply

Table 7.3: Abbreviation of components and activities of activity diagram 4

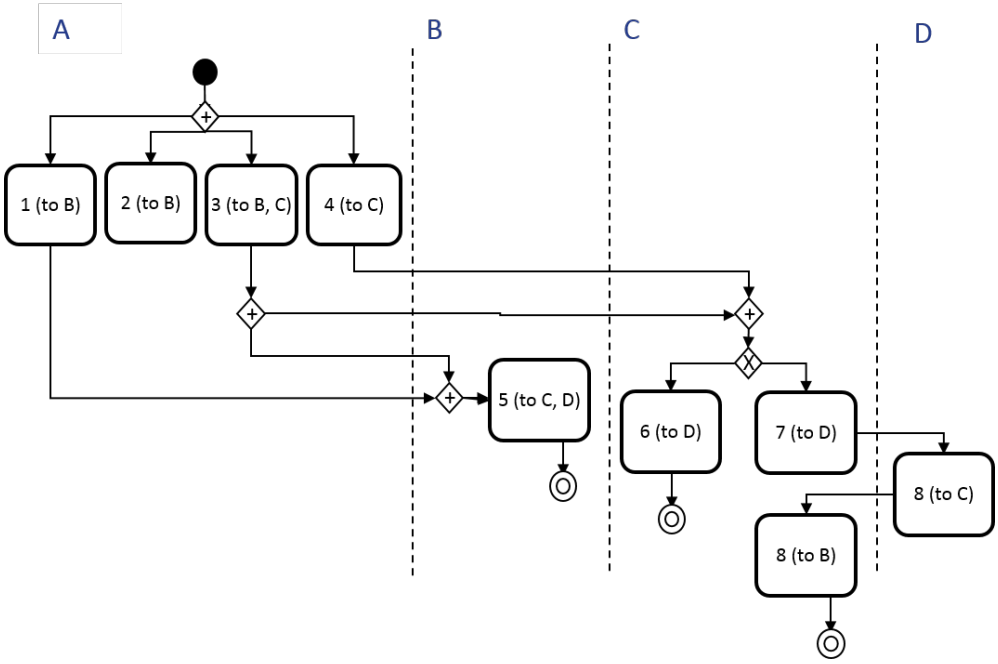


Figure 7.2: Activity diagram of the communication between the QoD Broker components

The use case and time sequence diagram from Table 7.4 and Figure 7.3 represent an instance of the activity diagram illustrated in Figure 7.2.

Use Case 4: QoD Broker internal functioning for QoD qualification and technological recommendation provision	
Brief description	Occurs when the clinical data is processed
Primary actors	QoD Logic, QoD Qualifier, Technological Recommendation Composer (TRC)
Secondary actors	External (ICT resources, mobile storage, patient GUI, mobile CDSS)
Pre-conditions	• QoD logic has acquired the knowledge and data from external components • ICT resources has provided QoS data to the QoD Broker
Main flow	• QoD Logic provides QoD computational rules to the QoD Qualifier • QoD Logic provides QoS computational rules to the QoD Qualifier and TRC • QoD Logic provides treatment context information to the QoD Qualifier and TRC • QoD Logic provides technological recommendation composition rules to the TRC • TRC computes the QoS data considering the treatment context, and sends a technological recommendation to the patient (external*) • The patient (external*) replies the technological recommendation to the TRC. • TRC provides the technological recommendation reply to QoD Qualifier • QoD Qualifier will process the reply together with QoS data to provide the QoD information to the external components

Table 7.4: Use case 4 - QoD Broker

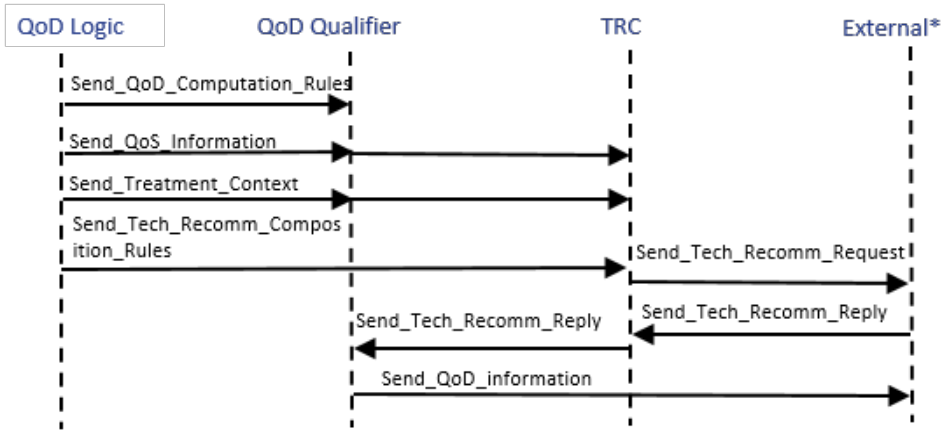


Figure 7.3: Time sequence diagram corresponding to use case 4 (QoD Broker)

7.2 QOD DIMENSIONS

In order to discuss how QoD is assessed and managed by QoD Broker, we need to understand how it is composed. In Chapter 2, we already defined QoD and discussed that it is a multidimensional concept. Yet we did not provide an answer to how the QoD dimensions should be selected and which QoD dimensions we study in this thesis. Here, we present the state-of-the-art on the approaches to select the QoD dimensions, together with our own approach. Thereafter, we present the QoD dimensions adopted in this thesis.

7.2.1 APPROACH TO SELECT QOD DIMENSIONS

We present three possible approaches to study QoD dimensions, discussed by Wang et al. [21]: intuitive, theoretical, and empirical. The **intuitive approach** selects the 'important' QoD dimensions based on researchers' experience or intuitive understanding in a specific domain. The **theoretical approach** focuses on those attributes of data quality which present the deficiency of the data during the data manufacturing process, i.e. inconsistencies between a real-world view inferred from an information system and the view that can be obtained by directly observing the real-word [49]. However, none of these approaches capture attributes that are important to data consumers. Hence, the **empirical approach** analyzes data from the data consumer's point of view in order to determine the characteristics that users apply to assess whether data is "fit for use".
Each of these approaches has its advantages and disadvantages in the

telemedicine domain. Initially, it is essential to study the commonly used QoD dimensions in healthcare to have an overview of previous studies. This is covered by the intuitive approach [21], but it may not guarantee that all the QoD requirements of the user are supported. Then we need to study QoD dimensions that can cover possible data inconsistencies that a telemedicine system could introduce when compared to real-world data. Lastly, we have to consider data consumers' needs. Hence, we conclude that in order to get the "right" QoD dimensions it is necessary to combine these three approaches, as applied in this study.

1. First, we applied the intuitive approach. As researchers, we studied the commonly used QoD dimensions in computer science and healthcare [9, 25, 50, 76, 96, 97, 98]. The three most commonly mentioned QoD dimensions are accuracy (or correctness), dependability (or completeness) and timeliness (or currency) [96, 98]. However, cost and quality-of-evidence (QoEvidence) were also described in relevant healthcare studies [9, 76].
2. In our next step, we applied the theoretical approach and we obtained the same QoD dimensions (i.e. accuracy, dependability, and timeliness), since these dimensions best describe the inconsistencies between the real world phenomena and the data obtained from the ICT resources.
3. Finally, we applied the empirical approach to identify the dimensions of QoD that are important to data consumers, i.e. healthcare domain experts. In this case, we conducted semi-structured interviews with medical practitioners taking part in the MG study by using the scenario-based approach [2]. Medical practitioners were capable of understanding and specifying clinical data quality requirements, including the QoD dimensions required to fulfil clinical data quality aspects for telemedicine systems. They understood and found important the QoD aspects addressed by Accuracy, Timeliness, Dependability, Cost, and QoEvidence.

Hence, as result of the application of these three approaches, it was agreed to adopt the following five QoD dimensions: Accuracy, Timeliness, Dependability, Cost, and QoEvidence, which are described in the following section.

7.2.2 QoD DIMENSIONS

In this section, we define each of the selected QoD dimensions and their relation with other QoD dimensions presented in literature.

- **Accuracy**
  We define accuracy as *"the degree of correctness at which a relevant phenomenon is represented by the data"*. Accordingly, our definition is closely related with "correctness" [49, 98]. In our study, inaccuracy implies that the data represents the real-world phenomena differently from the real-world (which is what should be represented). We also relate accuracy to "consistency", "stability", and physiological and contextual "soundness". The latter indicates whether data is in a logical range and coherent with the known probability distribution.
  For example, if the signal of the monitored heart rate (HR) data is noisy due to motion artifacts, the accuracy of that data will be "poor".
- **Timeliness**
  We follow Scannapieco et al. [97] study to define timeliness, which is defined from three points of view: *"currency (how promptly data are updated), volatility (frequently data vary in time) and timeliness (usefulness of the data based on its currency for specific usage)"*. Similarly, Wand et al. [49] address three factors that affect timeliness: how fast the information system state is updated after relevant changes in the real-world ("system currency"); the rate at which changes happen in the real-world ("volatility"); and the time or moment the data is used by the user ("usage currency"). All these time aspects, which we will refer as "timeliness", are addressed in our study.
  For example, HR data may have a "significant" delay while making a treatment decision (on time) due to data processing or transmission delay. This may lead to "poor" timeliness and increase treatment risk if the patient needs to be notified immediately.
- **Dependability**
  We define dependability as *"the degree of certainty that the data can be used to make meaningful decisions regardless of speed or accuracy"*. Accordingly, we relate it to "completeness", "reliability" and "accessibility". "Completeness" is one of the most common quality dimensions in literature [49, 98]. In some studies, "completeness" refers to data availability or absence of missing data [76], which is in alignment with our definition of dependability. "Reliability", extensively mentioned in literature [49], is linked to three factors: the probability of preventing errors or failures; the consistency and dependability of the output information; and how well data ranks in relation to accepted characteristics. "Accessibility" [21, 25] represents how accessible is the data to the data consumers.
  An example of "poor" dependability is when it is not possible to measure

HR due to the sensor unavailability, due to lack of battery or when data connectivity is poor and data cannot be transmitted.

- **Cost**
  We define cost as *"the amount of money required to acquire data for the decision-making process"*. Cost is a quality dimension that is addressed in some QoD related studies [76, 99], but it is an important QoD dimension since it may affect other QoD dimensions, such as timeliness. Ballou and Pazer [99] studied the tradeoff between cost and other QoD dimensions (see Table 7.5) and found that in a majority of the cases the best solution in terms of error rate is the worst in terms of cost. Moreover, while conducting semi-structured interviews, medical practitioners attested the significance of cost in telemedicine systems, since the data itself carries certain costs (e.g. data transmission cost) that can influence the treatment guidance.
  As an example of the use of the cost QoD dimension, consider a situation where a patient pays more for roaming data connection than for Wi-Fi. When Wi-Fi is not available the patient incurs extra cost if s/he uses the roaming option, leading to a poor 'cost' QoD value. Besides, if the roaming option is not chosen by the patient due to the additional expenses, data will not be transmitted immediately, implying additional data delay; otherwise, data can be transmitted immediately, but at higher expenses (i.e. poorer 'cost' QoD).
- **Quality-of-Evidence**
  In the context of data quality, we define QoEvidence dimension as the degree to which the data conforms to guidelines and rules of certification/legislation bodies and evidence based medicine. This Quality of Evidence term used by GRADE [9], describes the confidence in estimating the effect of a guidance or treatment based on the available medical evidence of clinical studies or trials . We closely relate QoEvidence, in the context of data, to three aspects: 1) data authenticity [56], defined as the authentication mechanisms adopted to guarantee data provenance (e.g. device used for the measurement); 2) reliability [49], which is related to the nature of data production (e.g. external conditions during the measurement); and 3) patient authentication [100], since the patient can be the data source, and so, the subject of the data.
  For example, a "poor" QoEvidence is defined when the blood pressure device does not hold the Conformité Européenne (CE) certificate that guarantees high quality standards or if the data (e.g. blood pressure) entry is performed manually by a patient with no prior training or teaching.

As discussed above, the selected five QoD dimensions also cover other similar quality dimensions addressed in other studies. Table 7.5 presents the mapping interpretation between the selected QoD dimensions and other proposed QoD dimensions from literature.
By limiting our design to these five QoD dimensions, we do not overwhelm the users with unnecessary QoD information, but cover all the user QoD requirements. None of the quality dimensions are independent of each other. Therefore, there is a tradeoff between different QoD dimensions, as already discussed in [76, 97].

Literature	**Accuracy**	**Dependability**	**Timeliness**	**Cost**	**QoEvidence**
Wand et. al [49]	Accuracy	Completeness	Timeliness		Reliability
	Consistency Precision	Reliability	Currency		
Scannapieco et al.[97]	Accuracy	Completeness	Currency		
			Timeliness Volatility		
Widya et al. [76]		Availability	Freshness	Cost	
Endler et al. [98]	Correctness	Completeness	Currency		
Shin [100]	Accuracy	Info loss	Synchronization		Patient Authentication
	Granularity Soundness				
Ballou [99]	Accuracy Consistency	Completeness	Timeliness	Cost	

Table 7.5: Mapping between selected QoD dimensions and QoD dimensions from literature [11]

7.3 QOD MANAGEMENT TECHNIQUES

In order to provide useful QoD information to the components of the system, we designed and developed several QoD management techniques which have been implemented in the QoD Broker. They are:

- Computational models
- QoD stratification model
- Overall QoD
- QoD temporal abstraction
- QoD improvement

7.3.1 COMPUTATIONAL MODELS

As presented in [19], we use different computational models to quantify the five quality dimensions identified in Section 7.2. For our convenience, in this section, we use the term QoD to denote any of the five quality dimensions. We also denote QoS as the data used for the specific QoD dimension.
Each computational model is determined by a set of transfer functions. As illustrated in Figure 7.4, quality of output data from technological resource i (QoD_i) depends on the resource's quality of input data (QoD_{i-1}) and its provided quality of service (QoS_i):

$$QoD_i = f_i(QoS_i, QoD_{i-1})$$

, with transfer function f_i (7.1)

This QoD computation can be generalized as a chain of technological resources within a system (Figure 7.5):

$$QoD_i = f_i(QoS_i, f_{i-1}(QoS_{i-1}, f_{i-2}(QoS_{i-2}, ...))) \quad (7.2)$$

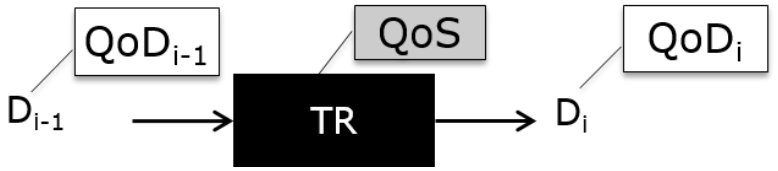


Figure 7.4: Simplified representation of the relation between QoD (of data) and QoS (of technological resource)

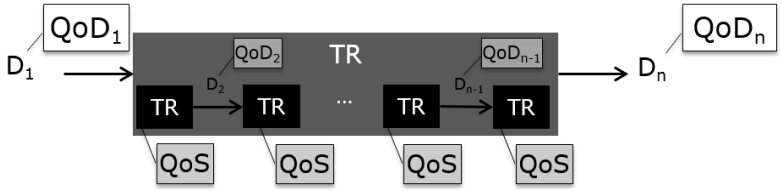


Figure 7.5: Extended representation of the relation between QoD (of data) and QoS (of technological resources)

For example, if a data processing and delivery chain consists of two technological resources, the calculated quality of output data is:
$QoD_2 = f_2\ (QoS_2, f_1\ (QoS_1, QoD_0)))$, with two (potentially) different transfer functions f_1 and f_2. Note that QoD_0 is input data (e.g. cardiac electrical signal) of the first technological resource (e.g. ECG sensing component) in the data processing and delivery chain. The quality of QoD_0 is not directly measureable. Therefore, QoD_0 contributes to the QoS_1 of the first technological resource (with a neutral impact).
A transfer function depends on each quality dimension and the QoS data we can obtain. For example, an *"arithmetic summation"* function can be used for "Timeliness" and "Cost" quality dimensions calculation when we have time delay and monetary cost respectively. *"Boolean algebra"* can be used for the "Quality-of-Evidence" quality dimension calculation when we check if the technological resources have the required CE certificate. In case quality dimension calculation is not straightforward, *"graph based mapping"*, *"look-up tables"* or more advanced *"mathematical functions"* are required. In the sequel, we address four computational models applied in our study. However, additional computational models may also be required depending on the type of data, type of information system or other relevant aspects of the application.

- **Summation and Multiplication Arithmetic Functions**

The transfer function f_i of technological resource i could be the arithmetic summation SUM (x;y). The quality of output data is calculated by: QoD_i = SUM (QoS_i, QoD_{i-1}). In a data processing and delivery chain of n technological resources with the SUM as the only transfer function, quality of output data is expressed by:

$$QoD_n = (\sum_{i=1}^{n} QoS_i) + QoD_0 \tag{7.3}$$

Similarly, the transfer function f_i could be a multiplication MULTIPLY(x;y). Accordingly, the output data's quality of a chain of n technological resources with the same multiplication transfer function is expressed by:

$$QoD_n = (\prod_{i=1}^{n} QoS_i) \times QoD_0 \tag{7.4}$$

Example: Timeliness sub-qualifiers (e.g. delay) are calculated with the summation arithmetic function. In a delivery chain of concatenated technological resources of Zephyr BioHarness 3 (BH) sensor [71], BH processor and Bluetooth technological resources (see Figure 7.5), their delay contribution to timeliness is calculated by (assuming the provision of the electrode signal is instantaneous):

$$Timeliness = d_{\text{BHsensor}} + d_{\text{BHprocessor}} + d_{\text{Bluetooth}} \tag{7.5}$$

- **Boolean Functions**

The transfer function f_i of technological resource i is based on Boolean algebra, expressed in terms of Boolean variables and logical operators "AND", "OR" and "XOR" (Equation 7.6). Accordingly, quality of output data of resource i can be expressed by:

$$QoD_{\text{i}} = AND\ (QoS_{\text{i}},\ QoD_{\text{i-1}}) \tag{7.6}$$

Example: Quality-of-Evidence (QoEvidence) is computed by the Boolean transfer function "AND". It uses Boolean sub-qualifiers like the availability (true) or non-availability (false) of a monitoring device's CE certificate to determine to overall QoEvidence. For example, if one of the technological resources to obtain HR data does not have a CE certificate, the Quality of Evidence of HR clinical variable may be negatively affected (e.g. QoEvidence = False).

- **Mathematical Functions**

Mathematical transfer functions are based on formulae from mathematical or statistical methods or theories. For example, arithmetic "mean" or utility functions (weighting function) applied to RQPs or QoD dimensions' sub-qualifiers (Equation 7.7).

$$Accuracy = Se \times w + Sp \times (1-w), w \in [0,1] \tag{7.7}$$

Example: Accuracy of clinical data of an "AF episode" can be calculated using a utility function and the AF detection algorithm's Se and Sp values, which depend on preceding RQPs (see example for *Graph-Based Mapping Function*). During design phase, the medical practitioner determines the utility function's weighting factor w to express his preference to true positives or true negatives (Equation 7.7).

- **Graph-Based Mapping Functions**

The use of graph-based mapping (usually implemented by look-up tables) is an alternative for deriving complex transfer function formulas. It captures the relation between variables based on prior experimental work. Quality dimensions' sub-qualifiers could be determined by graph-based mapping transfer functions. This approach is common in medical practice, since medical studies typically use empirical methods which yield tables or graphs of studied relationships (Figure 7.6).
Example: Sensitivity (Se) and Specificity (Sp) are sub-qualifiers of accuracy QoD dimension. Se and Sp are related to the robustness of a particular data processing algorithm to input data's Signal to Noise Ratio (SNR). Figure 7.6 shows an example of SNR effect on Se and Sp values of an AF detection algorithm [7].

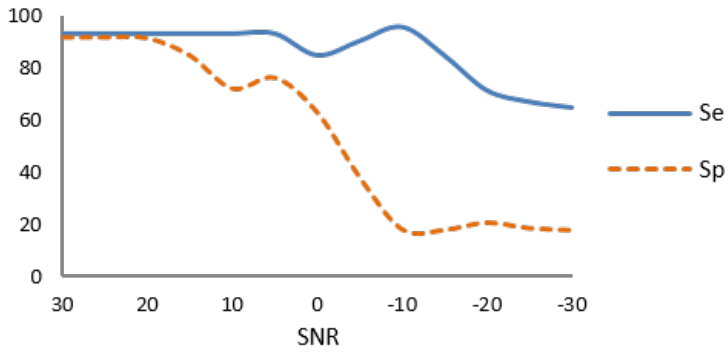


Figure 7.6: AF algorithm's Se and Sp relation to input data's SNR [7]

The result of these computational models is an "objective" scalar value for each of the five quality dimensions of a clinical variable. Therefore, contrary to other studies reported in [58], we do not introduce questionnaires or "subjective" models in this step. However, in medical practice, this value is relative and depends on the patient and the treatment context. Therefore, QoD Broker introduces the *QoD Stratification Model*, discussed in the following section.

7.3.2 QOD STRATIFICATION MODEL

In medical practice, "quality" is often represented by four quality grades: "High" (H), "Medium" (M), "Low" (L) and "Very Low" (VL), as identified by GRADE healthcare working group [10]. With the help of medical practitioners involve in the MG project, we first determined if it was suitable to map the scalar values of Qod dimensions to these four grades [19]. Once these four grades were accepted by medical practitioners, we adopted this in our approach. The underlying stratification model is based on the medical practitioner's interpretation of the computed scalar values. For that, the practitioners consider patient and treatment context to ensure conformity of the stratification model with the medical "way of working". This stratification model is represented as mapping tables, exemplified in Table 7.6, and they are part of the QoD Broker Treatment QoD Manifesto. Hence, QoD Broker is able to map the specific scalar value of a quality dimension to a QoD grade for each treatment context. Table 7.6 presents the stratification model for Accuracy quality dimension of scalar values of HR_{mon} clinical variables, which has been approved by the medical practitioner for the AF patients' physical exercise treatment.

Clinical Variable HR_{mon}	
Scalar Ranges	**Grade Value**
$[0\% - 69.9\%]$	Very Low
$[70\% - 79.9\%]$	Low
$[80\% - 94.9\%]$	Medium
$[95\% - 100\%]$	High

Table 7.6: Example of a stratification model for HR_{mon} accuracy

7.3.3 OVERALL QOD

QoD is a multidimensional concept and, a priory, the clinical data user (e.g. medical practitioners or decision support system) has to process and interpret each QoD dimension grade. This is denoted as the ***"fine grained"*** approach. However, the processing and interpretation of the multi-dimensional QoD can be complex for the users.
In order to simplify this process, we support aggregation of the five QoD dimensions, described earlier, into one overall QoD, and we refer to this as the ***"coarse grained"*** approach. The overall QoD assessment requires detailed information about the set of QoD dimensions that play a role. We can use different computation functions for overall QoD assessment. Here, we describe three pervasive functions addressed in Pipino et al. [101]: weighted average, simple ratio, and min/max. Next, we describe our motivation to apply one of these techniques and its implementation strategy.

- ***Weighted average***

Weighted average deals with situations where the QoD dimensions are not equally important. To determine the impact of each dimension on the overall QoD assessment, the domain expert (i.e., medical practitioner) involved in the QoD management team must have a good understanding of each QoD dimension in the addressed context for which we apply the scenario-based approach [2].
For example, for atrial fibrillation (AF) diagnosis, the electrocardiogram (ECG) data must be accurate (e.g. M or H) in order to be usable. Consequently, the weighting factor of accuracy is higher (e.g. w_a=0.8) than the weighting factors of other dimensions. In contrast, in an ambulatory emergency case, where the ECG data needs to be analyzed immediately, the weight assignment for QoD dimensions is different: timeliness weight is higher (e.g. w_t=0.5) than accuracy weight (e.g. w_a=0.3).
Equation 7.8 represents the weighted average function, assuming the sum of the weight factors equals 1 and the valuations of the QoD dimensions are normalized (e.g. percentages between 0% and 100%). To compute Equation 7.8, we map each grade to a numerical value that is "equally" distributed (e.g. $VL \leftrightarrow 1, L \leftrightarrow 2, M \leftrightarrow 3, H \leftrightarrow 4$).
The overall QoD will have the grade that corresponds to the closest numerical value (e.g. IF overall QoD = $3.9 \simeq 4$(H $\leftrightarrow$ 4), THEN QoD grade = H).

$$\begin{aligned} OverallQoD = (w_{\mathrm{a}} \times Accuracy) + (w_{\mathrm{t}} \times Timeliness) + \\ (w_{\mathrm{d}} \times Dependability) + (w_{\mathrm{c}} \times Cost) + (w_{\mathrm{q}} \times QoEvidence) \end{aligned} \tag{7.8}$$

- ***Simple ratio***

Simple ratio is a particular case weighted average, where all QoD dimensions weight are equal, i.e. assigned the same weight, namely 0.2 for five dimensions assuming an aggregated weight of 1 (Equation 7.9).

$$\begin{aligned} OverallQoD = (0.2 \times Accuracy) + (0.2 \times Timeliness) + \\ (0.2 \times Dependability) + (0.2 \times Cost) + (0.2 \times QoEvidence) \end{aligned} \tag{7.9}$$

- ***Max-min***

Max-min prioritizes the QoD dimension with the largest impact on the treatment. This usually corresponds to the QoD dimensions which have the lowest quality grade (e.g. VL). For example, if the patient treatment needs to be stopped (strongest/safest recommendation) when Accuracy = VL, the overall QoD will be qualified as VL independent of the other QoD dimension grades. This is aligned to fuzzy logic. The overall QoD is either H, M, L or VL based on certain conditions.

In the MG project, medical practitioners opted to implement the max-min function to guarantee that the safest treatment (i.e. the one with least impact on the patient's health) is always enforced. To implement the max-min function, medical practitioners, supported by QoD experts, first determined the effects of the five QoD dimensions for each of the considered medical cases and contexts. Next, they studied which QoD dimension has the strongest/safest impact in each case, which then determine the overall QoD. In the implemented cases, the lowest quality grade, VL, has the strongest/safest impact on the treatment. For example, in the physical exercise treatment for AF patients, when any one of the QoD dimensions is VL, the treatment was required to be stopped. Hence, the overall QoD is VL when any of the QoD dimensions is VL. The result can be presented in pseudo code (Equation 7.10). For example,

$$\begin{aligned} IF\,(Accuracy = VL\ or\ Timeliness = VL\ or \\ Dependability = VL\ or\ Cost = VL\ or \\ QoEvidence = VL)\ THEN\ (overallQoD = VL) \end{aligned} \tag{7.10}$$

Both the "coarse grained" and the "fine grained" approaches have their benefits and limitations. With the "coarse grained" approach, the treatment effects are limited to the overall QoD grades, and the information of the QoD dimensions can be lost. However, this approach facilitates QoD management for the user. The "fine grained" approach supports five QoD dimensions with 4 grade values for each dimension, which allows for distinguishing between a high number of treatment effects (maximum of $5^4 = 625$ possible combinations) but requires a much more complex QoD management.

7.3.4 QOD TEMPORAL ABSTRACTION

By default, QoD has the same processing rate as the monitored data (e.g. 1 Hz) since every data item has a QoD label. The clinical data is often monitored and processed at "high" sample frequencies by ICT systems. We refer to automatically acquired data with a sample frequency that is higher than once per minute "streaming data". For example, patient vital signs, such as Heart Rate (HR), are streaming data monitored at 1 Hz. Data users, such as a CDSS, have to process (receive and interpret) this data and its quality at the same rate for the decision making process.
Usually, data users (e.g. CDSS) contain an internal component to perform a temporal abstraction of the clinical data [6, 80]. These temporal abstractions mitigate any problem of information overload from the "raw" (streaming) data, such as potential fluctuations of the CDSS decisions or decisions based on outliers. However, QoD may also fluctuate per sample or contain outliers that may cause problems in CDSS decisions. For example, the CDSS may confront the patient with continuously alternating clinical recommendations (e.g. in the AF physical exercise treatment, the CDSS may send: "slow down", "speed up", "slow down" etc.), showing nervous behavior.
There are two possibilities to avoid this problem: the QoD user (e.g. CDSS) deals with fluctuating QoD grades by abstracting "raw" QoD internally and determining the impact of QoD (e.g. clinical recommendations) at a fixed interval (e.g. 5 minutes); or the QoD provider deals with "raw" QoD by performing a temporal abstraction of the QoD before providing it to the users.
QoD experts prefer the second option based on the assessment that this is a QoD provider task. Accordingly, in the implemented MG telemedicine system prototype, the QoD Broker, which is the QoD provider, applies a temporal abstraction to an observation window of calculated QoD grades [11]. It is possible to apply the temporal abstraction to each QoD dimension and then

compute the overall QoD (if needed). But in the MG project, we applied the temporal abstraction to the overall QoD (and not to each QoD dimension). This way, the QoD management process is much quicker.
The steps to derive the temporal abstraction of the overall QoD are (notice that we often cite QoD when referring to the overall QoD used for the temporal abstraction):

- **Step 1:** Observation Window

In order to perform the temporal abstraction, we need an observation window that considers at least one QoD sample and a maximum of all QoD samples. In order to prioritize 'urgent' situations (e.g. samples with QoD = "Low") that require a safety action (e.g. "stop treatment"), it should be possible to shrink the observation window. To implement this dynamic length observation window, the length has to depend on the samples' QoD grade. Consequently, each QoD grade has a different contribution to the window (number of samples added), which will determine the window length. This contribution is determined by the medical practitioners in collaboration with the QoD experts.
As an example, the sample contribution of each QoD grade can be d_{High}= 1 sample, d_{Medium}= 0 sample, d_{Low}= - 0.5 samples and $d_{Very\ Low}$ = -1 sample. These contributions could be more disparate: higher (e.g. d_{High}= 6 samples) or lower (e.g. $d_{Very\ Low}$ = -3 samples), reflecting the influence of the QoD grades on the time interval (represented by the window length) between two consecutive QoD output computations.
As shown in Equation 7.11, we compute the observation window at sample i ($observ_w$(i)) by aggregating the contribution of the current QoD (d(i)) to the previous sample's observation window ($observ_w$(i-1)), always considering that the minimum observation window length is 1 sample.

$$observ_w(i) = max(1, \lfloor observ_w(i-1) + d(i) \rfloor)\ samples \tag{7.11}$$

Notice that we can translate this observation window to time by dividing it by the sample frequency (f_s). Hence, by having f_s = 1 Hz, the minimum observation window is 1 second. Notice also that although we compute an observation window with each sample, QoD output is not refreshed with each sample as this would defy the goal of temporal abstraction. QoD output is first computed after processing the number of samples indicated by the first observation window (which must be initialized with some number as shown in Table 7.7). At this point, which we call QoD output 'refreshment point', the applicable observation window, according to Equation Equation 7.11, determines the next

refreshment point. This process is repeated as long as necessary. The QoD output computation is discussed in the next step.

- **Step 2:** QoD Output from Temporal Abstraction

The QoD output of the samples between two consecutive refreshment points does not vary. In order to compute the QoD output at a refreshment point, we consider the overall QoD grades of the samples since the last refreshment point and the impact factor (or weight) of each overall QoD grade. The domain experts, i.e. medical practitioners, assisted by QoD experts, specified the relative weight (W) of each grade.
For example, W_{High}=0.1, W_{Medium}=0.2, W_{Low}=0.3 and $W_{Very\ Low}$ =0.4, usually gives higher significance to lower quality grades for safety reasons. Imagine an observation window at a refreshment point with 4 samples (see in Table 7.8, samples i+1 to i+4) with weight factors as mentioned above. The grade that gets the highest score after multiplying the number of samples of each grade by each impact factor is the QoD output of this observation window.
In Figure 7.7, we exemplify an observational window where the predominant grade is "High" (H). However, if we multiply the number of each grade with the relative weight presented above, we get "Very Low" (VL) as the final result for the QoD output (Table 7.7).

Figure 7.7: Example of the QoD grades in an observational window

Grade	Number samples	Weight	Results
H	3	0.1	0.3
L	1	0.3	0.3
VL	2	0.4	**0.8**

Table 7.7: Example of the QoD output from 6 samples on the observation window of Figure 7.7

In Table 7.8, we present an example of the temporal abstraction technique (Step 1 and Step 2) with a 9 sample data. For this, we consider the sample contribution and weight contribution of each grade presented in Step 1 and Step 2. The *"grade"* column represents the QoD grade of the sample before the temporal abstraction, and *"temp. abst. QoD"* column represents the

QoD grade of each sample after the temporal abstraction with the refreshment points ("*"). The *"sample"* column represents the sample number, *"d(i)"* column represents the delay contribution of the sample and *"observ$_w$"* column represents the observational window that corresponds to that sample instant. The starting point, sample (i), is assumed to be a refreshment point which indicates an observation window of 4 samples and a QoD output grade equal to "High". This means that the following 4 samples starting from i will have QoD grade equal to "High". The next sample that has a refreshment (symbolized with "*") is (i+4), whose QoD output is calculated by considering QoD grades from sample (i+1) till sample (i+4), resulting in "Very Low" output. In addition, the observation window at sample (i+4) determines the length of the next interval: $observ_{\mathrm{w(i+4)}} = \lfloor 3+0-1 \rfloor = 2$. Hence, the next refreshment point is at sample (i+6). The computed QoD output at this new refreshment point will be fixed until the next refreshment point and represents a potential QoD change from the previous observation window. The user (e.g. CDSS) is informed of this refresh event, and can adapt its feedback to the patient accordingly.

sample	**grade**	**d(i)**	**observ$_w$**	**temp. abst. QoD**
i	High	2	4*	High*
i+1	High	2	5	High
i+2	Low	0,5	4	High
i+3	Very Low	0	3	High
i+4	Very Low	0	2*	Very Low*
i+5	Very Low	0	1	Very Low
i+6	High	2	2*	Very Low*
i+7	High	2	3	Very Low
i+8	High	2	4*	High*

Table 7.8: Example of the QoD temporal abstraction

Medical practitioners involved in the MG project validated this QoD temporal abstraction technique by using data with a sampling frequency of 1 Hz. For this case, we elicit the requirements for a minimum observation window in terms of seconds (e.g. 1 second, which corresponds to 1 sample if f_s = 1 Hz). Data with lower sampling frequency requires a minimum observation window of 1 sample. Hence, if f_s=0.01 Hz, the minimum observational window in time terms of is 100 seconds.

7.3.5 QOD IMPROVEMENT

When there is a degradation of QoD, the adapted treatment can ensure patient safety, but may also lower the efficacy of the treatment. Therefore, when possible, the optimal solution is to predict QoD degradation and avoid this potential QoD degradation by using different techniques [58].
In our approach, we did not study techniques that manipulate ICT resources to avoid QoD degradation. Instead, our technique is based on the usage of technological context to generate technological recommendations and ICT information. These are formulated by the technological recommendation composer of QoD Broker (see Section 7.1.1). The technological recommendations are directed to the user and the ICT information to the resource configuration manager (RCM), which is in charge of configuring the ICT resources (see Chapter 6). In the following subsections, we describe these two cases.

7.3.5.1 TECHNOLOGICAL RECOMMENDATIONS - USER

As discusses in Chapter 3, the ICT technological resources' performance (in terms of QoS) degradation may lead to a technological context with "poor" QoD. But the "poor" QoD may not only depend on the technological resources and treatment context, but also on the incompetence usage of the system by the patient (e.g. due to lack of education) [59]. Therefore, one of our approaches to prevent "poor" QoD is to provide technological recommendations to the user (patient), so that s/he is instructed on how to improve the usage of the system and on the technological resources management. To do so, QoD Broker's technological recommendations composer sends technological recommendations to the patient via the patient GUI. These recommendations are sent in the form of notifications or surveys, and they are intended for one of these purposes:

- **Improve Qo**
  Often, recommendations that aim at improving QoD are sent in the form of notifications, which do not require a patient's reply. For example, one of the notifications may be to "charge the smartphone battery" or to "re-enter the clinical data" if QoD Broker detects that the cause of "low" QoD is due to factors, such as "smartphone battery level is below %20" or "manual input data is out of realistic range of values" (see Section 5.3.3, Use case 3).
  This is closely related to the "process modeling" addressed by Batini et al. [58], a strategy often used for QoD improvement.

- **More reliable QoD information**
  Alternatively, in our approach, the technological recommendations are also used to provide more reliable QoD information when the user-context information is required. Often, these technological recommendations are sent to the user in the form of a survey. The user's reply to the survey is used by the QoD Broker to better understand the user-context, potentially related with the causes of degraded QoS. By using this user-context information, the QoD Broker is capable of computing more reliable QoD information. For example, when QoS of an ICT resource (e.g. battery of the smartphone) does not fulfil the treatment requirements, the patient may be asked "if the smartphone battery was recently charged". This information is used by QoD Broker to determine, more accurately, the technological context: "either the battery is low because the patient has not charged it, or the battery is damaged". Accordingly, the QoD Broker may take different actions (i.e. QoD grade may be different: "Low" if patient has not charged the battery or "Very Low" if battery is damaged).

During our literature study, we found studies that use technological recommendations for QoD management purposes. One of the cases is the usage of technological recommendations in combination with QoD validation [31, 59]. Vavilis et al. [31] propose to build a troubleshooting mechanism to determine the impact of data qualifiers (or quality dimensions) on the overall quality of measurements. Consequently, the system can investigate the cause of QoD degradation. In contrast, we acquire QoS data of technological resources to determine QoD without patient's involvement. We only consult the patient if additional patient context information is required to understand the causes of a particular QoS degradation in order to provide more reliable QoD information. Berti [59], on the other hand, proposes a multicriteria recommendation mechanism in order to present the most appropriate data to the user. For example, their system requests user (preference) information to understand if s/he may prefer quicker data updates rather than highly accurate data. However, in medical practice, medical practitioners are in charge of determining the most relevant QoD dimensions and QoD grades based on patient and treatment context. Hence, we perform this QoD dimensions identification and implement the QoD grade stratification model during the system design.

7.3.5.2 ICT INFORMATION - RESOURCE CONFIGURATION MANAGER (RCM)

As discussed in Section 6.4, the ICT resources component contain the resource configuration manager (RCM), which is in charge of configuring data sources. For this configuration, QoD Broker provides ICT information, which contains ICT resources management information (e.g. required to switch of AF detection algorithm), in order to guarantee 'best' possible performance of essential ICT resources that prevent QoD degradation.
For example, the QoD Broker may acquire low battery level information from the smartphone. The QoD Broker uses this information, along with other smartphone applications' information (e.g. smartphone camera status ON), to grade the resources. Hence, in order to guarantee the continuation of the clinical guidance, the QoD Broker may suggest to save smartphone battery by sending ICT information that contains "very low" grade for the smartphone camera. This way, the RCM, which interprets the ICT information, interrupts the smartphone camera application.
The RCM prototype was not implemented in the MG system. Hence, this functionality needs to be tested and validated in a real setting .

7.4 QOD MANAGEMENT TECHNIQUES IN MOBIGUIDE

The MobiGuide (MG) project is the environment where we implemented the QoD Broker prototype and its QoD management techniques. In this section, we present an example of the QoD computation and temporal abstraction techniques implemented in the MG telemedicine system.
In this example, we provide QoD of heart rate (HR) clinical data, which is monitored during AF physical exercise treatment and HR monitoring sessions. To monitor HR data, we used a Zephyr BioHarness 3 (BH) device [71]. The BH device captures, processes and transmits a patient's vital-signs (e.g. ECG or HR) and QoS information (e.g. ECG amplitude, ECG noise, battery level) with a sampling frequency of 1 Hz (f_s = 1 Hz). The QoD Broker acquires the QoS data and applies the presented QoD management techniques. First, it computes the grades of the five QoD dimensions (Section 7.3.1 and Section 7.3.2), then calculates the overall QoD (Section 7.3.3), and finalizes with the overall QoD temporal abstraction (Section 7.3.4).
In Figure 7.8, we illustrate the results obtained during a physical exercise treatment (with healthy subject). At the top part of the figure, we represent the noise and activity levels. In the middle of the figure, we present the moni-

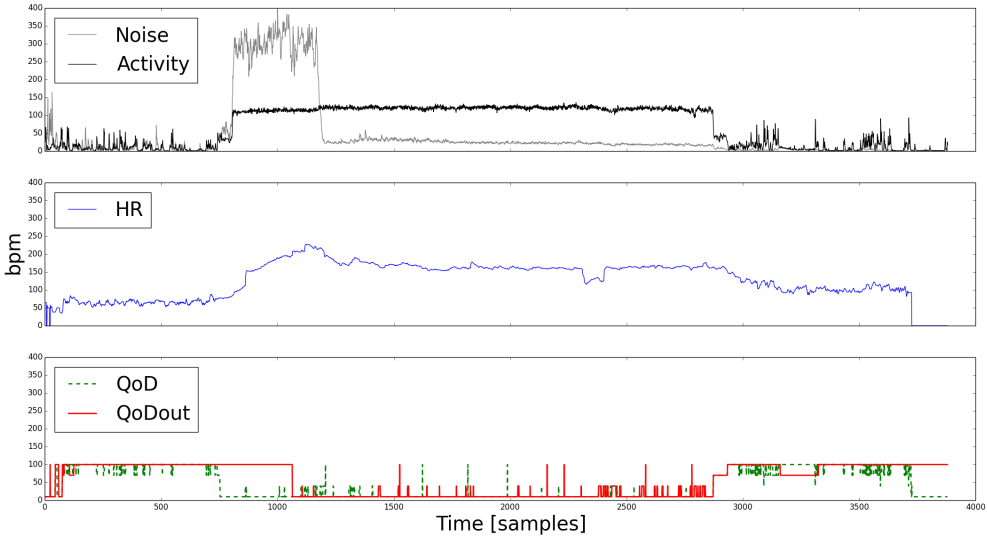


Figure 7.8: Example of monitored HR, it's overall QoD and the temporal abstraction QoD performed in MG

tored HR in beats per minute (bpm). At the bottom of the figure, we illustrate the overall QoD of HR (QoD) in 'green' and the the overall QoD after the application of the QoD temporal abstraction (QoD_{out}) in 'red'.

As shown in Figure 7.8, when the HR increases due to higher activity, the sensor performance degrades (e.g. ECG noise level increases due to motion artifacts) affecting its QoD. When QoD fluctuates between "Low" and "Very Low", QoD_{out} chooses the safest option, which is "Very Low", preventing recommendations associated with "Low" which may be less safe than recommendations associated with "Very Low". In fact, as expected, the temporal abstraction based QoD is more stable. Thus, we prevent the CDSS, being the QoD user, from behaving nervously (e.g. providing alternating recommendations 'slow down', 'speed up') due to QoD fluctuations.
However, we can still see fluctuations, especially at the beginning of the monitoring session (between sample 0 and sample 100) and when the QoD degrades (between sample 1000 and sample 2800). The reasons for this are the following:
On the one hand, the fluctuations at the beginning of the monitoring session occurs due to the configuration of the first observational window, w = 1. Hence, at the beginning, we may expect several fluctuations till the QoD is the observational widow increases. For that we need "High" QoD, since its delay

contribution is d_{High}= 1 sample, and it forces the increment of the observational window.
On the other hand, when the QoD becomes "Low" or "Very Low" (with delay contribution d_{Low}= - 0.5 samples and $d_{Very\ Low}$ = -1 sample) the observational window shrinks. Consequently, the QoD_{out} fluctuations increase (between sample 1000 and sample 2800).
Notice that we used the delay contributions described in Section 7.3.4: d_{High}= 1 sample, d_{Medium}= 0 sample, d_{Low}= - 0.5 samples and $d_{Very\ Low}$ = -1 sample. In order to avoid the fluctuations at the beginning of the signal, we could configure the first window length with higher number of samples (e.g. 60 samples). Additionally, when the QoD lowers, we could have a delay contribution that does not have such an impact on the observational window (e.g. d_{Low}= 0.2 samples and $d_{Very\ Low}$ = - 0.5). This way we could reduce the number of QoD_{out} fluctuations, but at cost of slower response to degraded QoD.

7.5 DISCUSSION

This chapter addresses the QoD Broker architecture and its internal QoD management techniques for healthcare systems that require 'real-time' QoD information to provide the best possible healthcare services. Telemedicine system are typical example of systems that are based on CDSS and require QoD information to provide safe guidance to ambulatory patients.
The presented QoD Broker architecture covers the generic architecture of a QoD provider and manager that imparts the QoD-awareness into a system. In addition to that, the presented QoD management techniques solve some of the challenges of managing QoD in the following manner:

- Firstly, we need to establish all the appropriate QoD dimensions required for QoD management in telemedicine, keeping in mind that these dimensions should be sufficient, but do not overwhelm the user (either a system or a human being).
- Secondly, QoD dimensions' valuation is performed. For that, we develop computational models where the scalar values of the QoD dimensions (e.g. Accuracy= 75%), based on ICT resources quality of service, are acquired.
- Thirdly, the QoD stratification model technique is developed. This includes the mapping of the scalar values of the QoD dimensions to one of the four possible QoD grades. This mapping is determined by medical practitioners, who understand best the treatment context.

- Furthermore, to facilitate the QoD information processing, we aggregate the QoD dimensions into one overall QoD by applying a max-min operation, which prioritizes the QoD dimension with the highest ("worst") treatment impact. Hence, the adapted treatment guidance enhances patient safety.
- We also apply a temporal abstraction technique to prevent the QoD user (e.g. CDSS) from performing nervously due to QoD fluctuations. This way, the QoD user (e.g. CDSS) can provide firm and safe decisions to the patient.
- Finally, we developed a simple technique to improve QoD by providing technological recommendations to the system user (patient) and ICT information to the resource configuration manager. This way, we can 1) improve the performance of the system, and hence, the clinical data quality, and 2) improve the reliability of QoD information.

CHAPTER 8

VALIDATION

This chapter aims to validate the proposed system design and determine whether QoD-aware telemedicine systems following this design would contribute to stakeholder goals if implemented in practice. The main stakeholder role that we consider is the medical domain expert.
This chapter is structured as follows: Section 8.1 presents our validation approach. In Sections 8.2 through 8.8, we describe the results of seven validation activities that we have performed. Finally, Section 8.9 discusses the contribution to stakeholder goals when considering all validation results together and reflects on the usefulness of additional validation activities.

8.1 VALIDATION APPROACH

Besides the validation of the QoD-aware telemedicine system architecture (Chapter 6 and Chapter 7), the work described in this chapter also has the aim of validating intermediate results that were essential for the development of our architecture. Specifically, we want to validate the step from stakeholder goals to system requirements (i.e. the requirements elicitation method presented in Chapter 3), the interpretation of these requirements which resulted in the QoD-framework ontology (Chapter 4) and the formalization of a QoD-aware clinical guideline (Chapter 5).
Therefore, we see our research as a nested problem solving process, where solutions proposed to problems need to be validated. The top-level process is concerned with the development of a QoD-aware telemedicine system architecture that addresses the issues of possible QoD degradation. In order to

develop this proposed solution, we need to establish requirements on the architecture which are relevant to stakeholder goals and we need to correctly interpret these requirements when moving to architecture solutions. The latter are nested problems which were separately addressed and their solutions were separately validated. Figure 8.1 illustrates the validation of solutions to these nested problems relative to the top-level design/engineering cycle phases of our research.

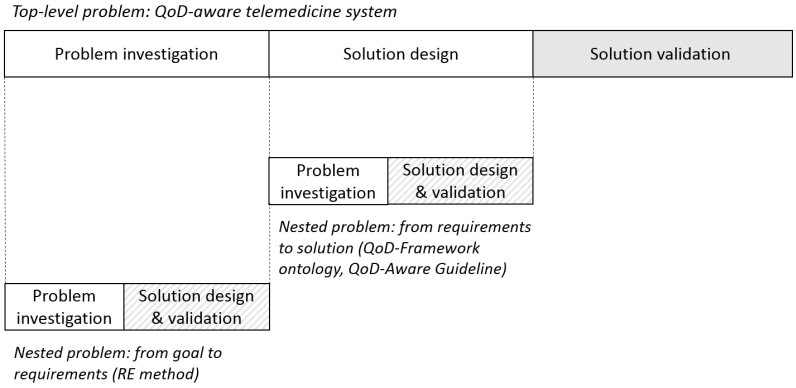


Figure 8.1: Top-level design cycle and nested problem solving

We identify four validation goals related with the research results presented in previous chapters:

Goal 1: Validate the requirements on a QoD-aware telemedicine system - Chapter 3

Goal 2: Validate the QoD-framework ontology - Chapter 4

Goal 3: Validate the augmented QoD-aware clinical guidelines - Chapter 5

Goal 4: Validate the QoD-aware telemedicine architecture - Chapter 6 and 7

We performed several validation activities using various validation methods to pursue these goals. For goals 1, 2 and 3 we used the same validation method (namely, participatory design, which is further explained below), and for goal 4 we used four different methods (also explained below). The use of different methods for goal 4 served to validate different aspects of the designed solution and/or under different conditions of practice. Table 8.1 lists the various validation activities, the goals of each of these activities, and the

validation methods that were applied.

Validation activity	Goal	Validation method
VA1: involving medical practitioners in requirements elicitation	Goal 1	Participatory design
VA2: involving medical practitioners in the QoD-framework ontology design	Goal 2	Participatory design
VA3: involving medical practitioners in the augmented QoD-aware guideline design	Goal 3	Participatory design
VA4: use prototype in test scenario	Goal 4 (esp.: are architecture solutions appropriate?)	Single-case mechanism experiment
VA5: ask experts about expected effects of solution	Goal 4 (esp.: are requirements satisfied?)	Semi-structured interview
VA6: test prototype with healthy volunteers	Goal 4 (esp.: are requirements satisfied?)	Pre-pilot study
VA7: test prototype with patients	Goal 4 (esp.: are goals supported?)	Technical action research and questionnaire

Table 8.1: Validation Activities

Below we briefly describe the validation activities and the methods that were applied. Details on these activities and a presentation and discussion of the validation results follow in the subsequent sections.

- **VA1: Involvement of medical practitioners in the requirements elicitation process.**
  This validation activity was performed to achieve Goal 1. Requirements engineers need to formulate the requirements on a solution for the considered problem. These requirements are derived from the goals of the stakeholders. The medical domain expert, or more specifically the medical practitioner, is the main stakeholder role that we consider, since actors with this role have intimate knowledge of the domain in which the solution needs to be applied. However, the medical practitioner should first understand how the considered problem (i.e., variation in QoD due to technological disruptions) impacts his goal (i.e., providing helpful treatment to patients), before requirements can be formulated that would support mitigation of negative impact of the problem on the

goal. Hence, the involvement of medical practitioners in the problem investigation phase leads to a better alignment of requirements to goals in the problem context.

In this activity we used **'participatory design'** as validation method. Participatory design aims at involving all relevant stakeholders in the design process to ensure that the resulting design appropriately meets their needs and supports their goals [102]. This is closely aligned with the 'collaboration' approach described in [103]. In our study, medical practitioners and requirements engineers collaborated in an iterative process. First, the medical scenario is discussed by both parties and later this scenario is extended with a description of user-system interactions. Both parties need to reach a point of understanding, which is accomplished by a "handshake protocol". This validation method is effective with a limited number of stakeholders who are committed. In MobiGuide limited number of medical practitioners were involved during the whole system development process and they were able to participate in this participatory design process.

- **VA2: Involvement of medical practitioners in the QoD-framework ontology.**

  This validation activity was performed to accomplish Goal 2. Once the requirements were formulated, a QoD-framework ontology was derived from the requirements. At this stage, medical practitioners need to verify if the requirements were correctly interpreted in this ontology. If the interpretation is found to be incorrect, the requirements need to be reformulated* and the ontology rebuilt.

  In this activity we also used the **'participatory design'** validation method. In this case, medical practitioners were asked whether the requirements were correctly interpreted in the designed solution (i.e. QoD-framework ontology) by requirements engineers. If needed, the requirements were refined in order to fulfil the medical practitioners expectations.

- **VA3: Involvement of medical practitioners in the augmented QoD-Aware guideline validation.**

  This validation activity was performed to accomplish Goal 3. Once the requirements were formulated, they were formalized into an augmented QoD-aware guideline, which was validated by medical practitioners. If the requirements were not correctly interpreted, they were reformulated and the augmented QoD-aware guideline modified.

In this activity we also used the **'participatory design'** validation method. In this case, the medical practitioners were asked whether the treatment adaptation mechanisms specified in the augmented QoD-aware guideline were correctly interpreted by requirements engineers. Any necessary changes were performed before the final prototype was applied in the guideline-based decision support system.

- **VA4: Use prototype in test scenario**
  This validation activity was performed to partially accomplish Goal 4. We built a prototype of a QoD-aware telemedicine system according to the proposed architecture and studied this prototype using a test scenario.
  The validation method applied here is the **'single-case mechanism experiment'**. A single-case mechanism experiment is a test in which the researcher applies stimuli to a validation model (e.g. prototype) and explains the responses in terms of mechanisms internal to the model [104]. If a response does not fulfill stakeholder expectations, the mechanism responsible for the response can be redesigned in order to create the desired effect. In this case, a test scenario was conducted by applying different types of patient-related data (stimuli) to the MobiGuide prototype. The reactive behaviors (responses) of the prototype were analyzed with respect to stakeholder expectations and responsible architecture solutions (mechanisms) were embedded in the prototype.
- **VA5: Ask experts about expected effects of solution.**
  This validation activity was performed to partially accomplish Goal 4. We discussed the problem we were trying to solve and the solution we provided with the medical domain experts. By this means we were able to discover if the developed solution fulfilled their expectations or if any changes were required.
  In this activity we used as validation method the **'semi-structured interviews'**. The semi-structured interviews validation method is conducted by exposing the proposed solution to a panel of experts, who imagine how such a solution will interact with problem contexts and then predict what effects they think this would have; if the predicted effects do not satisfy requirements, this is a reason to redesign the solution [104]. The semi-structured interviews give us the opportunity to obtain additional information from the medical practitioners, which would be less likely using a questionnaire.

- **VA6: Test prototype with healthy volunteers.**
  This validation activity was performed to partially accomplish Goal 4. We applied the QoD-aware telemedicine system prototype in an operational setting with healthy volunteers instead of patients, collected the users' experience with using the system, and studied the reported experience in order to determine whether the requirements derived from the stakeholder goals are satisfied.
  The validation method applied is **'pre-pilot study'**. Where a pilot study (see VA7) makes use of a system prototype under conditions of practice with actual end-users, a pre-pilot study only simulates conditions of practice with substitute users. The user-system interactions were observed and compared to the elicited requirements, but, since no patients were involved, the clinical goals of the medical domain experts were not tested in this activity.
  The pre-pilot study was conducted in an iterative process. Section 8.7 presents the steps of these iterative process. This validation method ensures that all functionalities of the system are working before the system is given to end-users (i.e. patients).
- **VA7: Test prototype with patients.**
  This validation activity was performed to accomplish Goal 4. We applied the QoD-aware telemedicine system prototype in an operational setting with actual patients, collected user experience using the system, and studied the experience in order to determine the contribution to clinical goals.
  The validation method applied is **'technical action research'** (TAR) and **'questionnaires'**. The technical action research method makes use of a system prototype in a real-world problem (e.g. Atrial Fibrillation disease guidance) to help a user (e.g. patients and care practitioners) and to verify if the designed solution fulfills the expectations [104]. The user experience information was obtained by using questionnaires, with a set of QoD related questions with a choice of answers. The usage of the TAR in combination with 'questionnaires' allows us to verify the prototype system performance in the real-world environment and to obtain qualitative answers from the users, who need to evaluate different aspects of the system with limited time.

8.2 INVOLVING MEDICAL PRACTITIONERS IN THE REQUIREMENTS ELICITATION PROCESS

This validation activity uses 'participatory design' as validation method in order to formulate the medical practitioners' requirements on QoD-aware telemedicine systems. First, we discuss how the validation method was applied in this activity. Next, we present and discuss the results.

8.2.1 METHOD APPLICATION

The 'participatory design' validation method involves the collaboration of medical practitioners and requirements engineers. Medical practitioners, often using the available clinical guidelines [67, 82], describe the treatment scenarios to be supported by the envisioned system. Additionally, requirements engineers, more knowledgeable about the envisioned system, proposed plausible treatment scenarios that could be conducted with the envisioned system. For that, often they took the role of "medical assistants" (due to the lack of medical researchers) and studied the AF and GDM guidelines (i.e. cross disciplinary study [64]). This way, the proposed scenarios, which involved the usage of the envisioned system, were aligned with the available clinical guidelines.
Next, requirements engineers identified the potential technological disruptions in the context of the ambulatory patient treatment execution. The requirements engineers discussed the potential disruptions with the medical practitioners, so that medical practitioners can understand how these disruptions may impact clinical data quality, and consequently the treatment of patients. This is particularly relevant since in the medical domain there is often the assumption that the clinical data by default fulfills the medical quality requirements. However this may not be true, especially in telemedicine, where the quality control entities present in medical settings (e.g. hospital) may be absent [23].
Thereafter, medical practitioners need to think about possible treatment adaptation mechanisms when the QoD degrades, which the requirements engineers could then translate into system functional requirements. This activity was an iterative process to define the adaptation mechanisms needed and to integrate these into the current clinical guidelines. The requirement engineers, taking the role of medical assistants, addressed treatment scenarios where technological context may vary, leading into degraded QoD that may affect the clinical treatments [2]. Requirements engineers together with medical practitioners came up with requirements for treatment adaptation mechanisms, which consider different QoD grades and treatment scenarios.

Later, the medical scenarios, described in terms of iPACT elements, are extended with the description of user-system interactions, described in terms of FICS elements (Chapter 3). The FICS analysis results in the specification of the QoD-aware telemedicine system functional requirements, which are used for the system architecture design.
The "final" scenario is discussed with medical practitioners, until both parties reach a point of understanding, which is accomplished by a "handshake protocol".

8.2.2 RESULTS

In this iterative process the scenarios and the requirements were established in order to satisfy medical domain experts' expectations.

- iPACT scenarios selection: As discussed in [64], requirements engineers developed plausible treatment scenarios which could be supported by the envisioned system. However, the treatment scenarios could be based on different levels of evidence (see Section 2.2.2, which could affect its acceptance by medical practitioners.
  - *Example: Clinical Evidence Available*
    One of the (easily) accepted scenarios was Blood Glucose (BG) monitoring, since it is already addressed in GDM guidelines [82]. This treatment scenario (guideline) was adapted to take QoD into account such that it could be applied in a QoD-aware telemedicine system.
  - *Example: Clinical Evidence Partly Available*
    One of the accepted scenarios was AF physical exercise guidance. As discussed in [68], exercise training activities for AF patients require physiotherapist's supervision during training and they are often prescribed by medical practitioners. Hence, this scenario with partial evidence was adopted into the QoD-aware telemedicine system, where each patient was personally guided in a target training range by monitoring several vital-signs and their QoD.
  - *Example: Clinical Evidence Not Available*
    One of the abandoned scenarios was AF patient guidance at high-altitude. AF is associated with oxygen saturation [105], since oxygen-rich blood is not properly being delivered to the body and brain. Therefore, one of the symptoms of AF is shortness of breath. On the other hand, at high-altitude the oxygen levels fall.

Consequently, requirements engineers (taking the role of medical assistants) thought of possible AF patient guidance in high-altitude with the envisioned system. This way, the system may guide the patient and avoid possible symptoms.
However, medical practitioners considered this scenario uncommon and difficult to proof the hypothesis of the relation between high-altitude and symptoms (e.g. shortness of breath). Therefore, it was abandoned and not addressed in our study.

- FICS adjustment: Once the FICS elements were incorporated into the medical scenario in order to define the user-system interactions, medical practitioners discussed further how these interactions need to be handled by the users and modified when necessary these FICS elements. Hence, the requirements were modified accordingly.
  - *Example: Heart Rate sensor placement*
    During physical exercise and HR monitoring sessions, AF patients were recommended to wear a HR sensor. Yet, the requirements to educate the patient on this task and how to alert the patient when the physical exercise and HR monitoring sessions start were not specified in the initial scenario. Hence, these scenarios were extended with this information.

  - *Example: QoD aspects*
    Before the physical exercise and HR monitoring sessions medical practitioners together with QoD experts discussed preventive actions, so that patient safety is enhanced (guaranteed). Hence, the QoD_{INT} processes were incorporated to the FICS.

8.2.3 CONCLUSION

This validation activity had several effects in our study. First, it addressed the possible lack of awareness among medical practitioners concerning the impact of degraded data quality. Second, it supported medical practitioners to select and extend the medical scenarios that are applicable in the study. Besides, in this collaboration setting the impact of degraded QoD on patient treatment, which follows the evidence based medicine principle, is defined. This answers the question as to how to control treatment risk when QoD degradation occurs, particularly for pervasive healthcare, following the medical way of working

(working ways in the medical practice, following the medical protocols). Finally, it demonstrates that it is feasible to translate the goals (also QoD-related concerns) of medical practitioners into functional requirements for the development of a QoD-aware telemedicine system architecture.
Hence, this validation activity fulfilled the goal of establishing the requirements on QoD-aware telemedicine systems which are desired by the medical practitioners.

8.3 INVOLVING MEDICAL PRACTITIONERS IN THE QOD-FRAMEWORK ONTOLOGY DESIGN

As discussed in Section 8.1, the goal of this validation activity is to establish if the requirements are correctly interpreted in the QoD-framework ontology. This validation activity also uses the 'participatory design' validation method. First, we discuss how the 'participatory design' validation method is being applied in this activity, and next, we present and discuss the results.

8.3.1 METHOD APPLICATION

In this case the 'participatory design' validation method is applied to validate if the requirements were correctly interpreted into the QoD-framework ontology. The ontology is the formalization of the conceptual model for QoD-aware telemedicine systems and represents the knowledge of the QoD-aware telemedicine system. As presented in 4, the QoD-framework ontology consists of two parts: the clinical domain ontology, which captures the knowledge on the clinical layer, and the technical domain ontology, which captures the knowledge on the technological layer.
In this case, the participatory design method involved medical practitioners, knowledge engineers and QoD-experts.
Knowledge engineers formalized the medical vocabulary specified by medical practitioners, with the support of clinical guidelines. Besides, knowledge engineers discussed with QoD-experts and medical practitioners the additional QoD-related concepts which needed to be added into the clinical domain ontology (e.g. adapted treatments).
QoD-experts formalized the technological domain ontology and discussed with knowledge engineers any necessary adjustments, so that both ontologies are correctly linked.
The QoD-framework ontology, specified in the Web Ontology Language (OWL), was verified by all parties. Knowledge engineers helped medical prac-

titioners to understand the OWL ontology, so that they could confirm the correct representation of domain knowledge or detect incorrect representations. Note that in this case, we focused on the QoD related concepts and their relations presented in Chapter 4.

8.3.2 RESULTS

In this validation activity, the ontology underwent the following modifications:

- Clinical domain ontology extension: Additional treatment scenarios were included while discussing the clinical domain ontology, so that all scenarios were QoD-aware.
  - *Example:* The AF physical exercise and monitoring treatment control was further discussed. The output of this discussion was an additional requirement to include initial QoD information (QoD_{INIT}) before outpatients treatment execution (pre-condition). This way, the system ensures better system performance and, consequently, guarantees higher QoD during the treatment.

- Technological domain ontology extension: Based on the modifications done in the clinical domain ontology, we extended the technological domain ontology with additional technological context information.
  - *Example:* The technological context regarding the QoD before the physical exercise and the AF monitoring treatment starts was studied. All possible technological context factors that may affect the QoD were studied, so that the QoD_{INIT} was computed accordingly.

8.3.3 CONCLUSION

This activity fulfilled the goal of validating the QoD-framework ontology. All stakeholders involved - medical practitioners, knowledge engineers, and QoD-experts - in the end were satisfied with the QoD-framework ontology, which was applied in the system.

8.4 INVOLVING MEDICAL PRACTITIONERS IN THE AUGMENTED QOD-AWARE GUIDELINE DESIGN

The goal of this validation activity is to verify if the specified requirements are correctly interpreted when moving to the treatment adaptation mechanisms formalized in the augmented QoD-aware guideline. In this validation activity we also applied the 'participatory design' validation method. First, we discuss how the 'participatory design' validation method is being applied in this activity, and next, we present and discuss the results.

8.4.1 METHOD APPLICATION

In this case the 'participatory design' validation method is applied to validate if the treatment adaptation mechanisms determined by medical practitioners were correctly implemented into the QoD-aware guideline. Hence, in this case, medical practitioners and requirements engineers were involved.
First, the requirements of the adapted treatments were formalized by requirements engineers into augmented treatment (parallel) workflows [81, 106]. These workflows were verified by medical practitioners in order to add additional information or remove any potential inconsistencies or conflicting conditions. Next, requirements engineers modified these parallel workflows based on the discussions.
Only after the medical practitioners agreed with the final result, these workflows were formalized in the computer interpretable guideline (CIG) using the selected modeling language (i.e. Asbru [16]).

8.4.2 RESULTS

In this validation activity, the augmented QoD-aware guideline underwent the following modifications:

- Guideline modification: Currently most clinical guidelines do not address the guidance required for ambulatory patients undergoing mobile monitoring in a community setting. Hence, the guidance needed to be exhaustively specified and some of the aspects where completed during this validation activity.
  - *Example:* The frequency of the BG measurements were further discussed using the workflow diagrams. Hence, depending on the previous BG measurements of the patient, the frequency requested for the BG measurements was modified.

8.4.3 CONCLUSION

This activity fulfilled the goal of validating the formalized augmented QoD-aware guideline by medical practitioners. The QoD-aware guideline is embedded into a QoD-aware telemedicine system, so that the treatment is adapted according to the specified requirements when the ambulatory patient is in the extramural setting. The results show that this validation activity was successful since medical practitioners were satisfied with the final formalized QoD-aware guideline.

8.5 USE PROTOTYPE IN TEST SCENARIO

This validation activity aims to validate partially the QoD-aware telemedicine architecture (Goal 4). In this validation activity we applied the 'single-case mechanism experiment' validation method. First, we discuss how the validation method is being applied in this activity, and next, we present and discuss the results.

8.5.1 METHOD APPLICATION

In this validation activity the single-case mechanism experiment validation method is applied in order to test if an instance of the designed solution (namely the MobiGuide (MG) system prototype) fulfills the functional requirements and is able to support stakeholder goals (i.e., is beneficial to medical practitioners). Hence, this is not only a functional validation, which checks whether the prototype (technically) works according to the requirements, but also a clinical validation, since we aim to verify if medical practitioners agree with the result and feel that their expectations are fulfilled.
We focus on the performance of QoD-awareness, which is the focus of our study. To accomplish this, we applied the following test plan:

1. Feed the MG prototype with test data
2. Observe what is the response of the prototype
3. Compare the response with the desirable outcome that medical domain experts would expect
4. Verify if the responses and expected outcome match and which part of the prototype is responsible for this

The first two bullets are discussed in Section 8.5.2 - Results, and the two other bullets are discussed in Section 8.5.3 - Conclusion.

8.5.2 RESULTS

Here we present the three types of data discussed in this research study and the response of the prototype for each of type of data: periodic data, streaming data and initialization data.

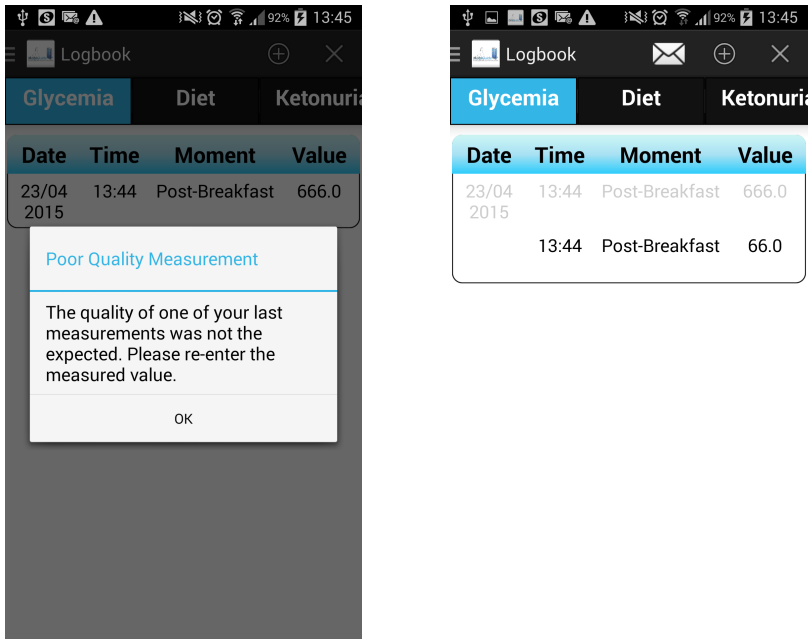
- **Periodic Data**
  In this thesis we refer to periodic data, as data with a sampling frequency not higher than once per minute (e.g. blood pressure measurements taken once a day), and it can be manually or automatically entered. This is the periodic data discussed in MobiGuide:
  - Blood Pressure: used in both GDM and AF medical cases to observe potential complications. In some cases the data was inserted in the system manually and in other cases the data was inserted automatically.
  - Blood Glucose: used in GDM to observe the glucose levels of diabetic patients. The data was expected to be inserted in the system automatically, but a manual input option was provided in MG.
  - Weight: used in both GDM and AF, but not as compulsory measurement. The data was inserted in the system manually.
  - INR: used in AF to observe the coagulation levels of the patient. The data was inserted in the system manually.

  The response of the prototype towards the periodic data was studied from four different aspects: Human errors consideration, Technological recommendations, Visualization and CDSS output.

  1. Human errors consideration:
     As discussed, the periodic data is inserted in the MG system automatically or manually. For all the data manually inserted, the MG system assignss a maximum QoD grade of “Medium” due to potential human errors or human incompetence (e.g. lack of training) that could be implied.
  2. Technological recommendations:
     When the QoD is “Low” or “Very Low” due to potential errors inserted in the system manually, the MG system (QoD Broker) provides a technological recommendation (pop-up message) to the

patient. This recommendation is provided within the same screen of the measurement to be re-entered: "The quality of one of your last measurements was not the expected. Please re-enter the measured value." (Figure 8.2a).

3. Visualization:
   The data (measurements) with QoD "Low" or "Very Low" are distinguished (in grey) in the patient GUI, as shown in Figure 8.2b. Additionally, the MG system provides the overall QoD grade (and additional QoD dimensions grades) to the medical practitioner via the caregiver GUI.



(a) Technological recommendation to re-enter erroneous measurement

(b) Entered measurements with different QoD grades in patient GUI

Figure 8.2: Visualization of manually entered Blood Glucose measurement

4. CDSS output
   The CDSS does not consider measurements with QoD "Low" or "Very Low" for the decision making process (Figure 8.3). This is also presented in Section 5.3.3(Figure 5.9), which was specific for the Blood Glucose data. But the CDSS does the same for the other periodic data as well.

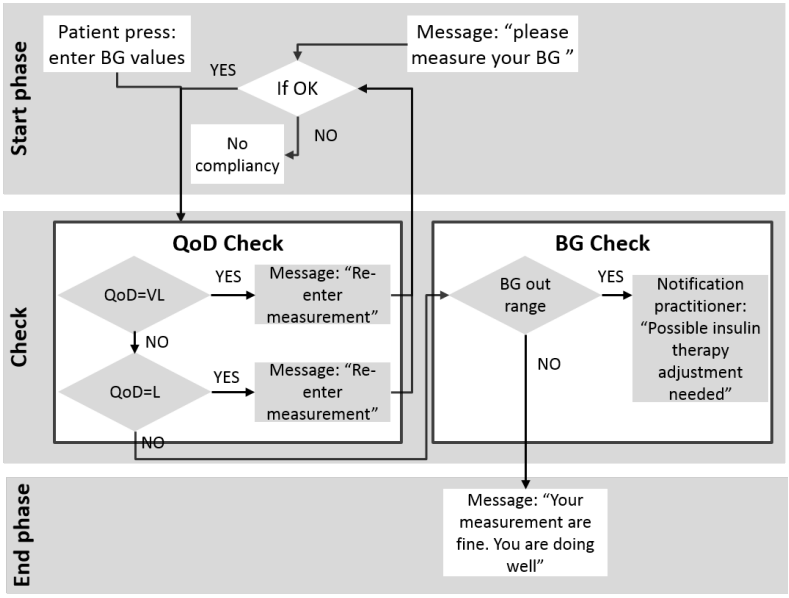


Figure 8.3: Data workflow diagram of Blood Glucose Monitoring in the GDM guideline with the representation of the impact of BG QoD in the CDSS (BG Check)

- **Streaming data**
  As discussed in Section 7.3.4, we refer to streaming data as the automatically acquired data with a sample frequency that is higher than once per minute (e.g. heart rate measurements). The streaming data discussed in MG is the following:
  - Heart Rate: As presented in Chapter 5 (Section 5.3.1), the QoD of HR was used during the physical exercise treatment to adjust the treatment and avoid potential unsafe situations. As presented in Chapter 7, in order to avoid fluctuations in treatment adjustment, the HR QoD was further processed with temporal abstractions. Thereafter, the CDSS processed the abstracted QoD in order to adjust the physical exercise treatment accordingly.

  The response of the prototype towards the streaming data was studied with respect to two different aspects:

  1. HR QoD temporal abstraction
     In Fig 8.4 we illustrate a test done to check the behavior of QoD Broker. First, we illustrate two of the RQPs used to compute QoD:

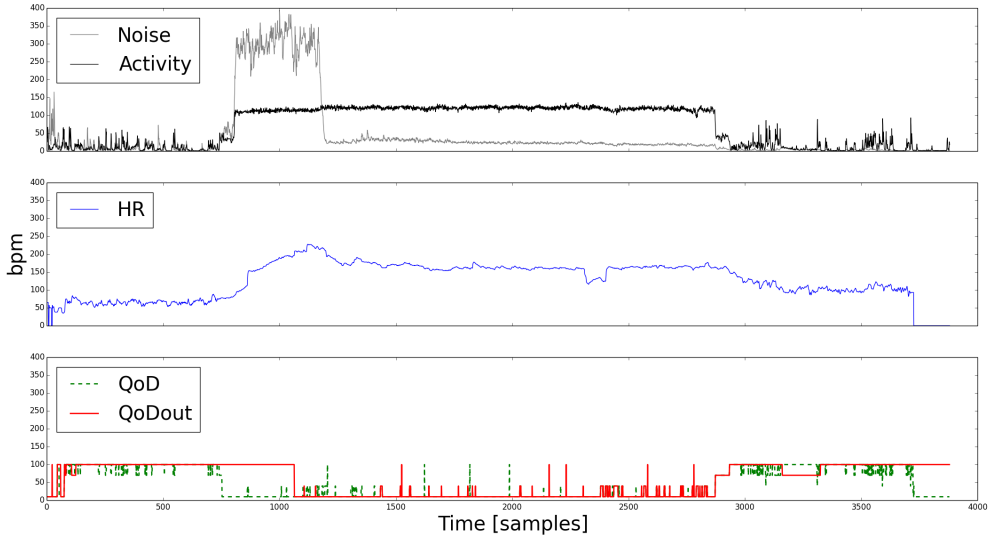


Figure 8.4: *Top:* Noise and Activity levels used for HR QoD computation; *Middle:* HR; and *Bottom:* QoD and temporal abstraction QoD_{out}

activity level and noise level. Thereafter we illustrate the HR obtained during the same test, and finally the QoD before and after the temporal abstraction (QoD_{out}), which is also presented in Chapter 7.

As shown on top and bottom of Figure 8.4, when the noise levels or activity levels increase, the computed QoD grade decreases. This is the case since QoD Broker considers these RQPs (e.g. noise, activity levels) as potential factors for QoD degradation. Figure 8.4 represents noise levels and activity levels to illustrate some of the RQPs used, but other RQPs are also used to determine the QoD.

As shown in the bottom of Figure 8.4, in order to avoid QoD fluctuations, QoD Broker's QoD temporal abstraction results into an stable QoD_{out} . The BioHarness sensor used in this study [71] requires to moisten the heart rate sensor pads with water to improve skin conductivity. The QoD at the start of the HR measurement is often unstable, which usually is due to initial low skin connectivity. Hence, we should provide a “initializing” special value to the QoD for 3 minutes. This does not put the patient at risk since the treatments (e.g. physical exercise treatment) have an initialization time (pre-exercise time 5.3.1)

2. CDSS output
   We also tested the output of the CDSS with this computed HR QoD_{out} in the physical exercise treatment (use case 1 presented in Section 5.3.1 - Figure 5.7). This consists of the following stages, illustrated in Figure 8.5:
   When the QoD is "High", the treatment was continued with no changes. When the QoD falls to "Medium" the treatment is adapted, in this case exercise intensity is lowered, so that the CDSS could ask the patient to *"slow down"*. The same way, if the QoD becomes "Low" the intensity is further lowered (higher grade than fore QoD "Medium"), so that the CDSS could ask the patient to *"slow down"*. Finally, when the QoD becomes "Very Low", the system asks the patient to *"stop the treatment"*.

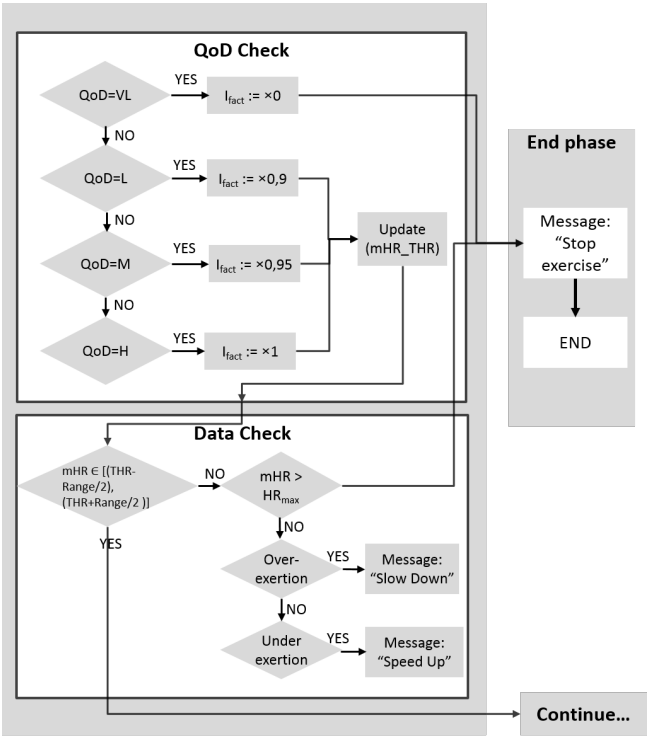


Figure 8.5: QoD check and data check workflow diagram for AF physical exercise treatment

- **Initialization data**
  Finally, initialization data refers to data required before the treatment starts. Hence, the system needs to guarantee available data with "valid" QoD before the treatment starts.
  The initialization data discussed in MobiGuide was the following:
  - ECG and Heart Rate: As presented in Section 5.3.2, before certain treatments were executed, QoD_{INIT} was verified in order to guarantee available clinical data during the treatment execution. In MobiGuide we tested QoD for both monitoring and physical exercise treatments. The monitoring treatment goal is to monitor patient's heart condition by measuring a one-lead ECG to detect AF episodes and possible changes in the patient's condition. The physical exercise treatment goal is to safely guide the patient during the outdoor physical exercise by using HR data.

The following tests represents the response of the prototype for the initialization data:

1. To compute QoD_{INIT}, the QoD Broker considers the RQPs (e.g. battery level, status) of the mobile ICT resources used for these treatments (i.e. smartphone and bioharness sensor [71]). The QoD_{INIT} output is one of the four possible overall QoD grades. The role of QoD_{INIT} is also illustrated in Figure 8.6 and Section 5.3.2, Figure 5.8):
   When the ICT resources provide RQPs that fulfill the QoD requirements, QoD Broker computes QoD_{INIT} with "High" grade. Hence, the CDSS would continue with the treatment execution.
   If the ICT resources are not ready (e.g. due to low battery power), the QoD Broker requests additional information to the patient (e.g. *"Did you charge the sensor recently?"*), which is used for the final QoD_{INIT} computation.
   If the QoD Broker can derive that the ICT resources are malfunctioning (e.g. reply of patient: *"Yes. I charged the sensor recently"*), the QoD_{INIT} is set to "Very Low". Consequently, the CDSS decides to stop the treatment execution due to potential technical malfunctions.
   Alternatively, when the patient ignores the QoD Broker's request, the QoD Broker sets the QoD_{INIT} to "Low" due to uncertainty

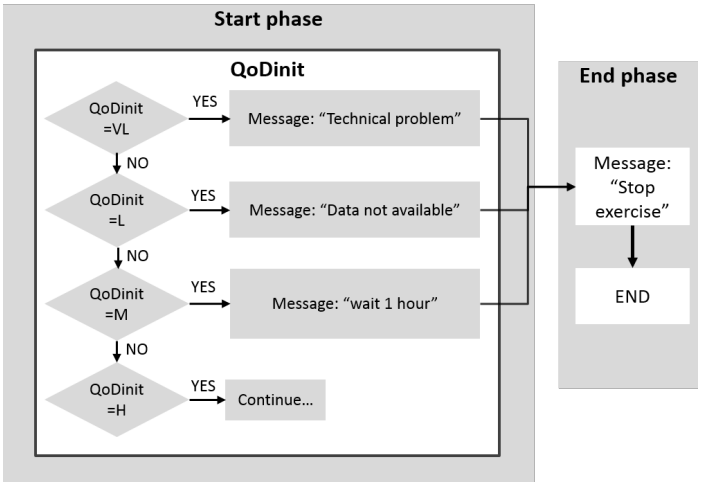


Figure 8.6: QoD_{INIT} workflow diagram for AF physical exercise treatment

of the data. The CDSS decides to stop the treatment execution due to data uncertainty. Finally, if the QoD Broker can derive that the patient could contribute to better ICT resources' performance (e.g. reply of patient: *"No. I did not charge the sensor recently"*), QoD Broker provides a technological recommendation for potential QoD improvement (e.g. *"Please, charge the sensor for 1 hour"*) and the QoD_{INIT} is set to "Medium". In this case the CDSS stops, but by postponing the treatment for 1 hour, so that the ICT resources could be ready.

In Table 8.2 we represent the tested data types, measured data, QoD grades and CDSS output for each case. Note that in MobiGuide, the response of the CDSS is the same for each measured data value of the same data type. However, we can easily implement this differently, such that CDSS responses also depend on measured data values. Additionally, the overall QoD was taken into account and not every QoD dimension. Yet, as presented in Section 7.3.3, for every QoD dimensions grade and their multiple combinations ($5^4 = 625$ possible combinations), the CDSS could output a different treatment decision (i.e. implementing a "fine grained" approach).

Data type	Measured Data	QoD grades	CDSS output
Periodic	Blood Pressure	High	Continue
	Blood Glucose	Medium	Continue
	Weight	Low	Ignore
	INR	Very Low	Ignore
Streaming	Heart Rate	High	Continue
		Medium	Lower intensity factor
		Low	Lower intensity factor
		Very Low	Stop treatment
Initialization	Heart Rate	High	Continue
	ECG	Medium	Stop treatment (postpone 1 h)
		Low	Stop treatment (data uncertainty)
		Very Low	Stop treatment (technical malfunctioning)

Table 8.2: Single case mechanisms test within MobiGuide

8.5.3 CONCLUSION

Here we revise the previous tests to verify whether MobiGuide system is useful to the medical practitioners' daily practice.

- **Periodic Data**
  As discussed, we studied four main aspects regarding periodic data: human errors consideration, technological recommendations, visualization, and CDSS output.
  Firstly, medical practitioners are used to deal with the patient reliability issues. Hence, they validated the behavior of the QoD-aware telemedicine system, which considers manual data as well as automatic data for QoD computation.
  Secondly, medical practitioners found it essential that the system takes additional actions when manually inserted data is detected as suspicious. Hence, they validated the technological recommendations that are sent to the patient.
  Besides, medical practitioners identified the necessity of having the system to inform the patient and medical practitioners about the QoD grades for the decision making process. Hence, they validated, and considered it essential, to have this QoD grades information in both the patient GUI and caregiver GUI.
  Finally, as medical practitioners considered QoD information essential for their decision making process, they also considered that data with

quality that does not fulfill the medical requirements should not be processed by the CDSS. Hence, the CDSS should only make treatment decisions based on the clinical data that fulfills the QoD requirements.

- **Streaming Data**
  Regarding the streaming data we tested the HR QoD temporal abstraction, and the CDSS output based on different QoD values.
  As shown in Fig8-5, when the QoS information signals potential data errors the QoD Broker responds by lowering the QoD, which demonstrates the QoD Broker computation. Additionally, the QoD Broker computes the QoD temporal abstraction, fulfilling the user requirements.
  Regarding the CDSS output, medical practitioners want to prevent any harm or inconvenience to the patient. In all cases they expect the system to take the "safest" option. In this case they considered that to reduce the physical exercise intensity level, or even to stop the physical exercise treatment is the "right" procedure in order to enhance (guarantee) the patient's safety, in accordance with the user requirements.
- **Initialization QoD**
  We checked the behavior of the system when the battery levels of the smartphone and the BioHarness system were "too low" (i.e. they were not able to measure the clinical data during the requested treatment duration). Medical practitioners expected some QoD control before the patient starts a treatment. Hence, this QoD_{INIT} was validated favorably.

In conclusion, this activity validated that the outcome of stimuli applied (e.g. degraded QoD) fulfilled the design functional requirements, such as the behavior of the system during physical exercise treatment when HR QoD fluctuates and possibly degrades too much. Additionally, this activity also demonstrated that clinical experts are satisfied with the system as a value-added support tool for daily practice.

8.6 ASK EXPERTS ABOUT EXPECTED EFFECTS OF SOLUTION

This validation activity aims to partially validate Goal 4. In this validation activity we applied the 'semi-structured interviews' validation method. First, we discuss how the 'semi-structured interviews' validation method is being applied in this activity, and next, we present and discuss the results.

8.6.1 METHOD APPLICATION

The semi-structured interviews are conducted by exposing the proposed solution to a panel of experts. In our study, the panel of experts is composed by medical practitioners and nurses from both the diabetes and cardiology domain (hence we consider them as medical domain experts).This method allows new ideas to be brought up during the interview.
To conduct the semi-structure interviews, first, we present the context of this research study (an example shown in Figure 8.7) to medical domain experts.

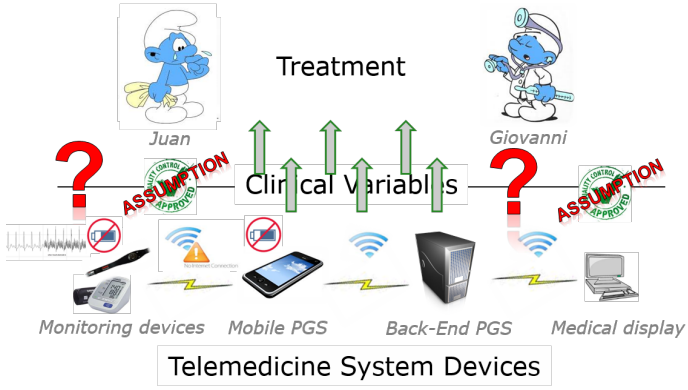


Figure 8.7: Example of the presentation for the semi-structure interview

This presentation also includes 9 questions (with sub-questions) related to QoD-awareness in telemedicine systems. The presentation facilitates the interviewees to understand the context. The aim of the interview is to validate the impact of QoD-awareness in telemedicine systems. The answers were categorized in 5 levels using the "Likert scale" [107]. The questions are classified in five different aspects to validate the system:

- ***Effectiveness (Perceived usefulness):*** These questions aim to determine how useful the medical domain experts find the integration of QoD awareness in telemedicine system. This not only involves

the QoD information provided to them, but also the technological recommendations for patients to improve clinical data quality and the treatment adaptation mechanisms triggered by QoD (*Questions 1, 2, 3, 4, 5 - Table 8.3*).

- ***User control:*** This question aims to determine if medical domain experts will use the QoD information and (if yes) "how" (*Questions 6 - Table 8.4*).

- ***Safety:*** This question aims to determine how safe the medical domain experts expect the patient to be in the extramural setting with the additional QoD-awareness measures into the telemedicine system. (*Questions 7 - Table 8.5*)

- ***Ethical considerations:*** This question aims to check if there is any kind of ethical issue when technological recommendations are sent to the patient in case the clinical data introduced in the system manually by the patient is detected as "suspicious" (low QoD) by the system. (*Question 8 - Table 8.6*)

- ***Expectations:*** This question aims to discover how medical domain experts would like the QoD information to be integrated in healthcare (*Question 9 - Table 8.7*).

To recruit medical domain experts that did not work into the MG system development, we had the support of the MobiGuide project medical practitioners from Fondazione Salvatore Maugeri (FSM) in Pavia (Italy) and Corporació Sanitària Parc Taulí (CSPT) in Sabadell (Spain). The recruited medical domain experts were aware of the medical cases studied in MobiGuide: 2 cardiovascular disease medical experts and 6 diabetes medical experts. Some of the medical domain experts were familiar with the MobiGuide prototype. However, the presentation and the questions were the same in order to mitigate any bias from the experience.
Two of the interviewed medical domain experts were cardiologists. One of them was familiar with the MG system. From the diabetes domain, we interviewed four endocrinologists and two nurses. Two of the endocrinologists were familiar with the MG system.

8.6.2 THE RESULTS

During the semi-structured interview we went through 9 main questions, which often contained sub-questions. We present the results of their responses based on the five different validation aspects presented above.
The answers were graded using the Likert scale [107] in 5 equivalent categories, and are presented in percentages. Hence, the percentage value of the last column in Tables 8.3, 8.4, 8.5, 8.6 is the transformation of this scale to a %, with favourable answers receiving higher values.

- **Effectiveness**

The first five questions were related to effectiveness. As shown in Table 8.3, the first two questions were to determine if the medical domain experts find it useful to provide technological recommendations to the patient to re-enter a measurement (e.g. blood pressure or blood glucose) when the values are "incorrect" or "suspicious" and when technical disruptions occur. Most of the professionals completely agreed. However, some of the professionals commented that it depends also on how good these "incorrect" or "suspicious" measurements are detected and how the technical disruptions are determined. Besides, they commented that "if the system is able to detect possible values as false ones the usability and the benefits towards the treatment will increase". In Section 8.5 and Section 8.7 we validated QoD Broker behavior, which describes how good these "incorrect" or "suspicious" measurements are detected. However, future work would be to work on prediction mechanisms to further analyze QoD information.
The third question, which was to determine if the medical domain experts find it useful that data with QoD "Low" or "Very Low" may trigger "safer treatment decisions", was labeled as very useful for most of the professionals (Table 8.3).
The fourth question (Table 8.3) was to determine how useful they found the QoD information for their own use: (a) for better treatment guidance, (b) for awareness of potential quality of data errors, (c) for performing additional measurements and (d) for investigating device problems or usage problems. In general they found it useful in all cases. In some cases, they stressed that it depends on how much time the care professional has.
The fifth question was to determine how easy medical domain experts found it to understand the QoD information and the technological recommendations for patients (Table 8.3). In some cases they found that the QoD dimensions

require an explanation (e.g. "accuracy = *Medium* due to noise in the signal"), and some of the professionals thought that young experts may have a better understanding of the QoD information. They also found it handy to have the overall QoD information (i.e. *"coarse grained"* approach discussed in Section 7.3.3) for easier interpretation of the QoD information. Regarding the technological recommendations, they thought that it may depend on the patient's education. If the patient is well educated or used to technology, the technological recommendations may be very simple. However, for some other patients, which may be elderly patients not used to technology, the technological recommendations may be difficult to understand.

Number	Question	%
1	**I find useful to provide technological recommendations to the patient to re-enter the measurement** (e.g. blood pressure or blood glucose) when the values are "incorrect" or "suspicious"	91
2	**I find useful to provide technological recommendations to the patient to:**	
2a	"Configure" some system device (e.g. battery of phone) that enables "better" or "good" QoD and proper functioning of the system	86
2b	Provide system (performance) awareness to patients	80
3	**I find useful that "incorrect" data may trigger "safer treatment decisions"**	84
4	**The quality of the clinical data metadata information in the care giver interface is useful to:**	
4a	Provide better treatment guidance	86
4b	Provide awareness regarding potential quality of data errors to domain experts	81
4c	Perform the necessary additional measurements by experts	78
4d	Investigate if there is any problem with the system devices (BP device malfunctioning) or its usage	80
5	**I perceive easy to understand**	
5a	I am comfortable with my ability to understand quality of data (QoD) meaning	64
5b	I find the technological recommendations easy to use (understand) for the patient	72

Table 8.3: Semi-structured interviews response for effectiveness (Perceived Usefulness)

- **User control**

The sixth question (Table 8.4) was to determine if the medical domain experts would use QoD information for different treatment phases: diagnosis, treatment decisions and recommendations to the patients. The requirement for high quality data is very important during diagnosis, however, some stressed that QoD is assumed [*rightly or wrongly!*] to be "High" during diagnosis. On this assumption, these clinical professionals (half of the interviewees) did not consider it so relevant to have access to the QoD information during diagnosis, which occurs in the hospital setting. However, the other half of the interviewees graded the relevance of QoD information for diagnosis with maximum Likert scale ("strongly agree"), since it is essential to ensure that QoD information is best quality to avoid wrong diagnosis. Due to these disparities, the answers to this question for diagnosis were either "High" or "Low" and the final average result was 59%. In the questions related with treatment decisions and recommendations to the patients all clinical professionals agreed with the importance of QoD information, so that the final result was 84% (Table 8.4).

Number	Question	%
6	**I would potentially use QoD information for (User control):**	
6a	Diagnosis	59
6b	Treatment Decisions	91
6c	Recommendations to the patient	84

Table 8.4: Semi-structured interviews response for user-control

- **Safety**

The seventh question was to determine if medical domain experts feel that the patients are safer with this data quality control and if the safety measures provided by the QoD-aware system are similar to the one provided in a supervised treatment (Table 8.5). The first part of this question was answered positively (average score 88%). However, none of the professionals agreed with the second part of the question due to the fact that they find that a "machine" cannot replace medical professionals (average score 58%). Yet, most of them recognized that systems may more accurately detect errors and respond to them than humans. But at the same time, clinical professionals argued that machines are lacking other contextual information and other parameters that may be needed

to provide the best decision. Therefore, they considered that a combination of both may be the safest option.

Number	Question	%
7	**Regarding to safety, I find (Safety):**	
7a	Patients are more safe (in the extramural setting) by knowing that the treatment adapts when some data is "suspicious" or "incorrect"	88
7b	I feel that the safety measures provided by the QoD-aware system is similar to the one provided in a supervised treatment (e.g. additional measurement when the data is suspicious)	58

Table 8.5: Semi-structured interviews response for safety

- **Ethics**

The medical domain experts reacted positively when presented with questions on the matter of ethics (Table 8.6). The action of QoD control, which triggers recommendations when manually entered data is qualified by the QoD Broker as "suspicious", was considered a positive step (with average score 89%). The provision of technological recommendations during device malfunction had an average score of 94%. The provision of QoD information to the care giver received the maximum score of 95%. These results prove that the medical domain experts consider the current implementation of QoD controls as a solution to improve patient treatment without contradicting ethical principles.

Number	Question	%
8	**Regarding to ethical considerations (Ethical considerations)**, I feel it is right to provide technological recommendation to the patient when:	
8a	The manually entered data is "suspicious"	89
8b	The devices have some problems (e.g. battery of sensor or phone need to be charge)	94
8c	It is right to provide the quality of data information in the care giver interface	95

Table 8.6: Semi-structured interviews response for ethics

- **Expectations**

Table 8.7 lists the major expectations of medical domain experts. The medical domain experts expect the inclusion of QoD for all clinical data, including EHR (average score of 89%). They anticipate a large scale implementation of telemedicine systems, for out patient care, in in the future (average score of 72%). However, they see the need for domain experts to be made aware of the relevant technological recommendations that patients receive from the system (average score of 84%), especially if they want to understand the patient context (e.g. if the patient is capable of using the system correctly).

Number	Question	%
9	**In the future I expect (Expectations):**	
9a	All clinical data to be quality graded (also in intramural hospital settings)	89
9b	Quality of clinical data is used in treatments for outpatients	72
9c	Technological recommendations provided to the patient must be available to medical domain experts (caregiver)	84

Table 8.7: Semi-structured interviews response for expectations

8.6.3 CONCLUSION

The medical domain experts (i.e. the cardiologists at FSM in the AF case and the endocrinologists and nurses in the GDM case) found it very useful to include QoD awareness in healthcare systems, providing the QoD is always correctly assessed. They also considered it necessary to have proper QoD information to understand its meaning. Regarding user control, they found that QoD information is necessary during the treatment guidance, when the ambulatory patient is not in the clinical setting. The requirement for high quality data is very important during diagnosis, however, some stressed that QoD is assumed [rightly or wrongly!] to be high during diagnosis. This assumption resulted in very diverse answers. They also considered that QoD control has the potential to improve patient safety. Regarding the question on ethics, they did not find any ethical issue with the use of QoD control. To conclude, they found QoD information as a necessary feature to be implemented in future healthcare systems.
Hence, the results of these semi-structured interviews demonstrated that the QoD-awareness is required in healthcare, especially in telemedicine systems

where unexpected technological disruptions may occur affecting clinical data quality. However, it should be noted that we did not perform a statistical validation due to the low number of medical domain experts participating.

8.7 TEST PROTOTYPE WITH HEALTHY VOLUNTEERS

In this validation activity we tested the prototype in order to partially validate Goal 4. We refer to the validation method as 'pre-pilot study'. First, we discuss how the validation method is being applied in this activity, and next, we present and discuss the results.

8.7.1 METHOD APPLICATION

As reported in MobiGuide deliverable [8], we conducted a pre-pilot study. This study involved the participation of healthy volunteers (subjects were technical and clinical professionals) who could test the QoD-aware telemedicine system prototype for both medical cases (AF and GDM) of the study. This validation method was conducted in an iterative process, with each iteration comprising the following steps:
Each of the healthy volunteers, who were enrolled in the MobiGuide study, got the system prototype and tested its functionalities. Every time an error, an unexpected behavior or a perceived missing functionality was detected, this issue was reported to technical partners. The technical partner in charge of solving the issue took care of it. Thereafter, a new release of the system prototype was prepared, all the volunteers and the technical partners were notified, and each volunteer got a new version of the system prototype. Additionally, during this process the changes were tested and open issues were discussed (Figure 8.8).

The aim of this study was a functional validation of the system, but in this research study it also contributes to the clinical validation since it involves clinical partners.
The tests were performed in real clinical environments at Fondazione Salvatore Maugeri (FSM) and Corporació Sanitària Parc Taulí (CSPT), where also the actual pilot was planned. To do this, a set of 'fake' patients were created in the hospital electronic medical records (EMR) and then imported in the Personal Health Record (PHR) used in MobiGuide. This way we could simulate all the phases of the MobiGuide process. Smartphones and sensors were prepared for all the volunteers, who were then enrolled in the system and started testing the functionalities.
The AF pre-pilot involved nine volunteers: six subjects from UNIPV and three

from FSM (in particular: one IT staff subject, a physician and a nurse). The GDM pre-pilot lasted for two and a half months. It involved 7 volunteers: two engineers from UPM, and one IT staff subject, two endocrinologists and two nurses from CSPT.

8.7.2 RESULTS

During the pre-pilot study we improved the MobiGuide QoD-aware subsystem, including the QoD Broker subsystem. Here, we focus on the QoD Broker test results. Note that all QoD-aware telemedicine system components went through the same process.
The QoD Broker issues that were reported most often referred to both domains (AF and GDM). In the issues reported, five entries were related to the QoD Broker and they refer both to errors and new functionalities. Here, we describe the main changes grouped under three headings:

1. Technological recommendations
   During the pre-pilot test, we realized that there were some problems related with the AF monitoring sessions. The patient may be asked to start a monitoring session to study the AF episodes and the HR of the patient. Some of these monitoring sessions last for more than 12 hours, which requires the BioHarness system and smartphone to be charged (at least 80%) before starting. Therefore, in some cases, the QoD Broker sent a technological recommendation to the patient to charge the smartphone (if lower than 80%). In some cases this message was sent while

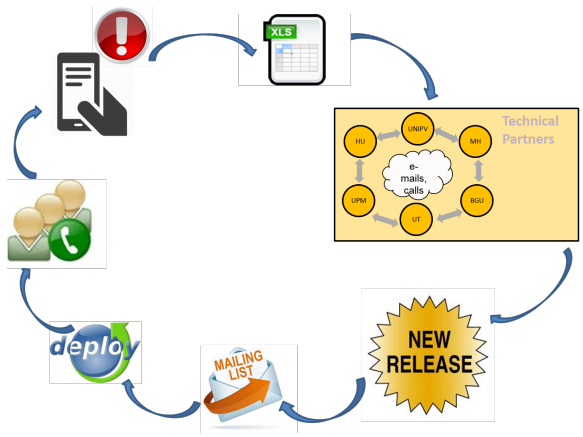


Figure 8.8: Pre-pilot testing phase iterative steps [8]

the patient was charging the smartphone. Hence, we modified this functionality so that, if the smartphone is charging, the QoD Broker will not request the patient charge the battery of the smartphone and postpone the monitoring session.

2. QoD labels for additional measurements
   In the original version of the QoD Broker there were no requirements for the QoD of international normalized ratio index of blood coagulability (INR) and weight measurements. However, during the pre-pilot study it emerged that the QoD of these measurements was also of clinical importance, and a new requirement was established to provide a technological recommendation (e.g. *"re-enter the weight measurement value"*) if the values were detected "suspicious". Hence, we augmented the functionalities of the QoD Broker as follows: if the entered values are not in the admissible range (e.g. input weight=500 Kg) the QoD of these measurements decreases and technological recommendation (e.g. *"re-enter the weight measurement value"*) is sent to the patient via the patient GUI.

3. QoD Broker bugs
   QoD Broker bugs. Some QoD Broker bugs relating to AF were detected and fixed during the pre-pilot. One of the bugs was related to channel subscription protocols. Hence, QoD Broker was sending multiple technological recommendations due to missing unsubscribed channels. This was solved during this pre-pilot phase.

8.7.3 CONCLUSION

As shown, during this validation activity several fixes were done in different components of the MobiGuide system prototype. This way we validated each of the system components, their integration and the QoD-aware telemedicine system as a whole.
The medical practitioners involved in the project also verified if the system was fulfilling the medical requirements. Hence, after the pre-pilot study, the final QoD-aware telemedicine system prototype was ready to be used by patients. Some of the MobiGuide components had major improvements after this study. Therefore, we consider this pre-pilot validation method a necessary step towards testing the system with patients.

8.8 TEST PROTOTYPE WITH PATIENTS

This validation activity applies 'technical action research' (TAR) and 'questionnaires' validation methods in order to test the MobiGuide prototype with patients under real-life conditions (Goal 4). In the following sections we present how these methods were applied, the results and discussion of these results.

8.8.1 METHOD APPLICATION

As reported in MobiGuide deliverable [8], we conducted a pilot study, which combines 'technical action research' (TAR) and 'questionnaires'.
The aim of MobiGuide is to develop a patient guidance system. The developed system prototype supports two medical cases: atrial fibrillation (AF) cardiology healthcare environment and gestational diabetes mellitus (GDM) endocrinology healthcare environment. Therefore, in the TAR we enrolled 9 AF patients and 9 GDM patients and conduct a pilot study during the period of 3-4 months in average [108].
Besides, MobiGuide also requires the involvement of medical practitioners in charge of controlling the treatment. In this case cardiologists and endocrinologists were involved respectively. They conducted the enrollment process of the patients and treated the patients during the pilot study. Hence, they were also part of the TAR study.
Once the TAR finalized, both patients and medical practitioners answered questionnaires, so that we could evaluate different aspects of the study.
Since the focus of this research is on the QoD-aware guidance for systems, we analyzed the answers to the questions related to QoD-awareness. These questions had a set of choices (e.g. score from 1 to 5 from "completely agree" to "completely disagree" following Likert scales [107]). The complete questionnaires to validate the overall prototype are presented in Appendix E. Table 8.8 presents the number of participants in each group and the number of QoD-related questions given to each of the group.

We did not consider any specific information from medical domain experts to interpret the results. Nevertheless, in order to interpret the results from the questions presented to patients, we considered the following aspects:

– Age and education of the patient
  Atrial Fibrillation patients in the AF case are men and women in the age above 59. Mean and standard deviation of age of the 9 enrolled patients was 66.3 ± 9.2 years. Their education level was diverse. From very

To whom	Number of participants	Number of questions
Medical domain experts	8	2
Patients GDM	9	6
Patients AF	9	7

Table 8.8: Participants and number of questions presented to each group

basic education level to technical and university education.
Gestational diabetes patients in the GDM case are in all cases women in the age range between 20 and 40. Mean and standard deviation of age of the 9 enrolled patients was 34.9 ± 3.7 years. In all cases the patients were educated and in 8 out of 9 cases the patients had a university degree.

– Duration in the pilot study
The average time of the pilot for AF patients was 141 days (and the standard deviation was 28 days), since it was important to have a 3 months study to see potential changes on a patient's condition and validate the system.
In the GDM case the pilot was finalized after patient's delivery. In some of the cases the gestational diabetes was detected in the last stage of pregnancy and hence, the pilot duration was less than a month. The average time of the pilot for GDM patients was 49 days (and the standard deviation was 21 days).
– QoD-aware related recommendations that to patients
Both the AF patients and GDM patients received QoD-aware related recommendations. Some of these recommendations where clinical recommendations triggered by QoD information. However, they also got specific technological recommendations that aimed to improve the quality of the clinical data (see Chapter 7). The number of these technological recommendations varied significantly with the patients: AF patients received in average 13.4 ± 11.06 technological recommendations; GDM patients received in average 7.5 ± 8.02 technological recommendations. The difference on the number of technological recommendations between AF patients and GDM patients was due to the difference in the duration of the pilot, since the weekly average of the technological recommendations was similar in both cases.
– Physical exercise treatment (in the AF case)
The MobiGuide system aims to enhance the patient's safety during physical exercise sessions. In the case of an AF patient, this is accom-

plished by processing HR data and its QoD. Therefore, this study considers important the information regarding the number of physical exercise sessions conducted by patients. Additionally, one of the questions for AF patients was related with the safety feeling during the physical exercise.
Due to the limited time for the pilot study, the physical exercise treatment was not prescribed for AF patients. Consequently, some of the patients did not perform any physical exercise and in most of the cases the number of physical exercise sessions was not high.
In the GDM case, one of the reasons for low physical exercise sessions is that traditionally women in Spain (fallaciously) think that exercise is not recommended during pregnancy.
The number of physical exercise sessions varied significantly over the patients: AF patients conducted in average 4.4 ± 4.5 sessions; GDM patients conducted in average 2 ± 2.5 sessions. Again, one of the main reasons for this difference between AF patients and GDM patients might be the difference on the duration of the pilot.

8.8.2 THE RESULTS

Following we present the results of the patients and medical domain experts. Notice that we retrieved the answers from a longer questionnaire. The question numbers used below correspond to those used in of the original questionnaire Appendix E. One of the enrolled AF patients suspended the pilot, and hence, the results correspond to 8 patients.

- **Patients**

In Table 8.9 we present the questions and the average score of the answers provided by AF patients.

In Table 8.10 we show the questions and the average score of the answers provided by GDM patients.

- **Medical Domain Experts**

Table 8.11 presents the questions and the average score of the answers provided by two experts (1 nurse and 1 physician) in the AF medical domain and six experts (2 nurses and 4 physicians) in the GDM medical domain.

Number	Question	%
Q19	If you have received a notification to re-enter a measurement value, the information provided by the system is:	90
Q20	The number of notifications received to re-enter a measurement value is:	80
Q21	If you have received a notification to re-enter a measurement value, the information provided by the system is:	80
Q22	If you have received a notification to charge the sensor or smartphone battery, the information provided by the system is:	93
Q23	The number of notifications received to charge the sensor or smartphone battery is:	85
Q24	If you have received a notification to charge the sensor or smartphone battery, the information provided by the system is:	85
Q34	The system improves my safety when performing physical exercise	76

Table 8.9: AF patients' questions and answers after the pilot study

Number	Question	%
Q17	If you have received a notification to re-enter a measurement value, the information provided by the system is:	80
Q18	The number of notifications received to re-enter a measurement value is:	74
Q19	If you have received a notification to re-enter a measurement value, the information provided by the system is:	73
Q20	If you have received a notification to charge the sensor or smartphone battery, the information provided by the system is:	93
Q21	The number of notifications received to charge the sensor or smartphone battery is:	87
Q22	If you have received a notification to charge the sensor or smartphone battery, the information provided by the system is:	80

Table 8.10: GDM patients' questions and answers after the pilot study

Number	Question	%
Q13	Perceived usefulness: Using MobiGuide system clinical data quality-aware increases the outpatient's treatment safety	80
Q22	User control: the quality of the clinical data provided by MobiGuide has an impact on my treatment decisions	85

Table 8.11: Medical domain experts' questions and answers after the pilot study

8.8.3 CONCLUSION

In order to retrieve conclusions from this validation activity, we analyzed the results of the patients' and medical domain experts' questionnaires and discuss some of the factors that had an impact on the results.

- **Patients**

In order to interpret the results of the patients' questionnaires we considered the aspects discussed in Section 8.8.1 (e.g. age, physical sessions conducted, number of technological recommendations each of the patients received).
Notice that the first 6 questions in both the GDM and AF case are the same. Therefore, we discuss both cases together for these first 6 questions, and include the seventh question (Q34) for AF patients at the end.

- Technological Recommendations: RE-enter measurement
  The first 3 questions were related with the recommendations to patients to re-enter the measurements (BG, BP etc.) in cases where the QoD Broker detects that the measurements may be erroneous. In the AF case few (only 2) patient replied to these questions. One of the reason could be that they did not receive these type of technological recommendations.
  The first question referred to the clearness of the recommendations. On average the patients responded "clear" or "very clear". The second question (number of recommendations received), was considered "appropriate" for most of the patients. However, one out of seven patients found the number of recommendations "annoying". Concerning the third question regarding the usefulness of recommendations, half of the patients graded the usefulness as neutral, the other half considered the recommendations "useful" or "very useful".
- Technological Recommendations: Charge sensor or smartphone
  The next 3 questions were related to the recommendations the patient may receive to charge the sensor or smartphone battery. In the AF case this recommendation was sent before the monitoring and physical exercise treatment execution for both the Bioharness sensor and smartphone battery. Additionally, the patient received this recommendation when the smartphone was running out of battery. Hence, all patients answer this question. In the GDM case this recommendation was only sent when the smartphone was running out of battery. Therefore, only 3 out of 9 patients replied to this questions; possibly the patients that did not answer these questions did not receive the recommendation.

These recommendations were judged to be "clear" or "very clear"; the number of recommendations were judged "appropriate" or "very appropriate" by most of the patients (1 graded it "neutral"); regarding utility, most patients considered these recommendations very useful or useful while one of the patients considered it not useful in the GDM case.

- Safety during physical exercise
  As shown in previous chapters (Chapter 3 and Chapter 5), QoD-awareness during physical exercise is one of the principal use cases of this research study to demonstrate the safety role of QoD-awareness in telemedicine systems. Hence, question Q34 of the AF patients' questionnaire was focused on this.
  As discussed before, the number of sessions performed by patients was low since the physical exercise treatment was not prescribed. The patient that performed the highest number of physical exercise sessions (total of 12 over 161 days) replied with the highest score to this question. This patient had the opportunity to interact more and more frequently with the system due to more physical exercise sessions.
  Nevertheless, (all) patients (who replied to this answer) performed physical exercise sessions, but did not feel the additional safety measures implemented in the QoD-aware system. One of the reasons could be that QoD did not degrade and, hence, the system did not provide additional recommendations. In fact, some patients would have preferred more user-system interaction during the outdoor sessions even if the QoD was optimal.

- **Medical Domain Experts**

Additionally, we also could validate the results of medical domain experts from two different aspects after the pilot study: the usefulness of QoD in the role of providing safer treatment and QoD-awareness for medical practitioners to potentially make better treatment decisions.

- Perceived usefulness: medical domain experts found the role of QoD necessary, as the treatment can be adapted when QoD degrades to guarantee patients' safety.
- User Control: medical domain experts considered that QoD information is important since it may impact their treatment decisions.

8.8.3.1 FACTORS TO CONSIDER

Here we present some of the factors that could have affected some of the results.

- The answers to some of the questions are influenced by how the patients' used the system. For example, if they often did physical exercise, the feeling they may get regarding safety measures provided by the system during physical exercise is higher than if they did rarely perform physical exercise, and consequently, did not get many QoD related feedback from the system.
- Some of the questions were not answered by some patients. This may be due to lack of experience regarding these questions (e.g. re-enter measurement in case of AF patients, charge sensor or smartphone in case of GDM patients).
- Some patients need more interaction with the system than others. Hence, the feedback frequency should be personalized.
- The small number of participants, specially the small number of medical domain experts, did not allow to present representative results.

8.9 DISCUSSION

Different validation activities were used to investigate different aspects QoD-awareness in telemedicine systems. Together these validations demonstrate the following:

1. System conformance to evidence-based principles: compliance: conformance of the system design towards evidence based principles and medical practice due to the involvement of medical domain experts (specially medical practitioners) during different validation activity phases (VA1, VA2, VA3, VA5).

2. Functional validation: the fulfillment of functional requirements when applying stimuli to the prototype in a test scenario and during real-world test scenarios with healthy volunteers and patients (VA4, VA6, VA7).

3. Medical acceptance: medical domain experts understood the implication of QoD in healthcare systems. They recognized that since not only human errors may occur, but also technical errors, and these errors could

put the patient care at risk. Hence, this validated the approach of our study (VA1, VA2, VA3, VA7).

4. Patient acceptance: after the usage of the QoD-aware telemedicine system in the pilot study, patients got the feeling that the technological recommendations (which are triggered by QoD-Broker) contribute positively to the usefulness and safety feeling of the system (VA7).

5. Lack of statistical results: The constrains on the MobiGuide project, such as time and resources, limited other validation activities. Hence, the sample (patients and practitioners involved in the pilot study) was not large or representative enough to warrant performing a statistical analysis.

Here we have presented a qualitative evaluation of our research, demonstrating the contribution to the stakeholders goals. One of the future validation activities would be to perform the pilot-study on a large scale, with the involvement of a larger number of patients and medical domain experts to create a realistic output of the solution and retrieve representative results for a statistical analysis.

CHAPTER 9

CONCLUSIONS

As modern day healthcare is evolving to more mobile based companions, we aimed to develop a QoD-aware telemedicine system that can improve the reliability of such systems and guarantee patients' safety when technological context varies and low quality data is detected.
In Section 9.1 we revisit the research questions presented in this thesis. Section 9.2 presents the general contributions presented in this thesis. Section 9.3 discusses the generalization of our research findings in healthcare to other fields. Finally, Section 9.4 provides further research directions for the future.

9.1 REFLECTION ON THE RESEARCH QUESTIONS

In Section 1.3, we presented the research questions of this research. We will revisit them one by one:

Can QoD-awareness integration improve healthcare systems, in particular telemedicine systems, by preserving system reliability and enhancing (guaranteeing) patient safety when QoD degrades?

- ***How to design a QoD-aware patient guidance (telemedicine) system that preserves patient's safety when QoD degrades?***
  In order to design a QoD-aware telemedicine system that complies with the user requirements, we need to identify the user requirements first. In Chapter 3, we introduced an adapted requirement elicitation method which we applied in this research study. This requirement elicitation method has two stages: the first stage focuses on the user activities

from the clinical perspective, which forms the foundation to develop a conceptual model; the second stage focuses on the user-system interactions, which leads to the identification of the functional requirements for the QoD-aware telemedicine system. Hence, Chapter 3 presents the approach of this thesis to design a QoD-aware patient guidance system.

- ***How to develop a conceptual model for Quality-of-Data aware treatment guidance?***
  We focused on the impact of technological context (i.e. performance variations of technological resources) on clinical data quality, and the impact of clinical data quality on clinical context (i.e. treatment guidance and patient's safety). In Chapter 3, we presented the layering technique, which bridges the gap between the technological context and the clinical context. It defines the conceptual and qualitative relation between the technological resources (in the technological layer) and the patient treatment (in the clinical layer). This has resulted in the conceptual model (QoD-framework ontology) for QoD-aware treatment guidance, presented in Chapter 4.

- ***How to include QoD-awareness in executable clinical guidelines?***
  Current clinical guidelines assume that the clinical data fulfill the medical quality requirements. However, in pervasive healthcare systems, this assumption may be erroneous and the clinical data, used to guide patients in a pervasive intramural environment, may not fulfill the medical quality requirements at all times. Hence, in Chapter 5 we describe a method to determine the impact of the degraded clinical data quality on the treatment, and built treatment adaptation mechanisms in the guideline (customized executable computer interpretable guideline), which is the way to include QoD-awareness in executable clinical guidelines.

- ***What is the architecture of a QoD-aware telemedicine system?***
  In Chapter 3, we introduced the method to derive functional requirements. These requirements are described in Chapter 6, where we addressed the functional requirements in three levels of abstraction. We derived the QoD-aware telemedicine system architecture from these functional requirements and we identified the system components and interactions in each level of abstraction (Chapter 6). Furthermore, Chap-

ter 7 extends this system architecture with the description of the QoD Broker architecture and functionalities. It presents the QoD management method to provide useful QoD information and to preserve high QoD. Herewith a complete architecture of a QoD-aware telemedicine systems has been described.

The generic (main) research question has also been addressed by the results discussed in Chapter 8, where the added value (benefits) of the QoD-awareness integration in telemedicine systems was validated. Additionally, Chapter 8 supports the validation of the decomposed research questions, which copes with the applied methodology and its design.

9.2 RESEARCH CONTRIBUTIONS

This research has contributed in both fundamental and applied areas of development of healthcare technologies.
The *fundamental contribution* of this research is twofold:

- First, we refined a requirements elicitation method and developed a context layering technique, which helps to bridge the gap between technological context and clinical context (Chapter 3). First, the applied requirements elicitation methodology was refined in our study to cover the QoD related requirements of telemedicine systems. This method results in the development of a QoD-framework ontology (Chapter 4), with the support of the context layering technique, and the identification of the system functional requirements (Chapter 6, Chapter 7). Hence, this requirement elicitation method and context layering technique can be used by requirements engineers and knowledge engineers to extract clinical knowledge from medical domain experts and to formalize this knowledge in a QoD-framework ontology. The ontology represents the clinical-context and technological-context knowledge of two of the QoD-aware telemedicine system's components: clinical decision support system and QoD Broker.
  Thereafter, we discussed the process of formalizing the clinical-context knowledge, which comprise guideline adaptation mechanism (Chapter 5). This is essential in order to include technological context awareness in terms of QoD in the current clinical guidelines which will be applied in autonomous clinical decision support systems.

- Second, we have developed a QoD information management method to provide useful QoD information to the user (Chapter 7). This involves the method to select the appropriate QoD dimensions, their computation and management. In our research study, we discovered that QoD information should to be adapted to every user. In some cases, the user may prefer to get an overall QoD rather than five QoD dimensions information, or may require a stable QoD (temporal abstraction) rather than a QoD that fluctuates frequently.

The *applied science contribution* has been made in two main themes:

- First, we designed the architecture of a QoD-aware telemedicine system (Chapter 6). We decomposed the QoD-aware telemedicine system into several levels of abstraction and specified the components and their interactions needed in the QoD telemedicine system. This architecture could be used as a guideline by developers of healthcare applications and telemedicine systems, so that QoD-awareness is integrated in their system.
- Second, we have designed the architecture of a QoD-Broker and described its main functions, which include QoD management techniques that provide useful QoD information and prevent (if possible) QoD degradation (Chapter 7). The design of QoD Broker could be used by software developers to integrate a QoD engine in their systems.

9.3 GENERALIZATION OF QOD-AWARENESS IN OTHER DOMAINS

The application domain of this research study is healthcare. However, ICT and data driven systems are used in several fields. They are applied in the automotive industry, smart houses/cities, information systems, water management services, military applications etc. Hence, we believe that the following contributions are applicable in other domains:

- Our requirements elicitation method and context layering technique can be modified by applying a domain specific context (instead of clinical context). For that, it is required to specify the concepts (data) used in the domain specific context.
  For example, nowadays, ICT plays a key role in “smart cities”. Smart city is a place where inhabitants and business benefit from the usage of ICT. Some of the services imply the improvement of transportation by advancing the use of electric cars and bike sharing, usage of sensor

systems that guides drivers to find available parking spaces, lighting systems that use smart technologies to enhance the efficiency and utility of city lampposts, which at the same time are also part of the city's Wi-Fi network, providing consistent, free internet access throughout the city. Moreover, lampposts and other city furniture are equipped with sensors that collect data on air quality, relaying information to city agencies and to the public.
In order to apply the requirements elicitation method and the layering technique described in Chapter 3, we could replace the clinical context by the smart city context. Additionally, we could replace the clinical variables addressed in our research by "smart city variables" that are used in this context, which is diverse (from available electric cars charging stations to air quality). This way, we may be able to define a QoD-framework ontology in the "smart city" domain, capable of addressing adaptation mechanisms for the automobile performance. Hence, when unexpected ICT disruptions occur, which may degrade the quality of the data being used (e.g. available electric cars charging stations, air quality), the system may still be able to adapt and perform according to the requirements (e.g. provide the user data quality information, or give precautionary recommendations).

- Our second contribution is the development of a QoD information management method to provide useful QoD information to the user (Chapter 7). In order to make it domain specific, we need to investigate the quality requirements of data used in the domain. Hence, the domain experts would need to cooperate when defining the stratification of the scalar values of QoD to grades.
  For example, advanced driver assistance systems (ADAS) being developed in the automotive domain, timeliness (data speed) and accuracy QoD dimensions play a major role in system performance. In some scenarios, such as curved roads, the data (e.g. road line detection) needs to "be on time" in order to react accordingly and guarantee the performance of safety systems. Hence, automotive experts need to define the QoD grades that correspond to different time boundaries. This way, if the QoD does not fulfill the requirements, the system could automatically adapt its performance and notify the driver sufficiently of an impending hazardous situation.

- The first of the applied contributions is the development of the QoD-aware telemedicine system architecture. The discussed system incorporates a clinical decision support system. This could be replaced by the usage of a domain specific decision support system, whose knowledge engine needs to be augmented with QoD-awareness in order to adapt its output according to the QoD.
  For example, in the aviation industry, navigating requires constant monitoring of "good" quality weather information, altitude, speed, which is then used by the pilot to alter the course of the aircraft if necessary. Considering a congested air space and the limited efficiency of human beings as controllers (as pilots and air traffic controllers), a QoD-aware decision control system could, more efficiently, determine and calculate the safest course for the aircraft based on the available data and its quality, in combination with traffic information. This, coupled with the already existing auto pilot system of the aircraft, could make navigation through stormy weather much safer.

- The second of the applied contributions is the development of QoD Broker architecture, which is generic. Hence, when the approach is generalized, the QoD information management techniques should be adjusted to the user and domain requirements.
  For example, in transport systems, where the activation of road lights vary according to the number of cars in the immediate vicinity, we could incorporate the QoD Broker component that asses the quality of the detected number of cars. This way, the system is able to acquire useful QoD information that supports the QoD-awareness of the system in order to guarantee road safety and efficiency.

9.4 DIRECTIONS FOR FUTURE RESEARCH

The research described in this thesis can be further exploited in different directions. This section discusses some of the research challenges and opportunities:

- **Predictive models for quality of clinical data**
  Predictive models are often used in healthcare systems to forecast probabilities and trends of a patient condition and his/her future response to a treatment. QoD has been demonstrated to improve the performance of clinical predictive models [109]. But there are no many

current investigations on the use of predictive models for QoD. Hence, we believe this work could be augmented by researching predictive models for QoD.

- **Quality of manually inputted data**
  Characteristics like educational background, age etc. are some aspects that could influence the QoD, especially when the data is inputted manually into a system. However, human characteristics and their impact on QoD are complex to assess. Therefore, we need to further study how a smart system can compute manual input data quality by considering human characteristics.

- **Implementation of a resource configuration manager for QoD optimization**
  This thesis proposes the implementation of a resource configuration manager (RCM) component comprised in the ICT resources component of the telemedicine system (Chapter 6). The aim of this component is to optimize the resources used in order to prevent QoD degradation and optimize QoD. However, due to MG project time constrains, this functionality was not implemented in our study, neither validated. Therefore, we consider the further investigation and implementation of the RCM controlled by the QoD Broker, so that the system is even more autonomous and robust against ICT disruptions that have an impact of QoD.

- **Improving healthcare systems**
  The current study enables the development of telemedicine systems, with the additional support of QoD-awareness, to ensure safe treatment guidance for ambulatory patients. The globalization of this QoD-awareness to all clinical data used in healthcare systems would lead to a major improvement of healthcare systems and services. It is not "right" to assume that the quality of the data obtained in the hospital settings is reliable. In several studies [23, 25, 51], we already see that the clinical data in medical records does not always fulfil the medical quality requirements. Therefore, it is not enough to include QoD-awareness in telemedicine systems, but also in the entire healthcare system. This may not only have a positive impact on the treatment, but also in the diagnosis and prognosis of a disease.

- **A next level of context awareness in telemedicine systems**
  Telemedicine system have been working in context awareness for several years [110, 111]. However, the technological context has not been considered in these context awareness studies. In this thesis, we bring up the technological context as one of the major factors that influence clinical data quality. In the coming years, we expect to acquire data by using ubiquitous ICT without direct human interaction. Hence, the quality of the collected data would depend solely on the performance of the technology being used. Therefore, we consider technological context, which is characterized by the technological resources performance, as a major feature to consider. This broadens the spectrum of context awareness, where, till now, we considered personal context and clinical context as main placeholders.

- **Broader quality of data assessment**
  Patients can benefit from transferring data, generated on their mobile devices, to their personal health records, other applications or healthcare provider. Therefore, in addition to computing quality of "clinical data",we would also compute other types of data that were previously not considered to be "useful" data in the healthcare domain.

- **Interoperability of quality of data**
  Interoperability is a hot topic in healthcare. However, we should remember that we also need standards for clinical data quality (e.g. QoD dimensions, QoD grades), so that we can exchange, understand and act on the data as well as its quality. This way, the data and its quality can be used when sharing it with other linguistically and culturally disparate clinicians, patients and other actors or organizations within and across health system jurisdictions, in a collaborative manner [53].

APPENDIX A

iPACT'-FICS' IN THE ATRIAL FIBRILLATION (AF) CASE

Here we present the conducted RE method in the Atrial Fibrillation (AF) medical case. Notice that we describe the second cycle of the refined RE method, iPACT' and FICS' elements, in a high level of abstraction. Additionally, we present an medical scenario (i.e. iPACT' scenario) and the merged scenario (i.e. iPACT'-FICS' scenario), which are examples of possible MG project scenarios [4].

A.1 iPACT'

The iPACT' describes the user activities from the medical perspective. In our study we provide a table of the iPACT' elements (Table A.1). The activities are decomposed in tasks. The intention, context and technology are also presented in high level of abstraction and decomposed in more detailed elements.

Intention	**Provide safe treatment guidance to the ambulatory patient** • support the treating cardiologist in further diagnose the patient (e.g. to detect changes in earlier classification of patient's AF or changes in the duration and frequency of the episodes); • improve patient's medication compliance, patient's heart or physical condition and to reduce the likelihood of patient's symptoms; • facilitate clinical data monitoring (e.g. occurrences or onsets of symptoms); • provide personalized safe treatment recommendations, based on personal clinical data and its quality.
People	• Patient: person who suffers atrial fibrillation cardiac disease

	• Cardiologist (medical practitioner): person who treats the patient for his/her disease in order to cure or improve his/her condition • Nurse practitioner: person who supports the cardiologist on the patient's treatment • *Informal Care Givers: Family, friends etc. which could help the patient during his treatment

Activities	**A1. Medical consultation (after patient symptoms):**
	• Physical examination
	• Further tests (e.g. Holter)
	  • Diagnosis: paroxysmal atrial fibrillation in hypertensive cardiomyopathy.
	  • Risk and therapeutically decision (thromboembolic risk/Transesophageal echocardiography)
	
	A2. Patient enrollment and education of AF management programme:
	• AF management programme explanation
	• The nurse explains to John the medical interventions facilitated by the programme and including the intentions of these interventions.
	• Patient signs the consent to participate in the programme
	• The nurse enrolls the patient into the AF management programme
	• The nurse explains the AF management programme (including the patient guidance system functionalities) and that he/she is expected to wear the system during the day.
	• The nurse instruct the patient how to wear the system (e.g. sensor)
	• Together they introduce into the system all required personal information (including treatment preferences)
	A3. Exercise treatment measurement and patient's preferences:
	• Bruce (or Modified Bruce) protocol stress test performance
	• The cardiologist discusses with the patient the test results and determines the exercise treatment baselines (e.g. HR maximum, the target intensity to perform an effective exercise, the range of HR), and the safety margins for different physical intensity levels (obtained based on the different HRs measured in each Bruce test stage), which are introduced into the system.
	• The nurse discusses with the patient his/her preferences about the way he likes to be guided
	A4. Daily exercise to improve heart condition
	• The patient wears the patient guidance system, which guides the patient to perform physical exercise.
	• The system ensures that the devices (ICT resources) required for the physical exercise treatment are performing correctly.
	• he patient starts his daily walking exercise guided by the system. There are three main stages:

	• Warm-up • Target training • Cool down • In each stage the patient is guided to reach the 'optimal' intensity level • In case the monitored clinical data quality is not good enough (due to some device performance problem), the patient is safely guided (e.g. with a recommendation to slow down). • The cardiologist and the system may use patient's physical exercise clinical data for further treatment purposes. **A5. Symptom reporting** • The patient suffers AF symptom(s) • The patient reports the symptoms in the patient guidance system • The system will guide the patient to start the AF monitoring session for a short period (e.g. 30 minutes) • The system will check if the patient is having an AF episode(s) • The detected AF episodes data are stored into the system • The cardiologist and the system may use patient's clinical data (symptoms and AF episodes) for further treatment purposes **A6. Medication compliance** • Every X hour/day the patient needs to take his medication prescribed by his cardiologist for heart rate control in the event of AF recurrences. • The patient guidance system supports the patient in the medical compliance with reminders and checks if the patient is compliant • The cardiologist and the system may use this patient's clinical data (medication intake) for further treatment purposes
Context	**C1. Personal Context:** Patient's personal state over a time frame (time interval). The patient personal state is an expression over non-clinical personal patient variables. The personal variables describe different aspects of a patient's condition and his environment, including family support, daily routine, pain status, etc. [112] • Hospital context: supervised context, educational context (A1) • Extramural daily activities: unsupervised outdoor context, home environment, family support, routine/ no routine (e.g. holidays, wedding) (A4-A6) **C2. Technological context:** The technical information provided by the system technological resources that has an impact on the quality of clinical data (QoD) and hence, characterizes patient's treatment (Section 1.2) • Ideal performance • Non-Ideal performance
Technology	Mobile patient guidance system, which is QoD-aware, being carried by the ambulatory patient, that supports interaction with the patient and the remote medical practitioner • Wearable • Interactive with patient and medical practitioners

• Personalized • Intelligent • QoD-aware

Table A.1: Description of the iPACT' elements for the AF scenario

A.2 MEDICAL SCENARIO (IPACT' SCENARIO)

John is a male of 69 years. He is married and retired, but still he has several hobbies (walking, biking). He suffers from several symptoms (mainly shortness of breath and palpitation) that can be associated with the atrial fibrillation arrhythmia.
After his first consultation with the cardiologist, where a physical examination and several tests are conducted, John is diagnosed with Paroxysmal AF. He has some thromboembolic risk, so he needs medication, but also ECG and HR monitoring control to check his evolution. The cardiologist considers John an appropriate candidate to be enrolled on AF management programme. Hence, he has a face to face meeting with the MG AF management program's nurse practitioner, Lucy. Lucy introduces herself and thereafter asks John for his consent to be involved in the AF management programme. Once he has his consent, Lucy enrolls John into the AF management programme such that he has access to his personalized AF management programme from anywhere and anytime.
Lucy explains to John the medical interventions facilitated by the programme, including the intentions of these interventions. She explains that his heart condition needs to be improved by doing daily physical exercise at an intensity level determined by his physiotherapist or cardiologist. To determine the adequate physical exercise intensity values, John performs the Bruce protocol stress test [69] in the supervised setting with Lucy. These Bruce protocol stress test values are stored into the MG system and used for the autonomous patient guidance. Additionally, John will be asked to report symptoms and monitor HR, BP (and potentially other vital signs) by using the patient guidance system. All patient data will be used for the treatment control, cardiologist informative data, and potential treatment adjustments. Lucy will introduce all patient test values into patient guidance system. She explains John that he will get treatment guidance during his daily routine. Additionally, he may get some guidance regarding system devices (e.g. charge sensor battery) that would ensure 'good' quality clinical data (e.g. HR) being monitored during the whole

treatment, which ensures patients safety. After 4 weeks they will have the next consultation to see the progress.
From that day John starts using the patient guidance system in his daily life. In the morning he gets the reminder for his daily medication. He takes the medication and acknowledges by using the system. This way the Lucy and the cardiologist can check the medication compliance of John. After reading his morning newspaper, John prepares his daily physical exercise. The system ensures that the devices (ICT resources) required for that treatment are performing correctly. Additionally, John can inspect his bio-signals (e.g. HR). He walks to the park and starts his daily walking exercise. The first 5 minutes warm-up he walks with a normal and steady tread. Then he speeds up to the targeted intensity level and he is guided to keep this pace. After a while the HR quality is not good enough. Hence, John is guided to slow down and he walks in a slower tread. After a while, the monitored HR quality is good, so that John is asked to increase slightly his physical exercise.
Once John finishes his daily physical exercise session, he can check the results, such as how good he did, the physical activity he performed and the average HR during his exercise. His physical exercise clinical data is available for the system and cardiologist (or physiotherapist) analysis. Events which deviates from his routine performance will also be available, for example his HR in case his exercise has to be aborted by the system (e.g. due to poor HR quality) or by John.
Next day John does not feel very good and he decides to be at home. In the afternoon, he feels some palpitation. He reports the symptom into the system, which requires him to start the ECG monitoring session for 30 minutes. Once the session is completed, John removes the ECG sensor required for the monitoring session. This data is used to see if John is suffering an AF episode, and to correlate this information with the reported symptoms.
At the end of the week, John's cardiologist has a look into John's data to check how he is doing. He inspects that John has been doing exercise, and that one day he suffered from palpitation, which in fact is related with an AF episode. He decides not to modify the guideline (e.g. medication or routine) from now, and they will assess the situation in the next consultation.
After four weeks of treatment, John visits Lucy and his cardiologist (in vivo) for a regular consultation. Lucy and the cardiologist could observe all the data and discuss it with John. They conclude that John symptoms are less severe and his condition has improved. They decide to update his personal treatment information and keep the treatment supported by the system, since

John also feels that it has improved his quality of life.

A.3 FICS'

The FICS' elements describe the user-system interactions based on the iPACT' activities. Hence, in order to map the FICS to the activities in the iPACT' analysis, we first indicate the activity described in Table A.1, followed by the FICS' elements that correspond to it (Table A.2). Notice that the first activity described in iPACT' table is not addressed in Table A.2 since it does not comprise any user-system interaction.

Activity	**A2.** Patient enrollment and education of MG AF management programme
Interaction	• The nurse start-ups MG system and selects patient enrollment tag • The nurse saves the new data related to the MG AF disease management program • The nurse logouts from the system (if the appointment it's finished).
Functionality	• Nurse login (to enable reliable and secure access) and get confirmation • Patient login (if new patient, create an account) • Logout of the system (for security)
Content	• Nurse ID and password • Patient ID and his/her (socio-) demographic information and any other clinical information that he could provide (if he/she was registered, the stored information would get on the system once the nurse enters his MG ID)
Service	• Session oriented service: user confirmation service for login and for log out • New patient account creation service
Activity	**A3.** Exercise treatment measurement and patient's preferences settings into MG system
Interaction	• The nurse selects the tag of exercise stress test data on the MG system • The nurse fills in the corresponding sections the measurements got from the stress test and press the save bottom and close
Functionality	• Fill Stress test information of the patient
Content	• Information got from the stress test (Bruce Protocol) cardiologist • Information (baselines) got from cardiologist-physiotherapist advise and with patient discussion
Service	• Information collector service • Storage service
Activity	**A4.** Daily exercise to improve heart condition
Interaction	• The patient runs the MG AF management application of the system • The patient visualizes the information of his bio signals (ECG, HR, physical activity) • The system checks if all the devices are performing adequately to provide clinical data with quality that fulfils the requirements

	• The system analyses the data monitored (activity pattern) and its quality • The system stores the data • The system guides the patient with recommendations during the physical exercise treatment (also visualization) • The patient checks the final screen which shows the physical exercise treatment data • This final results are stored on the system to make possible a future checking of the exercise done
Functionality	• Patients own sense of safety • System safety measure • Data analysis and storage • Training and motivation in a secure mode • Future checking of the exercise done each day • System quality of data awareness
Content	• Patient's bio signals, processed data, and their quality • 'Beeps or vibrations', Notification-message, Visual Graph
Service	• Provider confirmation service • Quality assurance service • Data processing and storage service • Feedback service • Storage service
Activity	**A5.** Symptoms reporting
Interaction	• Patient press a button on the MG smart phone (an accessible button) when he gets the first signs of an AF symptom (e.g. shortness of breath) • The smart phone will show through a pop-up message if he pressed the button due to any AF symptom feeling and if he wants to report the symptom enabling the patient to report the symptom next time he wants to use the smart phone. • The patient can input the symptoms he suffer with the checklist provided by MG AF management system according with the most frequent symptoms he can suffer, but also he can add some extra information that could be relevant for his AF management treatment • The patient presses save
Functionality	• Fast and easy access to the system for symptom reporting • Annotate the specific symptom and extra information relevant for the AF management program
Content	• Pop-up message • Symptom options checklist and extra free space
Service	• Symptoms notification service • Confirmation Service • Storage service
Activity	**A6.** Medication compliance
Interaction	• The MG system notifies the patient to intake a medication • The system would remind the patient every X minutes (specify on the preferences the repeating reminders frequency, tone, etc.)

	• Until the patient replies (e.g. "Yes. Medication intake" or "Don't remind me anymore"), which is stored in the system
Functionality	• Remind the patient about his need of medication intake.
Content	• Medication intake timing (e.g. frequency, doses), patient reminder preferences • Pop-up message with vibration or tone (preferences) • Patient response (e.g. "Yes. Medication intake", "Don't remind me anymore") • Repeating reminders via vibration
Service	• Reminder Service • Storage service

Table A.2: Description of the FICS' elements for the AF scenario

A.4 MERGED SCENARIO (IPACT'-FICS' SCENARIO)

John is a male of 69 years. He is married and retired, but still he has several hobbies (walking, biking). He suffers from several symptoms (mainly shortness of breath and palpitation) that can be associated with the atrial fibrillation arrhythmia. After his first consultation with the cardiologist, where a physical examination and several tests are conducted, John is diagnosed with Paroxysmal AF. He has some thromboembolic risk, so he needs medication, but also ECG and HR monitoring control to check his evolution. The cardiologist considers John an appropriate candidate to be enrolled on MG AF management programme. Hence, he has a face to face meeting with the MG AF management program's nurse practitioner, Lucy. Lucy introduces herself and thereafter asks John for his consent to be involved in the MG AF management programme. Once he has his consent, Lucy enrolls John into the MG AF management programme such that he has access to his personalized AF management programme from anywhere and anytime.
Lucy explains to John the medical interventions facilitated by the programme, including the intentions of these interventions. She explains that his heart condition needs to be improved by doing daily physical exercise at an intensity level determined by his physiotherapist or cardiologist. To determine the adequate physical exercise intensity values, John performs the Bruce protocol stress test [69] in the supervised setting with Lucy. These Bruce protocol stress test values are stored into the MG system and used for the autonomous patient guidance. Additionally, John will be asked to report symptoms and monitor HR, BP (and potentially other vital signs) by using the MG system. All patient data will be used for the treatment control, cardiologist informative data, and

potential treatment adjustments.
Lucy will introduce all patient test values into MG system by using the MG caregiver interface. She explains John that he will get clinical recommendation(s) of the MG system during his daily routine. Additionally, he may get some technical recommendations related with the technological devices perfoance (e.g. charge sensor battery) that would ensure "good" quality of clinical data (e.g. HR) being monitored during the whole treatment, which ensures patients safety. After 4 weeks they will have the next consultation to see the progress. From that day John starts using MG in his daily life. In the morning he gets the reminder for his daily medication. He takes the medication and acknowledges by using the MG mobile application. This way the Lucy and the cardiologist can check the medication compliance of John using the MG caregiver interface.
After reading his morning newspaper, John prepares his daily physical exercise. The system ensures that the devices (ICT resources) required for that treatment are performing correctly. Additionally, John can inspect that the MG system monitors his bio-signals (e.g. HR), checking that everything works. He walks to the park and starts his daily walking exercise. The first 5 minutes warm-up he walks with a normal and steady tread. Then he speeds up to the targeted intensity level (stored in the system), the MG system notifies him if he reaches this level and helps him to keep this pace by personalized controlled feedback (using a mode he or Lucy has configured before). After a while the MG system detects that the devices are not performing correctly and the monitored HR quality is not good enough. Hence, the MG system sends John a recommendation to slow down and he walks in a slower tread. After a while, the performance improves and the monitored HR quality is good, so that John is asked by the interactive MG system to increase slightly his physical exercise. Once John finishes his daily physical exercise session, he can check the results of his exercise on a "final" screen of MG which shows the patient how good he did, the physical activity he performed, the average HR during his exercise, and some other data. His activity pattern and duration of his exercise will be stored by the system for the MG system and his cardiologist (or physiotherapist) analysis. Events which deviates from his routine performance will also be stored, for example his HR in case his exercise has to be aborted by the system (e.g. due to poor HR quality) or by John.
Next day John does not feel very good and he decides to be at home. In the afternoon, he feels some palpitation. He reports the symptom into MG system, which requires him to start the ECG monitoring session for 30 minutes. Once

the session is completed, John removes the ECG sensor required for the monitoring session. This data is used to see if John is suffering an AF episode, and to correlate this information with the reported symptoms.
At the end of the week, John's cardiologist has a look into John's data via the MG caregiver interface to check how he is doing. He inspects that John has been doing exercise, and that one day he suffered from palpitation, which in fact is related with an AF episode. He decides not to modify the guideline (e.g. medication or routine) from now, and they will assess the situation in the next consultation.
After four weeks of treatment, John visits Lucy and his cardiologist (in vivo) for a regular consultation. Lucy and the cardiologist could observe all the data stored by the system by using the MG caregiver interface and discuss it with John. They conclude that John symptoms are less severe and his condition has improved. They decide to update his personal treatment information and keep the treatment supported by the MG system, since John also feels that it has improved his quality of life.

APPENDIX B

ABBREVIATIONS, TERMS AND NOTATIONS FOR THE ARCHITECTURE DESCRIPTION

Here we address the meaning of the abbreviations, terms and notations used in this section.

B.1 ABBREVIATIONS USED IN THE MESSAGES EXCHANGED BETWEEN SYSTEM COMPONENTS

Abbreviation	Meaning
Req	Request
Rep	Reply
Treat	Treatment
Info	Information
Clin	Clinical

Abbreviation	Meaning
Tech	Technological
Recomm	Recommendation
Mon	Monitored
BE	Back end
GL	Guideline

Table B.1: Abbreviations for messages

B.2 TERMS

- *System:* an abstraction of a complex interacting set of elements, for which it is possible to identify a boundary, an environment, inputs and outputs, a control mechanism and some process or transformation that the system achieves [90]. We make use of subsystem and components in the similar way, by just differing from their level of abstraction.
- *Service:* external observational behavior of the system (that has some

desired effect for the service user). A service is defined in terms of interactions and the relation between interactions. ([4])

- *Provider:* an entity (system or human) that provides a particular service (in terms of interactions).
- *User:* external entity of any form (system or human) that interacts with the provider, i.e. uses the services provided by another system or human.
- *Information:* knowledge obtained from investigation, study or instructions, which can be merged with data.
- *Data:* Factual information (as measurements or statistics) used as a basis for reasoning, discussion, calculation or information. Notice that often information and data are used interchangeably.
- *Interaction:* data/information message flow between two or more cooperating systems or users in which a common understanding is established.
- *Recommendations:* proposal as to best course of action based on the knowledge and information that a system or human has.

B.3 NOTATIONS

The notations below (Table X) corresponds to the ones illustrated in the conceptual architecture diagrams.

Symbol	Meaning
◇	Split data streams
→	Iterations (from – to)
→	QoD required interaction
■	Join data streams
-→	Respond to a message
→	External interaction (out focus of the abstraction level)

Table B.2: Notations used in architecture diagrams

APPENDIX C

MOBIGUIDE IMPLEMENTED INTERACTIONS - MOBILE BAN

- **Retrieve a data source callback**

  Method Name: subscribeToDataSource
  Description: Subscribe to a data source with given ID. Upon success the callback will be called when there is new BANData
  Example: service.subscribeToDataSource (DATA_SOURCE_ID)
  Input Parameters:

Parameter	Type	Description
DatasourceID	String	Identification of the data source.
Callback	BanDataCallback	Callback object to retrieve broadcasted data.

- **Broadcast data**

  Method Name: broadcastBanData
  Description: sends BanData to all subscribers, as well as forwarding a copy to the backend storage (data integrator) if indicated using a flag
  Example: service.broadcastBanData (DATA_SOURCE_ID, data, typeData)
  Input Parameters:

Parameter	Type	Description
DatasourceID	String	Identification of the data source.
Data	BanData	Object containing the broadcasted data.
Flag	byte	Indication for data forwarded to the backend storage, with the type of data (e.g. associated data)

Types of flag:

1. byte FLAG_NONE = 0;
   BanData is an original (not associated) measurement, and will not be forwarded to the Data Integrator on the backend
2. byte FLAG_FORWARD_TO_DATA_INTEGRATOR
   Indicates that this BanData should be forwarded from the BAN via the BAN Backend to the Data Integrator.
3. byte FLAG_ASSOCIATED_DATA = 1 « 0;
   Indicates that this BanData is associated to another (earlier, existing) BanData. If the flag FLAG_FORWARD_TO_DATA_INTEGRATOR is also set, this influences how the data is delivered to the Data Integrator.

An example of the BanData that corresponds to QoD type data is described below:

"data":
"relatedClinicalStatement":[
"observationResult":"observationFocus":"codeSystem":"MG","code":"Accuracy","observationValue":
"text":"value":"High","targetRelationshipToSource":"codeSystem":"MG","code":"QoD",
"observationResult":"observationFocus":"codeSystem":"MG","code":"Timeliness","observationValue":
"text":"value":"High","targetRelationshipToSource":"codeSystem":"MG","code":"QoD",
"observationResult":"observationFocus":"codeSystem":"MG","code":"Cost","observationValue":
"text":"value":"High","targetRelationshipToSource":"codeSystem":"MG","code":"QoD",
"observationResult":"observationFocus":"codeSystem":"MG","code":"Dependability","observationValue":
"text":"value":"High","targetRelationshipToSource":"codeSystem":"MG","code":"QoD",
"observationResult":"observationFocus":"codeSystem":"MG","code":"QualEvid","observationValue":
"text":"value":"Low","targetRelationshipToSource":"codeSystem":"MG","code":"QoD"],
"observationResult":"observationFocus":"codeSystem":"MG","code":"oQoD","observationValue":
"text":"value":"High","targetRelationshipToSource":"codeSystem":"MG","code":"QoD",
"vmrClass":"ObservationResult","targetObject":"vmr*:patient*:
clinicalStatements*:observationResults*:observationResult*:id[@root='e2709eea-2fe1-4ff0-a3c0-
7391e04b3685'].."

- **Subscribe to a message channel**

Method Name: subscribeToMessageChannel
Description: Subscribes to a specific message channel to receive messages in the specific callback
Example: subscriptionId = service.subscribeToMessageChannel (MSG_CHANNEL_ID, new MessageCallback.Stub()
Input Parameters:

Parameter	Type	Description
MessageChannelId	String	The id of the message channel
MessageCallback	MessageCallback	The message callback object to which a message can be notified.

Return Parameters:

Parameter	Type	Description
SubscriptionID	int	Identifier to mark the subscription, can be used for unsubscription

- **Send message**

Method Name: sendMessage
Description: Sends a Message through a specific channel
Input Parameters:

Parameter	Type	Description
SenderID	String	Identification of the sender.
MessageChannelID	String	Identification of the message channel.
MessageType	String	Type of the message
Data	Byte[]	Content of the message.
Retention	Byte	Retention strategy

Return Parameters:

Parameter	Type	Description
ResultCode	int	Success = 0, Fail = 1

An example of the technological recommendations transmission:

techR: "recID": "TR12",
"title": "Title of sample survey.",
"description": "Description of sample survey.",
"date": "05/03/2014",
"time": "08:00",
"validity": "01/01/2020",
"action":
"action": "survey",
"value":
"question": "Question in sample survey.",
"options": [
"key": "key01",
"value": "value01"
, "key": "key02",
"value": "value02"
, "key": "key03",
"value": "value03"
]

APPENDIX D

MOBIGUIDE IMPLEMENTED INTERACTIONS - BACK END

- **Subscribe to a message channel**

Method Name: subscribeToDataSource
Provider BAN back-end
Description: Subscribes to a specific message channel to receive messages in the specific callback
Input Parameters:

Parameter	Type	Description
Message ChannelId	String	ID of the message channel
CallbackUri	String	Uri of the callback service of a MG back-end component to be used to notify of incoming messages on the subscribed channel with MessageChannelID from a BAN front-end component.

Return Parameters:

Parameter	Type	Description
ResultCode	int	Success = 0, Fail = 1

- **Send message**

Method Name: sendMessage
Provider BAN back-end
Description: Sends a Message through a specific channel
Input Parameters:

Parameter	Type	Description
SenderID	String	Name of the sender, can be used as a reply channel ID.
ReceiverMobiguideId	String	MobiGuide ID associated with the BAN front-end
MessageType	String	Type of message to be send, to be used to identify message content
MessageDataHex	String	Hexadecimal representation of the content of the message
Retention	String	Retention strategy

Return Parameters:

Parameter	Type	Description
ResultCode	int	Success = 0, Fail = 1

- **Notification of an incoming message**

Method Name: MessageNotification
Provider: Registered message consumer (i.e. MG back-end component)
Description: Get notified of an incoming message
Input Parameters:

Parameter	Type	Description
SenderId	String	Name of the sender, can be used as a reply channel ID.
ReceiverMobiguideId	String	MobiGuide ID associated with the BAN front-end
MessageChannelId	String	ID of the message channel
MessageType	String	Type of message to be send, to be used to identify message content
MessageDataHex	String	Hexadecimal representation of the content of the message
Retention	String	Retention strategy (currently not yet in use)

Return Parameters:

Parameter	Type	Description
ResultCode	int	Success = 0, Fail = 1

APPENDIX E

MOBIGUIDE - COMPLETE QUESTIONNAIRES

E.1 QUESTIONNAIRE FOR AF PATIENTS

USER DATA

1. Level of education
   ❑ *Elementary school*
   ❑ *Secondary School studies*
   ❑ *High school studies*
   ❑ *University studies*

PREVIOUS EXPERIENCE

2. Please, select if you have frequent access to one or more of the following devices:
   ❑ *Personal Computer or Laptop*
   ❑ *Mobile phone*
   ❑ *Smartphone*
   ❑ *Tablet*

GENERAL IMPRESSION USING THE MOBIGUIDE APPLICATION

3. The application is:
   ❑Very Boring ❑Boring ❑Neutral ❑ Interesting ❑Very interesting

4. The application is:
   ❑Very difficult to use ❑Difficult to use ❑Neutral ❑ Easy to use ❑Very easy to use

5. The sequence of activities that can be accomplished with the app is:
   ❑Very confusing ❑Confusing ❑Neutral ❑ Clear ❑Very clear

6. The response time of the application for most of the actions is:
   ❑Very slow ❑Slow ❑Neutral ❑ Fast ❑Very fast

7. I have experienced errors with the MG system:
❑Very frequently ❑Frequently ❑Neutral ❑ Rarely ❑Never

8. Learning to use the application has been:
❑Very difficult ❑Difficult ❑Neutral ❑ Easy ❑Very easy

9. I travelled abroad when using MobiGuide: ❑Yes ❑No

10. If yes, during my trips I have used the application: ❑Very frequently ❑Frequently ❑Neutral ❑ Rarely ❑Never

USEFULNESS

11. I think that the MobiGuide system helps me to be more confident with my decisions when taking care of AF:
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

12. I think that the application has helped me to visualize and interpret my monitoring data (heart rate, INR, weight) in a faster and more effective way:
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

13. I think that using the app has complicated my daily life:
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

14. I like the fact that the system can adapt to my daily life and context changes:
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

15. I would recommend the use of the system to other AF patients: ❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

SPECIFIC FUNCTIONALITY

16. The recommendations that are shown in the app. are:
❑ Very confusing ❑Confusing ❑Neutral ❑ Clear ❑ Very clear

17. The number of recommendations received in the app. is:
❑ Too low ❑ Low ❑Adequate ❑ High ❑Too high

18. If you have received automatic therapy advice, the information provided by the system is:
❑ Very confusing ❑Confusing ❑Neutral ❑ Clear ❑ Very clear

19. If you have received a notification to re-enter a measurement value, the information provided by the system is: ❑ Very confusing ❑Confusing ❑Neutral ❑ Clear ❑ Very clear

20. The number of notifications received to re-enter a measurement value is:
❑ Very annoying ❑ Annoying ❑Neutral ❑ Adequate ❑Very adequate

21. If you have received a notification to re-enter a measurement value, the information provided by the system is:
❑ Not useful at all ❑ Not useful ❑Neutral ❑ Useful ❑ Very useful

22. If you have received a notification to charge the sensor or smartphone battery, the information provided by the system is:
❑ Very confusing ❑Confusing ❑Neutral ❑ Clear ❑ Very clear

23. The number of notifications received to charge the sensor or smartphone battery is:
❑ Very annoying ❑ Annoying ❑Neutral ❑ Adequate ❑Very adequate

24. If you have received a notification to charge the sensor or smartphone battery, the information provided by the system is:
❑ Not useful at all ❑ Not useful ❑Neutral ❑ Useful ❑ Very useful

25. I have downloaded my ECG sensor data to the system without difficulty:
❑ Never ❑Rarely ❑Neutral ❑ Often ❑ Always

26. The information and graphical elements in the Exercise scenario are:
❑ Very confusing ❑Confusing ❑Neutral ❑ Clear ❑ Very clear

27. The physical activity type and level detected by the application represents the exercise I'm really doing:
❑ Never ❑Rarely ❑Neutral ❑ Often ❑ Always

28. In general, the buttons to access the app functionalities from the app interface are:
❑ Very confusing ❑Confusing ❑Neutral ❑ Clear ❑ Very clear

29. The system reduces the activation time of the healthcare personnel whenever an intervention is required (e.g., waiting time for a visit is shortened) :
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

30. The system improved the interaction with my doctors
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

31. The system reduced the number of control visits at the hospital
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

32. The system allowed to save money (due to fewer visits, travels to the hospital, etc)
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

33. The system improves my peace of mind when travelling away from home
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

34. The system improves my safety when performing physical exercise
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

35. Would you recommend the system to a friend of yours? ❑ Yes ❑No

36. Would you use the system in your daily routine (after this study)? ❑ Yes ❑No

37. If yes, would you be willing to pay something for using it? ❑ Yes ❑ No
If yes, indicate the maximum amount of €

E.2 QUESTIONNAIRE FOR GDM PATIENTS

USER DATA

1. Level of education ❑ Elementary School studies
❑ High School studies
❑ Technical studies
❑ University studies

PREVIOUS EXPERIENCE

2. Please, select if you have frequent access to one or more of the following devices:
❑ Personal Computer or Laptop
❑ Mobile phone
❑ Smartphone
❑ Tablet

GENERAL IMPRESSION USING THE MOBIGUIDE APPLICATION

3. The application is:
❑Very Boring ❑Boring ❑Neutral ❑ Interesting ❑Very interesting

4. The application is:
❑Very difficult to use ❑Difficult to use ❑Neutral ❑ Easy to use ❑Very easy to use

5. The sequence of activities that I need to perform with the application (for example enter a measurement of ketonuria or modify my preferences) is:
❑Very confusing ❑Confusing ❑Neutral ❑ Clear ❑Very clear

6. The response time of the application for most of the actions is:
❑Very slow ❑Slow ❑Neutral ❑ Fast ❑Very fast

7. I have experienced errors with the MG system:
❑Very frequently ❑Frequently ❑Neutral ❑ Rarely ❑Never

8. Learning to use the application has been:
❑Very difficult ❑Difficult ❑Neutral ❑ Easy ❑Very easy

USEFULNESS

9. To what extent MobiGuide has helped me to be more confident when managing my diabetes (for example about regularity to measure my glycemia values). With MobiGuide I feel:
❑ Not confident at all ❑Less confident ❑Neutral ❑ More Confident ❑ Much more confident

10. I think that the application has helped me to visualize and interpret my monitoring data (glycemia, diet) in a faster and more effective way:
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

11. I think that using the app. has NOT complicated my daily life:
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

12. I like that MobiGuide can be adapted to my lifestyle (e.g. time of meals) and to other changes in my personal context(e.g. holidays, working days, etc.)
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

13. I would recommend the use of the system to other patients with GDM:
❑ Totally disagree ❑Disagree ❑Neutral ❑ Agree ❑ Totally agree

SPECIFIC FUNCTIONALITY (please, answer if applicable)

14. The recommendations that are shown in the app. are:
❑ Very confusing ❑Confusing ❑Neutral ❑ Clear ❑ Very clear

15. The number of recommendations received in the app. is:
❑ Too small ❑ Small ❑ Suitable ❑ High ❑Too high

16. If you have received automatic therapy modifications, the information provided by the system is:
❑ Very confusing ❑Confusing ❑Neutral ❑ Clear ❑ Very clear

17. If you have received a notification to re-enter a measurement value (e.g. glycemia, blood pressure), the information provided by the system is:
❑ Very confusing ❑Confusing ❑Neutral ❑ Clear ❑ Very clear

18. If you have received a notification to re-enter a measurement value (e.g. glycemia, blood pressure), the information provided by the system is:
❑ Very annoying ❑ Annoying ❑Neutral ❑ Appropriate ❑Totally appropriate

19. If you have received a notification to re-enter a measurement value (e.g. glycemia, blood pressure), the information provided by the system is:
❑ Counter-productive ❑ Useless ❑Neutral ❑ Useful ❑Totally useful

20. If you have received a notification to charge the smartphone battery, the information provided by the system is:
❑ Very confusing ❑Confusing ❑Neutral ❑ Clear ❑ Very clear

21. The number of notifications received to charge the smartphone battery is:
❑ Very annoying ❑ Annoying ❑Neutral ❑ Adequate ❑Very adequate

22. If you have received a notification to charge the smartphone battery, the information provided by the system is:
❑ Counter-productive ❑ Useless ❑Neutral ❑ Useful ❑Totally useful

23. I have experienced technical problems to download my glucose meter to the system:
❑ Never ❑Rarely ❑Sometimes ❑ Often ❑ Always

24. I have experienced technical problems to download my Blood Pressure meter to the system:
❑ Never ❑Rarely ❑ Sometimes ❑ Often ❑ Always

25. The information and graphical elements in the Exercise scenario are:
❑ Very confusing ❑Confusing ❑Neutral ❑ Clear ❑ Very clear

26. The physical activity type and level detected by the application represents the exercise I'm really doing:
❑ Never ❑Rarely ❑Sometimes ❑ Often ❑ Always

27. Would you recommend the use of MobiGuide to a friend? ❑ Yes ❑No

28. Would you like to use MobiGuide again (after this study)? ❑ Yes ❑No

29. Would you be willing to pay something for using the system?
❑ Yes ❑No
If yes, indicate the maximum amount of €
Other comments:

E.3 QUESTIONNAIRE FOR MEDICAL PRACTITIONERS

QUALITY OF WORK LIFE

1. I think MobiGuide has been a positive addition to AF/GDM patient care [1 2 3 4 5]

2. I think MobiGuide has been a positive addition to our organization

3. MobiGuide technology is an important part of our staffing process

PERCEIVED USEFULNESS

4. Using MobiGuide makes it easier to manage AF/GDM patients

5. Using MobiGuide enables me to manage AF/GDM patients more quickly

6. Using MobiGuide makes it more likely that I better care for my patients
7. Using MobiGuide is useful for managing AF/GDM patients
8. I think MobiGuide presents a more equitable process for managing AF/GDM patients
9. I am satisfied with MobiGuide for management of AF/GDM patients
10. I manage AF/GDM patients in a timely manner because of MobiGuide
11. Using MobiGuide increases my overall productivity
12. I'm able to idenify priorities whenever I use MobiGuide
13. Using MobiGuidesystem clinical data quality-aware increases the outpatient's treatment safety

PERCEIVED EASE OF USE

14. I am confortable with my ability to use MobiGuide
15. Learning to operate MobiGuide is easy for me
16. It is easy for me to became skillful at using MobiGuide
17. I find MobiGuide easy to use
18. I can always remember how to log on and how to use MobiGuide

USER CONTROL

19. MobiGuide gives error messages that clearly tell me how to fix problems
20. Whenever I make a mistake using MobiGuide, I recover easily and quickly
21. The information (such as online help, on-screen messages, and other documentation) provided with MobiGuide is clear
22. The quality of the clinical data provided by MobiGuide has an impact on my treatment decisions

INTERFACE

23. The arrengement of windows/menus comply with the way I work
24. I can find the right window/menu quickly
25. I can read the information well

26. I consider the arrengement of windows/menus logical
27. I appreciate the layout and use of colors of the windows
28. It is easy to enter data in the right way

BIBLIOGRAPHY

[1] D. B. Libraries. (2015) Evidence-based medicine (ebm) resources. [Online]. Available: http://www.dartmouth.edu/~biomed/resources.htmld/guides/ebm_resources.shtml

[2] N. Larburu, I. Widya, R. G. Bults, H. J. Hermens *et al.*, "Making medical treatments resilient to technological disruptions in telemedicine systems," in *Biomedical and Health Informatics (BHI), 2014 IEEE-EMBS International Conference on*. IEEE, 2014, pp. 285–288.

[3] N. Larburu, R. G. Bults, M. J. Van Sinderen, I. Widya, and H. J. Hermens, "An ontology for telemedicine systems resiliency to technological context variations in pervasive healthcare," *Translational Engineering in Health and Medicine, IEEE Journal of*, vol. 3, pp. 1–10, 2015.

[4] MobiGuide-consortium. (2011) Mobiguide project. [Online]. Available: http://www.mobiguide-project.eu/

[5] E. Glossary. (2012) Evidence based medicine: when best evidence from research meets clinical information and patient values, optimal decisions are possible. [Online]. Available: http://med.mercer.edu/library/mobile-ebm/glossary.htm

[6] N. Larburu, B. van Schooten, E. Shalom, N. Fung, M. van Sinderen, H. Hermens, and V. Jones, "A quality-of-data aware mobile decision support system for patients with chronic illnesses," in *Knowledge Representation for Health Care*. Springer, 2015, pp. 126–139.

[7] N. Larburu, T. Lopetegi, and I. Romero, "Comparative study of algorithms for atrial fibrillation detection," in *Computing in Cardiology, 2011*. IEEE, 2011, pp. 265–268.

[8] UNIPV, BGU, CSPT, FSM, HU, UPM, and UT, "Deliverable 9.1: Functional and usability evaluation report," MobiGuide, Tech. Rep., 2015.

[9] G. W. Group *et al.*, "Grading quality of evidence and strength of recommendations," *BMJ: British Medical Journal*, vol. 328, no. 7454, p. 1490, 2004.

[10] G. H. Guyatt, A. D. Oxman, R. Kunz, Y. Falck-Ytter, G. E. Vist, A. Liberati, H. J. Schunemann, and G. W. Group, "Going from evidence to recommendations," *BMJ*, vol. 336, no. 7652, pp. 1049–51, 2008.

[11] N. Larburu, R. Bults, M. van Sinderen, and H. Hermens, "Quality-of-data management for telemedicine systems," *Procedia Computer Science*, vol. 63, pp. 451–458, 2015, the 5th International Conference on Current and Future Trends of Information and Communication Technologies in Healthcare (ICTH-2015).

[12] U. Varshney, "Pervasive healthcare: applications, challenges and wireless solutions," *Communications of the Association for Information Systems*, vol. 16, no. 1, p. 3, 2005.

[13] U. Varshney *et al.*, "Pervasive healthcare," *Computer*, vol. 36, no. 12, pp. 138–140, Dec 2003.

[14] J. E. Bardram *et al.*, "Pervasive healthcare as a scientific discipline," *Methods of information in medicine*, vol. 47, no. 3, pp. 178–185, 2008.

[15] D. L. Sackett, W. M. Rosenberg, J. Gray, R. B. Haynes, and W. S. Richardson, "Evidence based medicine: what it is and what it isn't." *BMJ: British Medical Journal*, vol. 312, no. 7023, p. 71, 1996.

[16] N. Mulyar, W. M. Van der Aalst, and M. Peleg, "A pattern-based analysis of clinical computer-interpretable guideline modeling languages," *Journal of the American Medical Informatics Association*, vol. 14, no. 6, pp. 781–787, 2007.

[17] E. J. Benjamin, P. A. Wolf, R. B. D'Agostino, H. Silbershatz, W. B. Kannel, and D. Levy, "Impact of atrial fibrillation on the risk of death the framingham heart study," *Circulation*, vol. 98, no. 10, pp. 946–952, 1998.

[18] N. L. San Fung, T. Broens, N. Larburu, R. Bults, E. Shalom, V. Jones, H. Hermens *et al.*, "Application of a conceptual framework for the modelling and execution of clinical guidelines as networks of concurrent processes," *Procedia computer science*, vol. 35, pp. 671–680, 2014.

[19] N. Larburu, R. G. Bults, I. Widya, H. J. Hermens *et al.*, "Quality of data computational models and telemedicine treatment effects," in *e-Health Networking, Applications and Services (Healthcom), 2014 IEEE 16th International Conference on*. IEEE, 2014, pp. 364–369.

[20] D. M. Strong, Y. W. Lee, and R. Y. Wang, "Data quality in context," *Communications of the ACM*, vol. 40, no. 5, pp. 103–110, 1997.

[21] R. Y. Wang and D. M. Strong, "Beyond accuracy: What data quality means to data consumers," *Journal of management information systems*, pp. 5–33, 1996.

[22] W. Linzhang, Y. Jiesong, Y. Xiaofeng, H. Jun, L. Xuandong, and Z. Guo, "Generating test cases from uml activity diagram based on gray-box method," in *Software Engineering Conference, 2004. 11th Asia-Pacific*. IEEE, 2004, pp. 284–291.

[23] E. S. Berner, R. K. Kasiraman, F. Yu, M. N. Ray, and T. K. Houston, "Data quality in the outpatient setting: impact on clinical decision support systems," in *AMIA Annual Symposium Proceedings*, vol. 2005. American Medical Informatics Association, 2005, p. 41.

[24] M. J. Field, K. N. Lohr *et al.*, *Clinical Practice Guidelines:: Directions for a New Program*. National Academies Press, 1990, vol. 90, no. 8.

[25] J. L. McCormack and J. S. Ash, "Clinician perspectives on the quality of patient data used for clinical decision support: a qualitative study," in *AMIA Annual Symposium Proceedings*, vol. 2012. American Medical Informatics Association, 2012, p. 1302.

[26] X. H. Wang, D. Q. Zhang, T. Gu, and H. K. Pung, "Ontology based context modeling and reasoning using owl," in *Pervasive Computing and Communications Workshops, 2004. Proceedings of the Second IEEE Annual Conference on*. Ieee, 2004, pp. 18–22.

[27] L. Ahmadian, M. van Engen-Verheul, F. Bakhshi-Raiez, N. Peek, R. Cornet, and N. F. de Keizer, "The role of standardized data and terminological systems in computerized clinical decision support systems: literature review and survey," *International journal of medical informatics*, vol. 80, no. 2, pp. 81–93, 2011.

[28] L. Osterberg and T. Blaschke, "Adherence to medication," *New England Journal of Medicine*, vol. 353, no. 5, pp. 487–497, 2005.

[29] G. H. Guyatt, A. D. Oxman, R. Kunz, G. E. Vist, Y. Falck-Ytter, and H. J. Schünemann, "Grade: What is" quality of evidence" and why is it important to clinicians?" *Chinese Journal of Evidence-Based Medicine*, vol. 2, p. 009, 2009.

[30] G. H. Guyatt, A. D. Oxman, R. Kunz, Y. Falck-Ytter, G. E. Vist, A. Liberati, and H. J. Schünemann, "Rating quality of evidence and strength of recommendations: Going from evidence to recommendations," *BMJ: British Medical Journal*, vol. 336, no. 7652, p. 1049, 2008.

[31] S. Vavilis, N. Zannone, and M. Petkovic, "Data reliability in home healthcare services," in *Computer-Based Medical Systems (CBMS), 2013 IEEE 26th International Symposium on*. IEEE, 2013, pp. 377–380.

[32] S. Bosems and M. van Sinderen, "Models in the design of context-aware well-being applications," in *On the Move to Meaningful Internet Systems: OTM 2014 Workshops*. Springer, 2014, pp. 37–42.

[33] R. Wieringa and H. Heerkens, "Designing requirements engineering research," in *Comparative Evaluation in Requirements Engineering, 2007. CERE'07. Fifth International Workshop on*. IEEE, 2007, pp. 36–48.

[34] R. Wieringa and A. Moralı, "Technical action research as a validation method in information systems design science," in *Design Science*

Research in Information Systems. Advances in Theory and Practice. Springer, 2012, pp. 220–238.

[35] K. Peffers, T. Tuunanen, M. A. Rothenberger, and S. Chatterjee, "A design science research methodology for information systems research," *Journal of management information systems*, vol. 24, no. 3, pp. 45–77, 2007.

[36] J. L. Cardoso de Moraes, *Methodological support to develop interoperable applications for pervasive healthcare*. University of Twente, 2014.

[37] J. E. Bardram, "Clinical proof-of-concept–a evaluation method for pervasive healthcare systems," in *Proc. Ubiquitous Computing*, vol. 51. Citeseer, 2008.

[38] A. H. Encyclopedia. (2009) Eancient history encyclopedia. [Online]. Available: http://www.ancient.eu/

[39] A. Mihailidis and J. E. Bardram, *Pervasive Computing in Healthcare*. CRC Press, 2006.

[40] P. Healthcare, "Guest editorial introduction to the special section on pervasive healthcare," *IEEE transactions on information technology in biomedicine*, vol. 8, no. 3, p. 229, 2004.

[41] J. Craig and V. Patterson, "Introduction to the practice of telemedicine," *Journal of Telemedicine and Telecare*, vol. 11, no. 1, pp. 3–9, 2005.

[42] S. H. Woolf, R. Grol, A. Hutchinson, M. Eccles, and J. Grimshaw, "Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines," *BMJ: British Medical Journal*, vol. 318, no. 7182, p. 527, 1999.

[43] E. Shalom, Y. Shahar, A. Goldstein, E. Ariel, M. Sheinberger, N. Fung, V. Jones, and B. Van Schooten, "Implementation of a distributed guideline-based decision support model within a patient-guidance framework," in *Knowledge Representation for Health Care*. Springer, 2015, pp. 111–125.

[44] P. Szolovits *et al.*, "Uncertainty and decisions in medical informatics," *Methods of Information in Medicine-Methodik der Information in der Medizin*, vol. 34, no. 1, pp. 111–121, 1995.

[45] G. Kong, D.-L. Xu, and J.-B. Yang, "Clinical decision support systems: a review on knowledge representation and inference under uncertainties," *International Journal of Computational Intelligence Systems*, vol. 1, no. 2, pp. 159–167, 2008.

[46] K. Sheikh, M. Wegdam, and M. Van Sinderen, "Middleware support for quality of context in pervasive context-aware systems," in *Pervasive Computing and Communications Workshops, 2007. PerCom Workshops' 07. Fifth Annual IEEE International Conference on*. IEEE, 2007, pp. 461–466.

[47] A. K. Dey, "Understanding and using context," *Personal and ubiquitous computing*, vol. 5, no. 1, pp. 4–7, 2001.

[48] G. K. Tayi and D. P. Ballou, "Examining data quality," *Communications of the ACM*, vol. 41, no. 2, pp. 54–57, 1998.

[49] Y. Wand and R. Y. Wang, "Anchoring data quality dimensions in ontological foundations," *Communications of the ACM*, vol. 39, no. 11, pp. 86–95, 1996.

[50] S. Hasan and R. Padman, "Analyzing the effect of data quality on the accuracy of clinical decision support systems: a computer simulation approach," in *AMIA annual symposium proceedings*, vol. 2006. American Medical Informatics Association, 2006, p. 324.

[51] E. S. Berner, "Clinical decision support systems: state of the art," *AHRQ Publication*, no. 09-0069, pp. 4–26, 2009.

[52] C. W. Fisher, I. Chengalur-Smith, and D. P. Ballou, "The impact of experience and time on the use of data quality information in decision making," *Information Systems Research*, vol. 14, no. 2, pp. 170–188, 2003.

[53] EU, "Green paper on mobile health ("mhealth")," EUROPEAN COMMISSION, Tech. Rep., 2014.

[54] J. Cowie and F. Burstein, "Quality of data model for supporting mobile decision making," *Decision Support Systems*, vol. 43, no. 4, pp. 1675–1683, 2007.

[55] S. Vavilis, M. Petković, and N. Zannone, "Impact of ict on home healthcare," in *ICT Critical Infrastructures and Society*. Springer, 2012, pp. 111–122.

[56] T. H. Broens, M. M. Vollenbroek-Hutten, H. J. Hermens, A. T. van Halteren, L. J. Nieuwenhuis *et al.*, "Determinants of successful telemedicine implementations: a literature study," *Journal of telemedicine and telecare*, vol. 13, no. 6, pp. 303–309, 2007.

[57] J. Sriram, M. Shin, D. Kotz, A. Rajan, M. Sastry, and M. Yarvis, "Challenges in data quality assurance in pervasive health monitoring systems," in *Future of Trust in Computing*. Springer, 2009, pp. 129–142.

[58] C. Batini, C. Cappiello, C. Francalanci, and A. Maurino, "Methodologies for data quality assessment and improvement," *ACM Computing Surveys (CSUR)*, vol. 41, no. 3, p. 16, 2009.

[59] L. Berti, "Quality and recommendation of multi-source data for assisting technological intelligence applications," in *Database and Expert Systems Applications*. Springer, 1999, pp. 282–291.

[60] I. Widya, R. Stap, L. Teunissen, and B. F. Hopman, "On the end-user qos-awareness of a distributed service environment," in *Protocols for Multimedia Systems*. Springer, 2001, pp. 222–237.

[61] K. Sheikh, M. Wegdam, and M. van Sinderen, "Middleware support for quality of context in pervasive context-aware systems," in *Pervasive Computing and Communications Workshops, 2007. PerCom Workshops '07. Fifth Annual IEEE International Conference on*, March 2007, pp. 461–466.

[62] J. Shaikh, M. Fiedler, and D. Collange, "Quality of experience from user and network perspectives," *annals of telecommunications-annales des telecommunications*, vol. 65, no. 1-2, pp. 47–57, 2010.

[63] EU. (2016) New eu working group aims to draft guidelines to improve mhealth apps data quality. [Online]. Available: https://ec.europa.eu/digital-agenda/en/news/new-eu-working-group-aims-draft-guidelines-improve-mhealth-apps-data-quality

[64] N. Larburu, I. Widya, R. G. Bults, H. J. Hermens, C. Napolitano *et al.*, "Early phase telemedicine requirements elicitation in collaboration with medical practitioners," in *Requirements Engineering Conference (RE), 2013 21st IEEE International*. IEEE, 2013, pp. 273–278.

[65] D. Benyon and C. Macaulay, "Scenarios and the hci-se design problem," *Interacting with computers*, vol. 14, no. 4, pp. 397–405, 2002.

[66] I. Widya, R. Bults, R. de Wijk, B. Loke, N. Koenderink, R. Batista, V. Jones, H. Hermens *et al.*, "Requirements for a nutrition education demonstrator," in *Requirements Engineering: Foundation for Software Quality*. Springer, 2011, pp. 48–53.

[67] V. Fuster, L. E. Rydén, D. S. Cannom, H. J. Crijns, A. B. Curtis, K. A. Ellenbogen, J. L. Halperin, G. N. Kay, J.-Y. Le Huezey, J. E. Lowe *et al.*, "2011 accf/aha/hrs focused updates incorporated into the acc/aha/esc 2006 guidelines for the management of patients with atrial fibrillation: a report of the american college of cardiology foundation/american heart association task force on practice guidelines developed in partnership with the european society of cardiology and in collaboration with the european heart rhythm association and the heart rhythm society," *Journal of the American College of Cardiology*, vol. 57, no. 11, pp. e101–e198, 2011.

[68] P. S. Osbak, M. Mourier, J. H. Henriksen, K. F. Kofoed, and G. B. Jensen, "Effect of physical exercise training on muscle strength and body composition, and their association with functional capacity and quality of life in patients with atrial fibrillation: a randomized controlled trial," *Journal of rehabilitation medicine*, vol. 44, no. 11, pp. 975–979, 2012.

[69] R. A. Bruce, "Exercise testing for evaluation of ventricular function," *New England Journal of Medicine*, vol. 296, no. 12, pp. 671–675, 1977.

[70] E. Shalom and Y. Shahar, "A graphical framework for specification of clinical guidelines at multiple representation levels," in *AMIA Annual*

Symposium Proceedings, vol. 2005. American Medical Informatics Association, 2005, p. 679.

[71] Z. T. Corporation. (2012) Bioharness 3 medical data sheet. [Online]. Available: http://www.zephyr-technology.com/media/pdf/BioHarness_3-DataSheet-Medical-2012-JUL-26.pdf

[72] F. Paganelli and D. Giuli, "An ontology-based system for context-aware and configurable services to support home-based continuous care," *Information Technology in Biomedicine, IEEE Transactions on*, vol. 15, no. 2, pp. 324–333, 2011.

[73] Y. Shahar, O. Young, E. Shalom, M. Galperin, A. Mayaffit, R. Moskovitch, and A. Hessing, "A framework for a distributed, hybrid, multiple-ontology clinical-guideline library, and automated guideline-support tools," *Journal of Biomedical Informatics*, vol. 37, no. 5, pp. 325–344, 2004.

[74] M. Peleg, S. Tu *et al.*, "Decision support, knowledge representation and management in medicine," *Yearb Med Inform*, vol. 45, pp. 72–80, 2006.

[75] D. L. McGuinness, F. Van Harmelen *et al.*, "Owl web ontology language overview," *W3C recommendation*, vol. 10, no. 10, p. 2004, 2004.

[76] I. Widya, B.-J. van Beijnum, and A. Salden, "Qoc-based optimization of end-to-end m-health data delivery services," in *Quality of Service, 2006. IWQoS 2006. 14th IEEE International Workshop on*. IEEE, 2006, pp. 252–260.

[77] I. R. Legarreta, P. S. Addison, M. Reed, N. Grubb, G. R. Clegg, C. E. Robertson, and J. N. Watson, "Continuous wavelet transform modulus maxima analysis of the electrocardiogram: beat characterisation and beat-to-beat measurement," *International Journal of Wavelets, Multiresolution and Information Processing*, vol. 3, no. 01, pp. 19–42, 2005.

[78] M. Peleg, S. Tu, J. Bury, P. Ciccarese, J. Fox, R. A. Greenes, R. Hall, P. D. Johnson, N. Jones, A. Kumar *et al.*, "Comparing computer-interpretable guideline models: a case-study approach," *Journal of the American Medical Informatics Association*, vol. 10, no. 1, pp. 52–68, 2003.

[79] A. Goldstein, S. Quaglini, L. Sacchi, S. Panzarasa, C. Napolitano, N. Larburu, R. Bults, M. Rigla, and G. García-Sáez, "Mobiguide deliverable d4.1: Cigs kb," Tech. Rep., 2014.

[80] Y. Shahar, "A framework for knowledge-based temporal abstraction," *Artificial intelligence*, vol. 90, no. 1, pp. 79–133, 1997.

[81] L. Sacchi, A. Fux, C. Napolitano, S. Panzarasa, M. Peleg, S. Quaglini, E. Shalom, P. Soffer, and P. Tormene, "Patient-tailored workflow patterns from clinical practice guidelines recommendations." in *Medinfo*, 2013, pp. 392–396.

[82] M. Rigla, R. Tirado, A. Caixàs, B. Pons, and J. Costa, "Gestational diabetes guideline cspt. mobiguide project deliverable (fp7-287811) version 1.0," Tech. Rep., 2013.

[83] L. Bass, P. Clements, and R. Kazman, "Software architecture in practice, 2nd edn. sei series in software engineering," 2003.

[84] F. Davidoff, B. Haynes, D. Sackett, and R. Smith, "Evidence based medicine." *BMJ: British Medical Journal*, vol. 310, no. 6987, p. 1085, 1995.

[85] M. Peleg, "Computer-interpretable clinical guidelines: a methodological review," *Journal of biomedical informatics*, vol. 46, no. 4, pp. 744–763, 2013.

[86] P. Terenziani, G. Molino, and M. Torchio, "A modular approach for representing and executing clinical guidelines," *Artificial Intelligence in Medicine*, vol. 23, no. 3, pp. 249–276, 2001.

[87] E. Shalom, S. Quaglini, L. Sacchi, S. Panzarasa, and T. Broens, "Deliverable 5.1: Design documents," MobiGuide - available on request, Tech. Rep., 2012.

[88] M. Peleg, T. Broens, A. González-Ferrer, and E. Shalom, "Architecture for a ubiquitous context-aware clinical guidance system for patients and care providers," *KR4HC*, vol. 13, pp. 161–167, 2013.

[89] K. Wac, D. Konstantas, A. Van Halteren, R. Bults, N. Dokovsky, G. Koprinkov, I. Widya, V. Jones, R. Herzog *et al.*, "Wireless body area networks for healthcare: the mobihealth project," *Studies in health technology and informatics*, vol. 18, pp. 121–126, 2004.

[90] L. O. O. S. A. McGraw-Hill Global Education Holdings and D. using UML. (2016) Glossary of key terms. [Online]. Available: http://highered.mheducation.com/sites/0077110005/student_view0/glossary.html

[91] H. Sharp, A. Finkelstein, and G. Galal, "Stakeholder identification in the requirements engineering process," in *Database and Expert Systems Applications, 1999. Proceedings. Tenth International Workshop on*. Ieee, 1999, pp. 387–391.

[92] C. Marcos, A. González-Ferrer, M. Peleg, and C. Cavero, "Solving the interoperability challenge of a distributed complex patient guidance system: a data integrator based on hl7's virtual medical record standard," *Journal of the American Medical Informatics Association*, vol. 22, no. 3, pp. 587–599, 2015.

[93] A. Gonzalez-Ferrer, M. Peleg, C. Marcos, J. Verlinden, B. Verhees, and D. Klimov, "Deliverable d7.1: State of the art of existing clinical standards. fp7-287811," MobiGuide, Tech. Rep.

[94] S. Quaglini, L. Sacchi, S. Panzarasa, P. Tormene, E. Parimbelli, C. Napolitano, T. Broens, V. Jones, N. Fung, I. Widya, N. Larburu, R. G. A. Bults, M. Rigla, E. Hernando, G. Garcia-Saez, and I. Martinez-Sarriegui, "Deliverable 5.2.2.: Wp5 development progress," MobiGuide - available on request, Tech. Rep., 2013.

[95] E. Shalom, S. Quaglini, L. Sacchi, S. Panzarasa, P. Tormene, R. Di Salvo, C. Napolitano, T. Broens, D. Knoppel, V. Jones, N. Fung, B. van Schooten, I. Widya, N. Larburu, R. G. A. Bults, M. Rigla, E. Hernando, G. Garcia-Saez, and I. Martinez-Sarriegui, "Deliverable 5.2.2.: Wp5 development progress," MobiGuide - available on request, Tech. Rep., 2014.

[96] D. G. Arts, N. F. De Keizer, and G.-J. Scheffer, "Defining and improving data quality in medical registries: a literature review, case study,

and generic framework," *Journal of the American Medical Informatics Association*, vol. 9, no. 6, pp. 600–611, 2002.

[97] M. Scannapieco, P. Missier, and C. Batini, "Data quality at a glance." *Datenbank-Spektrum*, vol. 14, pp. 6–14, 2005.

[98] G. Endler, P. Baumgärtel, and R. Lenz, "Pay-as-you-go data quality improvement for medical centers," 2013.

[99] D. P. Ballou and H. L. Pazer, "Cost/quality tradeoffs for control procedures in information systems," *Omega*, vol. 15, no. 6, pp. 509–521, 1987.

[100] M. Shin, "Secure remote health monitoring with unreliable mobile devices," *BioMed Research International*, vol. 2012, 2012.

[101] L. L. Pipino, Y. W. Lee, and R. Y. Wang, "Data quality assessment," *Communications of the ACM*, vol. 45, no. 4, pp. 211–218, 2002.

[102] M. J. Muller and S. Kuhn, "Participatory design," *Commun. ACM*, vol. 36, no. 6, pp. 24–28, Jun. 1993. [Online]. Available: http://doi.acm.org/10.1145/153571.255960

[103] J. W. Creswell and D. L. Miller, "Determining validity in qualitative inquiry," *Theory into practice*, vol. 39, no. 3, pp. 124–130, 2000.

[104] R. J. Wieringa, *Design science methodology for information systems and software engineering*. Springer, 2014.

[105] T. Tanigawa, K. Yamagishi, S. Sakurai, I. Muraki, H. Noda, T. Shimamoto, and H. Iso, "Arterial oxygen desaturation during sleep and atrial fibrillation," *Heart*, vol. 92, no. 12, pp. 1854–1855, 2006.

[106] A. Goldstein, E. Shalom, D. Klimov, Y. Shahar, A. Fux, M. Peleg, P. Soffer, S. Quaglini, S. Panzarasa, L. Sacchi, and N. Larburu, "Mobiguide deliverable d3.1: Extended cig format," Tech. Rep., 2013.

[107] E. Allen and C. Seaman. (2007) Likert scales and data analyses. [Online]. Available: http://asq.org/quality-progress/2007/07/statistics/likert-scales-and-data-analyses.html

[108] UNIPV, BGU, CSPT, FSM, HU, UPM, and UT, "Deliverable 9.2: System impact report," MobiGuide, Tech. Rep., 2015.

[109] J. Jonnagaddala, S. Liaw, and P. Ray, "Impact of data quality assessment on development of clinical predictive models." *Studies in health technology and informatics*, vol. 216, pp. 1069–1069, 2014.

[110] T. Broens, A. Van Halteren, M. Van Sinderen, and K. Wac, "Towards an application framework for context-aware m-health applications," *International Journal of Internet Protocol Technology*, vol. 2, no. 2, pp. 109–116, 2007.

[111] M. J. Van Sinderen, A. T. Van Halteren, M. Wegdam, H. B. Meeuwissen, and E. H. Eertink, "Supporting context-aware mobile applications: an infrastructure approach," *Communications Magazine, IEEE*, vol. 44, no. 9, pp. 96–104, 2006.

[112] A. Fux, M. Peleg, and P. Soffer, "How can personal context improve adherence to clinical guidelines," in *Joint KR4HC/ProHealth Wrokhop*, 2012.

List of My Publications

N. Larburu, R. G. Bults, M. J. van Sinderen, I. Widya, and H.J. Hermens, *Quality-of-Data Broker for Quality-of-Data-Aware Telemedicine Systems*, Innovation and Research in BioMedical Engineering (IRBM) Journal, (2016), *Accepted*.

N. L. San Fung, V. M. Jones, I. Widya, T. H. M. Broens, N. Larburu, R. G. Bults, E. Shalom, and H. J. Hermens, *The Conceptual MADE Framework for Pervasive and Knowledge-Based Decision Support in Telemedicine*, International Journal of Knowledge and Systems Science (IJKSS), **7**,(2016), 25-39.

M. Peleg, Y. Shahar, S. Quaglini, Larburu, Nekane et al. *Assessment of a Personalized and Distributed Patient Guidance System*, International Journal of Medical Informatics (IJMI), (2016), *Manuscript in process for submission*.

N. Larburu, R. G. Bults, M. J. van Sinderen, I. Widya, and H. J. Hermens, *An ontology for telemedicine systems resiliency to technological context variations in pervasive healthcare*, Translational Engineering in Health and Medicine, IEEE Journal of, **3**,(2015), 1-10.

N. Larburu B. van Schooten, E. Shalom, N. Fung, M. J. van Sinderen, H. J. Hermens, and V. M. Jones, *A quality-of-data aware mobile decision support system for patients with chronic illnesses*, Knowledge Representation for Health Care, (2015), 126-139.

N. LARBURU, R. G. Bults, M. J. van Sinderen, and H. J. Hermens, *Quality-of-data management for telemedicine systems*, Procedia Computer Science, **63**,(2015), 451-458.

N. LARBURU, I. Widya, R. G. Bults, and H. J. Hermens, *Making medical treatments resilient to technological disruptions in telemedicine systems*, Biomedical and Health Informatics (BHI), 2014 IEEE-EMBS International Conference on, (2014), 285-288.

N. LARBURU, R. G. Bults, I. Widya, and H. J. Hermens, *Quality of data computational models and telemedicine treatment effects*, e-Health Networking, Applications and Services (Healthcom), 2014 IEEE 16th International Conference on, (2014), 364-369.

N. LARBURU, I. Widya, R. G. Bults, H. J. Hermens, and C. Napolitano *Early phase telemedicine requirements elicitation in collaboration with medical practitioners*, Requirements Engineering Conference (RE), 2013 21st IEEE International, (2013), 273-278.

N. L. San Fung, I. Widya, T. Broens, N. LARBURU, R. G. Bults, E. Shalom, V. M. Jones, and H. J. Hermens, *Application of a conceptual framework for the modelling and execution of clinical guidelines as networks of concurrent processes*, Procedia computer science, **35**,(2014), 671-680.

N. LARBURU, T. Lopetegi, and I Romero, *Comparative study of algorithms for atrial fibrillation detection*, Computing in Cardiology, 2011, (2011), 265-268.